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A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

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SMALL BUSINESS ADMINISTRATION

13 CFR Parts 124, 126, 127, 128, and 134

RIN 3245–AI04

Women-Owned Small Business Federal Contract Program Updates and Clarifications

AGENCY: U.S. Small Business Administration.

ACTION: Final rule.

SUMMARY: This final rule makes several changes to the Small Business Administration (SBA or Agency) Women-Owned Small Business (WOSB) Federal Contract Program regulations, including adding definitions that are not currently included in the regulations and conforming the regulations to current statutes that have not yet been integrated. The rule also adopts similar language to that used in SBA's other government contracting program regulations regarding requirements for the qualifying individual's control of an applicant concern and limits on outside employment and makes changes to the process by which an application for certification is reviewed by SBA in order to implement a statutory amendment from the National Defense Authorization Act for Fiscal Year 2022 regarding the effects of a status determination on a small business concern.

DATES: This rule is effective January 3, 2025. It applies to all solicitations issued on or after that date.

FOR FURTHER INFORMATION CONTACT: Harry T. Alexander Jr., U.S. Small Business Administration, Office of Contracting Assistance, 409 Third Street SW, Washington, DC 20416; (202) 619–0314, *harry.alexanderjr@sba.gov*.

SUPPLEMENTARY INFORMATION: On May 16, 2024, SBA published a proposed rule in the **Federal Register** to change the process by which an application for certification is reviewed by SBA. SBA proposed this change in order to implement a statutory amendment from the National Defense Authorization Act for Fiscal Year 2022 (Pub. L. 117–81) regarding the effects of a status determination on a small business concern. SBA also proposed to replace outdated references to the U.S. Department of Veterans Affairs Center for Verification and Evaluation with references to SBA's Veteran Small Business Certification (VetCert) Program, add definitions of terms used in the Women-Owned Small Business (WOSB) regulations, provide consistency across the regulations used in SBA's other government contracting programs, and define who is authorized to represent a firm when validating or signing certification pages during the certification process.

During the rule's 60-day comment period, SBA timely received comments from two commenters, with one commenter expressing full support for the proposed rule. The other commenter expressed general support for the substantive changes proposed by SBA, noting that the rule is ''generally well-conceived and addresses the concerns of the industry,'' and appreciated SBA's efforts to standardize the requirements of the government contracting programs.

Section-by-Section Analysis and Response to Comments

Sections 124.106(a), 127.202(c), and 128.203(i)

Sections 124.106(a), 127.202(c), and 128.203(i) address limitations on outside employment that can affect a business concern's eligibility for participation in the 8(a) Business Development (BD), WOSB, and VetCert programs, respectively, based on a qualifying individual's lack of control. Each of these provisions generally requires the qualifying individual to devote full time or the number of hours of normal operation to the business. Each also requires the business concern to demonstrate how a qualifying individual controls the day-to-day operations of the business concern, particularly if the qualifying individual devotes fewer hours to the business than its normal hours of operation. The language of the three provisions, however, is not identical. These discrepancies led to questions as to whether SBA intended different application of the control requirements for different programs. Current § 127.202 generally requires that a woman devote sufficient time to the business with a rebuttable presumption that the business does not qualify for WOSB if a woman devotes fewer hours to the business than its normal hours of operation. Where the presumption applies, the woman must provide evidence to SBA that she has ultimate managerial and supervisory control over both the long-term decision making and day-to-day management and administration of the business. This final rule aligns the language of this section to the current restriction in the VetCert Program. The business will still be generally required to have the qualified woman that controls the concern devote full time to the business during the business's normal hours of operation. The business may, however, demonstrate to SBA that the woman has ultimate managerial and supervisory control over both the long-term decision making and day-to-day management of the business although the woman may not meet full-time devotion.

One commenter expressed support for this change but identified minor inconsistencies remaining between the rule as proposed and §§ 124.106(a)(4) and 128.203(i). The commenter suggested SBA revise the rule to fully conform these sections. SBA has made minor wording changes to § 127.202 to conform that language to the language regarding outside employment contained in § 124.106(a) for the 8(a) BD program and § 128.203(i) for the VetCert program. The commenter additionally noted that the proposed rule does not clarify whether WOSB allows for exceptions to the control requirements in ''extraordinary circumstances'' as the VetCert regulations provide. SBA agrees that the ''extraordinary circumstances'' provisions should equally apply in the WOSB program and has proposed to incorporate them into the WOSB regulations in a separate rulemaking. *See* 89 FR 68274, 68316 (Aug. 23, 2024).

Sections 127.102, 126.103, 128.500, and 134.1002

Section 127.102 sets out the definitions for the WOSB Program. SBA proposed to add a definition for the term ''Applicant,'' as a definition was not included in the previous version of the regulations and appears in the regulations of SBA's other government

contracting programs. SBA believes that including this definition will provide consistency in the rules that apply to its various certification programs and make clear that a concern applying for certification in the WOSB Program is an ''Applicant.'' SBA received no comments to this provision and adopts it as final in this rule.

SBA also proposed to amend the current definition of the term ''System for Award Management (SAM) (or any successor system).'' SBA believes that the definition is outdated and should match the definition that is used in the FAR for consistency purposes. SBA received no comments to this provision and adopts it as final.

The proposed rule also removed the definition for ''WOSB Program Repository'' as this definition refers to the old repository system that is no longer in use. SBA believes that removing this definition, which is not used elsewhere in 13 CFR part 127, will alleviate any confusion.

Lastly, the proposed rule amended the definition of ''Interested party,'' limiting it to certified WOSB concerns or concerns that have a pending application for WOSB certification, either at SBA or a third-party certifier, and that submit an offer for a specific Economically Disadvantaged Women-Owned Small Business (EDWOSB) or WOSB requirement, rather than any concern that submits an offer for a specific EDWOSB or WOSB requirement. SBA believes that only certified WOSBs and EDWOSBs or concerns pending WOSB certification should be able to submit a protest against an apparent successful offeror's EDWOSB or WOSB status since only those firms can themselves be eligible for award and truly have an economic interest in the award. It is not uncommon for an incumbent contractor to file a bid or size/status protest in order for its performance to be extended pending the resolution of the protest. SBA does not want to encourage firms that are not certified WOSBs or certified EDWOSBs to submit offers merely to be able to file a status protest that could prolong their performance under a preceding contract. Such firms have no chance to be awarded a WOSB/EDWOSB contract, and such protests may be nothing more than delay tactics. Only firms that are capable of winning the WOSB set-aside contract or order should be able to protest the WOSB status of an apparent successful offeror. Furthermore, in Fiscal Year 2024, only one of the twelve protests received by the WOSB program office would have been impacted by this change in the definition of ''interested party.'' Thus, this change would have an insignificant impact on the number of status protests that would have been reviewed. Status protests for the VetCert program are heard by SBA's Office of Hearings and Appeals (OHA). The expected impact on firms able to submit a VetCert status protest would be similarly insignificant by this change in the definition of ''interested party.''

One commenter expressed support for this change, and suggested SBA similarly update the 8(a) BD Program, Historically Underutilized Business Zone (HUBZone) Program, and VetCert Program regulations. SBA first notes that it does not allow status protests in connection with the award of 8(a) contracts. Second, SBA proposed to similarly change the definition of interested party for the HUBZone program in a separate rulemaking. *See* 89 FR 68274, 68307. SBA received two positive comments and no negative comments about this proposed change for the HUBZone program. SBA agrees with the commenter that similar treatment should be afforded to the HUBZone program and VetCert program and, thus, has adopted this comment and amended §§ 126.103 and 128.500 in this final rule.

In addition to the changes made to §§ 126.103, 127.102, and 128.500, the definition for ''interested party'' must also be updated in OHA's regulations as OHA has jurisdiction over VetCert status protests and who may file a Veteran-Owned Small Business Concern (VOSB) or Service-Disabled Veteran-Owned Small Business Concern (SDVOSB) status protest. As such, SBA also amends § 134.1002(b) in this final rule for uniformity purposes and to dispel confusion about the appropriate definition.

Section 127.300

The proposed rule amended the outdated references in §§ 127.300(a)(2) and (b)(3) to certifications made by the U.S. Department of Veterans Affairs (VA) Center for Verification and Evaluation. Instead, the proposed rule referred to SBA's Veteran Small Business Certification Program. SBA believes this change will resolve any confusion caused by reference to the VA's Verification Program, which no longer certifies veteran-owned or service-disabled veteran-owned small business concerns following its transfer to SBA pursuant to section 862 of the National Defense Authorization Act for Fiscal Year 2021 (Pub. L. 116–283).

The proposed rule also amended § 127.300(c) by referring to SAM, in addition to the Dynamic Small Business Search (DSBS) system. This change recognizes that a concern that is a qualified WOSB or EDWOSB will be designated as such in both SAM and the DSBS system.

SBA did not receive any comments on either of these provisions and adopts them as final in this rule.

Section 127.303

SBA proposed to add a new paragraph and reorganize § 127.303(a)(1) to provide that a concern certified as a veteran-owned or service-disabled veteran-owned small business for the VetCert Program and owned and controlled by one or more women may use documentation of its VOSB or SDVOSB certification or more recent recertification in support of its application for WOSB certification. The proposed rule further provided that if the concern is also seeking EDWOSB certification, it must submit documentation that demonstrates it is owned and controlled by one or more women who are economically disadvantaged in accordance with § 127.203. This change recognizes a concern's ability to use documentation from SBA's other certification program in support of its application for WOSB certification. One commenter expressed specific support for this change. With no objections to this change, it is adopted as final in this rule.

Section 127.305

The proposed rule incorporated the same language used in § 124.207 for purposes of applying to the 8(a) BD Program. Section 124.207 provides that a concern that has applied to the 8(a) BD program and has been declined three times within 18 months of the date of the first final Agency decision finding the concern ineligible cannot submit a new application for admission to the program until 12 months from the date of the third final Agency decision to decline. SBA proposed this change to the WOSB program to provide consistency among its various certification programs. One commenter supported this change, and suggested SBA similarly conform the VOSB regulation at § 128.305. In a separate rulemaking after this proposed rule, SBA proposed to eliminate the language in § 124.207 that a concern must wait 12 months to reapply to the 8(a) BD program where it has been declined three times within 18 months. *See* 89 FR 68274, 68280. SBA noted that it believed such a provision was unnecessary and should not seek to thwart firms that have made legitimate attempts to overcome deficiencies from reapplying to the 8(a) BD program. Because the proposed change to the

WOSB program to incorporate the 12-month waiting period was intended to promote consistency in SBA's certification programs and SBA has now proposed to eliminate the similar provision in the 8(a) BD regulations, SBA does not finalize the proposed language to § 127.305 in this rule.

Section 127.356(c)

SBA proposed to revise § 127.356(c) to provide consistency between § 127.356(c) and § 127.356(a) and (b). Currently, § 127.356(c) states that an approved third-party certifier must ensure that all of a concern's documents are uploaded in *https://certify.sba.gov* or any successor system. SBA believes that is inconsistent with SBA's intent that it is the responsibility of the concern, not the SBA-approved third-party certifier, to ensure that all its documents are uploaded. Paragraphs 127.356(a) and (b) require the applicant concern to apply directly with a third-party certifier and register in SAM. Consistent with paragraphs (a) and (b), SBA believes that it is the responsibility of the applicant concern, and not the third-party certifier, to ensure that all documents necessary to determine its eligibility for certification by an approved certifier are uploaded with its application. SBA believes this uniformity within the section will lead to less confusion about whose duty it is to make sure documents have been made available to SBA when a third-party certifier is involved. Furthermore, a system has not yet been put in place for a third-party certifier to upload the documents on behalf of the concern. One commenter expressed support for this clarification. As such, the final rule adopts the change as proposed.

Section 127.504(a)

Section 127.504 permits a concern that has submitted a complete application for WOSB or EDWOSB certification to SBA or a third-party certifier and has not received a negative determination regarding that application to submit an offer for a competitive WOSB or EDWOSB award. The proposed rule sought to define ''pending application,'' as this term is not currently defined in § 127.504 or elsewhere in the WOSB regulations. SBA believes providing this definition will lead to less confusion amongst concerns and contracting officers who have been unsure when an application is pending and believed an application to be pending at the point of application. This change will support the acquisition process for WOSB and EDWOSB set-asides.

One commenter agreed with this addition but suggested that the rule also define when an application may be considered ''complete.'' The commenter suggested SBA define applications as ''complete'' once the applicant provides initial submissions of all required materials. SBA does not believe that is necessary. The only time a ''complete'' application is relevant is in determining whether all necessary documents have been provided to SBA to enable SBA to evaluate whether an applicant is eligible for the program. Current § 127.304(a) provides that SBA will advise each applicant within 15 calendar days after the receipt of an application whether the application is complete and suitable for evaluation. Whether an application is complete depends upon various factors. An exhaustive definition of ''complete'' application would not be simple and would introduce unnecessary complexity to the regulations. Different documents are required depending on the business structure of the applicant (*e.g.,* whether an applicant is a corporation or partnership), whether it is seeking EDWOSB or merely WOSB certification, or whether it has received another SBA certification. Although SBA could add a definition saying that a complete application is one where all required documents have been submitted, SBA does not believe that adds any meaningful substance to the current regulation. As such, SBA does not adopt this recommendation, but rather adopts the proposed language as final in this rule.

Section 127.604(f)(5)

SBA proposed to add language describing the effects of a status determination on a concern and the obligation of a concern to update the System for Award Management (or any successor system) within two business days of a final determination. This change implements section 863 of the National Defense Authorization Act of Fiscal Year 2022 (Pub. L. 117–81), which amended section 5(i) of the Small Business Act (15 U.S.C. 634(i)), to provide such language in the status determination of a concern.

One commenter expressed support for this addition and suggested SBA similarly revise § 128.500(d). The proposed additions to § 127.604(f)(5) are currently contained in § 128.500(d), except for new § 127.604(f)(5)(iii). SBA adds similar language to that contained in § 127.604(f)(5)(iii) to a new paragraph § 128.500(d)(3) for consistency purposes in this final rule.

Section 127.701

SBA proposed to remove this section entirely as it contains outdated language regarding the previous WOSB program and system whereby a concern certified its WOSB or EDWOSB status on SAM in relation with specific eligibility requirements. This section, in its entirety, is no longer necessary, as § 127.304(f) and other WOSB program regulations specify that SBA will update DSBS and SAM to indicate that a concern has been certified by SBA as a WOSB and/or EDWOSB. One commenter expressed support for this overall deletion. The final rule accordingly deletes this section.

Compliance With Executive Orders 12866, 12988, 13132, 13563, and the Paperwork Reduction Act (44 U.S.C. Ch. 35), the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Congressional Review Act (5 U.S.C. 801–808)

Executive Orders 12866, 13563, and 14094

Executive Order 12866, Regulatory Planning and Review, Modernizing Regulatory Review, requires agencies to provide a Regulatory Impact Analysis assessing costs and benefits and addressing available alternatives for any ''significant regulatory action'' as defined in Executive Order 14094, Modernizing Regulatory Review. The Office of Management and Budget has determined that this final rule is not a ''significant regulatory action'' under Executive Order 12866.

Executive Order 13563, Improving Regulation and Regulatory Review, reaffirms the principles of Executive Order 12866 and requires agencies to adopt regulations through a process that involves public participation and, to the extent feasible, base regulations on the open exchange of information and perspectives from affected stakeholders and the public as a whole. SBA has developed this rule in a manner consistent with these requirements. Executive Order 13563 also requires agencies to assess the benefits and costs of any regulations and address available alternatives to direct regulation. This rule amends the WOSB regulations to provide uniformity amongst SBA's government contracting programs and clarifies certain regulations that have been misunderstood by concerns and contract officers. As such, the rule has no effect on the amount or dollar value of any Federal contract requirements or of any financial assistance provided through SBA. Therefore, the rule is not likely to have an annual economic effect of $200 million or more, result in a

major increase in costs or prices, or have a significant adverse effect on competition or the United States economy. In addition, this rule does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency, materially alter the budgetary impact of entitlements, grants, user fees, loan programs, or the rights and obligations of such recipients, nor raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order.

Executive Order 12988

This action meets the standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform. SBA has taken the necessary steps to minimize litigation, eliminate drafting errors and ambiguity, reduce burden, and provide a clear legal standard for affected conduct. The action does not have preemptive or retroactive effect.

Executive Order 13132

This action does not have federalism implications as defined in Executive Order 13132, Federalism. The action would not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, this action does not warrant the preparation of a Federalism Assessment.

Paperwork Reduction Act

The SBA has determined that this final rule does not impose additional reporting or recordkeeping requirements under the Paperwork Reduction Act, 44 U.S.C. chapter 35.

Regulatory Flexibility Act

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (RFA) requires the agency to ''prepare and make available for public comment an initial regulatory flexibility analysis'' which will ''describe the impact of the proposed rule on small entities.'' (5 U.S.C. 603(a)). Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

This final rule may affect all WOSBs, HUBZone concerns, 8(a) concerns, and VOSB/SDVOSBs, of which there are currently 13,289, 4,015, 5,679, and 32,729, respectively, according to the Dynamic Small Business Search as of November 2024. All WOSBs, HUBZone concerns, 8(a) concerns, and VOSB/SDVOSBs are small entities. Given that this is a large portion of the SBA's contracting program portfolio, the SBA has determined that this proposed rule will have an impact on a substantial number of small entities.

However, SBA has determined that the impact on entities affected by the final rule will not be significant, because this rule does not increase the burden on small entities and instead is intended to clarify and provide consistency and uniformity to existing regulations. As consistency and uniformity are difficult items to measure and there is not a dataset available, this determination has been assessed qualitatively. The effect of the final rule will be to adopt similar language across SBA's government contracting programs regarding requirements for the qualifying individual's control of an applicant concern and limits on outside employment. In addition, this final rule will provide consistency within the WOSB regulations by clarifying definitions and by incorporating a statutory amendment from the National Defense Authorization Act for FY 2022. SBA expects the economic impact of the final rule will be negligible. SBA asserts that the economic impact, if any, will be minimal and beneficial to WOSBs, HUBZone concerns, 8(a), and VOSB/SDVOSBs due to conformity across the programs that will assist in limiting confusion for applicants.

SBA invited comments on whether this rule would have a significant impact on a substantial number of small entities in the proposed rule but received none. Accordingly, the Administrator of the SBA hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Congressional Review Act

This rule has been determined not to meet the criteria set forth in 5 U.S.C. 804(2). SBA will submit the rule to Congress and the Government Accountability Office consistent with the Congressional Review Act's requirements.

List of Subjects

13 CFR Part 124

Administrative practice and procedure, Government procurement, Government property, Small businesses.

13 CFR Part 126

Administrative practice and procedure, Government procurement, Penalties, Reporting and recordkeeping requirements, Small businesses.

13 CFR Part 127

Government contracts, Government employees, Reporting and recordkeeping requirements, Small businesses, Women.

13 CFR Part 128

Government contracts, Government procurement, Reporting and recordkeeping requirements, Small businesses, Technical assistance, Veterans.

13 CFR Part 134

Administrative practice and procedure, Claims, Confidential business information, Equal access to justice, Equal employment opportunity, Lawyers, Organization and function (Government agencies).

Accordingly, for the reasons stated in the preamble, SBA amends 13 CFR parts 124, 126, 127, 128, and 134 as follows:

PART 124—8(A) BUSINESS DEVELOPMENT/SMALL DISADVANTAGED BUSINESS STATUS DETERMINATIONS

■ 1. The authority citation for part 124 continues to read as follows:

Authority: 15 U.S.C. 634(b)(6), 636(j), 637(a), 637(d), 644, 42 U.S.C. 9815; and Pub. L. 99–661, 100 Stat. 3816; Sec. 1207, Pub. L. 100–656, 102 Stat. 3853; Pub. L. 101–37, 103 Stat. 70; Pub. L. 101–574, 104 Stat. 2814; Sec. 8021, Pub. L. 108–87, 117 Stat. 1054; and Sec. 330, Pub. L. 116–260.

■ 2. Amend § 124.106 by:
■ a. Revising paragraphs (a)(3) and (4);
■ b. Redesignating paragraph (a)(5) as paragraph (a)(6); and
■ c. Adding a new paragraph (a)(5).

The revisions and addition read as follows:

§ 124.106 When do disadvantaged individuals control an applicant or Participant?

* * * * *

(a) * * *

(3) One or more disadvantaged individuals who manage the applicant or Participant generally must devote full-time to the business concern during its normal hours of operations. The disadvantaged individual who holds the highest officer position of the business concern may not engage in outside employment that prevents the disadvantaged individual from devoting the time and attention to the concern necessary to control its management and daily business operations.

(4) Where a disadvantaged individual claiming to control a business concern devotes fewer hours to the business than its normal hours of operation, SBA will assume that the disadvantaged

individual does not control the business concern, unless the concern demonstrates that the disadvantaged individual has ultimate managerial and supervisory control over both the long-term decision making and day-to-day management of the business.

(5) Any disadvantaged individual who seeks to engage in outside employment after certification must notify SBA of the nature and anticipated duration of the outside employment and demonstrate to SBA that the outside employment will not prevent the disadvantaged individual from controlling the business concern.

* * * * *

PART 126—HUBZONE PROGRAM

■ 3. The authority citation for part 126 continues to read as follow:

Authority: 15 U.S.C. 632(a), 632(j), 632(p), 644 and 657a.

■ 4. Amend § 126.103 by revising the definition of ''Interested party'' to read as follows:

§ 126.103 What definitions are important in the HUBZone program?

* * * * *

Interested party means any certified HUBZone small business concern that submits an offer for a specific HUBZone set-aside contract (including a multiple award contract) or order, any concern that submitted an offer in full and open competition and its opportunity for award will be affected by a price evaluation preference given to a certified HUBZone small business concern or by a reserve of an award given to a certified HUBZone small business concern, the contracting activity's contracting officer, or SBA.

* * * * *

PART 127—WOMEN OWNED SMALL BUSINESS FEDERAL CONTRACT PROGRAM

■ 5. The authority citation for part 127 continues to read as follows:

Authority: 15 U.S.C. 632, 634(b)(6), 637(m), 644 and 657r.

■ 6. Amend § 127.102 by:

■ a. Adding a definition for ''Applicant'' in alphabetical order;

■ b. Revising the definitions of ''Interested party'' and ''System for Award Management (SAM) (or any successor system)''; and

■ c. Removing the definition of ''WOSB Program Repository''.

The addition and revisions read as follows:

§ 127.102 What are the definitions of the terms used in this part?

* * * * *

Applicant means a firm applying for certification in the WOSB Certification Program.

* * * * *

Interested party means a concern certified as, or pending certification as, a WOSB or EDWOSB that submits an offer for a specific EDWOSB or WOSB contract (including Multiple Award Contracts) or order, or SBA.

* * * * *

System for Award Management (SAM) (or any successor system) means the primary Government repository for prospective Federal awardee and Federal awardee information and the centralized Government system for certain contracting, grants, and other assistance-related processes. It includes—

(1) Data collected from prospective Federal Awardees required for the conduct of business with the Government;

(2) Prospective contractor-submitted annual representations and certifications in accordance with FAR subpart 4.12 (48 CFR subpart 4.12); and

(3) Identification of those parties excluded from receiving Federal Contracts, certain subcontracts, and certain types of Federal financial and non-financial assistance and benefits.

* * * * *

■ 7. Amend § 127.202 by revising paragraph (c) to read as follows:

§ 127.202 What are the requirements for control of an EDWOSB or WOSB?

* * * * *

(c) *Limitation on outside employment.* (1) A woman or economically disadvantaged woman generally must devote full time to the business concern during its normal hours of operations. The woman or economically disadvantaged woman who holds the highest officer position of the business concern may not engage in outside employment that prevents her from devoting the time and attention to the business concern necessary to control its management and daily operations.

(2) Where a woman or economically disadvantaged woman claiming to control a business concern devotes fewer hours to the business than its normal hours of operation, SBA will assume that she does not control the business concern, unless the concern demonstrates that she has ultimate managerial and supervisory control over both the long-term decision making and day-to-day management of the business.

(3) Any qualifying woman or economically disadvantage woman who seeks to engage in outside employment after certification must notify SBA of the nature and anticipated duration of the outside employment and demonstrate to SBA that the outside employment will not prevent her from controlling the business concern.

* * * * *

■ 8. Amend § 127.300 by revising the section heading and paragraphs (a)(2), (b)(3), and (c) to read as follows:

§ 127.300 How is a concern certified as an EDWOSB or WOSB?

(a) * * *

(2) A concern may submit evidence to SBA that it is a women-owned and controlled small business that is an SBA-certified participant in the Veteran Small Business Certification Program.

* * * * *

(b) * * *

(3) A concern may submit evidence to SBA that it is an economically disadvantaged women-owned and controlled small business that is a certified participant in the Veteran Small Business Certification Program.

* * * * *

(c) If SBA determines that the concern is a qualified WOSB or EDWOSB, it will issue a letter of certification and designate the concern as a certified WOSB or EDWOSB on the Dynamic Small Business Search (DSBS) system, SAM, or successor system.

■ 9. Amend § 127.303 by:

■ a. Redesignating paragraph (a)(1)(iii) as paragraph (a)(1)(iv);

■ b. Adding new paragraph (a)(1)(iii);

■ c. Removing paragraph (a)(2); and

■ d. Redesignating paragraph (a)(3) as paragraph (a)(2).

The addition reads as follows:

§ 127.303 What must a concern submit for certification?

(a) * * *

(1) * * *

(iii) A concern that is certified by SBA as a veteran-owned or service-disabled veteran-owned small business for the Veteran Small Business Certification Program and is owned and controlled by one or more women may use documentation of its VOSB or SDVOSB certification or most recent recertification in support of its application for WOSB certification. If the concern is also seeking EDWOSB certification, the concern must also submit documentation demonstrating that it is owned and controlled by one or more women who are economically disadvantaged in accordance with § 127.203(b)(3).

* * * * *

■ 10. Amend § 127.304 by revising paragraph (a) to read as follows:

§ 127.304 How is an application for certification processed?

(a) The SBA's Director of Government Contracting (D/GC) or designee is authorized to approve or decline applications for certification. SBA must receive all required information and supporting documents before it will begin processing a concern's application. SBA will not process incomplete applications.

(1) SBA will advise each applicant after the receipt of an application whether the application is complete and suitable for evaluation and, if not, what additional information or clarification is required to complete the application.

(2) SBA will make its determination within ninety (90) calendar days after receipt of a complete package, whenever practicable.

* * * * *

■ 11. Amend § 127.356 by revising paragraph (c) to read as follows:

§ 127.356 How does a concern obtain certification from an approved certifier?

* * * * *

(c) The concern must ensure that all documents necessary to determine its eligibility for certification by an approved certifier are uploaded in *https://certify.sba.gov* or any successor system.

■ 12. Amend § 127.504 by adding a sentence to the end of paragraph (a) introductory text to read as follows:

§ 127.504 What requirements must an EDWOSB or WOSB meet to be eligible for an EDWOSB or WOSB requirement?

(a) * * * An application is pending upon notification from SBA that the application is deemed complete and has sufficient documentation for full analysis.

* * * * *

■ 13. Amend § 127.604 by adding paragraph (f)(5) to read as follows:

§ 127.604 How will SBA process an EDWOSB or WOSB status protest?

* * * * *

(f) * * *

(5) Once a final determination has been made that a concern does not meet the requirements of a WOSB or EDWOSB, the concern cannot self-certify as a WOSB or EDWOSB, as applicable, for any WOSB or EDWOSB contract. If a concern does so, it may be in violation of criminal laws, including section 16(d) of the Small Business Act, 15 U.S.C. 645(d). If the concern has already certified itself as a WOSB or EDWOSB on a pending procurement, the concern must immediately inform the contracting officer for the procuring agency of its decertification.

(i) Not later than two days after the date on which a final determination is made, such concern must update its WOSB/EDWOSB status in the System for Award Management (or any successor system).

(ii) If a business concern fails to update its WOSB/EDWOSB status in the System for Award Management (or any successor system) in response to the final determination, SBA will make such update within two business days of the concern's failure to do so.

(iii) A concern required to make an update in the System for Award Management (or any successor system) shall notify a contracting officer for each contract with respect to which such concern has an offer or bid pending of the determination made, if the concern finds, in good faith, that such determination affects the eligibility of the concern to perform such contract.

§ 127.701 [Removed]

■ 14. Remove § 127.701.

PART 128—VETERAN SMALL BUSINESS CERTIFICATION PROGRAM

■ 15. The authority citation for part 128 continues to read as follows:

Authority: 15 U.S.C. 632(q), 634(b)(6), 644, 645, 657f, 657f–1.

■ 16. Amend § 128.203 by revising paragraph (i) to read as follows:

§ 128.203 Who does SBA consider to control a VOSB or SDVOSB?

* * * * *

(i) *Limitation on outside employment.* (1) A qualifying veteran generally must devote full time to the business concern during its normal hours of operations. The qualifying veteran who holds the highest officer position of the business concern may not engage in outside employment that prevents the qualifying veteran from devoting the time and attention to the concern necessary to control its management and daily business operations.

(2) Where a qualifying veteran claiming to control a business concern devotes fewer hours to the business than its normal hours of operation, SBA will assume that the qualifying veteran does not control the business concern, unless the concern demonstrates that the qualifying veteran has ultimate managerial and supervisory control over both the long-term decision making and day-to-day management of the business.

(3) Any qualifying veteran who seeks to engage in outside employment after certification must notify SBA of the nature and anticipated duration of the outside employment and demonstrate to SBA that the outside employment will not prevent the qualifying veteran from controlling the business concern.

* * * * *

■ 17. Amend § 128.500 by adding paragraphs (d)(3) and (e) to read as follows:

§ 128.500 What are the requirements for filing a VOSB or SDVOSB status protest?

* * * * *

(d) * * *

(3) A concern required to make an update in the System for Award Management (or any successor system) shall notify a contracting officer for each contract with respect to which such concern has an offer or bid pending of the determination made, if the concern finds, in good faith, that such determination affects the eligibility of the concern to perform such contract.

(e) Only interested parties may protest the VOSB or SDVOSB status of an apparent successful offeror for a VOSB or SDVOSB contract. An interested party means any certified VOSB or SDVOSB that submits an offer for a specific VOSB or SDVOSB set-aside contract (including a multiple award contract) or order, or SBA.

PART 134—RULES OF PROCEDURE GOVERNING CASES BEFORE THE OFFICE OF HEARINGS AND APPEALS

■ 18. The authority citation for part 134 continues to read as follows:

Authority: 5 U.S.C. 504; 15 U.S.C. 632, 634(b)(6), 634(i), 637(a), 648(l), 656(i), 657t and 687(c); E.O. 12549, 51 FR 6370, 3 CFR, 1986 Comp., p. 189.

Subpart J issued under 15 U.S.C. 657f.

Subpart K issued under 15 U.S.C. 657f.

Subpart L issued under 15 U.S.C. 636(a)(36); Pub. L. 116–136, 134 Stat. 281; Pub. L. 116–139, 134 Stat. 620; Pub. L. 116–142, 134 Stat. 641; and Pub. L. 116–147, 134 Stat. 660.

Subpart M issued under 15 U.S.C. 657a; Pub. L. 117–81, 135 Stat. 1541.

■ 19. Amend § 134.1002 by revising paragraph (b) to read as follows:

§ 134.1002 Who may file a VOSB or SDVOSB status protest?

* * * * *

(b) For all other procurements, any interested party may protest the apparent successful offeror's VOSB or SDVOSB status. An interested party means the contracting officer, SBA, VA, or any certified VOSB or SDVOSB that submits an offer for a specific set-aside

VOSB or SDVOSB contract (including Multiple Award Contracts) or order.

* * * * *

Isabella Casillas Guzman,

Administrator.

[FR Doc. 2024–28200 Filed 12–3–24; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 732, 734, 736, 740, 742, 744, 746, 748, 758, 762, 772, and 774

[Docket No. 241129–0307]

RIN 0694–XC111

Public Briefing on Changes to Advanced Computing and Semiconductor Manufacturing Items

AGENCY: Bureau of Industry and Security, U.S. Department of Commerce.

ACTION: Notification of public briefing on regulatory actions.

SUMMARY: On December 2, 2024, the Office of the Federal Register posted for public inspection two related Bureau of Industry and Security (BIS) rules: an interim final rule, ''Foreign-Produced Direct Product Rule Additions, and Refinements to Controls for Advanced Computing and Semiconductor Manufacturing Items,'' (RIN 0694–AJ74) and a final rule, ''Additions and Modifications to the Entity List; Removals from the Validated End-User (VEU) Program'' (RIN 0694–AJ77). This document announces that, on December 5, 2024, BIS will host a virtual public briefing on these rules. This document also provides details on the procedures for participating in the virtual public briefing.

DATES:

Virtual public briefing: The virtual public briefing will be held on December 5, 2024. The public briefing will begin at 3 p.m. Eastern Standard Time (EST) and conclude at 4 p.m. EST.

Deadline to register: Register by 1 p.m. EST on December 5, 2024, for virtual participation.

ADDRESSES: To attend this event virtually, register at: *https://events.gcc.teams.microsoft.com/event/abac2c31-743f-4f61-806f-0b7f4c376bcf@44cf3ec3-840c-4086-b7de-e3bc9a6c2db4.*

Recordkeeping: A summary of the briefing will be posted for the record at: *https://events.gcc.teams.microsoft.com/event/abac2c31-743f-4f61-806f-0b7f4c376bcf@44cf3ec3-840c-4086-b7de-e3bc9a6c2db4* and at *https://regulations.gov* under the *regulations.gov* ID for this notice (BIS–2024–0028).

FOR FURTHER INFORMATION CONTACT: For questions on this virtual public briefing, contact Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce at 202–482–2440 or by email: *RPD2@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

On December 2, 2024, the Office of Federal Register posted for public inspection the BIS interim final rule, ''Foreign-Produced Direct Product Rule Additions, and Refinements to Controls for Advanced Computing and Semiconductor Manufacturing Items,'' which amends the Export Administration Regulations (EAR). These amendments revise controls for certain advanced computing items, supercomputers, and semiconductor manufacturing equipment, which includes adding new controls for certain semiconductor manufacturing equipment and related items, creating new Foreign Direct Product (FDP) rules for certain commodities to impair the capability to produce ''advanced-node integrated circuits'' (''advanced-node ICs'') by certain destinations or entities of concern, adding new controls for certain high bandwidth memory (HBM) important for advanced computing, and clarifying controls on certain software keys that allow for the use of items such as software tools.

On the same day, the Office of Federal Register posted for public inspection the BIS final rule, ''Additions and Modifications to the Entity List; Removals from the Validated End-User (VEU) Program,'' which amends the EAR by adding 140 entities to the Entity List. These entries are listed on the Entity List under the destinations of China, People's Republic of (China), Japan, South Korea, and Singapore, and have been determined by the U.S. Government to be acting contrary to the national security and foreign policy interests of the United States.

That final rule also modifies 14 existing entries on the Entity List, consisting of revisions to 14 entries under China and is part of this larger effort to ensure that appropriate EAR controls are in place on these items, including in connection with transactions destined to or otherwise involving the entities being added to the Entity List, as well as for existing entries on the Entity List that are being modified. Additionally, that final rule designates nine of these entities being added and seven of the entries being modified as entities for which entity-specific restrictions apply with respect to certain foreign-produced items. The final rule also amends the EAR by removing three entities from the Validated End-User (VEU) Program.

Public Briefing

On December 5, 2024, BIS will host a public briefing to address the details of these two rules. The virtual public briefing will be held on December 5, 2024. The virtual public briefing will begin at 3 p.m. EST and conclude at 4 p.m. EST.

Procedure for Requesting Participation

To participate in the public meeting virtually, register at: *https://events.gcc.teams.microsoft.com/event/abac2c31-743f-4f61-806f-0b7f4c376bcf@44cf3ec3-840c-4086-b7de-e3bc9a6c2db4* no later than 1 p.m. EST on December 5, 2024, for virtual participation. This web page will also display the agenda of the public meeting and any other necessary information.

Special Accommodations

For any special accommodation needs, please send an email to: *rpd2@bis.doc.gov.*

Matthew S. Borman,

Principal Deputy Assistant Secretary for Strategic Trade and Technology Security.

[FR Doc. 2024–28423 Filed 12–2–24; 11:15 am]

BILLING CODE 3510–33–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 275

[Release No. IA–6773; File No. S7–03–22]

Private Fund Advisers; Documentation of Registered Investment Adviser Compliance Reviews

Correction

In Rule Document 2024–26524, appearing on pages 91252 through 91253, in the issue of Tuesday, November 19, 2024, make the following correction:

On page 91253, in the first column, in the 14th and 15th lines the text ''[INSERT DATE OF PUBLICATION IN THE **FEDERAL REGISTER**]'' should read ''November 19, 2024''.

[FR Doc. C1–2024–26524 Filed 12–2–24; 4:15 pm]

BILLING CODE 0099–10–D

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 883

[Docket No. FR–6378–F–02]

RIN 2502–AJ68

Updated Terminology for State Housing Agency Housing Assistance Payments Contracts

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development (HUD).

ACTION: Final rule.

SUMMARY: This final rule revises HUD's regulations for Housing Assistance Payments contracts that were initially issued and administered by a State Housing Finance Agency. This final rule clarifies the meaning of the terms ''HFA (Housing Finance Agency)'' and ''State Agency (Agency)'' when HUD either assumes contract administration responsibilities or assigns the contract administration responsibilities to a Performance-Based Contract Administrator. This final rule also clarifies how reserve accounts may be transferred following assumption of contract administration duties by a new party. These regulatory changes conform with longstanding HUD policy and practice. This final rule adopts HUD's July 17, 2024, proposed rule without change.

DATES: Effective January 3, 2025.

FOR FURTHER INFORMATION CONTACT: Jennifer Larson, Director, Office of Asset Management and Portfolio Oversight, U.S. Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410, telephone number 202–402–3823 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Section 8 Project-Based Rental Assistance Program

The Section 8 Project-Based Rental Assistance (Section 8 PBRA) program was enacted as part of the Housing and Community Development Act of 1974,[1] which amended the United States Housing Act of 1937.[2] Under the Section 8 PBRA program, either HUD or a public housing agency (PHA) acting pursuant to an annual contributions contract (ACC) with HUD provides rental assistance payments via a Housing Assistance Payments (HAP) Contract to project owners who, in turn, rent units covered by the HAP Contract to families who meet program eligibility rules. Either HUD or a PHA acting pursuant to an ACC serves as the contract administrator, which is responsible for performing multiple functions, from maintaining a reserve for replacement account and a residual receipts account to processing annual rent adjustments and periodic contract renewals. Pursuant to the United States Housing Act of 1937 and HUD regulations, a housing finance agency (HFA) meets the definition of a PHA and, as such, may serve as a Performance-Based Contract Administrator (PBCA).

B. Regulatory and Operational History of the 24 CFR Part 883 Section 8 PBRA Program

On April 15, 1975, HUD published 24 CFR part 883, establishing policies and procedures under which HFAs could select proposals for funding under the Section 8 New Construction and Substantial Rehabilitation Programs.[3] Pursuant to 24 CFR part 883, HFAs provided permanent financing and assumed the risk of default and foreclosure on selected project proposals. In selecting a project for permanent financing, HFAs and project owners could enter into HAP Contracts with initial mortgage terms of up to 40 years,[4] with the HFA serving as the HAP Contract administrator. Significantly for purposes of this rulemaking, in January of 1980, HUD issued a new regulation under 24 CFR part 883 that introduced a limit on annual distributions of project surplus cash for some project owners, a requirement for such owners to establish a residual receipts account, and a requirement to maintain a reserve for replacement account to address physical condition issues.[5] As HAP Contract administrators, the HFAs controlled the residual receipts and reserve for replacement accounts required by 24 CFR part 883.

In the 1990s, HAP Contracts between HFAs and project owners began to reach the end of the contracted term and expire. Where a HAP Contract expires and is not renewed, families eligible for Section 8 PBRA are at risk of displacement from their housing because there is no longer an agreement in place that allows project owners to receive Section 8 PBRA rental assistance for the applicable units. To authorize the renewal of expiring HAP Contracts, including HAP Contracts issued pursuant to 24 CFR part 883 (Part 883 HAP Contracts), Congress enacted the Multifamily Assisted Housing Reform and Affordability Act of 1997 (MAHRA).[6] As implemented by HUD, MAHRA allows the issuance of HAP Contracts that incorporate and renew nearly all provisions of an expired, original HAP Contract. Relevant to the purposes of this final rule, the provisions incorporated into renewed Part 883 HAP Contracts include references to the terms ''HFA'' and ''State Agency.''

Beginning in May of 1999, HUD began using PBCAs to streamline the renewal and administration of expiring HAP Contracts, including Part 883 HAP Contracts, by assigning administration and servicing tasks to PBCAs, which qualify as PHAs under the United States Housing Act of 1937 and act in accordance with an ACC that sets forth requirements and performance-based incentive standards. As Part 883 HAP Contracts expired, HUD began terminating ACCs with the HFAs of the expiring Part 883 HAP Contracts, with HUD then either taking over administration of the Part 883 HAP Contracts itself or assigning administration of the contracts to PBCAs. Relevant to the purpose of this final rule, references to the terms ''HFA'' and ''State Agency'' remained in both 24 CFR part 883 and the renewed Part 883 HAP Contracts that were now administered by either HUD or a PBCA.

As of the second quarter of 2023, there were approximately 2,690 Part 883 HAP Contracts in effect throughout the country. Of these contracts, the vast majority are now administered either by a PBCA or HUD, with only sixty-five (65) Part 883 HAP Contracts still being administered by an HFA. For the Part 883 HAP Contracts that were previously administered by an HFA but that are now administered by a PBCA or HUD, the terms ''HFA'' and ''State Agency'' still appear in the Part 883 HAP Contracts, along with references to the same terms in 24 CFR part 883. The references to these terms in the contracts and part 883 create confusion because HUD or a PBCA now administers these Part 883 HAP Contracts rather than an HFA or State

[1] Public Law 93–383, 88 Stat. 633 (1974).

[2] 42 U.S.C. 1437f.

[3] 40 FR 16934.

[4] The terms ''HFA'' and ''State Agency'' appear in both part 883 and corresponding HAP Contracts.

[5] 45 FR 6889 (Jan. 30, 1980).

[6] 42 U.S.C. 1437f.

Agency. This confusion is especially problematic with regard to the administration of project owners' restricted financial accounts (*i.e.,* the residual receipts and reserve for replacement accounts) because of unclear expectations regarding which entity must issue approvals to withdraw funds. HUD issues this final rule to eliminate this confusion.

C. Residual Receipts and Reserve for Replacement Project Accounts

Both the residual receipts account and the reserve for replacement account are project accounts. The project owner must make deposits to the residual receipts account and the reserve for replacement accounts, consistent with HUD requirements, and must receive prior approval before withdrawing funds from either account. When a HAP Contract associated with the project is administered by an HFA, the project owner requests fund withdrawal approval from the HFA. Once an ACC between the HFA and HUD expires, HUD must review such fund withdrawal requests; therefore, the HFA must release the funds in the accounts upon the request of the project owner. The project owner, in turn, must ensure that the residual receipts and reserve for replacement accounts funds are placed in accounts that meet HUD requirements, after which time any fund withdrawals will be made only with HUD approval.

II. The Proposed Rule

On July 17, 2024, HUD published for public comment a proposed rule entitled ''Updated Terminology for State Housing Agency Housing Assistance Payments Contracts.'' [7] The proposed rule proposed to amend the definitions of two terms defined in 24 CFR 883.302: ''HFA (Housing Finance Agency)'' and ''State Agency (Agency).'' In the proposed rule, HUD proposed that the definitions found in 24 CFR 883.302 for these terms continue to apply while an ACC between HUD and an HFA is in effect. When an ACC between HUD and the HFA expires and is not renewed, HUD proposed that the definitions of the terms ''HFA (Housing Finance Agency)'' and ''State Agency (Agency)'' then be defined the same as ''Contract Administrator'' is defined at 24 CFR 880.201. In addition to the proposed definition changes to 24 CFR 883.302, HUD also proposed to make a conforming change to 24 CFR 883.701. In the proposed rule, HUD also proposed to amend 24 CFR 883.306 and add a new § 883.702 to make clear that project owners are required to request the withdrawal of funds from residual receipts and reserve for replacement accounts administered by HFAs when the ACC between HUD and the HFA is terminated or expires.

III. This Final Rule

HUD is publishing this final rule without change from the proposed rule. HUD received a single public comment in response to the proposed rule that noted that the commenter has had no problem with PHFA. HUD appreciates the comment. As noted, HUD is revising the referenced terminology for clarity and accuracy.

HUD believes that the revision in 24 CFR 883.302 to the definitions of ''HFA (Housing Finance Agency)'' and ''State Agency (Agency)'' is necessary to eliminate the confusion that results when a renewed Part 883 HAP Contract is administered by HUD or a PBCA, rather than the former HFA. In addition, the conforming change to 24 CFR 883.701 makes clear that, for the purposes of 24 CFR part 883, subpart G, all references to ''contract administrator'' in 24 CFR part 880, subpart F, shall be construed to refer to ''Agency'' only while the ACC between the State Agency and HUD is in effect. The changes to 24 CFR 883.306 and the addition of a new § 883.702 are necessary to clarify that project owners are required to request the withdrawal of funds from residual receipts and reserve for replacement accounts administered by HFAs when the ACC between HUD and the HFA is terminated or expires.

V. Findings and Certifications

Regulatory Review—Executive Orders 12866, 13563, and 14094

Pursuant to Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The order also directs Executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' Executive Order 13563 further directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. Executive Order 14094 (Modernizing Regulatory Review) amends section 3(f) of Executive Order 12866, among other things.

This final rule clarifies that HUD or a PBCA may assume the HAP Contract administrator responsibilities when the ACC between HUD and an HFA expires. This final rule also clarifies how residual receipts and reserve for replacement accounts may be transferred following assumption of contract administration duties by a new party. These regulatory changes conform with longstanding HUD policy and practice. This rulemaking was determined to not be a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, as amended by Executive Order 14094, and is not an economically significant regulatory action and therefore was not subject to OMB review.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments, and on the private sector. This final rule does not impose any Federal mandates on any State, local, or Tribal government, or on the private sector, within the meaning of the UMRA.

Environmental Impact

A Finding of No Significant Impact (FONSI) with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The FONSI is available through the Federal eRulemaking Portal at *http://www.regulations.gov.* The FONSI is also available for public inspection during regular business hours in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, you must schedule an appointment in advance to review the FONSI by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication

[7] 89 FR 58092.

disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As discussed above, the changes in this final rule are limited to clarifying that HUD or a PBCA may assume the HAP Contract administrator responsibilities when the ACC between HUD or an HFA expires. The rulemaking also clarifies how residual receipts and reserve for replacement accounts may be transferred following assumption of contract administration duties by a new party. These regulatory changes conform with longstanding HUD policy and practice. Accordingly, the undersigned certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 13132, Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either: (1) imposes substantial direct compliance costs on State and local governments and is not required by statute, or (2) the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This final rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive order.

List of Subjects in 24 CFR Part 883

Accounting, Administrative practice and procedure, Government contracts, Grant programs-housing and community development, Low and moderate income housing, Public assistance programs, Public housing, Rent subsidies, Reporting and recordkeeping requirements, State and local governments.

For the reasons stated in the preamble, HUD amends 24 CFR part 883 as follows:

PART 883—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM—STATE HOUSING AGENCIES

■ 1. The authority citation for part 883 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f, 3535(d), and 13611–13619.

■ 2. In § 883.302, redesignate the definition of ''HFA (Housing Finance Agency)'' in alphabetical order and revise it, and revise the definition of ''State Agency (Agency)''.

The revisions read as follows:

§ 883.302 Definitions.

* * * * *

HFA (Housing Finance Agency). While the Annual Contributions Contract between the State Agency and HUD is in effect, ''Housing Finance Agency'' and ''HFA'' means a State Agency that provided permanent financing for newly constructed or substantially rehabilitated housing processed under this part and financed without Federal mortgage insurance or a Federal guarantee except coinsurance under section 244 of the National Housing Act. When the Annual Contributions Contract between the State Agency and HUD is no longer in effect, ''Housing Finance Agency'' and ''HFA,'' as used in this part and in the Housing Assistance Payments Contract, means ''Contract Administrator,'' as defined in 24 CFR 880.201.

* * * * *

State Agency (Agency). While the Annual Contributions Contract between the State Agency and HUD is in effect, ''State Agency'' and ''Agency'' means an agency that has been notified by HUD that it is authorized to apply for a set-aside and/or to use the Fast Track Procedures of this part. When the Annual Contributions Contract between the State Agency and HUD is no longer in effect, ''State Agency'' and ''Agency,'' as used in this part and in the Housing Assistance Payments Contract, mean ''Contract Administrator,'' as defined in 24 CFR 880.201.

* * * * *

■ 3. In § 883.306, add a sentence to the end of paragraph (e) to read as follows:

§ 883.306 Limitation on distributions.

* * * * *

(e) * * * Upon termination of the Annual Contributions Contract between HUD and the HFA, the Owner must request withdrawal of any funds that were placed in such an account at the direction of the HFA and immediately deposit such funds into an interest-bearing residual receipts account that complies with the requirements of 24 CFR 880.601(e)(2)(i).

* * * * *

§ 883.701 [Amended]

■ 4. In § 883.701, add the words ''while the Annual Contributions Contract between the State Agency and HUD is in effect'' to the end of the second sentence following ''Agency''.

■ 5. Add § 883.702 to read as follows:

§ 883.702 Replacement reserve.

For projects that are required to maintain a replacement reserve account to fund capital repairs and building system replacements, while the Annual Contributions Contract (ACC) between the State Agency and HUD is in effect, funds in that replacement reserve account may be drawn and used only in accordance with State Agency guidelines and with the approval of, or as directed by, the State Agency. Upon termination of the ACC, the Owner must request withdrawal of any funds in the replacement reserve account and immediately deposit such funds into an interest-bearing replacement reserve account that complies with the requirements of 24 CFR 880.602(a)(1)(iv).

Julia R. Gordon,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2024–28297 Filed 12–3–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2024–0962]

Special Local Regulations; Marine Events Within the Captain of the Port Charleston Zone

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulation to provide for the safety and security of certain navigable waterways of Charleston Harbor during the Charleston Parade of Boats. Our regulation for marine events within the Captain of the Port Charleston identifies the regulated area for this event in Charleston Harbor, SC. During the enforcement periods, no person or vessel may enter, transit through, anchor in, or remain within the designated area unless authorized by the

Captain of the Port Charleston (COTP) or a designated representative.

DATES: The regulations in 33 CFR 100.704 will be enforced for the location identified in Table 1 to § 100.704, Item 10, from 5 p.m. until 8 p.m. on December 14, 2024.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Chief, Marine Science Technician Tyler Campbell, Sector Charleston Waterways Management Division, U.S. Coast Guard; telephone (843) 740–3184, email *charlestonwaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation in 33 CFR 100.704, Table 1 to § 100.704, Item 10, for the Charleston Parade of Boats from 5 p.m. until 8 p.m. on December 14, 2024. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Captain of the Port Charleston, Table 1 to § 100.704, item 10, specifies the location of the regulated area for the Charleston Parade of Boats which encompasses portions of the Charleston Harbor including Anchorage A, Shutes Folly, Horse Reach, Hog Island Reach, Town Creek Lower Reach, Ashley River, and finishing at City Marina. During the enforcement periods, as reflected in 33 CFR 100.704(c), if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander or any official patrol vessel.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

Dated: November 26, 2024.

F.J. Delrosso,

Captain, U.S. Coast Guard, Captain of the Port Charleston.

[FR Doc. 2024–28340 Filed 12–3–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[USCG–2023–0749]

RIN 1625–AA01

Establish Anchorage Ground; Port Westward Anchorage, Columbia River, Oregon and Washington

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing an anchorage ground near Port Westward, Oregon on the Columbia River. The purpose of this rule is to improve safety of navigation by providing additional safe anchorages for commercial vessels in the navigable waters of the Columbia River.

DATES: This rule is effective January 3, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0749 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant Commander Jesse Wallace, Waterways Management Division, Sector Columbia River, U.S. Coast Guard; telephone 503–240–9319, email *SCRWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

In the last several years, the Columbia River Marine Transportation System has seen an increase in commercial traffic and vessel size near the Lower Columbia River, thus creating a concern for anchorage capacity within the river system. The Columbia River Steamship Operators Association and the Columbia River Pilots formally requested the Coast Guard review and evaluate the establishment of this new anchorage ground to address the safety and navigation concerns with the expanding vessel traffic in the Lower Columbia River. In response, on December 28, 2023, the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Establish Anchorage Ground; Port Westward Anchorage, Columbia River, Oregon and Washington'' (88 FR 89644). There we stated why we issued the NPRM and invited comments on our proposed regulatory action to establish this anchorage ground. During the comment period that ended February 26, 2024, we received 39 comments. The Coast Guard opened another 30-day comment period that ended June 7, 2024 (89 FR 38853), in which we received an additional 3 comments. In total, we had 90 days of comment period and received 42 total comments, including some duplicate submissions.

III. Legal Authority and Need for Rule

Under Title 33 of the Code of Federal Regulations (CFR) 109.05, the Commandant of the Coast Guard has delegated the authority to establish anchorage grounds to Coast Guard District Commanders. The Coast Guard establishes anchorage grounds under Section 7 of the Rivers and Harbors Act of March 4, 1915, as amended (38 Stat. 1053; 46 U.S.C. 70006) and places these regulations in Title 33 CFR part 110, subpart B. The purpose of this rule is to establish a Federal anchorage ground in the Lower Columbia River to improve safety of navigation by creating additional anchorage grounds for the increased vessel traffic transiting through the Lower Columbia River. The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received 42 total comments on our NPRM during the 2 comment periods. A few of the comments were duplicates. All comments received fully support this rule. We received significant input regarding how important it is to establish this anchorage, with many describing the environmental, safety, and economic benefits of this proposed anchorage, particularly in light of the increase in ship size in the channel since the 1970's. One comment suggested adding a stern anchor buoy to the anchorage. The United States Army Corps of Engineers is responsible for the establishment of stern anchor buoys, interested parties may request the addition of a buoy after the completion of this regulatory process. Another comment asked the Coast Guard to consider two observations regarding the establishment of the proposed anchorage ground. First, the anchorage ground depth. Second, a charted sandwave area that intersects the

proposed anchorage ground. Below is the Coast Guard's response to these observances.

A. Anchorage Ground Depth

The range of depths within the anchorage ground will accommodate a variety of vessel types and configurations. 33 U.S.C. 365 authorizes the United States Army Corps of Engineers to dredge within, and adjacent to, Federal anchorages established by the Coast Guard. Environmental reviews and approvals are required prior to dredging in the anchorage.

B. Horizontal Datum

The NPRM included the boundary coordinates for the anchorage ground as latitude and longitude without a statement of the associated horizontal datum. The associated horizontal datum has been implemented into the regulatory text at the end of this rulemaking. All other regulatory text remaining unchanged.

C. Final Rule

This rule establishes a Federal anchorage ground in the vicinity of Port Westward, in the Lower Columbia River. The specific coordinates for this anchorage ground are included in the regulatory text at the end of this document.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the location and size of the anchorage ground, as well as the vessel traffic and anchoring data provided by the Coast Guard Navigation Center. The regulation will ensure approximately 0.336 square miles of anchorage grounds are designated to provide necessary commercial deep draft anchorages and enhance the navigational safety of commercial vessels transiting to, from, and within the Columbia River. The impact on routine navigation is expected to be minimal because the anchorage ground is located outside the federal channel and is consistent with current anchorage habits. When not occupied, vessels will be able to maneuver in, around, and through the anchorages.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to use the anchorage ground may be small entities, for reasons stated in section V.A above, this rule would not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishing an anchorage ground, Port Westward Anchorage, in an area traditionally used by commercial ships for anchoring in the Lower Columbia River system; and increasing the navigation safety and anchorage

capacity of the river system. It is categorically excluded from further review under paragraph L59(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

List of Subjects in 33 CFR Part 110

Anchorage grounds.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 110 as follows:

PART 110—ANCHORAGE REGULATIONS

■ 1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 2071; 46 U.S.C. 70006, 70034; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 00170.1 Revision No. 01.3.

■ 2. Amend § 110.228 by adding paragraphs (a)(12) through (14) to read as follows:

§ 110.228 Columbia River, Oregon and Washington.

(a) * * *

(12) [Reserved]

(13) [Reserved]

(14) *Port Westward Anchorage.* All waters in the vicinity of Port Westward, Oregon, bound by a line connecting the following points, which are based on the World Geodetic System (WGS 84):

Latitude	Longitude
46°10′16.80″	123°12′58.80″
46°10′48.60″	123°11′25.20″
46°10′43.20″	123°11′21.60″
46°09′59.40″	123°12′46.80″

* * * * *

Dated: November, 26, 2024.

Charles E. Fosse,

Rear Admiral, U.S. Coast Guard, Commander, Thirteenth Coast Guard District.

[FR Doc. 2024–28311 Filed 12–3–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–1023]

RIN 1625–AA00

Safety Zone; Charleston Harbor, Charleston County, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of the Atlantic Ocean at the Charleston Harbor Entrance Channel, Charleston Harbor, and Cooper River, within a 100-yard radius of the M/V CAPE RACE and all towing vessels supporting its operations. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by the dead ship movement of M/V CAPE RACE from the Charleston Harbor Entrance Channel to Detyens Shipyard on the Cooper River in North Charleston, SC. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Charleston.

DATES: This rule is effective without actual notice from December 4 2024, through 8 p.m. December 4, 2024. For the purposes of enforcement, actual notice will be used from 8 a.m. on November 28, 2024, through December 4, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–1023 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Petty Officer First Class Thomas J. Welker, Sector Charleston, Waterways Management Division, U.S. Coast Guard; telephone (843) 740–3180 ext. 3339, email *thomas.j.welker@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable and contrary to the public interest.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard lacks sufficient time to provide for a comment period and then consider those comments before issuing the rule since this rule is needed by November 28, 2024.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to minimize the potential safety hazards associated with the dead ship movement of the M/V CAPE RACE on or about November 28, 2024.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Charleston (COTP) has determined that potential hazards associated with the dead ship movement and berthing of M/V CAPE RACE on or about November 28, 2024, will be a safety concern for anyone within a 100-yard radius of vessel and any towing vessels supporting the operation. This rule is needed to protect personnel, vessels, and the marine environment during the dead ship movement of M/V CAPE RACE while transiting from the Charleston Harbor Entrance Channel to berthing at Detyens Shipyards on the Cooper River in North Charleston, SC.

IV. Discussion of the Rule

This rule establishes a temporary moving safety zone on or about November 28, 2024, however the zone will only be enforced while the M/V CAPE RACE is underway with supporting, towing vessels. The moving 100-yard safety zone will be established for the M/V CAPE RACE and all towing vessels supporting its operations during transiting from Charleston Harbor Entrance Channel Buoy #6 in the Charleston Harbor Entrance Channel to berthing at Detyens Shipyards on the Cooper River in North Charleston, SC. The safety zone will only be enforced during the towing operations, while the vessel is in transit. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by the dead ship movement of M/V CAPE RACE while transiting the Charleson Harbor area. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and

Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on size, location, and scope of the safety zone. The zone is limited in size, location, and duration as it will cover all navigable waters of the Atlantic Ocean at the Charleston Harbor Entrance Channel, Charleston Harbor, and Cooper River within a 100-yard radius of the M/V CAPE RACE and any towing vessels supporting the operation. The zone is limited in scope as vessel traffic may be able to safely transit around this safety zone and vessels may seek permission from the COTP to enter the zone. The zone is limited in duration in that it will be enforced for no more than eight hours. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the safety zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves temporary, moving safety zone on waters of the Atlantic Ocean at the Charleston Harbor Entrance Channel, Charleston Harbor, and Cooper River, within a 100-yard radius of the vessel M/V CAPE RACE and all towing vessels supporting its operations until the vessel completes mooring at Detyens Shipyards on the Cooper River in North Charleston, SC. This zone is not expected to last more than eight hours. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Safety measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS.

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T07–1023 to read as follows:

§ 165.T07–1023 Safety Zone; Charleston Harbor, Charleston, SC

(a) *Location.* The following is a safety zone: The moving safety zone will include all navigable waters of the Atlantic Ocean at the Charleston Harbor Entrance Channel, Charleston Harbor, and Cooper River, within a 100-yard radius of the M/V CAPE RACE and all towing vessels supporting its operations, while transiting to berthing at Detyens Shipyards on the Cooper River in North Charleston, SC.

(b) *Definition.* The term ''designated representative'' means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) No person or vessel will be permitted to enter, transit, anchor, or remain within the safety zone unless authorized by the COTP Charleston or a designated representative. If authorization is granted, persons and/or vessels receiving such authorization must comply with the instructions of the COTP Charleston or designated representative.

(2) Persons who must notify or request authorization from the COTP Charleston may do so by telephone at (843) 740–7050, or may contact a designated representative via VHF radio on channel 16.

(d) *Effective and enforcement period.* This section is effective on November 28, 2024. The moving zone will be enforced while M/V CAPE RACE and all towing vessels supporting its operation are transiting, until moored at Detyens Shipyards on the Cooper River in North Charleston, SC.

Dated: November 26, 2024.

Francis J. DelRosso

Captain, U.S. Coast Guard Captain of the Port Charleston.

[FR Doc. 2024–28336 Filed 12–3–24; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2024–0209; FRL–11948–02–R9]

Air Plan Approval; California; Mojave Desert Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the Mojave Desert Air Quality Management District (MDAQMD or ''District'') portion of the California State Implementation Plan (SIP). These revisions concern recodification of prohibitory and administrative rules used by the District to regulate air pollutants under the Clean Air Act (CAA or the Act) including volatile organic compounds (VOCs), oxides of nitrogen (NO_X) and particulate matter (PM). The intended effect is to update the California SIP to reflect the recodified rules.

DATES: These rules are effective January 3, 2025.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2024–0209. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: La Kenya Evans-Hopper, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; phone: (415) 972–3245; email: *evanshopper.lakenya@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

Table of Contents

I. Proposed Action

On July 16, 2024 (89 FR 57819), under CAA section 110(k)(3), the EPA proposed to approve certain MDAQMD rules because they represent recodifications of existing SIP rules. The EPA also proposed to approve certain rescissions of existing SIP rules for the Riverside County portion of the MDAQMD SIP because they mirror recodified rules that were proposed for approval.[1]

In our proposed rule, we described the complicated regulatory history of the MDAQMD from the early 1970's to the present time. The applicable SIP for the area the District now regulates consists of a mixture of rules from current and former agencies. Rules adopted by MDAQMD apply District-wide; rules adopted by the San Bernardino County Air Pollution Control District (SBCAPCD) apply only in the San Bernardino County portion of the District; and rules adopted by the Riverside County APCD (RCAPCD), the Southern California APCD (SoCalAPCD), or the South Coast Air Quality Management District (SCAQMD) only apply in the Riverside County portion of the District. The purpose of the SIP revisions that are the subject of this action is to align the SIP versions of the rules with those that are in effect in the MDAQMD.

Table 1 lists the MDAQMD rules that were submitted for inclusion in the SIP with the date each rule was adopted and then submitted by the California Air Resources Board (CARB).[2] When these rules were submitted, CARB also requested rescission of the analogous rules in the SIP that were adopted by SCAQMD.[3] Table 2 lists the rules to be rescinded by this action with the dates that they were adopted by SCAQMD, approved by the EPA (with the associated **Federal Register** citations), subsequently rescinded by MDAQMD, and then submitted by CARB for rescission.

[1] The MDAQMD's jurisdiction includes the desert portion of San Bernardino County and the far eastern portion of Riverside County.

[2] The SBCAPCD rules have adoption dates prior to the formation of the MDAQMD because the rules were not revised or amended when the MDAQMD was formed and first adopted its rulebook. The rules were merely recodified as being MDAQMD rules that apply District-wide.

[3] The versions of Rules 104, 408, 443, 468, 469 and 472 that are currently part of the applicable SIP for the Riverside County portion of the MDAQMD were adopted by the SoCalAPCD, rather than the SCAQMD.

TABLE 1—SUBMITTED RULES

Local agency	Rule No.	Rule title	Adopted/amended/revised date	Submittal date
MDAQMD	104	Reporting of Source Test Data and Analyses	December 19, 1988	October 13, 2023.
MDAQMD	404	Particulate Matter—Concentration	July 25, 1977	May 11, 2023.
MDAQMD	405	Solid Particulate Matter—Weight	July 25, 1977	May 11, 2023.
MDAQMD	407	Liquid and Gaseous Air Contaminants	July 25, 1977	September 23, 2022.
MDAQMD	408	Circumvention	July 25, 1977	May 11, 2023.
MDAQMD	409	Combustion Contaminants	July 25, 1977	May 11, 2023.
MDAQMD	443	Labeling of Solvents	July 25, 1977	May 11, 2023.
MDAQMD	468	Sulfur Recovery Units	July 25, 1977	November 30, 2022.
MDAQMD	469	Sulfuric Acid Units	July 25, 1977	November 30, 2022.
MDAQMD	472	Reduction of Animal Matter	July 25, 1977	May 11, 2023.

TABLE 2—SUBMITTED RULE RESCISSIONS

Local agency	Title	Adopted/amended/revised date	SIP approval date and FR citation	Date of rescission by MDAQMD	Submittal date
SCAQMD Rule 104	Reporting of Source Test Data and Analyses.	January 9, 1976	June 14, 1978, 43 FR 25684	April 24, 2023	October 13, 2023.
SCAQMD Rule 408	Circumvention	May 7, 1976	June 14, 1978, 43 FR 25684	April 25, 2022	May 11, 2023.
SCAQMD Rule 443	Labeling of Solvents	January 1, 1977	June 14, 1978, 43 FR 25684	October 24, 2022	May 11, 2023.
SCAQMD Rule 468	Sulfur Recovery Units	October 8, 1976	June 14, 1978, 43 FR 25684	August 22, 2022	November 30, 2022.
SCAQMD Rule 469	Sulfuric Acid Units	October 8, 1976	June 14, 1978, 43 FR 25684	August 22, 2022	November 30, 2022.
SCAQMD Rule 472	Reduction of Animal Matter	May 7, 1976	June 14, 1978, 43 FR 25684	August 22, 2022	May 11, 2023.

Table 3 lists the previously-approved rules that had been adopted by the SBCAPCD along with their local adoption dates and EPA approval citations. Upon final approval of the MDAQMD rules listed in table 1, the SCBAPCD rules in table 3 will be superseded in the applicable SIP by the corresponding MDAQMD rules.

TABLE 3—SIP RULES TO BE SUPERSEDED UPON APPROVAL OF RULES LISTED IN TABLE 1

Local agency	Rule No.	Rule title	Adopted/amended/revised date	SIP approval date and FR citation
SBCAPCD	104	Reporting of Source Test Data and Analyses.	December 19, 1988	November 27, 1990, 55 FR 49281.
SBCAPCD	404	Particulate Matter—Concentration	July 25, 1977	December 21, 1978, 43 FR 59489.
SBCAPCD	405	Solid Particulate Matter—Weight	July 25, 1977	December 21, 1978, 43 FR 59489.
SBCAPCD	407	Liquid and Gaseous Air Contaminants	February 1, 1977	September 8, 1978, 43 FR 40011.
SBCAPCD	408	Circumvention	February 1, 1977	September 8, 1978, 43 FR 40011.
SBCAPCD	409	Combustion Contaminants	February 1, 1977	September 8, 1978, 43 FR 40011.
SBCAPCD	443	Labeling of Solvents	February 1, 1977	September 8, 1978, 43 FR 40011.
SBCAPCD	468	Sulfur Recovery Units	February 1, 1977	September 8, 1978, 43 FR 40011.
SBCAPCD	469	Sulfuric Acid Units	February 1, 1977	September 8, 1978, 43 FR 40011.
SBCAPCD	472	Reduction of Animal Matter	February 1, 1977	September 8, 1978, 43 FR 40011.

As explained in the proposed rule, we reviewed these particular submitted MDAQMD rules as recodifications of existing rules and did not review the substance of the rules at this time.[4] The EPA proposed to approve the rules in table 1 to replace identical rules in table 3 that were previously-approved by the EPA but that only apply to a geographic subset of the District. For additional information about our proposed action and rationale, please see our proposed rule.

[4] We followed the guidance from the EPA memorandum dated February 12, 1990, from Johnnie L. Pearson, Chief, Regional Activities Section, EPA Office of Air Quality Planning and Standards to Chief, Air Branch, Regions I–X, ''Review of State Regulation Recodifications.''

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received no comments.

III. EPA Action

Under CAA section 110(k)(3), and for the reasons given in the proposed rule and summarized herein, the EPA is taking final action to approve the submitted rules in table 1 because they represent recodifications of existing SIP rules. The rules in table 1 will supersede the rules in table 3. The EPA is also taking final action to approve the rescissions listed in table 2 because they mirror recodified rules that we are approving. Our final action incorporates the submitted rules into the SIP and removes from the applicable SIP the rules that have been rescinded or superseded.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the MDAQMD rules listed in table 1 of this preamble, which includes certain administrative and prohibitory rules that control emissions of VOCs, NO_X, and PM. The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX Office (please

contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on communities with environmental justice (EJ) concerns to the greatest extent practicable and permitted by law. The EPA defines EJ as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

The air agency did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving EJ for communities with EJ concerns.

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 3, 2025. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Dated: November 19, 2024.

Martha Guzman Aceves,

Regional Administrator, Region IX.

For the reasons stated in the preamble, the EPA amends part 52, chapter I, title 40 of the Code of Federal Regulations as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(31)(vi)(J), (c)(32)(iv)(H) through (J), (c)(37)(i)(E) and (F), (c)(39)(ii)(M) through (S), (c)(42)(xiii)(E) and (F), (c)(179)(i)(B)(*4*), (c)(610)(i)(D), and (c)(620) through (622) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(31) * * *

(vi) * * *

(J) Previously approved on June 14, 1978, in paragraph (c)(31)(vi)(B) of this section and now deleted with replacement in paragraph (c)(622)(i)(A)(*1*) of this section for implementation in the Mojave Desert Air Quality Management District: Rule 104.

* * * * *

(32) * * *

(iv) * * *

(H) Previously approved on June 14, 1978, in paragraph (c)(32)(iv)(A) of this section and now deleted with replacement in paragraph (c)(610)(i)(D)(*3*) of this section for implementation in the Mojave Desert Air Quality Management District: Rule 408.

(I) Previously approved on June 14, 1978, in paragraph (c)(32)(iv)(A) of this section and now deleted with replacement in paragraph (c)(610)(i)(D)(*5*) of this section for implementation in the Mojave Desert Air Quality Management District: Rule 443.

(J) Previously approved on June 14, 1978, in paragraph (c)(32)(iv)(A) of this section and now deleted with replacement in paragraph (c)(610)(i)(D)(*6*) of this section for implementation in the Mojave Desert

Air Quality Management District: Rule 472.

* * * * *

(37) * * *

(i) * * *

(E) Previously approved on June 14, 1978, in paragraph (c)(37)(i)(A) of this section and now deleted with replacement in paragraph (c)(621)(i)(A)(*1*) of this section for implementation in the Mojave Desert Air Quality Management District: Rule 468.

(F) Previously approved on June 14, 1978, in paragraph (c)(37)(i)(A) of this section and now deleted with replacement in paragraph (c)(621)(i)(A)(*2*) of this section for implementation in the Mojave Desert Air Quality Management District: Rule 469.

* * * * *

(39) * * *

(ii) * * *

(M) Previously approved on September 8, 1978, in paragraph (c)(39)(ii)(C) of this section and now deleted with replacement in paragraph (c)(620)(i)(A)(*1*) of this section: Rule 407.

(N) Previously approved on September 8, 1978, in paragraph (c)(39)(ii)(C) of this section and now deleted with replacement in paragraph (c)(610)(i)(D)(*3*) of this section: Rule 408.

(O) Previously approved on September 8, 1978, in paragraph (c)(39)(ii)(C) of this section and now deleted with replacement in paragraph (c)(610)(i)(D)(*4*) of this section: Rule 409.

(P) Previously approved on September 8, 1978, in paragraph (c)(39)(ii)(C) of this section and now deleted with replacement in paragraph (c)(610)(i)(D)(*5*) of this section: Rule 443.

(Q) Previously approved on September 8, 1978, in paragraph (c)(39)(ii)(C) of this section and now deleted with replacement in paragraph (c)(621)(i)(A)(*1*) of this section: Rule 468.

(R) Previously approved on September 8, 1978, in paragraph (c)(39)(ii)(C) of this section and now deleted with replacement in paragraph (c)(621)(i)(A)(*2*) of this section: Rule 469.

(S) Previously approved on September 8, 1978, in paragraph (c)(39)(ii)(C) of this section and now deleted with replacement in paragraph (c)(610)(i)(D)(*6*) of this section: Rule 472.

* * * * *

(42) * * *

(xiii) * * *

(E) Previously approved on December 21, 1978, in paragraph (c)(42)(xiii)(A) of this section and now deleted with replacement in paragraph (c)(610)(i)(D)(*1*) of this section: Rule 404.

(F) Previously approved on December 21, 1978, in paragraph (c)(42)(xiii)(A) of this section and now deleted with replacement in paragraph (c)(610)(i)(D)(*2*) of this section: Rule 405.

* * * * *

(179) * * *

(i) * * *

(B) * * *

(*4*) Previously approved on November 27, 1990, in paragraph (c)(179)(i)(B)(*1*) of this section and now deleted with replacement in paragraph (c)(622)(i)(A)(*1*) of this section: Rule 104, amended on December 19, 1988.

* * * * *

(610) * * *

(i) * * *

(D) Mojave Desert Air Quality Management District.

(*1*) Rule 404, ''Particulate Matter—Concentration,'' readopted on July 25, 1977.

(*2*) Rule 405, ''Solid Particulate Matter—Weight,'' readopted on July 25, 1977.

(*3*) Rule 408, ''Circumvention,'' readopted on July 25, 1977.

(*4*) Rule 409, ''Combustion Contaminants,'' readopted on July 25, 1977.

(*5*) Rule 443, ''Labeling of Solvents,'' readopted on July 25, 1977.

(*6*) Rule 472, ''Reduction of Animal Matter,'' readopted on July 25, 1977.

* * * * *

(620) The following regulations were submitted on September 23, 2022, by the Governor's designee.

(i*) Incorporation by reference.* (A) Mojave Desert Air Quality Management District.

(*1*) Rule 407, ''Liquid and Gaseous Air Contaminants,'' readopted on July 25, 1977.

(*2*) [Reserved]

(B) [Reserved]

(ii) [Reserved]

(621) The following regulations were submitted electronically on November 30, 2022, by the Governor's designee as an attachment to a letter dated November 22, 2022.

(i) *Incorporation by reference.* (A) Mojave Desert Air Quality Management District.

(*1*) Rule 468, ''Sulfur Recovery Units,'' readopted on July 25, 1977.

(*2*) Rule 469, ''Sulfur Acid Units,'' readopted on July 25, 1977.

(B) [Reserved]

(ii) [Reserved]

(622) The following regulations were submitted on October 13, 2023, by the Governor's designee.

(i*) Incorporation by reference.* (A) Mojave Desert Air Quality Management District.

(*1*) Rule 104, ''Reporting of Source Test Data and Analyses,'' amended on December 19, 1988.

(*2*) [Reserved]

(B) [Reserved]

(ii) [Reserved]

* * * * *

[FR Doc. 2024–27627 Filed 12–3–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2017–0015; FRL–5948.2–02–OAR]

RIN 2060–AV59

National Emission Standards for Hazardous Air Pollutants: Lime Manufacturing Plants Technology Review; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: The Environmental Protection Agency (EPA) is making corrections to the National Emission Standards for Hazardous Air Pollutants for Lime Manufacturing Plants (Lime Manufacturing NESHAP) technology review final rule that appeared in the **Federal Register** on July 16, 2024. Following publication of this final rule, the EPA discovered inadvertent errors in the regulatory text and is correcting them in this action.

DATES: The final rule is effective on December 4, 2024.

ADDRESSES: The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2017–0015. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov/.*

FOR FURTHER INFORMATION CONTACT: Mr. Brian Storey, Mail Drop: D243–04, 109

T.W. Alexander Drive, P.O. Box 12055, RTP, North Carolina 27711; telephone number: (919) 541–1103; and email address: *storey.brian@epa.gov.*

Preamble acronyms and abbreviations. Throughout this document the use of ''we,'' ''us,'' or ''our'' is intended to refer to the EPA. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

APA Administrative Procedure Act
BTF beyond the floor
CAA Clean Air Act
CFR Code of Federal Regulations
EPA Environmental Protection Agency
FR Federal Register
HAP hazardous air pollutants
MACT Maximum Achievable Control Technology
NAICS North American Industry Classification System
NESHAP National Emission Standards for Hazardous Air Pollutants

Organization of this document. The information in this preamble is organized as follows:

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

Regulated entities. Categories and entities potentially affected by this action are shown in table 1 of this preamble.

TABLE 1—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS FINAL ACTION

Source category and NESHAP	NAICS code [1]
Lime Manufacturing	32741, 33111, 3314.

[1] North American Industry Classification System (NAICS).

Table 1 of this preamble is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by the final action for the source category listed. To determine whether your facility is affected, you should examine the applicability criteria in the Lime Manufacturing NESHAP. If you have any questions regarding the applicability of any aspect of this NESHAP, please contact the appropriate person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this final action will also be available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at: *https://www.epa.gov/stationary-sources-air-pollution/lime-manufacturing-plants-national-emission-standards-hazardous.* Following publication in the **Federal Register** (FR), the EPA will post the FR version and key technical documents at the same website.

C. Statutory Authority

For major sources, the Clean Air Act (CAA) section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of emission reductions of hazardous air pollutants (HAP) achievable after considering cost, energy requirements, and non-air quality health and environmental impacts. These standards are commonly referred to as Maximum Achievable Control Technology (MACT) standards. CAA section 112(d)(3) also establishes a minimum control level for MACT standards, known as the MACT ''floor.'' The EPA must also consider control options that are more stringent than the floor, commonly referred to as ''beyond-the-floor'' (BTF) standards. Costs may not be considered when setting the MACT floor and may only be considered when determining whether BTF standards are appropriate.

D. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by February 3, 2025.

II. Summary of Final Action

The EPA finalized MACT standards for the lime manufacturing industry under CAA section 112(d) for 4 previously unregulated pollutants on July 16, 2024. The 4 pollutants regulated in the final rule included hydrogen chloride, mercury, total organic HAP, and dioxin/furans. Following publication of this final rule, the EPA discovered errors in the regulatory text and is correcting them in this action.

Specifically, the EPA is revising the Lime Manufacturing NESHAP July 16, 2024, final rule to correctly reference 40 CFR 63.7083(g). In the July 16, 2024, final rule amendatory text, 40 CFR 63.7083 was revised to include new compliance dates associated with the July 16, 2024, final rule. These additions were added to the section as paragraphs (c) and (d). The additions caused 40 CFR 63.7083(e) to be redesignated as 63.7083(g) in the July 16, 2024, final rule amendatory text. This action revises all applicable references in the rule that previously referenced 40 CFR 63.7083(e) to correctly reference 40 CFR 63.7083(g).

Additionally, the EPA is correcting 40 CFR 63.7083(h)(2) to correct the compliance date of the hydrogen chloride, mercury, total organic HAP, and dioxin/furan emissions limitations for new sources. The July 16, 2024, final rule inadvertently set the compliance date for these sources as the date the final rule was published in the **Federal Register** (89 FR 57738, July 16, 2024). This date is being revised to correctly identify the compliance date for these sources as January 5, 2023, or the date of initial startup, whichever is later. This date represents the date that these sources must be in compliance, and is based on the date the proposed amendments were published in the **Federal Register** (88 FR 805, January 5, 2023).

Lastly, the EPA is correcting 40 CFR 63.7112(o), which inadvertently referenced ''total hydrocarbons'' in the introductory paragraph and equation 5 of paragraph (o) in the July 16, 2024, final rule. The EPA is correcting these errors by revising 40 CFR 63.7112(o) to reference ''total organic HAP'' instead.

These corrections make the regulatory text consistent with what the preamble to the final rule describes. The EPA finds that there is good cause for finalizing these technical corrections without public notice or hearing, as

explained in greater detail in section IV of this preamble. Notice and comment procedures are unnecessary here because the public is already aware of this action and its contents. See 5 U.S.C. 553(b)(B).

III. Summary of Cost, Environmental, and Economic Impacts

This action will have no cost, environmental, or economic impacts beyond the impacts presented in the July 16, 2024, Lime Manufacturing NESHAP final rule (89 FR 57738).

IV. Rulemaking Procedures

The EPA's authority for the rulemaking procedures followed in this action is provided by the Administrative Procedure Act (APA), 5 U.S.C. 553. In general, an agency issuing a rule must provide prior notice and an opportunity for public comment, but APA section 553(b)(B) includes an exemption from notice-and-comment requirements ''when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' This action is being issued without prior notice or opportunity for public comment because the EPA finds that the APA ''good cause'' exemption from notice-and-comment requirements applies here.

Following notice-and-comment procedures is unnecessary for this action. This action corrects technical errors, correctly referencing 40 CFR 63.7083(g), correctly referencing the compliance date for new or reconstructed sources in 40 CFR 63.7083(h)(2) and correcting the references to ''total hydrocarbons'' in the text and in equation 5 of 40 CFR 63.7112(o) in the July 16, 2024, rule. It is critical to timely correct the identified error to avoid confusion.

This action is effective immediately upon publication. The APA typically requires publication of a final rule to precede its effective date by at least 30 days unless, as relevant here, the agency finds good cause to make the rule effective sooner. APA section 553(b)(B). Under APA section 553(d), these technical corrections both necessary and beneficial to regulated entities in understanding and complying with the final rule's requirements. Further, because this rule does not impose any new regulatory requirements, the regulated community does not need time to prepare for it to come into effect. See *Omnipoint Corp.* v. *Fed. Commc'n Comm'n,* 78 F.3d 620, 630 (D.C. Cir. 1996) (in determining whether good cause exists to make a rule immediately effective, an agency should ''balance the necessity for immediate implementation against principles of fundamental fairness which require that all affected persons be afforded a reasonable amount of time to prepare for the effective date of its ruling'').

Good cause exists for this rule to be made immediately effective. The EPA has balanced the necessity for immediate implementation against the benefits of delaying implementation. Because this rule makes technical corrections to a rule that has already been promulgated, the public is aware of the content of the rule. Making the technical corrections effective immediately will make the regulatory text consistent with what the proposed rule and the preamble to the final rule have described.

V. Statutory and Executive Order Reviews

For a complete discussion of all the statutes, executive orders and administrative requirements applicable to this action, see the final rule published in the Rules and Regulations section of the **Federal Register** (89 FR 57738).

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practices and procedures, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons stated in the preamble, the EPA amends title 40, chapter I, part 63 of the Code of Federal Regulations as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart AAAAA—National Emission Standards for Hazardous Air Pollutants for Lime Manufacturing Plants

■ 2. Amend § 63.7083 by revising paragraph (h)(2) to read as follows:

§ 63.7083 When do I have to comply with this subpart?

* * * * *

(h) * * *

(2) If your affected source commenced construction or reconstruction after July 16, 2024, then the compliance date for HCl, mercury, total organic HAP, and D/F emissions limitations is January 5, 2023, or the date of initial startup, whichever is later.

■ 3. Amend § 63.7090 by revising paragraph (c) to read as follows:

§ 63.7090 What emission limitations must I meet?

* * * * *

(c) On or after the relevant compliance date for your source as specified in § 63.7083(g), you must meet each startup and shutdown period emission limit in table 2 to this subpart that applies to you.

* * * * *

■ 4. Revise § 63.7100 to read as follows:

§ 63.7100 What are my general requirements for complying with this subpart?

(a) Prior to the relevant compliance date for your source as specified in § 63.7083(g), you must be in compliance with the emission limitations (including operating limits) in this subpart at all times, except during periods of startup, shutdown, and malfunction. On and after the relevant compliance date for your source as specified in § 63.7083(g), you must be in compliance with the applicable emission limitations (including operating limits) at all times. You may operate outside of the established operating parameter limit(s) during performance tests in order to establish new operating limits.

(b) Prior to the relevant compliance date for your source as specified in § 63.7083(g), you must be in compliance with the opacity and visible emission (VE) limits in this subpart at all times, except during periods of startup, shutdown, and malfunction. On and after the relevant compliance date for your source as specified in § 63.7083(g), you must be in compliance with the applicable opacity and VE limits at all times.

(c) Prior to the relevant compliance date for your source as specified in § 63.7083(g), you must always operate and maintain your affected source, including air pollution control and monitoring equipment, according to the provisions in § 63.6(e)(1)(i). On and after the relevant compliance date for your source as specified in § 63.7083(g), you must always operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require

the owner or operator to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether such operation and maintenance procedures are being used will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

(d) You must prepare and implement for each LMP, a written operations, maintenance, and monitoring (OM&M) plan. You must submit the plan to the applicable permitting authority for review and approval as part of the application for a 40 CFR part 70 or 40 CFR part 71 permit. Any subsequent changes to the plan must be submitted to the applicable permitting authority for review and approval. Pending approval by the applicable permitting authority of an initial or amended plan, you must comply with the provisions of the submitted plan. Each plan must contain the following information:

(1) Process and control device parameters to be monitored to determine compliance, along with established operating limits or ranges, as applicable, for each emission unit.

(2) A monitoring schedule for each emission unit.

(3) Procedures for the proper operation and maintenance of each emission unit and each air pollution control device used to meet the applicable emission limitations and operating limits in tables 1, 2, and 3 to this subpart, respectively. On and after the relevant compliance date for your source as specified in § 63.7083(g), your OM&M plan must address periods of startup and shutdown.

(4) Procedures for the proper installation, operation, and maintenance of monitoring devices or systems used to determine compliance, including:

(i) Calibration and certification of accuracy of each monitoring device;

(ii) Performance and equipment specifications for the sample interface, parametric signal analyzer, and the data collection and reduction systems;

(iii) Prior to the relevant compliance date for your source as specified in § 63.7083(g), ongoing operation and maintenance procedures in accordance with the general requirements of § 63.8(c)(1)(i) and (ii), (c)(3), and (c)(4)(ii). On and after the relevant compliance date for your source as specified in § 63.7083(g), ongoing operation and maintenance procedures in accordance with the general requirements of paragraph (c) of this section and §§ 63.8(c)(1)(ii), (c)(3), and (c)(4)(ii); and

(iv) Ongoing data quality assurance procedures in accordance with the general requirements of § 63.8(d).

(5) Procedures for monitoring process and control device parameters.

(6) Corrective actions to be taken when process or operating parameters or add-on control device parameters deviate from the operating limits specified in table 3 to this subpart, including:

(i) Procedures to determine and record the cause of a deviation or excursion, and the time the deviation or excursion began and ended; and

(ii) Procedures for recording the corrective action taken, the time corrective action was initiated, and the time and date the corrective action was completed.

(7) A maintenance schedule for each emission unit and control device that is consistent with the manufacturer's instructions and recommendations for routine and long-term maintenance.

(e) Prior to the relevant compliance date for your source as specified in § 63.7083(g), you must develop a written startup, shutdown, and malfunction plan (SSMP) according to the provisions in § 63.6(e)(3).

■ 5. Amend § 63.7112 by revising paragraphs (b), (c), (m), and (o) to read as follows:

§ 63.7112 What performance tests, design evaluations, and other procedures must I use?

* * * * *

(b) Prior to the relevant compliance date for your source as specified in § 63.7083(g), each performance test must be conducted according to the requirements in § 63.7(e)(1) and under the specific conditions specified in table 5 to this subpart. Beginning July 16, 2024, each performance test must include the methods specified in rows 19–24 of table 5 to this subpart. On and after the relevant compliance date for your source as specified in § 63.7083(g), each performance test must be conducted based on representative performance (*i.e.,* performance based on normal operating conditions) of the affected source and under the specific conditions in table 5 to this subpart. Representative conditions exclude periods of startup and shutdown. The owner or operator may not conduct performance tests during periods of malfunction. The owner or operator must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(c) Prior to the relevant compliance date for your source as specified in § 63.7083(g), you may not conduct performance tests during periods of startup, shutdown, or malfunction, as specified in § 63.7(e)(1). On and after the relevant compliance date for your source as specified in § 63.7083(g), you may not conduct performance tests during periods of startup, shutdown, or malfunction, as specified in § 63.7112(b).

* * * * *

(m) On and after the relevant compliance date for your source as specified in § 63.7083(g), during startup, kilns must be tested hourly to determine when lime product meets the definition of on-specification lime product.

* * * * *

(o) The concentration of total organic HAP and dioxins/furans shall be corrected to 7 percent oxygen using equation 5 to this paragraph (o):

Equation 5 to Paragraph (o)

$$C_{7\%} = C_{unc} * \frac{13.9}{(20.9 - C_{O2})} \qquad (Eq. 5)$$

Where:

$C_{7\%}$ = concentration of total organic HAP, ppmv on a dry basis or dioxins/furans in ng/dscm corrected to 7 percent oxygen.

C_{unc} = uncorrected total organic HAP, ppmv on a dry basis or dioxins/furans in ng/dscm.

C_{O2} = concentration of oxygen (percent).

■ 6. Amend § 63.7121 by revising paragraph (d) to read as follows:

§ 63.7121 How do I demonstrate continuous compliance with the emission limitations standard?

* * * * *

(d) Prior to the relevant compliance date for your source as specified in § 63.7083(g), consistent with §§ 63.6(e) and 63.7(e)(1), deviations that occur during a period of startup, shutdown, or malfunction are not violations if you demonstrate to the Administrator's satisfaction that you were operating in accordance with § 63.6(e)(1). The Administrator will determine whether deviations that occur during a period of startup, shutdown, or malfunction are violations, according to the provisions in § 63.6(e).

* * * * *

■ 7. Amend § 63.7130 by revising paragraph (e) introductory text to read as follows:

§ 63.7130 What notifications must I submit and when?

* * * * *

(e) If you are required to conduct a performance test, design evaluation, opacity observation, VE observation, or other initial compliance demonstration as specified in table 4 or 5 to this subpart, you must submit a Notification of Compliance Status according to § 63.9(h)(2)(ii). Beginning on the relevant compliance date for your source as specified in § 63.7083(g), submit all subsequent Notification of Compliance Status following the procedure specified in § 63.7131(h).

* * * * *

■ 8. Amend § 63.7131 by revising paragraphs (b)(6), (c)(4) through (6), (d) introductory text, and (e) introductory text to read as follows:

§ 63.7131 What reports must I submit and when?

* * * * *

(b) * * *

(6) Beginning on the relevant compliance date for your source as specified in § 63.7083(g), submit all subsequent compliance reports following the procedure specified in paragraph (h) of this section.

(c) * * *

(4) Prior to the relevant compliance date for your source as specified in § 63.7083(g), if you had a startup, shutdown or malfunction during the reporting period and you took actions consistent with your SSMP, the compliance report must include the information in § 63.10(d)(5)(i).

(5) If there were no deviations from any emission limitations (emission limit, operating limit, opacity limit, and VE limit) that apply to you, the compliance report must include a statement that there were no deviations from the emission limitations during the reporting period.

(6) If there were no periods during which the continuous monitoring systems (CMS) were out-of-control as specified in § 63.8(c)(7), a statement that there were no periods during which the CMS were out-of-control during the reporting period.

* * * * *

(d) For each deviation from an emission limitation (emission limit, operating limit, opacity limit, and VE limit) that occurs at an affected source where you are not using a CMS to comply with the emission limitations in this subpart, the compliance report must contain the information specified in paragraphs (c)(1) through (4) and (d)(1) and (2) of this section. The deviations must be reported in accordance with the requirements in § 63.10(d) prior to the relevant compliance date for your source as specified in § 63.7083(g) and the requirements in § 63.10(d)(1) through (4) beginning on the relevant compliance date for your source as specified in § 63.7083(g).

* * * * *

(e) For each deviation from an emission limitation (emission limit, operating limit, opacity limit, and VE limit) occurring at an affected source where you are using a CMS to comply with the emission limitation in this subpart, you must include the information specified in paragraphs (c)(1) through (4) and (e)(1) through (11) of this section, except that beginning on the relevant compliance date for your source as specified in § 63.7083(g), the semiannual compliance report must also include the information included in paragraph (e)(12) of this section. This includes periods of startup, shutdown, and malfunction.

* * * * *

■ 9. Amend § 63.7132 by revising paragraph (a)(2) introductory text to read as follows:

§ 63.7132 What records must I keep?

(a) * * *

(2) Prior to the relevant compliance date for your source as specified in § 63.7083(g), the records in § 63.6(e)(3)(iii) through (v) related to startup, shutdown, and malfunction. On and after the relevant compliance date for your source as specified in § 63.7083(g), the records in paragraphs (a)(2)(i) and (ii) of this section.

* * * * *

■ 10. Amend § 63.7143 by revising the definition of ''deviation'' to read as follows:

§ 63.7143 What definitions apply to this subpart?

* * * * *

Deviation means any instance in which an affected source, subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart, including but not limited to any emission limitation (including any operating limit);

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit; or

(3) Prior to the relevant compliance date for your source as specified in § 63.7083(g), fails to meet any emission limitation (including any operating limit) in this subpart during startup, shutdown, or malfunction, regardless of whether or not such failure is allowed by this subpart.

■ 11. Revise table 2 to subpart AAAAA to read as follows:

TABLE 2 TO SUBPART AAAAA OF PART 63—STARTUP AND SHUTDOWN EMISSION LIMITS FOR KILNS AND COOLERS

[As required in § 63.7090(b), on and after the relevant compliance date for your source as specified in § 63.7083(g), you must meet each emission limit in the following table that applies to you.]

For . . .	You must meet the following emission limit	You have demonstrated compliance, if after following the requirements in § 63.7112 . . .
1. All new and existing lime kilns and their associated coolers equipped with an FF or an ESP during each startup.	Emissions must not exceed 15 percent opacity (based on startup period block average).	i. Installed, maintained, calibrated and operated a COMS as required by 40 CFR part 63, subpart A, General Provisions and according to PS–1 of appendix B to part 60 of this chapter, except as specified in § 63.7113(g)(2); ii. Collected the COMS data at a frequency of at least once every 15 seconds, determining block averages for each startup period and demonstrating for each startup block period the average opacity does not exceed 15 percent.
2. All existing lime kilns and their associated coolers that have a wet scrubber during each startup.	See item 2.b of table 3 of subpart AAAAA for emission limit.	See item 1 of table 6 of subpart AAAAA for requirements for demonstrating compliance.
3. All new and existing lime kilns and their associated coolers equipped with an FF or an ESP during shutdown.	Emissions must not exceed 15 percent opacity (based on 6-minute average opacity for any 6-minute block period does not exceed 15 percent).	i. Installed, maintained, calibrated and operated a COMS as required by 40 CFR part 63, subpart A, General Provisions and according to PS–1 of appendix B to part 60 of this chapter, except as specified in § 63.7113(g)(2); ii. Collecting the COMS data at a frequency of at least once every 15 seconds, determining block averages for each 6-minute period and demonstrating for each 6-minute block period the average opacity does not exceed 15 percent.
4. All existing lime kilns and their associated coolers that have a wet scrubber during shutdown.	See item 2.b of table 3 of subpart AAAAA for emission limit.	See item 1 of table 6 of subpart AAAAA for requirements for demonstrating compliance.

■ 12. Revise tables 5 and 6 to subpart AAAAA to read as follows:

TABLE 5 TO SUBPART AAAAA OF PART 63—REQUIREMENTS FOR PERFORMANCE TESTS

[As required in § 63.7112, you must conduct each performance test in the following table that applies to you.]

For . . .	You must . . .	Using . . .	According to the following requirements . . .
1. Each lime kiln and each associated lime cooler, if there is a separate exhaust to the atmosphere from the associated lime cooler.	Select the location of the sampling ports and the number of traverse points.	Method 1 or 1A of appendix A to part 60 of this chapter; and § 63.6(d)(1)(i).	Sampling sites must be located at the outlet of the control device(s) and prior to any releases to the atmosphere.
2. Each lime kiln and each associated lime cooler, if there is a separate exhaust to the atmosphere from the associated lime cooler.	Determine velocity and volumetric flow rate.	Method 2, 2A, 2C, 2D, 2F, or 2G in appendix A to part 60 of this chapter.	Not applicable.
3. Each lime kiln and each associated lime cooler, if there is a separate exhaust to the atmosphere from the associated lime cooler.	Conduct gas molecular weight analysis.	Method 3, 3A, or 3B in appendix A to part 60 of this chapter.	You may use manual procedures (but not instrumental procedures) of ASME PTC 19.10–1981—Part 10 (available for purchase from Three Park Avenue, New York, NY 10016–5990) as an alternative to using Method 3B.
4. Each lime kiln and each associated lime cooler, if there is a separate exhaust to the atmosphere from the associated lime cooler.	Measure moisture content of the stack gas.	Method 4 in appendix A to part 60 of this chapter.	Not applicable.
5. Each lime kiln and each associated lime cooler, if there is a separate exhaust to the atmosphere from the associated lime cooler, and which uses a negative pressure PM control device.	Measure PM emissions	Method 5 in appendix A to part 60 of this chapter.	Conduct the test(s) when the source is operating at representative operating conditions in accordance with § 63.7(e) before the relevant compliance date for your source as specified in § 63.7083(g) and § 63.7112(b) on and after the relevant compliance date for your source as specified in § 63.7083(g); the minimum sampling volume must be 0.85 dry standard cubic meter (dscm) (30 dry standard cubic foot (dscf)); if there is a separate lime cooler exhaust to the atmosphere, you must conduct the Method 5 test of the cooler exhaust concurrently with the kiln exhaust test.

TABLE 5 TO SUBPART AAAAA OF PART 63—REQUIREMENTS FOR PERFORMANCE TESTS—Continued

[As required in § 63.7112, you must conduct each performance test in the following table that applies to you.]

For . . .	You must . . .	Using . . .	According to the following requirements . . .
6. Each lime kiln and each associated lime cooler, if there is a separate exhaust to the atmosphere from the associated lime cooler, and which uses a positive pressure FF or ESP.	Measure PM emissions	Method 5D in appendix A to part 60 of this chapter.	Conduct the test(s) when the source is operating at representative operating conditions in accordance with § 63.7(e) before the relevant compliance date for your source as specified in § 63.7083(g) and § 63.7112(b) on and after the relevant compliance date for your source as specified in § 63.7083(g); If there is a separate lime cooler exhaust to the atmosphere, you must conduct the Method 5 or 5D test of the separate cooler exhaust concurrently with the kiln exhaust test. Refer to item 5 of this table for sampling time and volume requirements.
7. Each lime kiln	Determine the mass rate of stone feed to the kiln during the kiln performance test.	Any suitable device	Calibrate and maintain the device according to manufacturer's instructions; the measuring device used must be accurate to within ±5 percent of the mass rate of stone feed over its operating range.
8. Each lime kiln equipped with a wet scrubber.	Establish the operating limit for the average gas stream pressure drop across the wet scrubber during the PM and HCl performance test(s).	Data for the gas stream pressure drop measurement device during the kiln performance test.	The continuous pressure drop measurement device must be accurate within plus or minus 1 percent; you must collect the pressure drop data during the period of the performance test and determine the operating limit according to § 63.7112(j).
9. Each lime kiln equipped with a wet scrubber.	Establish the operating limit for the average liquid flow rate to the scrubber during the PM and HCl performance test(s).	Data from the liquid flow rate measurement device during the kiln performance test.	The continuous scrubbing liquid flow rate measuring device must be accurate within plus or minus 1 percent; you must collect the flow rate data during the period of the performance test and determine the operating limit according to § 63.7112(j).
10. Each lime kiln equipped with a FF or ESP that is monitored with a PM detector.	Have installed and have operating the BLDS or PM detector prior to the PM performance test.	Standard operating procedures incorporated into the OM&M plan.	According to the requirements in § 63.7113(d) or (e), respectively.
11. Each lime kiln equipped with a FF or ESP that is monitored with a COMS.	Have installed and have operating the COMS prior to the performance test.	Standard operating procedures incorporated into the OM&M plan and as required by 40 CFR part 63, subpart A, General Provisions and according to PS–1 of appendix B to part 60 of this chapter, except as specified in § 63.7113(g)(2).	According to the requirements in § 63.7113(g).
12. Each stack emission from a PSH operation, vent from a building enclosing a PSH operation, or set of multiple storage bins with combined stack emissions, which is subject to a PM emission limit.	Measure PM emissions	Method 5 or Method 17 in appendix A to part 60 of this chapter.	The sample volume must be at least 1.70 dscm (60 dscf); for Method 5, if the gas stream being sampled is at ambient temperature, the sampling probe and filter may be operated without heaters; and if the gas stream is above ambient temperature, the sampling probe and filter may be operated at a temperature high enough, but no higher than 121 °C (250 °F), to prevent water condensation on the filter (Method 17 may be used only with exhaust gas temperatures of not more than 250 °F).
13. Each stack emission from a PSH operation, vent from a building enclosing a PSH operation, or set of multiple storage bins with combined stack emissions, which is subject to an opacity limit.	Conduct opacity observations ..	Method 9 in appendix A to part 60 of this chapter.	The test duration must be for at least 3 hours and you must obtain at least thirty, 6-minute averages.
14. Each stack emissions source from a PSH operation subject to a PM or opacity limit, which uses a wet scrubber.	Establish the average gas stream pressure drop across the wet scrubber during the PM and HCl performance test(s).	Data for the gas stream pressure drop measurement device during the PSH operation stack performance test.	The pressure drop measurement device must be accurate within plus or minus 1 percent; you must collect the pressure drop data during the period of the performance test and determine the operating limit according to § 63.7112(j).
15. Each stack emissions source from a PSH operation subject to a PM or opacity limit, which uses a wet scrubber.	Establish the operating limit for the average liquid flow rate to the scrubber during the PM and HCl performance test(s).	Data from the liquid flow rate measurement device during the PSH operation stack performance test.	The continuous scrubbing liquid flow rate measuring device must be accurate within plus or minus 1 percent; you must collect the flow rate data during the period of the performance test and determine the operating limit according to § 63.7112(j).
16. Each FF that controls emissions from only an individual, enclosed, new or existing storage bin.	Conduct opacity observations ..	Method 9 in appendix A to part 60 of this chapter.	The test duration must be for at least 1 hour and you must obtain ten 6-minute averages.
17. Fugitive emissions from any PSH operation subject to an opacity limit.	Conduct opacity observations ..	Method 9 in appendix A to part 60 of this chapter.	The test duration must be for at least 3 hours, but the 3-hour test may be reduced to 1 hour if, during the first 1-hour period, there are no individual readings greater than 10 percent opacity and there are no more than three readings of 10 percent during the first 1-hour period.
18. Each building enclosing any PSH operation, that is subject to a VE limit.	Conduct VE check	The specifications in § 63.7112(k).	The performance test must be conducted while all affected PSH operations within the building are operating; the performance test for each affected building must be at least 75 minutes, with each side of the building and roof being observed for at least 15 minutes.

TABLE 5 TO SUBPART AAAAA OF PART 63—REQUIREMENTS FOR PERFORMANCE TESTS—Continued

[As required in § 63.7112, you must conduct each performance test in the following table that applies to you.]

For . . .	You must . . .	Using . . .	According to the following requirements . . .
19. Each lime kiln	Measure hydrogen chloride	Method 320 or 321 of appendix A of this part or ASTM 6348–12e1 (Note 1).	The test duration must be at least one hour. HCl must be used for the analyte spiking. For a positive pressure FF or ESP, determine the number of sampling points per the stratification check procedures of section 8.1.2 of Method 7E using the sample points determined using the procedures of Section 8 of EPA Method 5D.
20. Each lime kiln	Measure mercury	Method 29 or 30B Appendix A to part 60 of this chapter or ASTM D6784–16.	For Method 29 and ASTM D6784–16 the test duration must be at least two hours and the sample volume must be at least 1.70 dscm (60 dscf). For Method 30B, the test duration must be at least one hour and the sample volume at least 100 liters. For a positive pressure FF or ESP, use the procedures of Section 8 of EPA Method 5D for sampling points.
21. Each lime kiln	Measure total organic HAP [2]	Method 18 and/or 320 in appendix A to part 60 of this chapter and/or ASTM D6348–12e1 [1].	The test duration must be at least 1 hour. For EPA Method 320 and ASTM D6348–12e1, for a positive pressure FF or ESP, determine the number of sampling points per the stratification check procedures of section 8.1.2 of Method 7E using the sample points determined using the procedures of Section 8 of EPA Method 5D.
22. Each lime kiln	Measure dioxins/furans	Method 23 in Appendix A to part 60 of this chapter.	The test duration must be at least 3 hours and the must be at least 3 dscm (106 dscf). For a positive pressure FF or ESP, use the procedures of Section 8 of EPA Method 5D for sampling points. When calculating TEQ, zero may be used for congeners that are below the EDL.
23. Each lime kiln equipped with dry sorbent injection.	Establish the operating limit for the dry sorbent flow rate during the HCl performance test.	Data for the dry sorbent flow rate device during the HCl performance test.	The flow monitor must meet the criteria in § 63.7113(h); you must collect the dry sorbent flow rate data during the period of the HCl performance test and determine the operating limit according to § 63.7112(j).
24. Each lime kiln equipped with a thermal oxidizer.	Establish the operating limit for the combustion chamber temperature during the total organic HAP and D/F performance test(s).	Data for the temperature device during the total organic HAP and dioxin/furan performance test(s).	The temperature device must meet the criteria in § 63.7113(i); you must collect the temperature data during the period of the total organic HAP and D/F performance test(s) and determine the operating limit according to § 63.7112(j).
25. Each lime kiln equipped with activated carbon injection.	Establish the operating limit for the combustion chamber temperature during the total organic HAP, D/F, and mercury performance test(s).	Data for the activated carbon flow rate device during the total organic HAP, dioxin/furan, and mercury performance test(s).	The flow monitor must meet the criteria in § 63.7113(h); you must collect the activated carbon flow rate data during the period of the total organic HAP, D/F, and mercury performance test(s)and determine the operating limit according to § 63.7112(j).

[1] When using ASTM D6348–12e1 (1) the test plan preparation and implementation in the Annexes to ASTM D6348–12e1, sections A1 through A8 are mandatory, (2) In ASTM D6348–12e1 Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (Equation A5.5). In order for the test data to be acceptable for a compound, %R must be $70\% \geq R \leq 130\%$. If the %R value does not meet this criterion for a target compound, the test data is not acceptable for that compound and the test must be repeated for that analyte (*i.e.,* the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound according to: Reported Results = ((Measured Concentration in Stack))/(%R) $\times$ 100.

[2] Total Organic HAP is the sum of the concentrations of compounds of formaldehyde, acetaldehyde, toluene, benzene, m-xylene, p-xylene, o-xylene, styrene, ethyl benzene, and naphthalene.

TABLE 6 TO SUBPART AAAAA OF PART 63—CONTINUOUS COMPLIANCE WITH OPERATING LIMITS

[As required in § 63.7121, you must demonstrate continuous compliance with each operating limit listed in table 3 to subpart AAAAA that applies to you, according to the following table.]

For . . .	For the following operating limit . . .	You must demonstrate continuous compliance by . . .
1. Each lime kiln controlled by a wet scrubber.	Maintain the 3-hour block average exhaust gas stream pressure drop across the wet scrubber greater than or equal to the pressure drop operating limit established during the performance test; and maintain the 3-hour block average scrubbing liquid flow rate greater than or equal to the flow rate operating limit established during the performance test.	Collecting the wet scrubber operating data according to all applicable requirements in § 63.7113 and reducing the data according to § 63.7113(a); maintaining the 3-hour block average exhaust gas stream pressure drop across the wet scrubber greater than or equal to the pressure drop operating limit established during the performance test; and maintaining the 3-hour block average scrubbing liquid flow rate greater than or equal to the flow rate operating limit established during the performance test (the continuous scrubbing liquid flow rate measuring device must be accurate within ±1% and the continuous pressure drop measurement device must be accurate within ±1%).

TABLE 6 TO SUBPART AAAAA OF PART 63—CONTINUOUS COMPLIANCE WITH OPERATING LIMITS—Continued

[As required in § 63.7121, you must demonstrate continuous compliance with each operating limit listed in table 3 to subpart AAAAA that applies to you, according to the following table.]

For . . .	For the following operating limit . . .	You must demonstrate continuous compliance by . . .
2. Each lime kiln or lime cooler equipped with a FF and using a BLDS, and each lime kiln equipped with an ESP or FF using a PM detector.	a. Maintain and operate the FF or ESP such that the bag leak or PM detector alarm, is not activated and alarm condition does not exist for more than 5 percent of the total operating time in each 6-month period.	(i) Operating the FF or ESP so that the alarm on the bag leak or PM detection system is not activated and an alarm condition does not exist for more than 5 percent of the total operating time in each 6-month reporting period; and continuously recording the output from the BLD or PM detection system; and (ii) Each time the alarm sounds and the owner or operator initiates corrective actions within 1 hour of the alarm, 1 hour of alarm time will be counted (if the owner or operator takes longer than 1 hour to initiate corrective actions, alarm time will be counted as the actual amount of time taken by the owner or operator to initiate corrective actions); if inspection of the FF or ESP system demonstrates that no corrective actions are necessary, no alarm time will be counted.
3. Each stack emissions source from a PSH operation subject to an opacity limit, which is controlled by a wet scrubber.	Maintain the 3-hour block average exhaust gas stream pressure drop across the wet scrubber greater than or equal to the pressure drop operating limit established during the performance test; and maintain the 3-hour block average scrubbing liquid flow rate greater than or equal to the flow rate operating limit established during the performance test.	Collecting the wet scrubber operating data according to all applicable requirements in § 63.7113 and reducing the data according to § 63.7113(a); maintaining the 3-hour block average exhaust gas stream pressure drop across the wet scrubber greater than or equal to the pressure drop operating limit established during the performance test; and maintaining the 3-hour block average scrubbing liquid flow rate greater than or equal to the flow rate operating limit established during the performance test (the continuous scrubbing liquid flow rate measuring device must be accurate within ±1% and the continuous pressure drop measurement device must be accurate within ±1%).
4. For each lime kiln or lime cooler equipped with a FF or an ESP that uses a COMS as the monitoring device.	a. Maintain and operate the FF or ESP such that the average opacity for any 6-minute block period does not exceed 15 percent.	i. Installing, maintaining, calibrating and operating a COMS as required by 40 CFR part 63, subpart A, General Provisions and according to PS–1 of appendix B to part 60 of this chapter, except as specified in § 63.7113(g)(2); and ii. Collecting the COMS data at a frequency of at least once every 15 seconds, determining block averages for each 6-minute period and demonstrating for each 6-minute block period the average opacity does not exceed 15 percent.
5. Each lime kiln equipped with dry sorbent injection.	Maintain the 3-hour block dry sorbent and/or activated carbon flow rate greater than or equal to the injection flow rate operating limit established during the most recent performance test..	Collecting the dry sorbent and/or activated carbon injection operating data according to all applicable requirements in § 63.7113 and reducing the data according to § 63.7113(a); maintaining the 3-hour block average injection flow rate greater than or equal to the injection flow rate operating limit established during the performance test
6. Each lime kiln equipped with a thermal oxidizer.	Maintain the 3-hour block average combustion chamber temperature greater or equal to the combustion chamber operating limit established in the most recent performance test.	Collecting the thermal oxidizer operating data according to all applicable requirements in § 63.7113 and reducing the data according to § 63.7113(a); maintaining the 3-hour block average combustion chamber temperature greater than or equal to the combustion chamber operating limit established during the performance test.

13. Revise table 8 to subpart AAAAA to read as follows:

TABLE 8 TO SUBPART AAAAA OF PART 63—REQUIREMENTS FOR REPORTS

[As required in § 63.7131, you must submit each report in this table that applies to you.]

You must submit a . . .	The report must contain . . .	You must submit the report . . .
1. Compliance report	a. If there are no deviations from any emission limitations (emission limit, operating limit, opacity limit, and VE limit) that applies to you, a statement that there were no deviations from the emission limitations during the reporting period;.	Semiannually according to the requirements in § 63.7131(b).

TABLE 8 TO SUBPART AAAAA OF PART 63—REQUIREMENTS FOR REPORTS—Continued

[As required in § 63.7131, you must submit each report in this table that applies to you.]

You must submit a . . .	The report must contain . . .	You must submit the report . . .
	b. If there were no periods during which the CMS, including any operating parameter monitoring system, was out-of-control as specified in § 63.8(c)(7), a statement that there were no periods during which the CMS was out-of-control during the reporting period;.	Semiannually according to the requirements in § 63.7131(b).
	c. If you have a deviation from any emission limitation (emission limit, operating limit, opacity limit, and VE limit) during the reporting period, the report must contain the information in § 63.7131(d);.	Semiannually according to the requirements in § 63.7131(b).
	d. If there were periods during which the CMS, including any operating parameter monitoring system, was out-of-control, as specified in § 63.8(c)(7), the report must contain the information in § 63.7131(e); and.	Semiannually according to the requirements in § 63.7131(b).
	e. Before the relevant compliance date for your source as specified in § 63.7083(g), if you had a startup, shutdown or malfunction during the reporting period and you took actions consistent with your SSMP, the compliance report must include the information in § 63.10(d)(5)(i). On and after the relevant compliance date for your source as specified in § 63.7083(g), if you had a startup, shutdown or malfunction during the reporting period and you failed to meet an applicable standard, the compliance report must include the information in § 63.7131(c)(3)..	Semiannually according to the requirements in § 63.7131(b).
2. Before the relevant compliance date for your source as specified in § 63.7083(g), an immediate startup, shutdown, and malfunction report if you had a startup, shutdown, or malfunction during the reporting period that is not consistent with your SSMP.	Actions taken for the event	By fax or telephone within 2 working days after starting actions inconsistent with the SSMP.
3. Before the relevant compliance date for your source as specified in § 63.7083(g), an immediate startup, shutdown, and malfunction report if you had a startup, shutdown, or malfunction during the reporting period that is not consistent with your SSMP.	The information in § 63.10(d)(5)(ii)	By letter within 7 working days after the end of the event unless you have made alternative arrangements with the permitting authority. See § 63.10(d)(5)(ii).
4. Performance Test Report	The information required in § 63.7(g) and § 63.7112(h).	According to the requirements of § 63.7131.

■ 14. Revise table 10 to subpart AAAAA to read as follows:

TABLE 10 TO SUBPART AAAAA OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART AAAAA

[As required in § 63.7140, you must comply with the applicable General Provisions requirements according to the following table.]

Citation	Summary of requirement	Am I subject to this requirement?	Explanations
§ 63.1(a)(1)–(4)	Applicability	Yes	
§ 63.1(a)(5)		No	
§ 63.1(a)(6)	Applicability	Yes	
§ 63.1(a)(7)–(a)(9)		No	
§ 63.1(a)(10)–(a)(14)	Applicability	Yes	
§ 63.1(b)(1)	Initial Applicability Determination	Yes	§§ 63.7081 and 63.7142 specify additional applicability determination requirements.
§ 63.1(b)(2)		No	
§ 63.1(b)(3)	Initial Applicability Determination	Yes	
§ 63.1(c)(1)	Applicability After Standard Established.	Yes	

TABLE 10 TO SUBPART AAAAA OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART AAAAA—Continued

[As required in § 63.7140, you must comply with the applicable General Provisions requirements according to the following table.]

Citation	Summary of requirement	Am I subject to this requirement?	Explanations
§ 63.1(c)(2)	Permit Requirements	No	Area sources not subject to subpart AAAAA, except all sources must make initial applicability determination.
§ 63.1(c)(3)–(4)		No	
§ 63.1(c)(5)	Area Source Becomes Major	Yes	
§ 63.1(c)(6)	Reclassification	Yes	
§ 63.1(d)		No	
§ 63.1(e)	Applicability of Permit Program	Yes	
§ 63.2	Definitions	Yes	Additional definitions in § 63.7143.
§ 63.3(a)–(c)	Units and Abbreviations	Yes	
§ 63.4(a)(1)–(a)(2)	Prohibited Activities	Yes	
§ 63.4(a)(3)–(a)(5)		No	
§ 63.4(b)–(c)	Circumvention, Severability	Yes	
§ 63.5(a)(1)–(2)	Construction/Reconstruction	Yes	
§ 63.5(b)(1)	Compliance Dates	Yes	
§ 63.5(b)(2)		No	
§ 63.5(b)(3)–(4)	Construction Approval, Applicability.	Yes	
§ 63.5(b)(5)		No	
§ 63.5(b)(6)	Applicability	Yes	
§ 63.5(c)		No	
§ 63.5(d)(1)–(4)	Approval of Construction/Reconstruction.	Yes	
§ 63.5(e)	Approval of Construction/Reconstruction.	Yes	
§ 63.5(f)(1)–(2)	Approval of Construction/Reconstruction.	Yes	
§ 63.6(a)	Compliance for Standards and Maintenance.	Yes	
§ 63.6(b)(1)–(5)	Compliance Dates	Yes	
§ 63.6(b)(6)		No	
§ 63.6(b)(7)	Compliance Dates	Yes	
§ 63.6(c)(1)–(2)	Compliance Dates	Yes	
§ 63.6(c)(3)–(c)(4)		No	
§ 63.6(c)(5)	Compliance Dates	Yes	
§ 63.6(d)		No	
§ 63.6(e)(1)(i)	General Duty to Minimize Emissions.	Yes before the relevant compliance date for your source as specified in § 63.7083(g). No on and after the relevant compliance date for your source as specified in § 63.7083(g).	On and after the relevant compliance date for your source as specified in § 63.7083(g), see § 63.7100 for general duty requirement.
§ 63.6(e)(1)(ii)	Requirement to Correct Malfunctions ASAP.	Yes before the relevant compliance date for your source as specified in § 63.7083(g). No on and after the relevant compliance date for your source as specified in § 63.7083(g).	
§ 63.6(e)(1)(iii)	Operation and Maintenance Requirements.	Yes	
§ 63.6(e)(2)		No	[Reserved]
§ 63.6(e)(3)	Startup, Shutdown Malfunction Plan.	Yes before the relevant compliance date for your source as specified in § 63.7083(g). No on and after the relevant compliance date for your source as specified in § 63.7083(e).	On and after the relevant compliance date for your source as specified in § 63.7083(g), the OM&M plan must address periods of startup and shutdown. See § 63.7100(d).
§ 63.6(f)(1)	SSM exemption	No	See § 63.7100. For periods of startup and shutdown, see § 63.7090(c).
§ 63.6(f)(2)–(3)	Methods for Determining Compliance.	Yes	
§ 63.6(g)(1)–(g)(3)	Alternative Standard	Yes	
§ 63.6(h)(1)	SSM exemption	No	See § 63.7100. For periods of startup and shutdown, see § 63.7090(c).
§ 63.6(h)(2)	Methods for Determining Compliance.	Yes	
§ 63.6(h)(3)		No	

TABLE 10 TO SUBPART AAAAA OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART AAAAA—Continued

[As required in § 63.7140, you must comply with the applicable General Provisions requirements according to the following table.]

Citation	Summary of requirement	Am I subject to this requirement?	Explanations
§ 63.6(h)(4)–(h)(5)(i)	Opacity/VE Standards	Yes	This requirement only applies to opacity and VE performance checks required in table 5 to subpart AAAAA.
§ 63.6(h)(5) (ii)–(iii)	Opacity/VE Standards	No	Test durations are specified in subpart AAAAA; subpart AAAAA takes precedence.
§ 63.6(h)(5)(iv)	Opacity/VE Standards	No	
§ 63.6(h)(5)(v)	Opacity/VE Standards	Yes	
§ 63.6(h)(6)	Opacity/VE Standards	Yes	
§ 63.6(h)(7)	COM Use	Yes	
§ 63.6(h)(8)	Compliance with Opacity and VE	Yes	
§ 63.6(h)(9)	Adjustment of Opacity Limit	Yes	
§ 63.6(i)(1)–(i)(14)	Extension of Compliance	Yes	
§ 63.6(i)(15)		No	
§ 63.6(i)(16)	Extension of Compliance	Yes	
§ 63.6(j)	Exemption from Compliance	Yes	
§ 63.7(a)(1)–(a)(3)	Performance Testing Requirements.	Yes	§ 63.7110 specifies deadlines; § 63.7112 has additional specific requirements.
§ 63.7(b)	Notification	Yes	
§ 63.7(c)	Quality Assurance/Test Plan	Yes	
§ 63.7(d)	Testing Facilities	Yes	
§ 63.7(e)(1)	Conduct of Tests	Yes before the relevant compliance date for your source as specified in § 63.7083(g). No on and after the relevant compliance date for your source as specified in § 63.7083(g).	On and after the relevant compliance date for your source as specified in § 63.7083(g), see § 63.7112(b).
§ 63.7(e)(2)–(4)	Conduct of Tests	Yes	
§ 63.7(f)	Alternative Test Method	Yes	
§ 63.7(g)	Data Analysis	Yes	
§ 63.7(h)	Waiver of Tests	Yes	
§ 63.8(a)(1)	Monitoring Requirements	Yes	See § 63.7113.
§ 63.8(a)(2)	Monitoring	Yes	
§ 63.8(a)(3)		No	
§ 63.8(a)(4)	Monitoring	No	Flares not applicable.
§ 63.8(b)(1)–(3)	Conduct of Monitoring	Yes	
§ 63.8(c)(1)(i)	CMS Operation/Maintenance	Yes before the relevant compliance date for your source as specified in § 63.7083(g). No on and after the relevant compliance date for your source as specified in § 63.7083(e).	On and after the relevant compliance date for your source as specified in § 63.7083(g), see § 63.7100 for OM&M requirements.
§ 63.8(c)(1)(ii)	CMS Spare Parts	Yes	
§ 63.8(c)(1)(iii)	Requirement to Develop SSM Plan for CMS.	Yes before the relevant compliance date for your source as specified in § 63.7083(g). No on and after the relevant compliance date for your source as specified in § 63.7083(g).	On and after the relevant compliance date for your source as specified in § 63.7083(g), no longer required.
§ 63.8(c)(2)–(3)	CMS Operation/Maintenance	Yes	
§ 63.8(c)(4)	CMS Requirements	No	See § 63.7121.
§ 63.8(c)(4)(i)–(ii)	Cycle Time for COM and CEMS	Yes	No CEMS are required under subpart AAAAA; see § 63.7113 for CPMS requirements.
§ 63.8(c)(5)	Minimum COM procedures	Yes	COM not required.
§ 63.8(c)(6)	CMS Requirements	No	See § 63.7113.
§ 63.8(c)(7)–(8)	CMS Requirements	Yes	
§ 63.8(d)(1)–(2)	Quality Control	Yes	See also § 63.7113.
§ 63.8(d)(3)	Quality Control	Yes before the relevant compliance date for your source as specified in § 63.7083(g). No on and after the relevant compliance date for your source as specified in § 63.7083(g).	
§ 63.8(e)	Performance Evaluation for CMS	Yes	See also § 63.7113
§ 63.8(f)(1)–(f)(5)	Alternative Monitoring Method	Yes	
§ 63.8(f)(6)	Alternative to Relative Accuracy Test for CEMS.	No	No CEMS required in subpart AAAAA.

TABLE 10 TO SUBPART AAAAA OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART AAAAA—Continued

[As required in § 63.7140, you must comply with the applicable General Provisions requirements according to the following table.]

Citation	Summary of requirement	Am I subject to this requirement?	Explanations
§ 63.8(g)(1)–(g)(5)	Data Reduction; Data That Cannot Be Used.	No	See data reduction requirements in §§ 63.7120 and 63.7121.
§ 63.9(a)	Notification Requirements	Yes	See § 63.7130.
§ 63.9(b)	Initial Notifications	Yes	
§ 63.9(c)	Request for Compliance Extension.	Yes	
§ 63.9(d)	New Source Notification for Special Compliance Requirements.	Yes	
§ 63.9(e)	Notification of Performance Test	Yes	
§ 63.9(f)	Notification of VE/Opacity Test	Yes	This requirement only applies to opacity and VE performance tests required in table 5 to subpart AAAAA. Notification not required for VE/opacity test under table 7 to subpart AAAAA.
§ 63.9(g)	Additional CMS Notifications	No	Not required for operating parameter monitoring.
§ 63.9(h)(1)–(h)(3)	Notification of Compliance Status	Yes	
§ 63.9(h)(4)		No	
§ 63.9(h)(5)–(h)(6)	Notification of Compliance Status	Yes	
§ 63.9(i)	Adjustment of Deadlines	Yes	
§ 63.9(j)	Change in Previous Information	Yes	
§ 63.9(k)	Electronic reporting procedures	Yes	Only as specified in § 63.9(j)
§ 63.10(a)	Recordkeeping/Reporting General Requirements.	Yes	See §§ 63.7131 through 63.7133.
§ 63.10(b)(1)	Records	Yes	
§ 63.10(b)(2)(i)	Recordkeeping of Occurrence and Duration of Startups and Shutdowns.	Yes before the relevant compliance date for your source as specified in § 63.7083(g). No on and after the relevant compliance date for your source as specified in § 63.7083(g).	
§ 63.10(b)(2)(ii)	Recordkeeping of Failures to Meet a Standard.	Yes before the relevant compliance date for your source as specified in § 63.7083(g). No on and after the relevant compliance date for your source as specified in § 63.7083(g).	On and after the relevant compliance date for your source as specified in § 63.7083(g), see § 63.7132 for recordkeeping of (1) date, time and duration; (2) listing of affected source or equipment, and an estimate of the quantity of each regulated pollutant emitted over the standard; and (3) actions to minimize emissions and correct the failure.
§ 63.10(b)(2)(iii)	Maintenance Records	Yes	
§ 63.10(b)(2)(iv)–(v)	Actions Taken to Minimize Emissions During SSM.	Yes before the relevant compliance date for your source as specified in § 63.7083(g). No on and after the relevant compliance date for your source as specified in § 63.7083(e).	On and after the relevant compliance date for your source as specified in § 63.7083(g), see § 63.7100 for OM&M requirements.
§ 63.10(b)(2)(vi)–(xii)	Recordkeeping for CMS	Yes	
§ 63.10(b)(2)(xiii)	Records for Relative Accuracy Test.	No	
§ 63.10(b)(2)(xiv)	Records for Notification	Yes	
§ 63.10(b)(3)	Applicability Determinations	Yes	
§ 63.10(c)	Additional CMS Recordkeeping	No	See § 63.7132.
§ 63.10(d)(1)	General Reporting Requirements	Yes	
§ 63.10(d)(2)	Performance Test Results	Yes	
§ 63.10(d)(3)	Opacity or VE Observations	Yes	For the periodic monitoring requirements in table 7 to subpart AAAAA, report according to § 63.10(d)(3) only if VE observed and subsequent visual opacity test is required.
§ 63.10(d)(4)	Progress Reports	Yes	

TABLE 10 TO SUBPART AAAAA OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART AAAAA—Continued

[As required in § 63.7140, you must comply with the applicable General Provisions requirements according to the following table.]

Citation	Summary of requirement	Am I subject to this requirement?	Explanations
§ 63.10(d)(5)(i)	Periodic Startup, Shutdown, Malfunction Reports.	Yes before the relevant compliance date for your source as specified in § 63.7083(g). No on and after the relevant compliance date for your source as specified in § 63.7083(g).	On and after the relevant compliance date for your source as specified in § 63.7083(g), see § 63.7131 for malfunction reporting requirements.
§ 63.10(d)(5)(ii)	Immediate Startup, Shutdown, Malfunction Reports.	Yes before the relevant compliance date for your source as specified in § 63.7083(g). No on and after the relevant compliance date for your source as specified in § 63.7083(g).	
§ 63.10(e)	Additional CMS Reports	No	See specific requirements in subpart AAAAA, see § 63.7131.
§ 63.10(f)	Waiver for Recordkeeping/Reporting.	Yes	
§ 63.11(a)–(b)	Control Device and Work Practice Requirements.	No	Flares not applicable.
§ 63.12(a)–(c)	State Authority and Delegations	Yes	
§ 63.13(a)–(c)	State/Regional Addresses	Yes	
§ 63.14(a)–(b)	Incorporation by Reference	No	
§ 63.15(a)–(b)	Availability of Information and Confidentiality.	Yes	
§ 63.16	Performance Track Provisions	Yes	

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 52i

[Docket No. NIH–2022–0001]

RIN 0925–AA70

National Institute on Minority Health and Health Disparities Research Endowment Programs

AGENCY: National Institutes of Health, HHS.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS or Department), through the National Institutes of Health (NIH), is amending the regulation governing the National Institute on Minority Health and Health Disparities (NIMHD) Research Endowment Programs (REP) to update the heading of the regulation to reflect the new name of the program, the eligibility requirements for the program to indicate the new expanded eligibility for research endowment awards that is mandated by statute, the heading of one section of the regulation, and certain references to regulations and policies cited in the regulation that apply to program grant awards.

DATES: This final rule is effective January 3, 2025.

FOR FURTHER INFORMATION CONTACT: Daniel Hernandez, NIH Regulations Officer, Office of Management Assessment, NIH, Rockledge 1, 6705 Rockledge Drive, Suite 601, Room 601–T, Bethesda, MD 20817, MSC 7901, by email at *dhernandez@mail.nih.gov,* or by telephone at 301–435–3343 (not a toll-free number). For program information contact: Dr. Nathan Stinson, Director, Division of Community Health and Population Sciences, NIMHD, by email *stinsonn@nih.gov,* or telephone 301–594–8704. Information concerning the requirements, application deadline dates, and an on-line application for NIMHD REP awards may be obtained from the NIMHD via *https://www.nimhd.nih.gov/programs/extramural/research-endowment.html.*

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Mandate

On March 18, 2022, the President signed into law the John Lewis NIMHD Research Endowment Revitalization Act of 2021, Public Law (Pub. L.) 117–104. Section 2 of this law amended section 464z–3(h) of the Public Health Service (PHS) Act, as amended (42 U.S.C. 285t(h)) by revising program eligibility requirements to include eligible current or former Health Resources and Services Administration (HRSA) centers of excellence under section 736 of the PHS Act and eligible current or former NIMHD centers of excellence under section 464z–4 of the PHS Act.

The program was originally authorized under the Minority Health and Health Disparities Research and Education Act of 2000 (Pub. L. 106–525). The law provided annual funding for up to five years to the endowments of active eligible HRSA centers of excellence. In 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) expanded eligibility to include active eligible NIMHD centers of excellence. Public Law 117–104, enacted in 2022, expanded the eligibility for NIMHD Research Endowment Program awards to eligible current or former HRSA and NIMHD centers of excellence. Endowment funds must be invested and maintained for at least 20 years after the award period ends.

The objective of the program and its awards is to build research and training capacity and infrastructure at eligible HRSA or NIMHD centers of excellence to facilitate minority health and other health disparities research and to close the disparity gap in the burden of illness and death experienced by racial and ethnic minority Americans and other health disparity populations. Program activities may include strengthening the research infrastructure through the renovation of facilities, purchasing of state-of-the-art instruments and equipment, and enhancing information technology; enhancing the academic environment by recruiting faculty and creating relevant training courses focused on minority health and health

disparities, in addition to the existing curriculum, such as research methodology and health disparities; and/or other relevant activities. The expansion of eligibility for the program, recently renamed the *John Lewis* NIMHD Research Endowment Program, to include eligible current or former HRSA and NIMHD centers of excellence will serve to expand the national capacity of academic institutions to conduct research to improve minority health and reduce health disparities.

Implementation of Public Law 17–104 necessitates HHS, through NIH, to update the regulation codified at 42 CFR part 52i that governs the program. Specifically, paragraph (a)(1) of § 52i.3 ''Who is eligible to apply?'' needs to be updated to specify the expanded statutory eligibility for program awards, such that eligible current or former centers of excellence under section 736 (42 U.S.C. 293) or section 464z–4 (42 U.S.C. 285t–1) of the PHS Act, respectively, may now apply.

Additionally, following enactment of Public Law 117–104, NIMHD changed the name of the program from the NIMHD Research Endowment Program to the *John Lewis* NIMHD Research Endowment Program to reflect the honor that the United States Congress bestowed upon John Lewis by naming the legislation expanding eligibility for the program after him. John Robert Lewis served in the U.S. House of Representatives, representing Georgia's 5th Congressional District from 1987 until his death in 2020 with longstanding commitment to improving minority health and health disparities. Consequently, the heading of the regulation that governs the program must be amended to reflect the new name of the program.

Other aspects of the regulation also need to be updated. In the heading for § 52i.1 and in the accompanying Table of Contents reference to § 52i.1, the word ''programs'' in ''To what programs does this part apply?'' needs to be changed to ''program'' to correctly indicate that there is only one program to which part 52i applies, not multiple programs as the current heading incorrectly indicates.

Additionally, in § 52i.13, ''Other HHS policies and regulations that apply'', there are outdated references to several regulations and policies with URLs that are not operational. The current references in paragraph (f) ''45 CFR part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and the certain grants and agreements with states, local governments and Indian tribal governments'', and paragraph (m) ''45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State, local and tribal governments'' are outdated and must be revised. The current references in paragraphs (o) concerning NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, (p) concerning NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, (q) concerning NIH Grants Policy Statement, and (r) concerning Public Health Service Policy on Humane Care and Use of Laboratory Animals contain outdated information and, in some cases, the URLs are not operational. These paragraphs need to be updated.

Previously, HHS issued a direct final rule on November 16, 2020 (85 FR 72899–72912) amending certain regulations as part of its Regulatory Clean Up Initiative to make miscellaneous corrections, including correcting references to other regulations, misspellings, and other typographical errors. These corrections included several changes in 42 CFR part 52i. However, the revisions that now are necessary in § 52i.13 were not included in the direct final rule.

HHS announced its intentions to initiate this rulemaking action in the notice of proposed rulemaking (NPRM) titled ''National Institute on Minority Health and Health Disparities Research Endowment Programs'' that was published in the **Federal Register** on October 4, 2023 (88 FR 68553). The NPRM provided a sixty-day public comment period. The comment period ended December 4, 2023.

In the NPRM, we proposed to amend the Code of Federal Regulations by revising the heading for 42 CFR part 52i to read ''Part 52i—*John Lewis* NIMHD Research Endowment Program'' to reflect the new name of the program, the *John Lewis* NIMHD Research Endowment Program.

We proposed to amend the heading for § 52i.1 ''To what programs does this part apply?'' by removing the word ''programs'' and adding the word ''program'' in its place to indicate that there is only one program, the *John Lewis* NIMHD Research Endowment Program, to which part 52i applies.

Additionally, we proposed to amend § 52i.3 ''Who is eligible to apply?'' by revising paragraph (a)(1) to read as follows: ''Must be a current or former center of excellence under section 736 (42 U.S.C. 293) or section 464z–4 (42 U.S.C. 285t–1) of the Act, and''.

We further proposed to amend § 52i.13 ''Other HHS policies and regulations that apply'' by:

(1) Revising current paragraph (f),

(2) Removing current paragraph (m), and redesignating current paragraph (n) as new paragraph (m),

(3) Redesignating current paragraph (o) as new paragraph (n) and revising it,

(4) Redesignating current paragraph (p) as new paragraph (o) and revising it,

(5) Redesignating current paragraph (q) as new paragraph (p) and revising it,

(6) Redesignating current paragraph (r) as new paragraph (q) and revising it, and

(7) Removing paragraph (r).

We stated in the NPRM that making these changes was necessary to implement Public Law 117–104 and would ensure the regulation is up to date. We added that the rule, when finalized, would add transparency for potential applicants regarding who is eligible to apply for a grant under the *John Lewis* NIMHD Research Endowment Program.

II. Summary of Public Comments

We received five comments in response to the NPRM. One of the commenters agreed with the proposed rule, noting that implementation of Public Law 117–104 will lead to an increase in eligible applicants and will have a positive impact in addressing minority health disparities.

A second commenter stated that the proposed rule was acceptable because it is more in line with the new name of the program recognized after the late John Lewis, and because the program aims to build more training and research capacity to reduce disparities in minority health treatment, the program eligibility requirements should mirror such to become more inclusive for minority applicants to apply.

A third commenter thought the proposed rule should be expanded to create new medical schools at Historically Black Colleges and Universities (HBCUs), noting that it missed the opportunity to expand the number of Black doctors. Additionally, the commenter noted that there are only six Black medical schools in the country, and that with major health disparities in the Black community, it is essential to expand the number of providers who are committed to serving that population, The commenter noted that out of 10 states with the highest Black populations, only three have HBCUs with medicals schools. The commenter reiterated his belief that the proposed rule also should expand to include establishing medical schools in

these states at HBCUs to expand the provider pool.

We appreciate the commenter taking the time to extensively comment on the proposed rule and we acknowledge the importance of addressing health disparities through a diverse healthcare workforce. The *John Lewis* NIMHD Research Endowment Program provides funding for endowments to invest in research infrastructure and training capacity at eligible institutions. The comment advocating expanding the criteria beyond the scope of the Program was determined to exceed the stated limited purpose of the proposed rule and beyond the authority provided by the Program's authorizing statute.

A fourth commenter stated the regulation should not be amended. No rationale was provided.

Finally, a fifth comment was deemed not pertinent to the proposed rule, and thus is not discussed here.

After considering these comments, we did not adopt any suggested changes.

III. Regulatory Impact Analysis

We examined the impacts of this rule under Executive Order 12866, Regulatory Planning and Review; Executive Order 13563, Improving Regulation and Regulatory Review; Executive Order 14094, Modernizing Regulatory Review; Executive Order 13132, Federalism; the Regulatory Flexibility Act (5 U.S.C. 601–612); and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled ''Modernizing Regulatory Review'' amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is ''not significant'' under section 3(f) and does not meet the criteria set forth in 5 U.S.C. 804(2) under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Thus, an RIA is unnecessary.

Executive Order 13132

Executive Order 13132, Federalism, requires Federal agencies to consult with State and local government officials in the development of regulatory policies with federalism implications. We reviewed the rulemaking as required under the Order and determined that it does not have any federalism implications. This rulemaking will not have effect on the states or on the distribution of power and responsibilities among the various levels of government.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to analyze regulatory options that would minimize any significant impact of the rule on small entities. For this analysis, small entities include small business concerns as defined by the Small Business Administration (SBA), usually businesses with fewer than 500 employees. Also, a not-for-profit entity is defined by the Regulatory Flexibility Act as small if it is independently owned and operated and not dominant in its field, regardless of the number of employees. Eligibility requirements of the *John Lewis* NIMHD Research Endowment Program, as codified in Public Law 117–104, limits the universe of potential applicants to an estimated maximum of 42 institutions of higher education (IHEs). Utilizing sources of information such as local business bureaus, workforce statistics, and institution websites, a reasonable determination can be made from the approximate number of employees of eligible institutions. The range estimates are from 51–200 employees for the smallest institution to 10,600 employees for the largest. While most eligible institutions are considered small entities, the impact of this rulemaking will not exceed 5 percent of revenues of the entities. Accordingly, the Secretary certifies this rulemaking will not have a significant impact on a significant number of small entities.

Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written statement, to include an assessment of anticipated costs and benefits, before proposing any rule that includes a Federal mandate that may result in the expenditure by State, local and tribal governments or more, in the aggregate or by the private sector, of $100,000.000 [adjusted annually for inflation (with base year 1995)] in any 1 year. The current inflation-adjusted statutory threshold is approximately $183 million based on the Bureau of Labor Statistics inflation calculator. The Secretary certifies that that this rulemaking does not mandate any spending by State, local, or tribal government in the aggregate or by the private sector. Participation in the *John Lewis* NIMHD Research Endowment Program is voluntary and not mandated.

Paperwork Reduction Act

This rule does not contain any new information collection requirements that are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). However, part 52i contains information collection and recordkeeping requirements. Specifically, §§ 52i.3(b)(2), 52i. 4(a), 52i.4(c), 52i.5(a), 52i.9(b), 52i.11(b), and 52i.11(d) of part 52i contain reporting requirements, and §§ 52i.10, 52i.11(a)(1), 52i.11(a)(2), 52i.11(a)(3), 52i.11(a)(4), and 52i.11(b) of part 52i contain recordkeeping requirements.

These reporting and recordkeeping requirements are addressed in the grant application forms per OMB Control Number 0925–0001 and 0925–0002, which address the instructions for SF–424 and SF–2590. There is nothing that needs to be done regarding the burden associated with these requirements in part 52i, because it is already estimated based upon the data that is collected through the various eRA systems that grantees use. The approvals under OMB Control Number 0925–0001 and OMB

Control Number 0925–0002 expire January 2026.

We do not expect an increase in average burden per respondent because of the enactment of Public Law 117–104 and the new expanded eligibility for research endowment awards that it mandates, or implementation of the program's new expanded eligibility requirements through this proposed rule. Also, we do not expect a change in the number of responses per respondent. However, there likely will be a change in the number of respondents from 4 to 22, and the total of burden hours will need to be adjusted based on the number of respondents.

We estimate the annualized burden to the respondents for reporting and recordkeeping under the *John Lewis* NIMHD Research Endowment Program as:

ESTIMATED ANNUALIZED BURDEN TO THE RESPONDENTS FOR REPORTING AND RECORDKEEPING UNDER THE *John Lewis* NIMHD RESEARCH ENDOWMENT PROGRAM

Citations	Number of respondents [1]	Number of responses per respondent	Average burden per respondents (in hours)	Total burden hours [2]
Reporting				
§ 52i.3(b)(2)	22	1	4	88
§ 52i.4(a)	22	1	1	22
§ 52i.4(c)	22	1	1	22
§ 52i.5(a)	22	1	22	484
§ 52i.9(b)	22	1	4	88
§ 52i.11(b)	6	1	15	90
§ 52i.11(d)	6	1	2	12
Subtotal			49	806
Recordkeeping				
§ 52i.10	6	1	2	12
§ 52i.11(a)(1)	6	1	2	12
§ 52i.11(a)(2)	6	1	2	12
§ 52i.11(a)(3)	6	1	2	12
§ 52i.11(a)(4)	6	1	2	12
§ 52i.11(b)	6	1	8	48
Subtotal			67	108
Total		158		914

[1] There is currently a total of 42 institutions eligible for the *John Lewis* NIMHD Research Endowment Program, we estimate 22 institutions will apply. Historically, requests for applications are solicited every 5 years.

[2] Annual number of respondents × annual number of responses × average burden per response.

When it is time to renew pre/post grant application forms, NIH will reach out to community members in a 2–3-year timeframe to determine if burden is the same, or if it has increased or decreased and provide additional input. The burden has already been accounted for at this time.

We estimate the current annualized cost burden to the respondents for reporting and recordkeeping under the *John Lewis* NIMHD Endowment Program as:

ESTIMATED ANNUALIZED COST BURDEN TO THE RESPONDENTS FOR REPORTING AND RECORDKEEPING UNDER THE *John Lewis* NIMHD RESEARCH ENDOWMENT PROGRAM

Final rule citations	Number of respondents [1]	Number of responses per respondent	Average burden per respondents (in hours)	Hourly wage rate [2]	Total burden [3]
Reporting					
§ 52i.3(b)(2)	22	1	4	[4] 39.72	$3,495.10
§ 52i.4(a)	22	1	1	39.72	873.78
§ 52i.4(c)	22	1	1	39.72	873.78
§ 52i.5(a)	22	1	22	[5] 193.25	93,533.25
§ 52i.9(b)	22	1	4	[6] 101.97	8,973.02
§ 52i.11(b)	6	1	15	[7] 139.66	12,569.84
§ 52i.11(d)	6	1	2	[8] 118.03	1,416.36
Subtotal			49		121,735.13
Recordkeeping					
§ 52i.10	6	1	2	[9] 236.06	2,832.72

ESTIMATED ANNUALIZED COST BURDEN TO THE RESPONDENTS FOR REPORTING AND RECORDKEEPING UNDER THE *John Lewis* NIMHD RESEARCH ENDOWMENT PROGRAM—Continued

Final rule citations	Number of respondents [1]	Number of responses per respondent	Average burden per respondents (in hours)	Hourly wage rate [2]	Total burden [3]
§ 52i.11(a)(1)	6	1	2	39.72	476.61
§ 52i.11(a)(2)	6	1	2	39.72	476.61
§ 52i.11(a)(3)	6	1	2	39.72	476.61
§ 52i.11(a)(4)	6	1	2	39.72	476.61
§ 52i.11(b)	6	1	8	39.72	1,906.42
Subtotal			18	39.72	6,645.56
Total			67		128,380.69

[1] There is currently a total of 42 institutions eligible for the *John Lewis* NIMHD Research Endowment Program, we estimate 22 institutions will apply. Historically, requests for applications are solicited every 5 years.
[2] Average cost per hour.
[3] Number of respondents × average burden per response × hourly wage rate.
[4] Based on contracts/grants staff costs.
[5] Based on the contributions of the principal investigator, participating faculty, contracts/grants staff, financial investment advisors, and administrative support. Aggregate cost is $205.05/hour.
[6] Based on principal investigator costs.
[7] Based on the contributions of the principal investigator, participating faculty, contracts/grants staff, financial investment advisors, and administrative support. Aggregate cost is $139.66/hour.
[8] Based on financial analyst/auditor costs.
[9] Based on financial investment advisor costs.

Federal Assistance Listings

The Federal Assistance Listings numbered program affected by this rulemaking is:

93.307—Minority Health and Health Disparities

List of Subjects in 42 CFR Part 52i

Grant programs—Health, Medical research.

For reasons described in the preamble, the Department of Health and Human Services amends 42 CFR part 52i as set forth below:

PART 52i—JOHN LEWIS NIMHD RESEARCH ENDOWMENT PROGRAM

■ 1. The authority citation for part 52i continues to read as follows:

Authority: 42 U.S.C. 216, 285t–285t–1.

■ 2. The heading to part 52i is revised to read as set forth above.

■ 3. The heading to § 52i.1 is revised to read as follows:

§ 52i.1 To what program does this part apply?

* * * * *

■ 4. Section 52i.3 is amended by revising paragraph (a)(1) to read as follows:

§ 52i.3 Who is eligible to apply?

(a) * * *

(1) Must be a current or former center of excellence under section 736 (42 U.S.C. 293) or section 464z–4 (42 U.S.C. 285t–1) of the Act, and

* * * * *

■ 5. Section 52i.13 is amended by revising paragraphs (f), and (m) through (q) and removing paragraph (r) to read as follows:

§ 52i.13 Other HHS policies and regulations that apply.

* * * * *

(f) 45 CFR part 75—Uniform administrative requirements, cost principles, and audit requirements for HHS awards.

* * * * *

(m) 45 CFR part 93—New restrictions on lobbying.

(n) NIH Guidelines for Research Involving Recombinant for Synthetic Nucleic Acid Molecules at *https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf.* Further information may be obtained from the NIH Office of Science Policy (OSP) via email at *NIHguidelines@od.nih.gov* or the OSP website at *https://osp.od.nih.gov/.*

(o) NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research at *https://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html,* Amendment: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research at *https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-014.html,* and the revised NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects at *https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html.* Further information may be obtained from the NIH Office of Research on Women's Health via email at *orwhinfo@nih.gov.*

(p) NIH Grants Policy Statement. The current version is located on the NIH website at *https://grants.nih.gov/policy/nihgps/index.htm.* [Note: this policy is subject to change and interested persons should contact the Division of Grants Policy in the Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research, NIH, via email at *GrantsPolicy@nih.gov*].

(q) Public Health Service Policy on Humane Care and Use of Laboratory Animals, Office of Laboratory Animal Welfare, NIH (Revised 2015). [*Note:* this policy is subject to change and interested persons should contact the Office of Laboratory Animal Welfare, NIH, 6700B Rockledge Drive, Suite 2500, MSC 6910, Bethesda, MD 20892–6910 (telephone 301–496–7163, not a toll-free number), to obtain references to the current version and any amendments.

Information may be obtained also by emailing *olaw@mail.nih.gov* or via the OLAW website at *https://olaw.nih.gov*].

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–28082 Filed 12–3–24; 8:45 am]

BILLING CODE 4140–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[GN Docket No. 23–65; IB Docket No. 22–271; FCC 24–28; FR ID 264973]

Single Network Future: Supplemental Coverage From Space Information Collection Approval for Space Station and Earth Station Applications

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collection associated with certain rules adopted in a Report and Order, FCC 24–28, in GN Docket No. 23–65 and IB Docket No. 22–271 (*SCS Report and Order*) for space station and earth station applicants wishing to provide supplemental coverage from space (SCS). The *SCS Report and Order* stated that the Commission would publish a document in the **Federal Register** announcing the effective date of rules which were delayed indefinitely. With this document, the Commission is announcing the effective date of the rules applicable to space station and earth station applicants.

DATES: The amendments to 47 CFR 25.125(b)(1) and (2) and (c), published at 89 FR 34148 on April 30, 2024, are effective on December 5, 2024.

FOR FURTHER INFORMATION CONTACT: Stephanie Neville, Space Bureau, at (202) 418–1671 or *Stephanie.Neville@fcc.gov.* For information regarding the Paperwork Reduction Act information collection requirements, contact Cathy Williams, Office of Managing Director, at (202) 418–2918 or via email at *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document announces that, on October 16, 2024, OMB approved the information collection requirements in 47 CFR 25.125(b)(1) and (2) and (c), as modified in the *SCS Report and Order* (89 FR 34148, April 30, 2024). The *SCS Report and Order* stated that the Commission would publish a document in the **Federal Register** announcing the effective date of those rules. This document announces the effective date of those rules. Rules adopted in the *SCS Report and Order* that did not require OMB approval became effective on May 30, 2024, as identified in the **Federal Register** publication of the *SCS Report and Order.* Moreover, the effective date of other rule amendments adopted in the *SCS Report and Order* that also required OMB approval either already have been announced (89 FR 81013, Oct. 7, 2024) or will be announced separately.

If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, *Cathy.Williams@fcc.gov,* regarding OMB Control Number 3060–0678. Please include the applicable OMB Control Number(s) in your correspondence. The Commission will also accept your comments via email at *PRA@fcc.gov.*

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received final OMB approval on October 16, 2024, for the information collection requirements in 47 CFR 25.125(b)(1) and (2) and (c), as modified in the *SCS Report and Order.*

Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number for the information collection requirements in these rules is 3060–0678.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–0678.

OMB Approval Date: October 16, 2024.

OMB Expiration Date: October 31, 2027.

Title: Part 25 of the Federal Communications Commission's Rules Governing the Licensing of, and Spectrum Usage By, Commercial Earth Stations and Space Stations.

Form Number: FCC Form 312 (Main Form and Schedules A, B, and S), FCC Form 312–R.

Respondents: Business or other for-profit, not-for-profit institutions.

Number of Respondents and Responses: 3,535 respondents and 3,587 responses.

Estimated Time per Response: 0.5–80 hours.

Frequency of Response: On occasion, one time and annual reporting requirements; third-party disclosure requirement; recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in 47 U.S.C. 151, 154(i), 157, 301, 303, 307, 308, 309, and 310.

Total Annual Burden: 27,620.

Annual Cost Burden: $4,154,267.

Needs and Uses: The Commission will use the information collected under this revised information collection to effect the policies adopted in *SCS Report and Order* released on March 15, 2024. The SCS regulatory framework enables collaborations between satellite service providers and terrestrial service providers to offer ubiquitous connectivity directly to consumer handsets using spectrum that was previously allocated only to terrestrial service. The Commission anticipates that SCS will enable consumers in areas not covered by terrestrial networks to be connected using their existing devices via satellite-based communications. SCS is a crucial component of the Commission's vision for a ''single network future,'' in which satellite and terrestrial networks work seamlessly together to provide coverage that neither network can achieve on its own.

The *SCS Report and Order* largely preserves the existing 47 CFR part 25 service rules governing satellite communications and applies them to operators who now seek to provide SCS services. For instance, the rules for 47 CFR part 25 license terms and renewals, spectrum milestones, surety bond requirements, automatic termination, and orbital debris mitigation requirements are unchanged. The *SCS Report and Order* further requires that parties who wish to provide SCS submit, via FCC Form 312, either a new application or a modification application to offer expanded services. Said applications must include certifications that: (1) a lease notification or application pursuant to 47 CFR 1.9047 has been filed; (2) the space station licensee or grantee of market access that seeks modification of its 47 CFR part 25 authority in order to provide SCS will do so in the same

geographic areas covered by the relevant geographically independent area (GIA); and (3) SCS earth stations will qualify as licensed by rule earth stations under 47 CFR 25.115(q). Applicants must also describe in detail their proposals to provide SCS service on existing FCC Form 312, Schedule S.

The Commission will use this information to assess applicants' legal, technical, and other qualifications to provide SCS, and to conclude whether, and under what conditions, grant of an authorization will serve the public interest. Further, this information collection will enable the Commission to monitor and enforce the entry criteria for SCS providers that the *SCS Report and Order* imposed, which are designed to minimize the possibility of interference between co-channel operators and geographically adjacent markets.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2024–28424 Filed 12–3–24; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2024–0058]

RIN 2127–AM64

Federal Motor Vehicle Safety Standards; FMVSS No. 213, ''Child Restraint Systems,'' FMVSS No. 213a, ''Child Restraint Systems—Side Impact Protection,'' and FMVSS No. 213b, ''Child Restraint Systems''—Response to Petitions for Reconsideration; Correction

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule; response to petitions for reconsideration; correction.

SUMMARY: On October 9, 2024, NHTSA issued a final rule responding to petitions for reconsideration of a June 2022 final rule establishing Federal Motor Vehicle Safety Standard (FMVSS) No. 213a and the December 2023 final rule establishing FMVSS No. 213b. That rule contained an amendatory instruction to amend a section of text that did not exist. This document provides the correct amendatory instruction. It does not change the regulatory text set forth in the October 9, 2024 final rule.

DATES: Effective on December 4, 2024.

FOR FURTHER INFORMATION CONTACT: For technical issues, you may call Cristina Echemendia, Office of Crashworthiness Standards (telephone: (202) 366–6345). For legal issues, you may call Matthew Filpi, Office of Chief Counsel (telephone: (202) 366–2992). Address: National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Washington, DC 20590.

SUPPLEMENTARY INFORMATION: This document corrects a drafting error in the amendatory instructions of an October 9, 2024 final rule (89 FR 81836) responding to petitions for reconsideration of a June 30, 2022 final rule (87 FR 39234) establishing FMVSS No. 213a and a December 5, 2023 final rule (88 FR 84514) establishing FMVSS No. 213b. Amendatory instruction 2.f in that final rule directed that, among other sections, section ''S5.8.2.1 introductory text'' of FMVSS No. 213 be revised. However, S5.8.2.1 has no introductory text—only a title. As set forth in the revised regulatory text, NHTSA intended to amend the introductory text of S5.8.2.1(a). Because of this drafting error, the Code of Federal Regulations could not be updated with the revised regulatory text. This document sets forth the same regulatory text set forth in the October 9, 2024 final rule with the proper amendatory instruction so that the revised regulatory text published on October 9, 2024 can be incorporated into the Code of Federal Regulations. Good cause exists for this change to be effective immediately because the regulatory text has not been altered from what was published on October 9, 2024.

List of Subjects in 49 CFR Part 571

Imports, Incorporation by Reference, Motor vehicle safety, Motor vehicles, and Tires.

In consideration of the foregoing, NHTSA corrects 49 CFR part 571 by making the following correcting amendment.

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

■ 1. The authority citation for part 571 continues to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117 and 30166; delegation of authority at 49 CFR 1.95.

■ 2. Section 571.213 is amended by revising the introductory text to paragraph S5.8.2.1(a) to read as follows:

§ 571.213 Child restraint systems; Applicable unless a vehicle or child restraint system is certified to § 571.213b.

* * * * *

S5.8.2.1 * * *

(a) Each electronic registration form provided for child restraint systems manufactured on or after June 30, 2025, shall:

* * * * *

Issued under authority delegated in 49 CFR 1.95 and 501.8.

Raymond R. Posten,

Associate Administrator, Rulemaking.

[FR Doc. 2024–28165 Filed 12–3–24; 8:45 am]

BILLING CODE P

Proposed Rules

Federal Register
Vol. 89, No. 233
Wednesday, December 4, 2024

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 985

[Doc. No. AMS–SC–24–0067]

Marketing Order Regulating the Handling of Spearmint Oil Produced in the Far West; Revision of the Salable Quantity and Allotment Percentage for Class 3 (Native) Spearmint Oil for the 2024–2025 Marketing Year

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the Far West Spearmint Oil Administrative Committee (Committee) to revise the quantity of Class 3 (Native) spearmint oil that handlers may purchase from, or handle on behalf of, producers in Washington, Idaho, and Oregon and parts of Nevada and Utah (Far West) for the 2024–2025 marketing year, which began on June 1, 2024. This action would increase the 2024–2025 marketing year Native spearmint oil salable quantity from 678,980 pounds to 731,220 pounds, and the allotment percentage from 26 percent to 28 percent.

DATES: Comments must be received by December 19, 2024.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments may be sent to the Docket Clerk, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237. Comments may also be submitted to the Docket Clerk electronically by email: *MarketingOrderComment@usda.gov* or via the internet at: *https://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register**. Comments submitted in response to this proposed rule will be included in the record and will be made available to the public and can be viewed at: *https://www.regulations.gov.* Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Joshua R. Wilde, Marketing Specialist, or Barry Broadbent, Chief, Northwest Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (503) 326–2282, or Email: *Joshua.R.Wilde@usda.gov* or *Barry.Broadbent@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–8085, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, proposes to amend regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under Marketing Order No. 985, as amended (7 CFR part 985), regulating the handling of spearmint oil produced in the Far West. Part 985 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and comprises spearmint oil producers operating within the area of production, and a public member.

The Agricultural Marketing Service (AMS) is issuing this proposed rule in conformance with Executive Orders 12866, 13563, and 14094. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 reaffirms, supplements, and updates Executive Order 12866 and further directs agencies to solicit and consider input from a wide range of affected and interested parties through a variety of means. This proposed action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This proposed rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires Federal agencies to consider whether their rulemaking actions would have Tribal implications. AMS has determined that this proposed rule is unlikely to have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

This proposed rule has been reviewed under Executive Order 12988—Civil Justice Reform. This proposed rule is not intended to have retroactive effect. Under the Order now in effect, salable quantities and allotment percentages have been established for classes of spearmint oil produced in the Far West. This proposed rule would increase the quantity of Native Spearmint oil produced in the Far West that handlers may purchase from, or handle on behalf of, producers during the 2024–2025 marketing year, which began on June 1, 2024.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the U.S. Department of Agriculture (USDA) a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This proposal invites comments on revisions to the quantity of Native spearmint oil that handlers may purchase from, or handle on behalf of, producers during the 2024–2025 marketing year. Prior to this proposed rule, the salable quantity and allotment percentage for Native spearmint oil was initially established at 678,980 pounds and 26 percent, respectively, in a final rule published May 23, 2024 (89 FR 45557). This proposed rule would increase the Native spearmint oil salable quantity from 678,980 pounds to 731,220 pounds and the allotment percentage from 26 percent to 28 percent.

Pursuant to the requirements in § 985.50 of the Order, the Committee meets each year to consider supply and demand of spearmint oil and to adopt a marketing policy for the ensuing marketing year. In determining such marketing policy, the Committee considers several factors, including, but not limited to, the current and projected supply of oil, estimated future demand, production costs, and producer prices for both Class 1 (Scotch) and Class 3 (Native) spearmint oil. Input from spearmint oil handlers and producers are considered as well.

Pursuant to the provisions in § 985.51, when the Committee's marketing policy considerations indicate a need to establish or to maintain stable market conditions through volume regulation, the Committee subsequently recommends to AMS the establishment of a salable quantity and allotment percentage for such class or classes of oil for the upcoming marketing year. Recommendations for volume control are intended to ensure market requirements for Far West spearmint oil are satisfied and orderly marketing conditions are maintained.

Salable quantity represents the total quantity of each class of oil (Scotch or Native) which handlers may purchase from, or handle on behalf of, producers during a given marketing year. The allotment percentage for each class of spearmint oil is the salable quantity for that class of oil divided by the total of all producers' allotment base for the same class of oil. A producer's allotment base is their calculated share of the spearmint oil market based on a statistical representation of past spearmint production and sales. In order to account for changes in production and demand over time, the Committee periodically reviews and adjusts each producer's allotment base in accordance with a formula prescribed by the Committee and approved by AMS. Each producer's annual allotment of the salable quantity is calculated by multiplying their respective allotment base for each class of spearmint oil by the allotment percentage for that class of spearmint oil. The total allotment base is revised each year on June 1 to account for producer allotment base being lost because of the ''bona fide effort'' production provision of § 985.53(e) and additional base made available pursuant to the provisions of § 985.153.

The Committee met on October 11, 2023, to consider its marketing policy for the 2024–2025 marketing year. At that meeting, the Committee determined that, based on the current market and supply conditions, volume regulation for both classes of oil would be necessary. The Committee unanimously recommended salable quantities and allotment percentages for Native spearmint oil of 678,980 pounds and 26 percent, respectively. In addition, the Committee unanimously recommended a salable quantity and allotment percentage for Scotch spearmint oil of 663,648 pounds and 29 percent, respectively. A proposed rule to that effect was published in the **Federal Register** on January 25, 2024 (89 FR 4835). Comments on the proposed rule were solicited from interested persons until February 26, 2024. No comments were received. Subsequently, a final rule establishing the salable quantities and allotment percentages for Scotch and Native spearmint oil for the 2024–2025 marketing year was published in the **Federal Register** on May 23, 2024 (89 FR 45557).

Pursuant to authority contained in §§ 985.50, 985.51, and 985.52, the Committee met again on October 9, 2024, to evaluate the current year's volume control regulation. At the meeting, the Committee assessed the current market conditions for spearmint oil in relation to the salable quantities and allotment percentages established for the 2024–2025 marketing year. The Committee considered several factors, including the current and projected supply and the estimated future demand for all classes of spearmint oil. The Committee determined that the established salable quantity and allotment percentage in effect for Native spearmint oil for the 2024–2025 marketing year should be increased to provide an adequate buffer to ensure available supply would continue to meet demand.

At the October 9, 2024, meeting, the Committee recommended increasing the 2024–2025 marketing year Native spearmint oil salable quantity from 678,980 pounds to 731,220 pounds and the allotment percentage from 26 percent to 28 percent. The recommendation to increase the salable quantity and allotment percentage passed with a vote of 6 in favor with 2 opposed. The members voting against the recommendation supported volume control, but did not believe that additional supply would be necessary to meet 2024–2025 marketing year demand.

Accordingly, this proposed rule would make additional amounts of Native spearmint oil available to the market by increasing the salable quantity and allotment percentage previously established under the Order for the 2024–2025 marketing year. This proposed rule would increase the Native spearmint oil salable quantity by 52,240 pounds, to 731,220 pounds, and would raise the allotment percentage 2 percentage points, to 28 percent. Such additional oil could come from 2024–2025 marketing year production or from releasing Native spearmint oil held by producers in the reserve pool. As of May 31, 2024, the Committee records show that the reserve pool for Native spearmint oil contained 1,026,336 pounds of oil.

At the October 9, 2024, meeting, the Committee staff reported, as of the meeting date, there was an estimated 356,302 pounds of salable quantity of Native spearmint available for purchase in the 2024–2025 marketing year, ending May 31, 2025. The Committee considered this amount to be low for this early in the marketing year. Based on the Committee's estimated sales demand for Native spearmint oil for the remainder of the 2024–2025 marketing year, the Committee projected that approximately 125,000 pounds of Native spearmint oil may be carried into the 2025–2026 marketing year. However, the Committee was concerned that, without increasing the salable quantity and allotment percentage, the market for Native spearmint oil may be shorted if demand were to increase unexpectedly. The increased quantity of Native spearmint oil (52,240 pounds) that would be made available to the market because of this rulemaking would ensure that market demand is fully satisfied in the current year. Should the available supply of Native spearmint oil exceed 2024–2025 marketing year demand, any unsold quantity would remain available to the market in future marketing years as salable carry-in.

In making the recommendation to increase the salable quantity and allotment percentage of Native spearmint oil, the Committee considered all currently available information on the price, supply, and demand of Native spearmint oil. The Committee also considered reports and

other information from handlers and producers in attendance at the meeting. Lastly, the Committee manager presented information and reports that were provided to the Committee staff by handlers and producers.

This proposal would increase the 2024–2025 marketing year Native spearmint oil salable quantity by 52,240 pounds to a total of 731,220 pounds. This amount, along with 446,420 pounds of salable carry-in, would result in available supply of 1,177,640 pounds. The Committee estimates 2024–2025 marketing year trade demand for Native spearmint oil to be 1,000,000 pounds. Actual sales of Native spearmint oil for the 2023–2024 marketing year totaled 987,041 pounds. The 5-year average of Native spearmint oil sales is 1,085,916 pounds.

The Committee estimates that this action would result in approximately 175,000 pounds of salable Native spearmint oil could be carried into the 2025–2026 marketing year which begins June 1, 2025. The Committee believes that this amount to be a sufficient buffer if demand exceeds the Committee's expectations for the remainder of the 2024–2025 marketing year. In addition, reserve pool oil could be released into the market under a future relaxation of the volume regulation should it be necessary to adequately supply the market prior to the beginning of the 2025–2026 marketing year. The Committee estimates that a total of 1,335,150 pounds of Native spearmint oil (1,026,336 currently in reserve and an estimated 308,814 pounds of excess oil produced during the 2024–2025 marketing year) would be available from the reserve pool, if needed.

The Committee's stated intent in the use of the Order's volume control regulation is to keep adequate supply available to meet market needs and to maintain orderly marketing conditions. With that consideration, the Committee developed its recommendation for increasing the Native spearmint oil salable quantity and allotment percentage for the 2024–2025 marketing year based on the information discussed above, as well as the summary data detailed below.

(A) *Initial Estimated 2024–2025 Native Allotment Base—2,611,463 pounds.* This figure is the allotment base estimate on which the original 2024–2025 salable quantity and allotment percentage was based.

(B) *Revised 2024–2025 Native Allotment Base—2,611,500 pounds.* This figure is 37 pounds more than the initial estimated allotment base of 2,611,463 pounds. The difference is the result of annual adjustments made to the allotment base at the beginning of the marketing year in accordance with the provisions of the Order.

(C) *Initial 2024–2025 Native Allotment Percentage—26 percent.* This percentage was unanimously recommended by the Committee on October 11, 2023.

(D) *Initial 2024–2025 Native Salable Quantity—678,980 pounds.* This figure is 26 percent of the original estimated 2024–2025 allotment base of 2,611,463 pounds.

(E) *Adjusted Initial 2024–2025 Native Salable Quantity—678,990 pounds.* This figure reflects the salable quantity available at the beginning of the 2024–2025 marketing year. This quantity is derived by applying the initial 26 percent allotment percentage to the revised allotment base of 2,611,500.

(F) *Proposed Revision to the 2024–2025 Native Salable Quantity and Allotment Percentage:*

(1) *Proposed Increase in the Native Allotment Percentage—2 percent.* The Committee recommended an increase of 2 percentage points over the initial Native allotment percentage.

(2) *Proposed Revised 2024–2025 Native Allotment Percentage—28 percent.* This percentage was derived by adding the increase of 2 percentage points to the initially established 2024–2025 Native allotment percentage of 26 percent.

(3) *Proposed Revised 2024–2025 Native Salable Quantity—731,220 pounds.* This figure is 28 percent of the revised 2024–2025 Native allotment base of 2,611,500 pounds.

(4) *Computed Increase in the 2024–2025 Native Salable Quantity as a Result of the Proposed Revision—52,240 pounds.* This figure represents the difference between the initial 2024–2025 Native salable quantity of 678,980 pounds and the proposed Native salable quantity of 731,220 pounds.

Scotch spearmint oil is also regulated by the Order. As mentioned previously, a salable quantity and allotment percentage for Scotch spearmint oil was established in a final rule published in the **Federal Register** on May 23, 2024 (89 FR 45557). At the October 9, 2024, meeting, the Committee considered the projected production, inventory, and marketing conditions for Scotch spearmint oil for the 2024–2025 marketing year. After receiving reports from the Committee staff and comments from the industry, the consensus of the Committee was that the previously established salable quantity and allotment percentage for Scotch spearmint oil was appropriate for the current market conditions. As such, the Committee took no further action with regards to Scotch spearmint oil for the 2024–2025 marketing year.

This proposed rule would relax the volume regulation requirements of Native spearmint oil and would allow producers to meet market demand while improving producer returns. The proposed increase in the Native spearmint oil salable quantity and allotment percentage would account for the anticipated market needs for that class of oil. In determining anticipated market needs, the Committee considered changes and trends in historical sales, production, and demand. In conjunction with the issuance of this proposed rule, AMS has reviewed the Committee's marketing policy statement for the 2024–2025 marketing year. The Committee's marketing policy statement, a requirement whenever the Committee recommends volume regulation, meets the requirements of §§ 985.50 and 985.51.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 89 producers of Native spearmint oil operating within the regulated production area. In addition, there are approximately 6 Native spearmint oil handlers subject to regulation under the Order. Small agricultural service firms are defined by the Small Business Administration (SBA) as those having annual receipts of equal to or less than $34.0 million (Postharvest Crop Activities, NAICS code 11514). Small agricultural producers of spearmint oil are defined as those having annual receipts of equal to or less than $2.5 million (All Other Miscellaneous Crop Farming, NAICS code 111998) (13 CFR 121.201).

The National Agricultural Statistics Service (NASS) reported that the 2023 U.S. season average spearmint oil producer price per pound was $18.40 (both Scotch and Native). Native spearmint oil utilization for the 2023–2024 marketing year, as reported by the

Committee, was 987,041 pounds for Native spearmint oil. Multiplying $18.40 per pound by 2023–2024 marketing year spearmint oil utilization of 987,041 pounds yields a crop value estimate of about $18.2 million.

Given the accounting requirements for the volume regulation provisions of the Order, the Committee maintains accurate records of each producer's production and sales. Using the $18.40 average spearmint oil price and Committee production data for each producer, the Committee estimates that all of the 89 Native spearmint oil producers could be classified as small entities under the SBA definition.

There is no third-party or governmental entity that collects and reports spearmint oil prices received by spearmint oil handlers. However, the Committee estimates an average spearmint oil handling markup at approximately 20 percent of the price received by producers. Twenty percent of the 2023 producer price ($18.40) is $3.68, which results in a handler Free on Board (f.o.b.) price per pound estimate of $22.08 ($18.40 + $3.68).

Multiplying this estimated handler f.o.b. price by the 2023–2024 marketing year total spearmint oil utilization of 1,536,364 pounds (987,041 pounds of Native + 549,323 pounds of Scotch) results in an estimated handler-level spearmint oil value of $33.9 million. Dividing this figure by the number of handlers (6) yields estimated average annual handler receipts of about $5.7 million, which is well below the $34.0 million SBA threshold for small agricultural service firms.

Furthermore, using confidential data compiled by the Committee on the pounds of spearmint oil handled by each handler and the abovementioned estimated handler price per pound, the Committee reported that it is not likely that any of the six handlers had 2023–2024 marketing year spearmint oil sales that exceeded SBA's threshold.

Therefore, in view of the foregoing, the majority of producers of spearmint oil may be classified as small entities, and all of the handlers of spearmint oil may be classified as small entities.

This proposed rule would increase the quantity of Native spearmint oil produced in the Far West, which handlers may purchase from, or handle on behalf of, producers during the 2024–2025 marketing year, which ends May 31, 2025. The 2024–2025 marketing year Native spearmint oil salable quantity was initially established at 678,980 pounds and the allotment percentage initially set at 26 percent. This proposed rule would increase the Native spearmint oil salable quantity to 731,220 pounds and the allotment percentage to 28 percent. The Committee recommended this proposed action to help maintain stability in the spearmint oil market by matching supply to estimated demand, thereby avoiding extreme fluctuations in supplies and prices. Establishing quantities that may be purchased from or handled on behalf of producers during the marketing year through volume regulation allows producers to coordinate their spearmint oil production with the expected market demand. Authority for this proposal is provided in §§ 985.50, 985.51, and 985.52 of the Order.

Based on the information and projections available at the October 9, 2024, meeting, the Committee considered several alternatives to this increase. The Committee considered leaving the salable quantity and allotment percentage unchanged, and also considered other potential levels of increase. The Committee reached its recommendation to increase the salable quantity and allotment percentage for Native spearmint oil after careful consideration of all available information and input from all interested industry participants and believes that the levels recommended would achieve the desired objectives. The recommendation to increase the salable quantity and allotment percentage passed with a vote of 6 in favor with 2 opposed. The members voting against the recommendation supported volume control, but did not believe that additional supply would be necessary to meet 2024–2025 marketing year demand. Without the increase, the Committee believes the industry may not be able to satisfactorily meet market demand.

The Committee's meeting was widely publicized throughout the spearmint oil industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the October 9, 2024, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit comments on this proposed rule, including the regulatory and informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178, Vegetable and Specialty Crops. No changes in those requirements would be necessary because of this proposed rule. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would relax the volume regulation requirements established under the Order. Accordingly, this action would not impose any additional reporting or recordkeeping requirements on either small or large Far West spearmint oil handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

AMS has not identified any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendations submitted by the Committee and other available information, AMS has determined that this proposed rule is consistent with and would effectuate the purposes of the Act.

A 15-day comment period is provided to allow interested persons to respond to this proposal. Fifteen days is deemed appropriate because handlers are aware of this proposed regulatory relaxation, which was recommended by the Committee at a public meeting, and the subject matter of this proposal is not complex. The 2024–2025 marketing year ends on May 31, 2025. For the additional salable quantity proposed in this rule to be available to the market, timely consideration of the proposal is essential to ensure orderly market conditions. AMS will consider all timely comments received before making a final determination on this matter.

List of Subjects in 7 CFR Part 985

Marketing agreements, Oils and fats, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service proposes to amend 7 CFR part 985 as follows:

PART 985—MARKETING ORDER REGULATING THE HANDLING OF SPEARMINT OIL PRODUCED IN THE FAR WEST

■ 1. The authority citation for 7 CFR part 985 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Amend § 985.234 by revising paragraph (b) to read as follows:

§ 985.234 Salable quantities and allotment percentages—2024–2025 marketing year.

* * * * *

(b) Class 3 (Native) oil—a salable quantity of 731,220 pounds and an allotment percentage of 28 percent.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2024–28214 Filed 12–3–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

7 CFR Part 1944

[Docket No. RHS–24–SFH–0037]

RIN 0575–AD37

Self-Help Technical Assistance Grants: Technical Corrections and Program Updates

AGENCY: Rural Housing Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Rural Housing Service (RHS or the Agency), a Rural Development (RD) agency of the United States Department of Agriculture (USDA), proposes to update and streamline the Single-Family Housing (SFH) Self-Help Technical Assistance Grant Program. The Self-Help Program has evolved, and the current regulations as codified restrict the Agency's ability to be flexible with market changes. The intent of this proposed rule is to reduce the regulatory burdens in the current regulation, to assist the Agency to better achieve the program objectives, streamline administrative regulatory requirements and make the program more effective in serving rural Americans by increasing decent, safe, and sanitary housing stock across the Nation.

DATES: Comments on the proposed rule must be received on or before February 3, 2025.

The comment period for the information collection under the Paperwork Act of 1995 must be received on or before February 3, 2025.

ADDRESSES: Comments may be submitted electronically by the Federal eRulemaking Portal: Go to *http://www.regulations.gov* and, in the ''Search Field'' box, labeled ''Search for dockets and documents on agency actions,'' enter the following docket number: (RHS–24–SFH–0037) or Regulation Identifier Number (RIN): (0575–AD37). To submit or view public comments, click the ''Search'' button, select the ''Documents'' tab, then select the following document title: ''Self-Help Technical Assistance Grants: Technical Corrections and Program Updates'' from the ''Search Results,'' and select the ''Comment'' button. Before inputting your comments, you may also review the ''Commenter's Checklist'' (optional). Insert your comments under the ''Comment'' title, click ''Browse'' to attach files (if available). Input your email address and select ''Submit Comment.'' Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''FAQ'' link.

All comments will be available for public inspection online at the Federal eRulemaking Portal (*http://www.regulations.gov*).

Other Information: Additional information about Rural Development and its programs is available on the internet at *http://www.rurdev.usda.gov/index.html.*

In accordance with 5 U.S.C. 553(b)(4), a summary of this proposed rule may be found by going to *http://www.regulations.gov* and in the ''Search for dockets and documents on agency actions'' box, enter the following docket number RHS–24–SFH–0037.

FOR FURTHER INFORMATION CONTACT: Sunceri Dade, Finance & Loan Analyst, SFH Direct Division, Rural Housing Service, Rural Development, United States Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250, Phone: 202–720–1485, Email: *Sunceri.Dade@usda.gov.*

SUPPLEMENTARY INFORMATION:

Statutory Authority

Section 510(k) of Title V the Housing Act of 1949 [42 U.S.C. 1480(k)], as amended, authorizes the Secretary of the Department of Agriculture to promulgate rules and regulations as deemed necessary to carry out the purpose of that title. The Self-Help program is authorized under Section 523 of Title V the Housing Act of 1949 (42 U.S.C. 1490(c)), as amended, authorizes the Secretary of the Department of Agriculture to promulgate rules and regulations as deemed necessary to carry out the purpose of that title. The program is implemented under 7 CFR part 1944, subpart I.

I. Background

The RHS offers a variety of programs to build or improve housing and essential community facilities in rural areas. RHS offers loans, grants, and loan guarantees for single- and multifamily housing, childcare centers, fire and police stations, hospitals, libraries, nursing homes, schools, first responder vehicles and equipment, housing for farm laborers. RHS also provides technical assistance loans and grants in partnership with non-profit organizations, Indian Tribes, state and federal government agencies, and local communities.

Well built, affordable housing is essential to the vitality of communities in rural America. RD SFH Programs give families and individuals the opportunity to buy, build, or repair affordable homes located in rural America. Eligibility for these loans, loan guarantees, and grants is based on income and varies according to the average median income for each area.

Section 510(k) of Title V the Housing Act of 1949 [42 U.S.C. 1480(k)], as amended, authorizes the Secretary of the Department of Agriculture to promulgate rules and regulations as deemed necessary to carry out the purpose of that title. The Self-Help program is authorized under Section 523 of Title V the Housing Act of 1949 (42 U.S.C. 1490(c)), as amended, authorizes the Secretary of the Department of Agriculture to promulgate rules and regulations as deemed necessary to carry out the purpose of that title. The RHS administers the Section 523 Self-Help Housing Technical Assistance Grant Program which is implemented under 7 CFR 1944, Subpart I and authorized by the Housing Act of 1949, as amended (42 U.S.C. 1490c). The purpose of the program is to provide grants to qualified organizations to help them carry out local self-help housing construction projects. Grant recipients supervise groups of very low- and low-income individuals and families as they construct or rehabilitate their homes in rural areas. The group members provide most of the construction labor on each other's homes, and rehabilitation project participants contribute construction hours based on the amount of work

being completed, all with technical assistance from the organization overseeing the project. Eligible applicants include government nonprofit organizations, federally recognized Tribes, and private nonprofit organizations.

The SFH program undertook a systematic review of its current regulation at 7 CFR 1944 Subpart I and the procedures to administer its programs. It was determined that several technical corrections and program updates are needed.

II. Discussion of the Proposed Rule

The SFH program routinely meets with staff and partners to provide them with the opportunity to discuss suggestions for process improvement(s) to reduce the burden on grantees and borrowers, increase the flexibility of the program and improve overall customer satisfaction. As a result of these consultations, SFH has identified several processes and regulatory improvements which are described in the next section. Continued stakeholder input is vital to ensure the proposed changes would support the Self-Help Program's mission, while ensuring that regulation changes are reasonable and do not overly burden the Agency's staff and their customers.

III. Summary of Proposed Changes

The following information details the changes in the proposed rule:

(1) Make general revisions to streamline and update 7 CFR part 1944, subpart I:

a. Remove/replace outdated references (e.g., County Office, County Supervisor, and District Director).

State personnel and office locations have changed over the years, and the terms ''County Office'', ''County Supervisor'', and ''District Director'' are no longer used by the Agency. The Agency personnel assigned to review Self-help Program applications, and the person assigned to service the grant, could be different people in different parts of the State. The term ''Authorized Agency Official'' will be used to generalize assignments and allow states the flexibility to assign work for the program as needed.

b. Replace references to ''FmHA or its successor agency under Public law 103–354'' with ''Rural Housing Service'' or ''Agency.''

In 2006, the FmHA was fully terminated, and its housing and community programs were transferred to the newly formed USDA Rural Development. The proposed rule intends to replace the term ''Farmers Home Administration'' with the terms ''Agency'' and ''Rural Housing Service.''

c. Replace references to ''SF–269A'' with ''SF–425.''

The Standard Form (SF 269A) was obsoleted several years ago. It will be replaced with the Federal Financial Report, Standard Form (SF)-425.

d. Remove paragraph (d) from 7 CFR 1944.406 ''Prohibited use of grant funds.''

Removing 7 CFR 1944.406(d) will align the regulation with 2 CFR part 200 language which allows grant funds to be used for employee training.

e. Remove requirements to submit a preapplication or application in an original and one copy.

The Agency has moved to Electronic Customer Files (ECF) and no longer requires hard copy paper preapplication or applications. This update will streamline and modernize the program while also reducing environmental impact.

f. Revise 7 CFR 1944.424 ''Dwelling construction standards.''

The Agency intends to update the paragraph to replace ''local codes'' with ''State, Tribal, or local requirements.''

g. Remove requirement to submit an Affirmative Fair Housing Marketing Plan (AFHMP).

The Agency has determined that the AFHMP is unnecessary considering marketing materials are collected and reviewed along with a very-low outreach plan. The Agency does not have its own AFHMP form, and the Housing and Urban Development form being used by Single-Family Housing has not been kept updated. This action will cause the removal of 1944.410(a)(10) and 1944.410(b)(1)(iv). Self-help organizations are must still comply with all civil right laws as directed in the grant agreement.

(2) Revise 7 CFR 1944.401 ''Objectives'' to remove outdated and incorrect statements.

The Agency intends to update the introductory paragraph to reflect the program's current objectives and represent the population it is designed to serve.

(3) Revise 7 CFR 1944.403 ''Definitions.''

Definitions will be added which are intended to provide additional clarity to stakeholders about the program.

(4) Revise 7 CFR 1944.404(d) to allow 'Board of Directors' to be defined at 7 CFR 1944.403 ''Definitions.''

SFH has determined that the language in this part of the regulation is out of place and should be moved to the definitions section. In addition, the requirement for all organizations to have a specific number of board members has been overly restrictive in some extremely rural areas. The Agency proposes to provide organizations with more flexibility related to the required number of board members in the regulatory definitions section.

(5) Revise 7 CFR 1944.407 ''Limitations.''

This section of the regulation limits the amount of technical assistance (TA) an organization may apply for. The Agency proposes that the limitations in paragraphs (a), (b), (c), and (d) should be as follows:

Remove the following sentence in paragraph (a), ''Upon request, the County Supervisor will provide the grantee the average cost of modest homes for the area.'' The equivalent value of a modest home will be established by the Agency on an annual basis as described in the definition at 7 CFR 1944.403. The National Office will use a percentage of the area loan limit to establish the equivalent value of a modest home annually.

Revise paragraph (b) ''An average TA cost per equivalent unit that does not exceed the difference between the equivalent value of modest homes in the area and the average mortgage of the participating families minus $1,000'' to increase to '. . . minus $10,000' which will reduce the historically higher than necessary amount that can be charged to the grant.

Revise paragraph (c) and move to paragraph (d) to remove the State Director's approval of a technical assistance cost above the limits set in paragraphs (a) and (b) in favor of this approval being at the National Office level. Add other limitations may apply which will be released in an annual funding policy. As program funding remains unchanged or decreases annually, funding limitations may be necessary to manage program funds.

The revised paragraph (c) will add a maximum TA cost per equivalent unit for rehabilitation-type programs. The maximum TA cost per equivalent unit will be no more than a percentage of the cost of the equivalent value of modest homes built in the area. The levels will be set in the regulation as not to exceed 12 percent for acquisition rehab, and 9 percent for owner-occupied.

(6) Revise 7 CFR 1944.409 ''Intergovernmental Consultation, Executive Order 12372.''

The Agency intends to update the title and paragraph language of this section.

(7) Revise 7 CFR 1944.410 ''Processing preapplications, applications, and completing grant dockets.''

As a consequence of historically limited funding for the Self-help Program, funds have not been available

for predevelopment grant awards. Proposed changes to the regulation will include items typically collected during the preapplication phase being incorporated into a part of the application docket.

Other proposed changes/clarifications to § 1944.410 include:

Add the requirement to submit the organization's previous years financial audit in paragraph (a)(3).

Remove the current requirement in paragraph (a)(5) ''. . . living in houses that are deteriorated, dilapidated, overcrowded, and/or lacking plumbing facilities.''

Specify in paragraph (b) that a preapplication review will only be completed when preapplications are accepted by the Agency. Typically, the full application docket will be reviewed.

Remove references to Form AD 622, ''Notice of Preapplication Review Action'' in paragraphs (b)(4)(i), (ii), and (e) in favor of issuing a letter of conditions for eligible preapplications/applications or denial letter with appeal rights for those found to be ineligible.

Remove the $10,000 limit in paragraph (d), and the up to six-month period of performance stipulation for predevelopment grants. Should funding allow for predevelopment grants these limitations will be set in an annual funding policy or other public release announcing the acceptance of preapplications.

In paragraph (e)(2) at the time of application, specify that the first group can be determined eligible by the Agency or the organization; and in paragraph (3) lots do not need to be optioned; however, both will be a condition of closing. The Agency does not have funding for predevelopment grants to aid organizations in meeting these requirements, and in many cases, it is unreasonable to have a group ready to begin construction prior to the approval of the application.

In paragraph (e)(7) clarify that a detailed budget is required in addition to SF 424A.

Remove paragraph (c) and renumber paragraphs (d) and (e) accordingly.

(8) Update 7 CFR 1944.411 paragraphs (e) and (g) requirements for fidelity bonding and to establish an interest-bearing checking account.

The regulation currently prohibits Grantees from drawing funding beyond a 30-day advancement, thus fidelity bonding is not needed. The Agency proposes to revise this section to read ''The grantee has established an interest-bearing checking account in accordance with 2 CFR 200.305(b)(8).''

(9) Remove 7 CFR 1944.412 ''*Docket preparation*'' *chart in favor of an application checklist to be provided by the program office.*

Remove the chart currently in this section and include a complete application checklist provided by the program office. Electronic applications will be accepted.

(10) Revise 7 CFR 1944.413 ''*Grant approval*'' *to reflect the current practices.*

The National Office reviews, approves, and obligates all funding for the Self-help Program. The current process for application review is the docket will first be reviewed by the Technical and Management Assistance (T&MA) Contractor before submission to the RD Office designated by the State. After the field review and recommendation, the docket is submitted to the National Office for final review, approval, and funding. In addition to outlining this process, paragraph (a)(2) will be edited to remove reference to the Finance Office, as the Finance Office no longer processes obligations or fund disbursements as described. Reference to and use of Form RD 440–57 will be removed.

(11) Revise 7 CFR 1944.415 ''*Grant approval and other approving authorities.*''

Funding for the Self-help Program remains limited, and the National Office must retain grant approval authority to manage the allocation of funds. SFH proposes to remove the State Director grant approval limits in paragraphs (a) and (b), and to combine the new paragraphs into one paragraph (a).

Renumber paragraph (d) to be paragraph(c), and update the former paragraph (d), (1), (2) and (3) regarding the Agency official authorized to approve monthly expenditures when a grantee serves more than one county or state. The monthly expenditures should normally be approved by the Housing Program Director or designee and update the options for grantees working in multiple states. Should an organization propose to operate in more than one state the National Office will determine the appropriate approval official.

(12) Update 7 CFR 1944.416 ''*Grant closing.*''

Revise the paragraph to replace 'Agreement' with 'Grant Agreement' and remove the reference to 7 CFR 1944.403(a);

Add that cost may not be allocated to the Grant Agreement prior to execution; and Authorize the State Director or designee to execute the Grant Agreement on behalf of the Agency.

(13) Update 7 CFR 1944.417 ''*Servicing actions after grant closing.*''

Revise paragraph (a) to state that draws may be requested as needed but no more than monthly, and that funding requests must be accompanied by an actual or projected budget.

Update paragraph (a)(1) to remove references to Form RD 440–57, ''Acknowledgment of Obligated Funds/Check Request'' which is no longer in use. Form RD 440–57 ''Acknowledgment of Obligated Funds/Check Request'' will also be removed from paragraph (a) (2)(i) and (ii).

Revise paragraph (b) to specify quarterly reports are based on the grant start date instead of listing the 15th day of January, April, July, and October; change reference to Exhibit B to Subpart I of Part 1944 ''Evaluation Report of Self-Help Technical Assistance (TA) Grants'' to state that generally a 'progress report' and/or 'quarterly report' will be submitted to allow for automated reporting systems to be used instead of Exhibit B to Subpart I of Part 1944 ''Evaluation Report of Self-Help Technical Assistance (TA) Grants'' which will remain in the instruction as a guide where it can be easily updated as needed; replace 'should' with 'will' in reference to grant oversight quarterly meetings; and add language to allow the option to require more frequent reporting if problems are identified.

In paragraph (b)(1)(iv), remove specific reference to Exhibit B–2 to Subpart I of Part 1944 ''Breakdown of Construction Development for Determining Percentage Construction Completed'' in favor of the general term 'construction development breakdown'.

Add paragraph (b)(1)(v) to reference the new grant goal proposed in 7 CFR 1944.419(a)(5).

Add paragraph (b)(1)(vi) to reference grant goal at 7 CFR 1944.419(a)(6).

(14) Update 7 CFR 1944.419 ''*Final grantee evaluation.*''

The requirements for obtaining a grant rating of 'successful' are minimal and do not accurately reflect rating a rehabilitation program. Update the grant goals to establish a minimum sweat equity/cost savings goal as part of the application process.

(15) Update 7 CFR 1944.420 ''*Extension or revisions of the grant agreement.*''

This change updates the grant extension period from a ceiling of no more than one year to less restrictive language of a period that is ''reasonable''. Reasonability will be determined based on consideration of grant goals completed, and the timeline to complete the remaining goals. Typically, this will be from one to two years.

(16) Update 7 CFR 1944.421 ''Refunding of an existing grantee'' to establish a process for 'Carry-over' equivalent units.

High producing grantees often start homes in one grant cycle but finish them in another. Language is purposed to allow this practice with parameters.

(17) Revise and update 7 CFR 1944.422 ''Audit and other reporting requirements.''

Remove special provisions for nonprofits, State and local governments, and Indian Tribes found at 7 CFR 1944.422 (a) and (b). 2 CFR part 200 does not have these exemptions listed which were previously authorized. All grantees will have the same reporting requirements as defined in 2 CFR part 200.

Add language regarding auditing requirements for 502/504 borrowers supervised or custodial accounts. Direction regarding the audit requirements for 502/504 borrowers supervised or custodial accounts when managed by the grantee is needed. While a separate audit is not necessary, these accounts should be reviewed under an agreed-upon procedures format, not a single audit, as the grantee only manages these funds in trust.

(18) Revise 7 CFR 1944.423 ''Loan/grant packaging and application submittal.''

This change updates the title of the section and adds reference to Section 504.

(19) Revise 7 CFR 1944.424 ''Dwelling construction standards''

This change adds State and Tribal requirements to the dwelling construction standards versus just local codes.

(20) Update 7 CFR 1944.425 ''Handling and accounting for borrower loan funds.''

This section's updates include stating that the Agency is responsible for the administration of borrower loan funds. Grantee involvement such as holding a custodial or supervised account to manage these funds will be approved at the State level with minimum approval guidelines for staff to be defined in the program Instruction.

(21) Revise 7 CFR 1944.426 ''Grant closeout.''

This change modifies the number of days, from 7 to 30, that the agency has to respond to the grantee regarding notification of termination and updates information on grant suspension appeal guidance.

(22) Remove Subpart I of Part 1944 Exhibits A, B, B–1, B–2, B–3, C, D, and E. Subpart I of Part 1944 Exhibits A, C, D, and E will be published as Forms.

References to Exhibits B, B–1, B–2, and B–3 will be eliminated from the CFR in favor of publishing them in the program Instruction with updates. These Exhibits will be provided to organizations by the program offices.

Exhibit A to Subpart I of Part 1944 ''Self-Help Technical Assistance Grant Agreement'' will be published as a Form and revised to include the new goals established with this proposed rule and add language to reference any closing conditions letter attached.

Exhibit C to Subpart I of Part 1944 ''Amendment to Self-Help Technical Assistance Grant Agreement'' and Exhibit D to Subpart I of Part 1944 ''Self-Help Technical Assistance Grant Predevelopment Agreement'' will be published as Forms and revised to update the year from '19__ to '20__.

Exhibit E to Subpart I of Part 1944 ''Guidance for Recipients of Self-Help Technical Assistance Grants (Section 523 of Housing Act of 1949)'' will be published as a Form and updated to remove outdated questions such as B.5. related to long distance phone call logs, B.8. regarding families being charged for the use of tools which is confusing given some grantees do rent tools to families when they are able to offer the best value, amongst other revisions.

(23) Revise instruction in Exhibit F to Subpart I of Part 1944 ''Site Option Loan to Technical Assistance Grantees'' and add it as a new section in 7 CFR 1944.428.

The limitations provided for in this exhibit are a barrier to applicants in the current market in which larger loan amounts and longer repayment terms are necessary. There has not been a Section 523 Site Loan awarded in many years because the program parameters are not feasible (*e.g.* low loan limit, revolving loan fund requirements, interest rate disparity, and short repayment terms).

Revise Section IV. 'Limitations' to remove the $10,000 loan limit in item (A) in favor of publishing limits as necessary (based on funding availability) in an annual funding policy and removing the loan limitation of fifteen percent of the purchase price in item (B); section V Rates and Terms to change item (A) so that the interest rate will be the lower of 3 percent or the current RHS monthly published rate, item (B) to revise the repayment period to allow for multiple payments.

The revision would align the program with current market trends and reference the Section 524 program requirements to ease the application process and promote the utilization of program funds. Program information will also be moved to the body of the regulation under 1944.428 as a new section.

Request for Comment

Stakeholder input is vital to ensure the proposed changes in the proposed rule would support the Agency's mission, while ensuring that new regulations and policies are reasonable and do not overly burden the Agency's staff and their customers. Comments must be submitted on or before February 3, 2025 and may be submitted electronically by going to the Federal eRulemaking Portal: *http://www.regulations.gov.* Details on how to submit comments to the Federal eRulemaking Portal are in the **ADDRESSES** section of this proposed rule.

IV. Regulatory Information

Executive Order 12372, Intergovernmental Review of Federal Programs

Intergovernmental Review of Federal Programs,'' applies to this program. This E.O. requires that Federal agencies provide opportunities for consultation on proposed assistance with State and local governments. Many states have established a Single Point of Contact (SPOC) to facilitate this consultation. For a list of States that maintain a SPOC, please see the White House website: *https://www.whitehouse.gov/omb/management/office-federal-financial-management/.* If your State has a SPOC, you may submit a copy of the application directly for review. Any comments obtained through the SPOC must be provided to your State Office for consideration as part of your application. If your state has not established a SPOC, you may submit your application directly to the Agency. Applications from Federally recognized Indian Tribes are not subject to this requirement. RHS conducts intergovernmental consultations for each loan in accordance with 2 CFR part 415, subpart C.

Executive Order 12866, Regulatory Planning and Review

This proposed rule has been determined to be not significant for purposes of Executive Order 12866 and, therefore, was not reviewed by the Office of Management and Budget (OMB).

Executive Order 12988, Civil Justice Reform

This proposed rule has been reviewed under Executive Order 12988. In accordance with this rule: (1) Unless otherwise specifically provided, all State and local laws that conflict with this rule will be preempted; (2) no

retroactive effect will be given to this rule except as specifically prescribed in the rule; and (3) administrative proceedings of the National Appeals Division of the Department of Agriculture (7 CFR part 11) must be exhausted before suing in court that challenges action taken under this proposed rule.

Executive Order 13132, Federalism

The policies contained in this proposed rule do not have any substantial direct effect on States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of Government. This proposed rule does not impose substantial direct compliance costs on State and local Governments; therefore, consultation with States is not required.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Consultation is also required for any regulation that preempts Tribal law or that imposes substantial direct compliance costs on Indian Tribal governments and that is not required by statute.

The Agency has determined that this proposed rule does not, to our knowledge, have Tribal implications that require formal Tribal consultation under Executive Order 13175. If a Tribe requests consultation, the Rural Housing Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

National Environmental Policy Act

In accordance with the National Environmental Policy Act of 1969, Public Law 91–190, this proposed rule has been reviewed in accordance with 7 CFR part 1970 (''Environmental Policies and Procedures''). The Agency has determined that i) this action meets the criteria established in 7 CFR 1970.53(f); ii) no extraordinary circumstances exist; and iii) the action is not ''connected'' to other actions with potentially significant impacts, is not considered a ''cumulative action'' and is not precluded by 40 CFR 1506.1. Therefore, the Agency has determined that the action does not have a significant effect on the human environment, and therefore neither an Environmental Assessment nor an Environmental Impact Statement is required.

Regulatory Flexibility Act

This proposed rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612). The undersigned has determined and certified by signature on this document that this rule will not have a significant economic impact on a substantial number of small entities since this rulemaking action does not involve a new or expanded program nor does it require any more action on the part of a small business than required of a large entity.

Unfunded Mandate Reform Act (UMRA)

Title II of the UMRA, Public Law 104–4, establishes requirements for Federal Agencies to assess the effects of their regulatory actions on State, local, and Tribal Governments and on the private sector. Under section 202 of the UMRA, Federal Agencies generally must prepare a written statement, including cost-benefit analysis, for proposed and Final Rules with ''Federal mandates'' that may result in expenditures to State, local, or Tribal Governments, in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires a Federal Agency to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective, or least burdensome alternative that achieves the objectives of the rule.

This proposed rule contains no Federal mandates (under the regulatory provisions of title II of the UMRA) for State, local, and Tribal Governments or for the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Paperwork Reduction Act

The information collection requirements contained in this regulation have been approved by OMB and have been assigned OMB control number 0575–0043. This proposed rulemaking contains new reporting requirements that would require approval under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

In accordance with the Paperwork Reduction Act of 1995, the Agency announces its intention to request a revision to a currently approved information collection for the Self-Help Technical Assistance Grant program and hereby open a 60-day public commenting period.

Title: 7 CFR 1944–I, Self-Help Technical Assistance Grants.

OMB Docket Number: 0575–0043.

Expiration Date of Approval: May 31, 2027.

Type of Request: Revision of currently approved information collection.

Abstract: This subpart set forth the policies and procedures and delegates authority for providing technical assistance funds to eligible applicants to finance programs of technical and supervisory assistance for self-help housing loan program, as authorized under section 523 of the Housing Act of 1949 under 42 U.S.C. 1472. This financial assistance may pay part or all of the cost of developing, administering, or coordinating a program of technical and supervisory assistance to aid very low- and low-income families in carrying out self-help housing efforts in rural areas. The primary purpose is to locate and work with low-income families to secure decent, safe, and sanitary housing. RHS will be collecting information from non-profit organizations to enter into grant agreements. These non-profit organizations will give technical and supervisory assistance, and in doing so, they must develop a final application for section 523 grant funds. This application includes Agency forms that contain essential information for deciding eligibility.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .99 hours per response.

Respondents: Public or private nonprofit organizations, State, Local or Tribal Governments.

Estimated Number of Respondents: 70.

Estimated Number of Responses per Respondent: 29.

Estimated Number of Responses: 2,046.

Estimated Reporting Burden Hours on Respondents: 1,865.

Estimated Recordkeeping Burden Hours on Respondents: 170.

Estimated Total Annual Burden on Respondents: 2,035.

Copies of this information collection can be obtained from Kimble Brown, Innovation Center—Regulations Management Division, at *Kimble.Brown@usda.gov.*

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the RHS, including whether the information will have practical utility; (b) the accuracy of RHS's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

E-Government Act Compliance

RHS is committed to complying with the E-Government Act by promoting the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information, services, and other purposes.

Civil Rights Impact Analysis

Rural Development has reviewed this rule in accordance with USDA Regulation 4300–4, Civil Rights Impact Analysis,'' to identify any major civil rights impacts the rule might have on program participants on the basis of age, race, color, national origin, sex, or disability. After review and analysis of the rule and available data, it has been determined that implementation of the rule will not adversely or disproportionately impact very low, low- and moderate-income populations, minority populations, women, Indian Tribes, or persons with disability by virtue of their race, color, national origin, sex, age, disability, or marital or familiar status. No major civil rights impact is likely to result from this rule.

Assistance Listing

The program affected by this regulation is listed in the Assistance Listing Catalog (formerly Catalog of Federal Domestic Assistance) under number 10.420, Rural Self-Help Housing Technical Assistance.

Non-Discrimination Statement

In accordance with Federal civil rights laws and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Mission Areas, agencies, staff offices, employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, staff office; or the 711 Federal Relay Service.

To file a program discrimination complaint, a complainant should complete a Form AD–3027, *USDA Program Discrimination Complaint Form,* which can be obtained online at *https://www.usda.gov/sites/default/files/document/ad-3027.pdf,* from any USDA office, by calling (866) 632–9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of an alleged civil rights violation. The completed AD–3027 form or letter must be submitted to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; or

(2) *Fax:* (833) 256–1665 or (202) 690–7442; or

(3) *Email: Program.Intake@usda.gov*

USDA is an equal opportunity provider, employer, and lender.

List of Subjects in 7 CFR 1944

Administrative practice and procedure, Aged, Cooperatives, Fair housing, Grant programs—housing and community development, Home improvement, Individuals with disabilities, Loan programs—housing and community development, Low and moderate income housing, Manufactured homes, Migrant labor, Rent subsidies, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Rural Housing Service proposes to amend 7 CFR part 1944 as set forth below:

PART 1944—HOUSING

■ 1. The authority citation for part 1944 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 1480.

Subpart I—Self-Help Technical Assistance Grants

■ 2. Revise § 1944.401 to read as follows:

§ 1944.401 Objective.

This subpart sets forth the policies and procedures and delegates authority for providing Technical Assistance (TA) funds to eligible applicants to finance programs of technical and supervisory assistance for self-help housing, as authorized under section 523 of the Housing Act of 1949. Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to Rural Development employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with a Rural Development employee. This financial assistance may pay part or all of the cost of developing, administering, or coordinating programs of technical and supervisory assistance to aid very low- and low-income families in carrying out self-help housing efforts in rural areas. Very low-income families must receive a priority for recruitment and participation and may not comprise less than the percentage stated in Section 502 of the Housing Act of 1949, as amended, of those assisted in any grant. The primary purpose is to fund organizations that are willing to locate and work with low-income families to secure decent, safe, and sanitary housing. Grantees will comply with the nondiscrimination regulation subpart E of part 1901 of this chapter which states that no person in the United States shall, on the grounds of race, color, national origin, sex, religion, marital status, mental or physical handicap, or age, be excluded from participating in, be denied the benefits of, or be subject to discrimination in connection with the

use of grant funds and all provisions of the Fair Housing Act of 1988, as amended.

■ 3. Revise and republish § 1944.403 to read as follows:

§ 1944.403 Definitions.

(a) *Agency.* The Rural Housing Service within the Rural Development mission area of the U.S. Department of Agriculture (or its successor agency) which administers Section 523 grants.

(b) *Administrator.* The official of the Rural Housing Service within the Rural Development mission area (or official of its successor agency) delegated authority by the Secretary of the U.S. Department of Agriculture to administer the Agency and its programs.

(c) *Applicant.* An organization that submits an application for a Section 523 technical assistance or predevelopment grant.

(d) *Acquisition Rehabilitation.* The method of self-help housing rehabilitation that assists a participant in acquiring and rehabilitating a home through the program.

(e) *Authorized Agency Official.* An individual within a Rural Development Office designated with responsibility for a Self-Help Program function (*e.g.* application reviewer, approval official, grant servicer, etc.).

(f) *Board of Directors.* The governing body of an organization and its members. Typically, a board of directors will consist of no less than five members. For smaller organizations (*i.e.,* less than 5 staff members) a board of 3 or 4 is authorized.

(g) *Borrower.* An applicant who has received a Section 502 Home Purchase Loan or Section 504 Home Repair Loan or Grant.

(h) *Closeout.* The process of taking final action connected with a completed or terminated grant, including closing of grantee accounts, auditing grantee expenditures, and completing final reports. See also ''Final Grantee Evaluation''.

(i) *Cost savings.* The value gained by the program participant through the contribution of their own labor to the project. This value is calculated as follows:

(1) *Acquisition Rehab.* The cost savings is the difference between the appraised values before and after project completion.

(2) *Owner-Occupied Rehab.* The cost savings is difference between the cost to have a contractor make the repair(s) and the self-help cost to the participant.

(j) Custodial account. An account with the project funding for the participating families that is managed by the Self-Help Grantee.

(k) *Date of completion.* The date when all work under a grant is completed or the expiration date in the TA grant agreement, or any supplement or amendment to it, when Federal assistance ends.

(l) *Debarment.* A determination that a party is ineligible to participate in, or receive assistance under, Federal programs made in accordance with 2 CFR parts 180 and 417.

(m) *Direct costs.* Those costs that are specifically identified with a particular project or activity. Grantees receiving funds from a single grant source would typically consider all costs as direct costs.

(n) *Disallowed costs.* Those charges to a grant which Rural Development determines cannot be authorized (see also 7 CFR 1944.406 Prohibited use of grant funds).

(o) *Environmental review.* An analysis of the impacts that an activity funded with Agency funds may have on the natural or manmade environment. See 7 CFR part 1970.

(p) *Equivalent units.* Equivalent units represent the ''theoretical number of units'' arrived at by adding the equivalent percentage of completion figure for each family in the self-help program (pre-construction and actual construction) together at any given date during program operations. The sum of the percentage of completion figures for all participant families represent the total number of ''theoretical units'' completed at any point in time. Equivalent units are useful in measuring progress during the period of the grant and are not a measurement of actual accomplishments. The number of equivalent units for any group can never exceed the number of planned or completed houses for that group.

(q) *Equivalent value of a modest house.* The typical cost of a recent contractor-built modest home in the area financed by the Agency plus the actual or projected costs of an acceptable site and site development. If the Agency has not financed a contractor-built house during the last twelve months, the value is established by use of online home sales sites; or as a percentage of the Area Loan Limits as published on the Agency website. The Equivalent value of a modest house is established by the Agency.

(r) *Existing grantee.* A grantee that is currently operating a grant from the Agency or that has operated a grant within the past two years.

(s) *Family Labor Contribution.* The value of labor contributed by a participating family to the process of constructing or rehabilitating their home. For new construction, each family in the group must contribute labor on each other's homes to accomplish the 65 percent of the total 100 percent of tasks defined to complete the dwelling. A participating family may use a substitute to perform the labor with prior approval of the Grantee and Rural Development. For rehabilitation type grants, participating families must complete a proportional amount of labor to the amount of rehabilitation tasks being completed but not less than 10 hours for owner occupied rehab, and 50 hours for acquisition rehab. Volunteer labor may be used in rehabilitation type projects.

(t) *Final grantee evaluation.* An Agency evaluation performed in accordance with 7 CFR 1944.419 at the end of the grant period to determine if the grantee met its projected performance goals and complied with program requirements.

(u) *Grant Agreement.* The legal document signed by the Self-Help grantee and the Agency that sets forth the terms and conditions under which technical assistance funds will be made available. The grant agreement will typically be for a period of 24 months but may be authorized for longer or shorter periods to accommodate the production of grantees (*i.e.,* larger grantees may require longer grant period and vice versa).

(v) *Grantee.* An organization for which the Agency has closed a Section 523 technical assistance or predevelopment grant.

(w) *Group.* Newly constructed homes under the Self-Help program are typically built by families working together in groups of five or more. State Director approval of groups less than five is required and may be granted only when it is determined the requirements of the Self-Help Program can be met (*e.g.* group labor, reduced building costs from bulk ordering, etc.).

(x) *Household.* One or more persons who maintain residency together in a home.

(y) *High Risk.* The designation given to a grantee by the State Office when a grantee is at risk of or currently is not meeting the self-help program's requirements.

(z) *Indirect costs.* Those costs that are incurred for common or joint objectives and therefore, cannot be readily and specifically identified with a particular project or activity, (*e.g.,* self-help).

(aa) *Low-income.* An adjusted income standard developed in accordance with the requirements of Section 501(b)(4) of the Housing Act of 1949.

(bb) *Membership Agreement.* The document signed by a grantee and a participating family that establishes

each party's responsibilities and obligations.

(cc) *Modest.* A property that is considered modest for the area, with a market value that does not exceed the applicable area loan limit as established by Rural Housing Service in accordance with 7 CFR 3550.63.

(dd) *Mutual Self-Help Method.* Refers to the contributory nature of homebuilding in the Self-Help Program. Each family contributes to the building of each home such that the total amount of labor contributed by each family is approximately equal. (See also family labor contribution.)

(ee) *Organization.*

(1) A State, political subdivision, or public nonprofit corporation (including Indian Tribes or Tribal corporations); or

(2) A private nonprofit corporation that is owned and controlled by private persons or interests and is organized and operated for purposes other than making gains or profits for the corporation and is legally precluded from distributing any gains or profits to its members.

(ff) *Owner-Occupied Rehabilitation.* The method of self-help housing rehabilitation that serves a participant that owns and occupies the home in need of repair at the time of application. Owners need not occupy the homes while repairs are being made, provided there is a plan for them to return to the home once the project is complete.

(gg) *Participating family.* Individuals and/or their families who agree to build homes by the mutual self-help method and rehabilitate homes by the self-help method. Participants are families with very low- or low-incomes who have the ability to furnish their share of the required labor input regardless of the handicap, age, race, color, national origin, religion, family status, or sex of the head of household.

(hh) *Program requirements.* Requirements set forth in any grant document, agreement, statute, or regulation applicable to Section 523 grants.

(ii) *Quarterly review.* A formal assessment conducted quarterly by those parties involved in the grant program (*e.g.,* Grantee staff, Agency staff including grant oversight official, field staff processing the grantees packages, etc., and Technical and Management Assistance contractor of a grantee's progress in meeting its Grant Agreement goals and program requirements).

(jj) *Reasonable costs.* A cost is reasonable if, in its nature and amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost. To be considered reasonable, costs must meet the following conditions:

(1) The cost is of a type generally recognized as ordinary and necessary for the operation of the organization or the performance of the Federal award.

(2) The cost meets the restraints or requirements imposed by such factors as sound business practices; arms-length bargaining; Federal, state, Tribal, and other laws and regulations; and terms and conditions of the award.

(3) Market prices for similar goods or services are comparable.

(4) The individuals concerned acted with prudence in the circumstances considering their responsibilities to the organization, its members, employees, clients, the public at large, and the Federal Government.

(5) In incurring the cost, the organization did not deviate significantly from its established practices and, thereby, unjustifiably increase the award's cost.

(kk) *Rural Housing Service.* The Agency within the Rural Development mission area of the U.S. Department of Agriculture which administers the Section 523 Mutual Self-Help grant program.

(ll) *Self-help Method.* The construction method by which an individual family utilizes their labor to reduce the construction cost of their home without an exchange of labor between participating families. Unless otherwise authorized by the National Office, this method is only funded for repair and rehabilitation type construction (owner occupied or acquisition rehabilitation).

(mm) *SHARES (Self-Help Automated Reporting and Evaluation System).* The primary monitoring tool used by the Agency. The information accessible on SHARES includes data on construction, recruiting, and budgetary data for each grantee, their participating families, and the homes they are building.

(nn) *Site inspections.* Construction site inspections may be conducted by the mortgage lender, or a qualified third party to ensure the construction/repair work is being completed adequately, and according to approved plans and specifications. At a minimum, inspection must be conducted three times during the construction of a house-after the footers are in place, once the framing is complete and mechanical, electrical, and plumbing are roughed in, and when the local authority has certified the house for occupancy.

(oo) *Specialty tools.* Specialty tools are those tools needed to complete the construction of a home, not including hand tools that are commonly needed to maintain a home, such as hammers, screwdrivers, tape measures, pliers, and wrenches. Specialty tools include, but are not limited to, power saws, electric drills, saber saws, ladders, and scaffolds.

(pp) *Sponsor.* An existing entity that is willing and able to assist an applicant, with or without charge, in applying for a grant and in carrying out responsibilities under the agreement. Examples of sponsors are local rural electric cooperatives, institutions of higher education, community action agencies and other self-help grantees. Also, when available, regional technical and management assistance contractors may qualify to serve as a sponsor at no charge.

(qq) *Supervised bank account.* An account with a financial institution established through a deposit agreement entered into between the borrower, the Agency or Grantee, and the financial institution.

(rr) *Sweat equity.* The benefit earned by the Mutual Self-Help program participant for the contribution of their own labor to the project construction. This value is calculated by subtracting the self-help construction cost of the homes from the appraised value of the homes.

(ss) *Technical assistance.* The organizing and supervising of groups of families in the construction of their own homes including but not limited to:

(1) Recruiting families who are interested in contributing labor in the construction or rehabilitation of their homes and assisting such families in obtaining housing loans.

(2) Conducting meetings with the participants to explain the self-help program and subjects related to home ownership, such as loan payments, taxes, insurance, maintenance, and upkeep of the property.

(3) Helping families in planning and developing activities that lead to the acquisition and development of suitable building sites or existing homes in the case of acquisition rehabilitation.

(4) Assisting families in selecting or developing house plans for homes which will meet their needs and which they can afford. For rehabilitation type projects, assisting families in assessing need repairs.

(5) Assisting families in obtaining cost estimates for construction materials and any contracting that may be required.

(6) Providing assistance in the preparation of loan and/or grant applications.

(7) Providing construction supervision and training for families while they construct or rehabilitate their homes.

(8) Providing financial supervision to individual families with loans and/or grants which will minimize the time and effort required by Rural Development in processing borrower expenditures for materials and contract services.

(tt) *Technical and Management Assistance (T&MA) contractor.* An organization which receives Agency funding to provide services to the Agency and training and management assistance to grantees and prospective grantees.

(uu) *Termination.* The Agency may terminate grantees when the grantee fails to meet certain requirements or when the grantee requests termination. A terminated grantee is ineligible for another Self-Help program TA grant for at least two years.

(vv) *Very low-income.* An adjusted income standard developed in accordance with the requirements of Section 501(b)(4) of the Housing Act of 1949.

■ 4. Amend § 1944.404 by revising paragraph (d)(4) to read as follows:

§ 1944.404 Eligibility.

* * * * *

(d) * * *

(4) Has a board of directors as defined in § 1944.403 of this subpart.

§ 1944.406 [Amended]

■ 5. Amend § 1944.406 by removing paragraph (d) and redesignating paragraph (e) as new paragraph (d).

■ 6. Amend § 1944.407 by revising paragraphs (a), (b), (c), and (d) to read as follows:

§ 1944.407 Limitations.

* * * * *

(a) An average TA cost per equivalent unit of no more than 15 percent of the cost of equivalent value of modest homes built in the area; or

(b) An average TA cost per equivalent unit that does not exceed the difference between the equivalent value of modest homes in the area and the average mortgage of the participating families minus $10,000; or

(c) For rehabilitation type programs, the maximum TA cost per equivalent unit will be no more than the provided percentage of the cost of equivalent value of modest homes built in the area:

(i) For acquisition rehabilitation, 12 percent;

(ii) For owner-occupied rehabilitation, 9 percent; or

(d) A TA per equivalent unit cost that does not exceed an amount established by the National Office. The National Office may establish other limitations as necessary that will be released in a notice published in the **Federal Register**.

■ 7. Revising § 1944.409 to read as follows:

§ 1944.409 Intergovernmental Consultation, Executive Order 12372.

The self-help program is subject to the provision of Executive Order 12372 which requires consultation with State and local officials to foster an intergovernmental partnership and strengthened federalism by relying on State and local processes for the State and local government coordination and review of proposed Federal financial assistance and direct Federal development.

Applicants for the self-help program are required to contact their state's Single Point of Contact (SPOC) to submit their Statement of Activities and find out more information on how to comply with the state's process under Executive Order 12372. To locate a SPOC for your state, the Office of Management and Budget (OMB) has an official SPOC list on their website. For those States that have a home page for their designated SPCO, a direct link has been provided by clicking on the State name.

States that are not listed on the OMB website page have chosen not to participate in the intergovernmental review process, and therefore do not have a SPOC. If you are located within a State that does not have a SPOC, you may send application materials directly to the awarding agency.

■ 8. Revise and republish § 1944.410 to read as follows:

§ 1944.410 Processing preapplications, applications, and completing grant dockets.

(a) Form SF–424, ''Application for Federal Assistance.'' Form SF–424 ''Application for Federal Assistance'' must be submitted by the applicant to the Agency. It will be used to establish communication between the applicant and RHS, determine the applicant's eligibility, determine how well the project can compete with similar applications from other organizations and eliminate any proposals which have little or no chance for Federal funding before applicants incur significant expenditures for preparing an application. In addition, the following information will be attached to and become a part of the preapplication or application:

(1) Complete information about the applicant's previous experience and capacity to carry out the objective of the agreement.

(2) If the applicant organization is already formed, a copy of or an accurate reference to the specific provisions of State or Tribal law under which the applicant is organized; a certified copy of the applicant's Articles of Incorporation and Bylaws or other evidence of corporate existence; certificate of incorporation for other than public bodies; evidence of good standing from the State or Tribe when the corporation has been in existence 1 year or more; the names and addresses of the applicant's members, directors, and officers; and, if another organization is a member of the applicant-organization, its name, address, and principal business. If the applicant is not already formed, attach copies of the proposed organizational documents demonstrating compliance with § 1944.404(d) of this subpart.

(3) The organization's previous year's financial audit, and a current (no more than 12 months old), dated and signed financial statement showing the amounts and specific nature of assets and liabilities together with information on the repayment schedule and status of any debt owed by the applicant. If the applicant is being sponsored by another organization, the same type of financial statement also must be provided by the applicant's sponsor. Newly formed organizations must have a sponsor.

(4) A narrative statement which includes information about the amount of the grant funds being requested, area(s) to be served, need for self-help housing in the area(s), the number of self-help units proposed to be built, rehabilitated or repaired during the agreement period, housing conditions of low-income families in the area and reasons why families need self-help assistance. Evidence should be provided that the communities support the activity and that there are low- income families willing to contribute their labor in order to obtain adequate housing. Evidence of community support may be letters of support from local officials, individuals and community organizations. The pre-application or application may contain information such as census materials, local planning studies, surveys, or other readily available information which indicates a need in the area for housing of the type and cost to be provided by the proposed self-help TA program.

(5) A plan of how the organization proposes to reach very low-income families.

(6) A proposed budget which will be prepared on Form SF–424A, ''Budget Information (Non-Construction Programs)'' and accompanied by the detailed budget being used by the organization will be completed to address applicable assurances as

outlined in 2 CFR part 200 as adopted by USDA through 2 CFR part 400. State and local Government will include an assurance that the grantee shall comply with all applicable Federal statutes and regulations in effect with respect to the periods for which it receives grant funding. The State and local governments shall also comply with 2 CFR part 200 as adopted by USDA through 2 CFR part 400.

(7) A preliminary survey as to the availability of lots and projected cost of the sites.

(8) A list of other activities the applicant is engaged in and expects to continue, and a statement as to other sources of funding and whether it will have sufficient funds to assure continued operation of the other activities for at least the period of the agreement. If multi-funded, its cost allocation plan or indirect cost rate must be part of the pre-application or application.

(9) Whether assistance under paragraph (d) of this section is requested and a brief narrative identifying the need, amount of funds needed, and projected time period.

(b) *Pre-application or application review.* When program funding does not allow the Agency to consider pre-application requests the following steps will apply to the full application:

(1) Rural Development, within 30 days of receipt of the application, Form SF–424 ''Application for Federal Assistance'', and all other required information and material will complete a thorough review for completeness, accuracy, and conformance to program policy and regulations. Incomplete applications will be returned to the applicant for completion. The Authorized Agency Official in the prospective county will be contacted as to the need for the program in the proposed area and if the necessary resources are available to the grantee. This will include a discussion of the number of 502 and 504 units that will need to be committed to the grantee and the potential work impact on the office during the grant period. If it is determined that the Office lacks the resources (either personnel or funds) to process all loan/grant requests in a timely manner, the local office will communicate this need to the State Office along with a recommended solution. (Lack of resources at the local level are not grounds to deny a request). After the Agency has determined that the application is complete and accurate, the materials in an applicant case file will be assembled and forward it to the State Director. The case file, as a minimum, must contain the following:

(i) Form SF–424 ''Application for Federal Assistance'',

(ii) Documentation required in accordance with 7 CFR part 1970, and

(iii) Eligibility recommendations.

(2) The State Director may, if needed, submit the organizational documents with any comments or questions to the Office of General Counsel (OGC) for a preliminary opinion as to whether the applicant is or will be a legal organization of the type required by these regulations and for advice on any other aspects of the preapplication or application.

(3) The State Director, if unable to determine eligibility or qualifications with the advice of the OGC, may submit the preapplication to the National Office for review. The preapplication or application will contain all memoranda from OGC giving the results of its review. The State Director will identify in the transmittal memorandum to the National Office the specific problem and will recommend possible solutions and any information about the applicant which would be helpful to the National Office in reaching a decision.

(4) After an eligibility determination has been made, which should be completed within 30 days unless OGC is involved, the State Director will:

(i) If the applicant is eligible, contact the National Office as to the availability of funds or submit the proposal to the National Office for authorization. If funds are available, the Deputy Administrator or designee for Single Family Housing will issue a letter of conditions that the applicant must meet.

(ii) If the applicant is determined ineligible, the Agency will issue a denial letter that will inform the applicant that an appeal of the decision may be made to the National Appeals Division under 7 CFR part 11.

(c) *Self-help technical assistance grant predevelopment agreement.* If funding is available, the applicant requested predevelopment assistance, and the Agency determines that the applicant lacks the financial resources to meet the conditions of grant approval, a grant can be made for the applicant to provide what is required by paragraph (d) of this section. Existing grantees proposing to operate in an area different from the area that they are currently funded to operate are eligible for this grant. However, this grant is available only once for a defined area. This grant is available only after the letter of conditions has been issued. Denial of this assistance is an appealable decision under 7 CFR part 11.

(d) *Form SF–424, ''Application for Federal Assistance.''* The applicant will submit Form SF–424 ''Application for Federal Assistance'' to the Agency. The application should provide a detailed proposal of its goals including:

(1) Names, addresses, number in household, and total annual household income of families who have been contacted by the applicant and are interested in participating in a self-help housing project. Community organizations including minority organizations may be used as a source of names of people interested in self-help housing.

(2) Proof that the first group of prospective participating self-help families have qualified for financial assistance by the organization or Rural Development.

(3) Evidence that lots are available for the groups.

(4) Detailed cost estimates of houses to be built by the mutual self-help method. Plans and specifications should be submitted with the cost estimates.

(5) Proposed staffing need, including qualifications, experience, proposed hiring schedule, and availability of any prospective employees.

(6) Name, address, and official position of the applicant's representative or representatives authorized to act for the applicant and work with Rural Development.

(7) Budget information including a detailed budget for the Grant Agreement period based upon the needs outlined in the proposal. The detailed budget will be attached to a completed Form SF 424A ''Application for Federal Assistance.''

* * * * *

■ 9. Amend § 1944.411 by revising paragraphs (b), (d), (e), (g), and (h) to read as follows:

§ 1944.411 Conditions for approving a grant.

* * * * *

(b) The applicant has met all of the conditions listed in § 1944.410(d) of this subpart.

* * * * *

(d) A resolution has been adopted by the board of directors which authorizes the appropriate officer to execute the required Grant Agreement and Form RD 400–4, ''Assurance Agreement.''

(e) The grantee has insurance against employee dishonesty and theft.

* * * * *

(g) The grantee has established an interest-bearing checking account in accordance with 2 CFR part 200.

(h) The grantee has developed a membership agreement to be executed by the grantee and the self-help participants which clearly sets forth what is expected of each and has

incorporated a construction development breakdown negotiated with the program office that clearly shows what work is expected of the participating family.

■ 10. Revise § 1944.412 to read as follows:

§ 1944.412 Docket preparation.

When the application and all items required for the complete docket have been received, the Agency will conduct a thorough review to ensure the application has been properly and accurately prepared and that it includes the required dates and signatures. The docket items will be assembled in the order identified by the checklist provided to the applicant by the program office.

■ 11. Revise and republish § 1944.413 to read as follows:

§ 1944.413 Grant approval.

(a) *Approval of grant.* Within 30 days of receiving a complete application including recommendation from the T&MA Contractor and State Authorized Official, the National Office will:

(1) Execute and distribute Form RD 1940–1 ''Request for Obligation of Funds.''

(2) Process the obligation of funds and issue an approval letter of conditions to the state.

(b) *Cancellation of an approved grant.* An approved grant may be canceled before closing if the applicant is no longer eligible, the proposal is no longer feasible, or the applicant requests cancellation. Cancellation will be accomplished as follows:

(1) The State Authorized Agency Official will prepare Form RD 1940–10, ''Cancellation of U.S. Treasury Check and/or Obligation,'' and send it to the State Director with the reasons for cancellation. If the State Director approves the request, Form RD 1940–10 ''Cancellation of U.S. Treasury Check and/or Obligation'' will be returned to the National Office for processing.

(2) The Agency will notify the applicant of the cancellation and the right to appeal under 7 CFR part 11. If the applicant requested the cancellation, no appeal rights are provided, but the applicant will still be notified of the cancellation.

(c) *Disapproval of grant.* If a grant is disapproved after the docket has been developed, the Agency will state the reason on the original Form RD 1940–1 ''Request for Obligation of Funds'', or in a letter to the applicant with appeal rights under 7 CFR part 11.

■ 12. Revise and republish § 1944.415 to read as follows:

§ 1944.415 Grant approval and other approving authorities.

(a) All application dockets, along with the T&MA Contractor and State Authorized Agency Official's recommendations must be submitted to the National Office for approval.

(b) The authority to contract for services is limited to the Administrator of Rural Housing Service (RHS).

(c) Monthly expenditures of the grantee will normally be approved by the Housing Program Director unless:

(1) The grantee operates in only one county; in which case the authority may be delegated by the Housing Program Director.

(2) The grantee operates in more than one county; in which case the State Director will designate the approving official.

(3) The grantee operates in more than one State, in which case the National Office will designate the approving official.

(4) The expenditure is under contract authority, in which case the Contracting Official Representative will approve the monthly expenditure.

■ 13. Revise and republish § 1944.416 to read as follows:

§ 1944.416 Grant Closing.

The grant is closed on the date the Grant Agreement is executed by the applicant and the Agency. Cost may not be allocated to, nor may funds be advanced prior to the signing of the Agreement. The State Director or designee is authorized to execute the agreement on behalf of the Agency. Person(s) authorized by resolution may sign for the applicant.

■ 14. Revise and republish § 1944.417 to read as follows:

§ 1944.417 Servicing actions after grant closing.

The Agency has a responsibility to help the grantee be successful and avoid cases of fraud and abuse. Servicing actions also include correlating activities between the grantee and Agency to the benefit of the participating families. The amount of servicing actions needed will vary in accordance with the experience of the grantee, but as minimum the following actions are required:

(a) As needed, but no more than Monthly, the grantee will provide the Agency with a request for additional funds on Form SF–270, ''Request for Advance or Reimbursement,'' and must be accompanied by a working budget. This request need only show the amount of funds used during the previous month, amount of unspent funds, projected need for the next 30 days, and written justification if the request exceeds the projected need for the next 30 days. Upon receipt of the grantee's request, the Agency will:

(1) If the request appears to be in order, process the request and make the payment by automatic transfer.

(2) If the request does not appear to be in order, immediately contact the grantee to resolve the problem. After the contact:

(i) If the grantee's explanation is acceptable, process the request, or

(ii) If the grantee's explanation is not acceptable, immediately notify the grantee and order the amount of funds that appear reasonable for the next 30 days. Unapproved funds that are later approved will be added to the next month's request.

(b) Quarterly, after the grant start date, the grantee will submit a progress report to the Authorized Agency Official which will verify its progress toward meeting the objectives stated in the Agreement and the application. A quarterly meeting will be scheduled between the grantee, T&MA Contractor, and Agency and will be used as an opportunity to review progress to date and make necessary adjustments for the future. More frequent meetings may be required if the grantee was previously identified as a High Risk grantee or will be identified as a High Risk grantee at this time. As part of the quarterly meeting the following will be done:

(1) The quarterly report and other information will be evaluated to determine progress made to date. The Agency will comment on the quarterly report as to whether the grantee is ahead or behind schedule in each of the following areas:

(i) *Assisting the projected number of families.*

(ii) *Serving very low-income applicants.* Is the grantee reaching a minimum of very low-income families as required in 42 U.S.C. 1472?

(iii) *Equivalent units (EUs).* Is the number of EUs completed representative of lapse of time of the grant? For example, if 25 percent of the grant period has elapsed, are 25 percent of the number of EUs completed?

(iv) *Labor contributions by the family.* Are the families working together and are they completing the labor tasks as established on the construction or rehabilitation development breakdown?

(v) *Meeting the approved sweat equity (new construction), or family cost savings goal.* Are the families receiving the amount of sweat equity or costing savings as described in the application?

(vi) *Meeting other objectives in the Agreement.* Is the grantee submitting timely quarterly reports, audits, or other

required information. Are their issues with the construction/rehabilitation projects or loan/grant packaging?

(2) The Agency will determine if the grantee is progressing satisfactorily. However, if the Agency determines the grantee is not performing satisfactorily, the Agency will notify the grantee that it has been classified a ''High Risk'' grantee. The notice will specify the deficiencies and inform the grantee of proposed remedies for noncompliance. The notice will advise the grantee that the Agency is available to assist and provide the name and address of an organization that is under contract with the Agency to assist them. The State Office will forward a copy of the report with comments, and the reasons for classifying them as ''High Risk'' to the National Office. When the period of time provided for corrective action has expired, an assessment will be made of the progress by the grantee toward correcting the situation. If the Agency determines:

(i) The situation has been corrected or reasonable progress has been made toward correcting the situation, then the ''High Risk'' status will be lifted, and the grantee so notified.

(ii) The situation has not been corrected, but it is correctable if additional time is granted, then an extension will be issued.

(iii) The situation has not been corrected and it is unlikely to be corrected if given additional time, then the grant will be terminated under § 1944.426(b)(1) of this subpart.

■ 15. Revise and republish § 1944.419 to read as follows:

§ 1944.419 Final grantee evaluation.

At the end of the grant period, an evaluation of the grantee will be conducted by the Agency. The Agency may use employees or an organization under contract to provide the evaluation. The evaluation is to determine how successful the grantee was in meeting goals and objectives as defined in the agreement, application, this regulation, and any amendments.

(a) This is a quantitative evaluation of the grantee to determine if it met its goals in:

(1) Assisting the projected number of families in obtaining adequate housing as proposed by the organization in the approved application.

(2) Meeting the goal of assisting very low-income families stated in section 502 of the Housing Act of 1949, and in § 1944.401 of this subpart.

(3) Meeting the Family Labor Contribution requirement specified in under § 1944.403(s) of this subpart, as applicable.

(4) Keeping costs within the approved budget in the application.

(5) Meeting the approved sweat equity (new construction), or family cost savings goal (rehabilitation) stated in section § 1944.403 of this subpart.

(6) Meeting other objectives in the Grant Agreement including, but not limited to timely reporting, construction standards, loan packaging standards, etc.

(b) The evaluation is a narrative addressed to the grantee and written in 3 parts, namely, findings, recommendations, and an overall rating. The rating will be either unacceptable, acceptable, or outstanding, as follows:

(1) Outstanding if the grantee met or exceeded all of the goals in paragraph (a) of this section.

(2) Acceptable if the grantee met or exceeded three of the grant goals.

(3) Unacceptable if the grantee failed to obtain an acceptable rating. An unacceptable rating may cause the organization to be ineligible for grant assistance should this say the following the proceeding 2 years.

(c) After the State Director has reviewed the evaluation, a copy will be mailed to the grantee. The grantee may request a review of the evaluation with the Agency. This review is for clarification of the material and to dispute the findings if they are known to be wrong. The rating is not open for discussion except to the extent it can be proven that the findings do not support the rating. If this is the case, the Agency may amend the rating.

■ 16. Revise and republish § 1944.420 to read as follows:

§ 1944.420 Extension or revisions of the grant agreement.

The State Director or designee may execute an extension or revision, at any time during the grant period, provided:

(a) The extension period is reasonable. The extension period is reasonable if the goals can be completed within the timeline without additional cost being incurred. Typically, an reasonable extension will not exceed two years.

(b) The need for the extension is clearly justified.

(c) If additional funds are needed, a revised budget is submitted with complete justification, and

(d) The grantee is within the guidelines in § 1944.407 of this subpart or the Agency determines that the best interest of the Government will be served by the extension.

■ 17. Revise and republish § 1944.421 to read as follows:

§ 1944.421 Refunding of an existing grantee.

Grantees wishing to continue with self-help efforts after the end of the current grant plus any extensions should file Form SF–424 ''Application for Federal Assistance,'' in accordance with § 1944.410. It is recommended that it be filed at least 6 months before the end of the current grant period. Funds from the existing grant may be used to meet the conditions of a new grant and equivalent units may be split between two grant cycles. In addition to meeting the conditions of an applicant as defined in § 1944.411 of this subpart, the grantee must also have received or will receive an acceptable rating on its current grant unless an exception is granted by the Agency. The Agency may grant an exception to the rating if it is determined that the reasons causing the previous unacceptable rating have been removed or will be removed with the approval of this grant.

■ 18. Revise and republish § 1944.422 to read as follows:

§ 1944.422 Audit and other report requirements.

The grantee must submit an audit to the Agency annually (or biennially if a State or local government with authority to do a less frequent audit requests it) and the earlier of 30 calendar days after receipt of the auditor's report or nine months after the end of the grantee's audit period. The audit, conducted by the grantee's auditors, is to be performed in accordance with Generally Accepted Government Auditing Standards (GAGAS), using the publication ''Standards for Audit of Governmental Organizations, Programs, Activities and Functions'' developed by the Comptroller General of the United States in 1981, and any subsequent revisions. In addition, the audits are also to be performed in accordance with 2 CFR part 200, as adopted by USDA through 2 CFR part 400, and Agency requirements as specified in this subpart.

Audits of borrower loan funds will be required when the grantee manages these funds during construction in a supervised or custodial bank account. These funds are not awarded to the grantee; therefore, they should not be shown on a Schedule of Federal Awards nor have the same auditing requirements. Instead, an agreed upon procedures audit that, at a minimum, includes a review of the draw down request to ensure charges listed can be traced back to source documents, and reconciliation of the bank account record. The number of borrower accounts audited will be determined by

the auditor. In incidences where it is difficult to determine the appropriate number of accounts to be audited, auditors should be authorized by the State Director to audit the lesser of 10 loans or 10 percent of total loans.

■ 19. Revise and republish § 1944.423 to read as follows:

§ 1944.423 Loan/grant packaging and application submittal.

A grantee is required to assist 502/504 program applicants in submitting their application for a loan and/or grant. Loan/grant packaging will be performed in accordance with 7 CFR part 3550; therefore, it is important that the grantee be trained at an early date. Typically, this training should take place before the first applications are submitted to the Agency Office and before the grant is closed. A grantee should become very knowledgeable of the Agency's eligibility requirements but must understand that only the Agency can approve or deny an applicant assistance. The Grantee must work cooperatively with the Agency in the loan approval process and must work within the regulations for the program and recognize the Agency's ultimate decision-making authority to approve or deny loans.

However, the grantee may ask for clarification that may be helpful in working with future applicants. Grant funds may not be used to pay any expense in connection with an appeal that the applicant may file or pursue.

■ 20. Revise and republish § 1944.424 to read as follows:

§ 1944.424 Dwelling construction standards.

All construction will be performed in accordance with subpart A of part 1924 of this chapter. The planned work must meet the building requirements of 7 CFR part 3550 and meet the Development Standards as defined in subpart A of part 1924 of this chapter and State, Tribal, or local requirements. Sites and site developments must conform to the requirements of subpart C of part 1924 of this chapter.

■ 21. Revise and republish § 1944.425 to read as follows:

§ 1944.425 Handling and accounting for borrower loan funds.

The Agency is responsible for administering borrower loan funds during the construction phases. The extent of grantee involvement will depend on the experience of the grantee and the amount of authority delegated to them by the Authorized Agency Official in accordance with Agency guidelines available in any Rural Development Office.

■ 22. Revise and republish § 1944.426 to read as follows:

§ 1944.426 Grant closeout.

(a) *Grant purposes completed.* Promptly after the date of completion, grant closeout actions will be taken to allow the orderly discontinuance of grantee activity.

(1) The grantee will immediately refund to the Agency any balance of grant funds that are not committed for the payment of authorized expenses.

(2) The grantee will furnish Form SF–425, ''Financial Status Report'' and detailed final budget to the Agency within 90 days after the date of completion of the grant. All other financial, performance, and other reports required as a condition of the grant also will be completed.

(3) After the grant closeout, the Agency retains the right to recover any disallowed costs. 7 CFR part 3550 will be used by the Agency to recover any unauthorized expenditures.

(4) The grantee will provide the Agency an audit conforming to those requirements established in this part, including audits of self-help borrower accounts.

(5) Upon request from the recipient, any allowable reimbursable cost not covered by previous payments shall be promptly paid by the Agency.

(b) *Grant purposes not completed.*

(1) *Notification of termination.* The State Director will promptly notify the grantee and the National Office in writing of the termination action including the specific reasons for the decision and the effective date of the termination. The notification to the grantee will specify that if the grantee believes the reason for the proposed termination can be resolved, the grantee should, within 15 calendar days of the date of this notification, contact the Agency in writing requesting a meeting for further consideration. The meeting will be an informal proceeding at which the grantee will be given the opportunity to provide whatever additional information it believes should be considered in reaching a decision concerning the case. The grantee may have an attorney, or any other person present at the meeting if desired. Within 30 calendar days of the meeting, the Agency will determine what action to take.

(i) If the Agency determines that termination is not necessary, the grantee will be informed in writing.

(ii) If the Agency determines that termination of the grant is appropriate, the grantee will be notified in accordance with 7 CFR part 11.

(2) *National Office review.*

(i) Upon receipt of a request from a grantee that the decision of the State Director be reconsidered, the National Office will make a preliminary decision concerning the continued funding of the grantee during the appeal period. Written notification of the decision will be given to the State Director and grantee.

(ii) The National Office will then obtain a comprehensive report on the matter from the State Office. This information will be considered together with any additional information that may be provided by the grantee.

(c) *Grant suspension.* When the grantee has failed to comply with the terms of the agreement, the Agency will consider termination or suspension of the grant usually only after a Grantee has been classified as ''high risk'' in accordance with 7 CFR 1944.417(b)(2). When the Agency determines that the grantee has a reasonable potential to correct deficiencies the grant may be suspended. The suspension will adhere to 2 CFR part 200 as adopted by USDA through 2 CFR part 400. The grantee will be notified of the grant suspension in writing by the Agency. The Agency will promptly inform the grantee of its rights to appeal the decision in accordance with 7 CFR part 11.

(d) *Grant termination.* The State Director may terminate the grant agreement whenever Rural Development determines that the grantee has failed to comply with terms of the Agreement. The reasons for termination may include, but are not limited to, such problems as listed in paragraph (e)(3)(i) of the Grant Agreement. The State Director may also withhold further disbursement of grant funds and prohibit the grantee from incurring additional obligations of grant funds with written approval of the National Office. Rural Development will allow all necessary and proper costs which grantee could not reasonably avoid.

(1) *Termination for cause.* The grant agreement may be terminated in whole, or in part, at any time before date of completion, whenever Rural Development determines that the grantee has failed to comply with terms of the Agreement. The State Director will notify the grantee in writing giving the reasons for the action and inform the grantee of its rights of appeal by use of Exhibit B–3 to Subpart B of part 1900 ''Letter for Notifying Applicants, Lender, Holders and Borrowers of Adverse Decisions Where the Decision Involves an Appraisal (Not To Be Used in Cases Involving Farmer Program Primary Loan Servicing Actions.)''

(2) *Termination for convenience.* RHS, or its successor agency, or the grantee

may terminate the grant in whole, or in part, when both parties agree that the continuation of the grant would not produce beneficial results. The two parties will agree in writing to the termination conditions including the effective date. No notice of rights of appeal will be issued by Rural Development.

■ 23. Add § 1944.428 to read as follows:

§ 1944.428 Site Loan to Technical Assistance Grantees

The objective of a Site Option (SO) loan under Section 523(b)(1)(B) of Title V of the Housing Act of 1949 is to enable technical assistance (TA) grantees or contractors to establish revolving fund accounts to obtain options on land needed to make sites available to families that will build their own homes by the self-help method. Loans may be made only as necessary to enable eligible applicants to establish revolving accounts with which to obtain options on land that will be needed as building sites by self-help families participating in the TA self-help housing program.

To be eligible for an SO loan, the applicant must be a TA grantee that is currently operating in a satisfactory manner under a TA grant agreement. If the SO loan applicant has applied for TA funds but is not already a TA grantee and it appears that the TA grant will be made, the SO loan may be approved but not closed until the TA grant is closed. Applications will be processed, approved or disapproved, and closed in accordance with 7 CFR 1822, subpart G, 1822.271 through 1822.275 and adhere to the special requirements for RHS section 523 loans at 7 CFR 1822.278.

■ 24. Revise and republish § 1944.450 to read as follows:

§ 1944.450 OMB control number.

The information collection requirements contained in this regulation has been approved by OMB and have been assigned OMB control number 0575–0043. This proposed rulemaking contains new reporting requirements that would require approval under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

Subpart I [Amended]

■ 25. Amend Subpart I by removing Exhibits A through F.

Joaquin Altoro,

Administrator, Rural Housing Service.

[FR Doc. 2024–28032 Filed 12–3–24; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–116787–23]

RIN 1545–BR31

Definition of the Term ''Coverage Month'' for Computing the Premium Tax Credit; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury

ACTION: Cancellation of a notice of public hearing on a proposed rulemaking and notice of public hearing.

SUMMARY: This document cancels a public hearing on proposed regulations that would amend the definition of ''coverage month'' and amend certain other rules in existing income tax regulations regarding the computation of an individual taxpayer's premium tax credit (PTC).

DATES: The public hearing scheduled for December 13, 2024, at 10 a.m. ET is cancelled.

FOR FURTHER INFORMATION CONTACT: Oluwafunmilayo Taylor of the Publications and Regulations Section, Associate Chief Counsel (Procedure and Administration) at (202) 317–6901 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and a notice of public hearing that appeared in the **Federal Register** on September 17, 2024 (89 FR 75984) announced that a public hearing being held in person and by teleconference was scheduled for December 13, 2024, at 10 a.m. ET. The subject of the public hearing is under 26 CFR part 1.

The public comment period for these regulations expired on November 1, 2024. The notice of proposed rulemaking and notice of public hearing instructed those interested in testifying at the public hearing to submit a request to testify and an outline of the topics to be addressed. We did not receive a request to testify at the Public Hearing. Therefore, the public hearing scheduled for December 13, 2024, at 10 a.m. ET is cancelled.

Oluwafunmilayo A. Taylor,

Section Chief, Publications and Regulations Section, Associate Chief Counsel, (Procedure & Administration).

[FR Doc. 2024–28358 Filed 12–3–24; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–112129–23]

RIN 1545–BQ84

Corporate Alternative Minimum Tax Applicable After 2022

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: This document extends the period to submit comments for a notice of proposed rulemaking (REG–112129–23), while retaining the deadline to submit requests to speak at, and outlines for, the public hearing for the proposed rulemaking which was published in the **Federal Register** on Friday, September 13, 2024. The proposed regulations relate to the corporate alternative minimum tax, which is imposed on the adjusted financial statement income of certain corporations for applicable taxable years beginning after 2022.

DATES: The comment period to submit written or electronic comments for the notice of proposed rulemaking published on September 13, 2024 (89 FR 75062) is extended from December 12, 2024, to Thursday, January 16, 2025. The deadline to request to speak at the public hearing and the deadline for submitting outlines for speaking at the public hearing, as stated in the notice of proposed rulemaking (REG–112129–23) published on September 13, 2024 (89 FR 75062) remains December 12, 2024. The IRS must receive speakers' outlines of the topics to be discussed at the public hearing by December 12, 2024. If no outlines are received by December 12, 2024, the public hearing will be cancelled.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically via the Federal eRulemaking Portal at *https://www.regulations.gov* (indicate IRS and REG–112129–23) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comments submitted to the IRS's public docket. Send paper submissions to: CC:PA:01:PR (REG–112129–23), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning proposed §§ 1.56A–1, 1.56A–9, 1.56A–11, 1.56A–12, 1.56A–23, except for paragraphs (e) and (f), and 1.59–2, except for paragraphs (e), (f) and (h), Madeline Padner at (202) 317–7006, concerning proposed §§ 1.56A–2 and 1.56A–3, Frank Dunham III at (202) 317–7009, concerning proposed § 1.56A–17, James Yu at (202) 317–4718, and concerning proposed §§ 1.56A–15 and 1.56A–16, except for issues related to partnerships, C. Dylan Durham at (202) 317–7005, each of the Office of Associate Chief Counsel (Income Tax and Accounting), and for issues related to partnerships, Elizabeth Zanet or Brian Barrett of the Office of Associate Chief Counsel (Passthroughs and Special Industries), at (202) 317–6850; concerning proposed § 1.56A–4, Daren J. Gottlieb at (202) 317–6938, concerning proposed § 1.56A–6, Dylan J. Steiner at (202) 317–6934, concerning proposed § 1.56A–7, Ryan Connery at (202) 317–6933, concerning proposed §§ 1.56A–8 and 1.59–4, John J. Lee at (202) 317–6936, concerning proposed § 1.56A–26(d), Michelle L. Ng at (202) 317–6939, concerning proposed § 1.56A–27, Joel Deuth at (202) 317–6938, and concerning proposed § 1.59–3, Karen Walny at (202) 317–6938, each of the Office of Associate Chief Counsel (International); concerning proposed §§ 1.56A–18, 1.56A–19, 1.56A–21, 1.56A–26, 1.1502–2, 1.1502–3, 1.1502–53, 1.1502–55, and 1.1502–56A, Jeremy Aron-Dine, William W. Burhop, or John Lovelace, concerning proposed §§ 1.56A–23(e) and (f) and 1.59–2(f) and (h), Jeremy Aron-Dine or William W. Burhop, each of the Office of Associate Chief Counsel (Corporate) at (202) 317–3181; concerning proposed § 1.56A–13, Diane Bloom at 202–317–6301, concerning proposed § 1.56A–14, Seth Groman at 202–317–5640, and concerning proposed § 1.59–2(e), Chris Dellana at 202–317–4726, each of the Office of Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes); concerning proposed §§ 1.56A–5, 1.56A–10, and 1.56A–20, Elizabeth Zanet or Brian Barrett, each of the Office of Associate Chief Counsel (Passthroughs and Special Industries) at (202) 317–6850; concerning proposed § 1.56A–22, Ian Follansbee at (202) 317–6995, concerning proposed §§ 1.56A–24 and 1.56A–25, Vanessa Mekpong at (202) 317–6842, each of the Office of Associate Chief Counsel (Financial Institutions and Products); concerning submissions of comments or the public hearing, the Publications and Regulations Section, at (202) 317–6901 (not toll-free numbers) or by email at *publichearings@irs.gov* (preferred).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and request for comments that appeared in the **Federal Register** on Friday, September 13, 2024 (89 FR 75062) announced that written or electronic comments must be received by December 12, 2024. The due date to receive comments has been extended to Thursday, January 16, 2025. The public hearing has not been extended and is still scheduled for January 16, 2025, at 10 a.m. ET. The deadline for submitting requests to speak at the hearing and submitting outlines for speaking at the hearing has not been extended and is still December 12, 2024, as originally stated in the notice of proposed rulemaking and notice of public hearing (REG–112129–23). Requests to speak at the public hearing must be made by email to *publichearings@irs.gov* and still must be received by December 12, 2024. Persons who wish to present oral comments at the public hearing must submit written or electronic comments and an outline of the topics to be discussed as well as the time to be devoted to each topic, not to exceed ten minutes in total, by December 12, 2024.

Kalle L. Wardlow,

Federal Register Liaison, Publications & Regulations Section, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2024–28217 Filed 12–3–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 73

[NPS–WASO–OIA–DTS–36537; PPWODIREI0–PIN00IO15.XI0000–234P104215]

RIN 1024–AE82

World Heritage Convention

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise regulations governing the National Park Service's coordination of U.S. participation in the Convention Concerning the Protection of the World Cultural and Natural Heritage. The proposed changes would reflect updates to the Operational Guidelines for the Implementation of the World Heritage Convention that have been made by the United Nations Educational, Scientific, and Cultural Organization Intergovernmental Committee for the Protection of the World Cultural and Natural Heritage since the regulations were first promulgated in 1982.

DATES: Comments on the proposed rule must be received by 11:59 p.m. ET on February 3, 2025.

ADDRESSES: You may submit comments, identified by Regulation Identifier Number (RIN) 1024–AE82, by either of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail or hand deliver to:* Office of International Affairs, National Park Service, 1849 C Street NW, Room 2415, Washington, DC 20240. Comments delivered on external electronic storage devices (flash drives, compact discs, etc.) will not be accepted.
- *Instructions:* Comments will not be accepted by fax, email, or in any way other than those specified above. All submissions received must include the words ''National Park Service'' or ''NPS'' and must include the docket number or RIN (1024–AE82) for this rulemaking. Comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and search for ''1024–AE82.''

FOR FURTHER INFORMATION CONTACT: Jonathan Putnam, Office of International Affairs, National Park Service, (202) 354–1809, *jonathan_putnam@nps.gov* and *international_affairs@nps.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. In compliance with the Providing Accountability Through Transparency Act of 2023, the plain language summary of the proposal is available on *Regulations.gov* in the docket for this rulemaking.

SUPPLEMENTARY INFORMATION:

Background

The Convention Concerning the Protection of the World Cultural and Natural Heritage (the Convention) was ratified by the U.S. Senate on October 26, 1973. The purpose of the Convention is to enhance worldwide understanding and appreciation of heritage conservation, and to recognize and preserve natural and cultural

properties throughout the world that have outstanding universal value. The World Heritage List is an international list of cultural and natural properties judged to possess outstanding universal value. Properties are nominated by the signatories to the Convention. The United Nations Educational, Scientific, and Cultural Organization Intergovernmental Committee for the Protection of the World Cultural and Natural Heritage (the Committee) is the governing body of the Convention. The Committee is composed of elected representatives of 21 nations and is responsible for implementing the Convention at the international level. Countries represented on the Committee are elected by participating nations. The Committee establishes criteria which properties must satisfy for inclusion on the World Heritage List. At its annual meeting, the Committee decides which properties to accept on the World Heritage List. Currently, there are 1,199 properties on the World Heritage List that are located in 168 of the 195 signatory countries. Twenty-five sites on the World Heritage List are located in the United States, including several units of the National Park System (*e.g.,* Mesa Verde National Park, Carlsbad Caverns National Park). Another property located in the United States has been nominated and is pending consideration by the Committee.

Title IV of the National Historic Preservation Act (NHPA) Amendments of 1980 (54 U.S.C. 307101) instructs the Department of the Interior (the Department) to direct and coordinate participation by the United States in the Convention. Regulations at 36 CFR part 73 implement the Convention pursuant to the 1980 NHPA Amendments. The Department, through the National Park Service (NPS), promulgated these regulations in 1982 (47 FR 23397) and made minor updates in 2001 (66 FR 57878). The regulations address (1) the U.S. World Heritage nomination process; (2) the criteria for inclusion on the World Heritage List and their application to nominated properties; (3) the role of the Federal Interagency Panel for World Heritage; (4) the protection of U.S. World Heritage properties; (5) International World Heritage activities; and (6) public information and education activities. The regulations also define key terms and explain the purpose and authority for the regulations and the role of the Assistant Secretary for Fish and Wildlife and Parks.

Since the NPS promulgated the regulations in 1982, the Committee has amended the Operational Guidelines for the Implementation of the World Heritage Convention (the Operational Guidelines) on numerous occasions, most recently in September 2023. The Operational Guidelines establish detailed procedures for (1) the inclusion of properties on the World Heritage List at the international level; (2) the protection and conservation of World Heritage properties; (3) the implementation of the World Heritage Fund; and (4) mobilization of support for the Convention.

Executive Summary

In this rulemaking, the NPS proposes to bring the regulations in part 73 in line with the Operational Guidelines and the current practice of program implementation by the NPS on behalf of the United States. The changes also would streamline certain procedural steps and provide clarity that would benefit the Department and the public. The proposed changes to each section of the existing regulations are explained below. In addition to the changes described below, the NPS would make non-substantive, editorial changes to the regulations to improve their readability. The NPS welcomes public comments on these changes and hopes to receive meaningful input as it considers a final rule.

Section 73.1 Purpose

Section 73.1 explains the purpose of the regulations. The NPS proposes to revise this section to remove references to the statutory authority for promulgating the regulations. The authority for promulgating the regulations is stated in section 73.5 (Authority).

Section 73.3 Definitions

Section 73.3 defines terms used in part 73. The NPS proposes to reorganize the defined terms in alphabetical order and add definitions for the following terms: ''Advisory Bodies,'' ''NPS,'' ''Operational Guidelines,'' ''Preliminary Assessment,'' ''Secretary,'' ''Tentative List,'' and ''State Party.'' The NPS proposes to shorten the definition of ''Committee'' to remove explanatory information that does not need to be in the definition and an outdated reference to six-year terms. Governments that have signed or become a party to the Convention now voluntarily limit their terms to four years. The NPS proposes to revise the definition of ''Owner'' to remove unnecessary language about nominations and refer to property interests rather than ownership to avoid a circular definition. The NPS proposes to further revise the definition to clarify that an owner means an individual, entity, government, or Indian Tribe that has a fee simple interest in all or part of a property, or in the case of an Indian Tribe a restricted fee interest, or a less than fee simple interest that is integral to the entire property's outstanding universal value. The revised definition would specifically refer to property interests held by an Indian Tribe or held in trust by the United States for the benefit of an Indian Tribe. Although there has never been a prohibition on nominating Tribal properties, and Tribal properties have been nominated in the past, these changes would clarify that Tribal properties may be nominated and that Indian Tribes will be considered the owners of those lands for purposes of the regulations regardless as to whether the properties are held in trust by the United States. This means that when a Tribal property is held in trust by the United States, the United States is not an owner of the property for purposes of these regulations and, as a result, the concurrence of the United States is not required for nominations. The NPS proposes to remove the definition of ''Owner concurrence'' and instead explain in the regulatory text that all property owners must concur in writing to nominations. The NPS proposes to remove the definitions of ''Cultural Heritage'' and ''Natural Heritage'' because they would be used only once in the revised regulations. Instead, the NPS would refer to the Articles of the Convention where they are defined.

Section 73.5 Authority

Section 73.5 identifies the statutory authority for the regulations. The NPS proposes to update the authority citation to reflect recodification of NPS statutory authorities from title 16 to title 54 of the U.S. Code.

Section 73.7 World Heritage Nomination Process

The regulations in this section set forth the procedures governing the nomination process. The NPS proposes to remove the question-and-answer format and make the following substantive revisions:

1. Be more specific about the role of the Federal Interagency Panel for World Heritage in various stages of the nomination process.

The NPS proposes to revise paragraphs (a)(4) and (5), (d)(3), and (f) to state that the NPS may consult with individual members of the Panel about matters in which they have expertise. Although the existing regulations do not prohibit consultation, these changes would emphasize its value as part of the Panel's role by stating clearly that consultation is allowed.

2. Revise the process for adding sites to the U.S. World Heritage Tentative List for consistency with the Operational Guidelines.

The NPS proposes to change the process for adding sites to the U.S. World Heritage Tentative List so that it is consistent with the Operational Guidelines. Existing regulations in paragraph (a)(2) state that the Assistant Secretary initiates the nomination process by publishing a ''First Notice'' requesting suggestions for candidate sites for the World Heritage List in the **Federal Register**. The Operational Guidelines do not require that the process for adding sites to the Tentative List be part of the process for authorizing and submitting nominations to the World Heritage List. These processes now operate on separate schedules. This rule would revise paragraph (a)(2) to refer only to the process for adding properties to the Tentative List, which would include consultation with the NPS and appropriate members of the Panel, and the publication of a notice in the **Federal Register** seeking public comment. In paragraphs (c) and (d), the rule would add information about the purpose and scope of the Tentative List and remove the obsolete term ''Indicative Inventory.'' In paragraph (c)(2), the rule would include a complete list of factors the Assistant Secretary may consider when deciding which properties to include on the Tentative List, including requirements that also apply to the nomination process and other requirements in the Operational Guidelines. Paragraph (c)(4) would state that the Department may update the Tentative List when warranted, but generally every ten years. Lastly, the NPS proposes to remove a requirement in the existing regulations that the Assistant Secretary publish the Tentative List in the **Federal Register** whenever a new nomination is considered. Instead, the proposed rule would require the NPS to publish the Tentative List in the **Federal Register** when it has been comprehensively updated by the Assistant Secretary. Publication of other changes would be at the discretion of the NPS.

3. Require a Preliminary Assessment for properties on the Tentative List prior to nomination.

In 2021, the Committee adopted a decision that will require the advisory bodies to the Committee—the International Union for Conservation of Nature, for sites of natural heritage, and the International Council on Monuments and Sites, for sites of cultural heritage—to provide a Preliminary Assessment to the requesting state party to the Convention about the potential of a site to have outstanding universal value before it can be nominated for the World Heritage List. Preliminary Assessments will be phased in starting with optional requests in 2023. Preliminary Assessments will be required for all nominations submitted after February 1, 2026. Consistent with this new requirement, the rule would revise paragraph (a)(3) to require the NPS, if required by the Operational Guidelines, to submit a request to the UNESCO World Heritage Centre for a Preliminary Assessment before recommending any property on the Tentative List for nomination. Revisions to paragraph (a)(4) would require the Assistant Secretary, prior to authorizing the preparation of a nomination, to receive a Preliminary Assessment, if that report is required by the Operational Guidelines. Paragraph (b)(4) would state that, in ordinary circumstances, the Preliminary Assessment should conclude that the property has potential to demonstrate outstanding universal value before the Assistant Secretary may consider it for nomination. The Assistant Secretary may consider a property for nomination even if the Preliminary Assessment concludes that the property does not have potential to meet this standard, but this should rarely or never happen.

4. Require verification of property ownership and appropriate legal protections for properties to be nominated.

The NPS proposes to revise paragraph (d)(3) to require verification of ownership and a review of legal protections before a property can be authorized for nomination. These steps are part of the process now but have typically occurred after nominations have been authorized and drafted. This change would ensure that any questions about ownership or legal protections would be identified before the nomination is authorized.

5. Supplement qualifications for national significance.

The 1980 NHPA Amendments (54 U.S.C. 307101) require properties in the United States to be of national significance before they can be nominated to the World Heritage List. The existing regulations identify several ways that a property may be considered nationally significant, including properties that the U.S. Congress has established as nationally significant and areas the President has proclaimed as a National Monument under the Antiquities Act of 1906 (16 U.S.C. 433). The NPS proposes to expand these qualifications to include any property established by a Federal agency as nationally significant under an authority provided by the United States Congress, and units of the National Park System, National Wildlife Refuges, National Marine Sanctuaries, and National Forests. Inclusion on the National Register of Historic Places or in a National Heritage Area, alone, would not qualify a property as nationally significant.

6. Simplify owner concurrence requirements.

The NPS proposes to consolidate paragraphs (b)(2)(i)–(iii) into one paragraph that includes existing requirements for all property owners to concur in writing to any nomination, and for owners of private property also to certify the protection of the property as required elsewhere in the regulations. This rule would remove references in section 73.7 and 73.13 to private parties controlling property, rather than owning it, regarding the need to obtain concurrence prior to nominations and to satisfy protection requirements. The 1980 NHPA Amendments do not mention non-Federal property being controlled, but not owned, for obtaining concurrence prior to nominations or other purposes.

7. Authorizing preparation of a U.S. World Heritage nomination.

As discussed previously, the NPS is proposing to separate the process for adding properties to the Tentative List from the process for nominating properties to the World Heritage List, consistent with current practice. Accordingly, certain provisions that appear in existing paragraph (i) about the approval and submission of nominations would be moved to new paragraph (c) in the revised regulations, which would be dedicated to the process for the Tentative List. These provisions include ownership verification and review of the property's legal protections. The provisions governing nominations to the World Heritage List would be moved and consolidated into new paragraphs (d)–(g), which would address authorizing the preparation of a nomination, preparing a nomination, evaluating a nomination, and approving and submitting a nomination, respectively. The provisions in paragraph (d) about authorizing the preparation of a nomination would incorporate the need to obtain and consider the content of a Preliminary Assessment before the NPS prepares a recommendation for the Assistant Secretary.

In addition, the NPS proposes to eliminate a requirement in paragraph (f)(1) of the existing regulations to publish notice in the **Federal Register**

that a property owner has been authorized to prepare a nomination document, which is referred to as a ''Second Notice.'' An authorization to prepare a nomination document does not guarantee that the property will be approved for nomination and therefore is not substantive enough to require formal notification to the public. The revised regulations would direct the NPS to notify the property owners and the U.S. Congress that the Assistant Secretary has decided to authorize a nomination, and also when the Assistant Secretary has decided to submit a nomination to the World Heritage Committee. Existing regulations in paragraphs (f)(1) and (j) require the Assistant Secretary to provide notice, but this authority has been delegated to the NPS in practice. The rule would update the name of the applicable Committee in the U.S. House of Representatives from the ''House Resources Committee'' to the ''House Natural Resources Committee.'' The rule would no longer refer to the notice of submitted nominations as the ''Third Notice.''

Section 73.9 World Heritage Criteria

The NPS proposes to revise this section to remove a recitation of the criteria used to assess whether a property has outstanding universal value. Instead, the rule would state that properties must meet at least one criterion that is published in the Operational Guidelines. The rule would state that the criteria are subject to revision by the Committee and refer to requirements in the Operational Guidelines about a property's integrity and authenticity, and legal protection and management. These proposed revisions would streamline the regulatory text and ensure that the criteria and other requirements that apply to U.S. properties are the same as stated in the Operational Guidelines at the time of assessment. These criteria are readily available on the website of the UNESCO World Heritage Centre which can be accessed directly or through a link on the website of the NPS Office of International Affairs. The criteria also are stated in brochures and other public information made available by the NPS.

Section 73.11 Federal Interagency Panel for World Heritage

This section of the regulations defines the responsibilities and composition of the Panel. The NPS proposes to change paragraph (a) to clarify that the Assistant Secretary may consult not only with the entire Panel, but also with individual members of the Panel on World Heritage matters. The NPS proposes to change paragraph (b)(1)(ii) to clarify that, in its role as a member of the Panel, the NPS represents Associate Directorships that are responsible for managing cultural and natural resources, which is separate from the NPS's administrative responsibilities stated elsewhere in the regulation. The NPS proposes to revise paragraph (b)(2) to clarify that additional representatives from other Federal agencies may have expertise in either natural or cultural heritage conservation.

Section 73.13 Protection of World Heritage Properties

This section of the regulations identifies in greater detail the protection measures that must be in place before the Assistant Secretary can nominate properties for inclusion on the World Heritage List. 54 U.S.C. 307101(c). The NPS proposes to revise paragraph (a)(1) to add language highlighting that the protection of World Heritage sites under the Convention is a government-wide obligation, to avoid an incorrect assumption that it is solely the responsibility of the Department. The NPS proposes to revise paragraph (c) to describe in more detail the protection measures required for private properties, including information about how the requirements may be satisfied. A statement at the end of paragraph (c) in the existing regulations, that protections are reviewed on a case-by-case basis, would become the first statement of the paragraph to make it clear that this approach governs the assessment. The rule would then provide examples of factors that the Assistant Secretary may consider when determining if protections are sufficient, such as the current and potential use of the property, the nature of its ownership, and the effectiveness of applicable legal instruments. The rule would move a statement describing the purpose of such legal instruments to the introductory language that appears before examples are given, to indicate that the statement applies to all of the examples. The stated purpose of such instruments is to sufficiently prohibit any use or physical alteration that is not consistent with, or which threatens or damages the property's universally significant value.

The existing regulations state that a written covenant or other trust or legal arrangement that prohibits in perpetuity any use that is not consistent with, or which threatens or damages the property's universally significant values, satisfy the protection requirements for private properties, provided there is an opinion of counsel on the legal status and enforcement of such a prohibition. Instead of identifying specific instruments that satisfy the protection requirements, the NPS proposes to provide examples of instruments that may satisfy the protection requirements. The rule would retain, as an example, a written covenant executed by the owner and continue to refer to other trusts or legal arrangements that may satisfy the protection requirements, with specific reference to easements and local historic preservation ordinances that include substantive protection for the property. Since the existing regulations were first promulgated in 1982, standards for local historic preservation ordinances have been established and widely adopted through the Certified Local Government Program authorized by the National Historic Preservation Act and implemented by the NPS. See 54 U.S.C. chapter 3025 and 36 CFR part 61. These ordinances may offer an effective means of long-term protection, subject to review by the Assistant Secretary that they offer sufficient protection for a property.

The NPS believes this approach is consistent with the 1980 NHPA Amendments that require legal protections as may be necessary to ensure preservation of the property and its environment. 54 U.S.C. 307101(c). The proposed rule would require the Assistant Secretary to determine, on a case-by-case basis, that the protections fulfill the mandate of the statute, giving consideration to what would constitute effective protection that is appropriate to the circumstances of the particular property. This approach is consistent with the intent of the 1980 Amendments and allows the Assistant Secretary to consider not just whether protections are in place, but also whether those protections are effective. The rule also would require private property owners to certify in writing to the protection measures for the property. The NPS believes that these revisions would provide the Assistant Secretary with more flexibility to determine that protections will ''ensure preservation of the property and its environment'' as required by the statute.

The NPS proposes to remove a requirement that there be an ''opinion of counsel'' about the status and enforcement of covenants. This provision is vague and unnecessary because the rule would require a determination by the Assistant Secretary that the protections are sufficient and comply with the standard for protection in the 1980 NHPA Amendments. Lastly, the NPS proposes to remove a reference

to the property owner willingly providing a right of first refusal for the acquisition of private property because this has never been used in the program's 45-year history and therefore is unnecessary.

§ 73.17 Public Information and Education Activities

This section of the regulations addresses the development and distribution of information and materials regarding the U.S. World Heritage properties and the Convention in general. The NPS proposes one revision to paragraph (c) that would remove an obsolete and unnecessarily specific reference to the distribution of slideshows.

Compliance With Other Laws, Executive Orders and Department Policy

Regulatory Planning and Review (Executive Orders 12866 and 13563 and 14094)

Executive Order 12866, as amended by Executive Order 14094, provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that the proposed rule is not significant.

Executive Order 14094 amends Executive Order 12866 and reaffirms the principles of Executive Order 12866 and Executive Order 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and be consistent with Executive Order 12866, Executive Order 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. Executive Order 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The NPS has developed this proposed rule in a manner consistent with these requirements.

Regulatory Flexibility Act

The NPS certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). A Regulatory Flexibility Analysis is not required. This proposed rule would revise regulations governing the NPS's coordination of U.S. participation in the Convention. The costs and benefits of a regulatory action are measured with respect to its existing baseline conditions. No changes are anticipated compared to baseline conditions because this regulatory action is procedural in nature with the purpose of changing existing regulations to reflect updates to the Operational Guidelines and current administrative practice. All property owners must concur in writing to nominations, which means the application of this rule to private entities is completely voluntary. Nomination and approval of properties for inclusion on the World Heritage List recognizes their universally significant value and enhances public understanding and appreciation of heritage conservation. Only a small number of select U.S. properties will be considered for World Heritage status. Small entities may provide information or assistance in the preparation of nominations, but such participation is completely voluntary on their part. In some instances, small entities may be reimbursed for providing detailed site information and analysis. Designation of a property as a World Heritage site may enhance its tourism value. Any effects would likely be of a very localized nature and may be beneficial to small entities in the surrounding area. This action will not impose restrictions on local businesses in the form of fees, training, record keeping, or other measures that would increase costs.

Congressional Review Act

This rulemaking is not a major rule under 5 U.S.C. 804(2). This rule:

(a) Does not have an annual effect on the economy of $100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

This proposed rule does not impose an unfunded mandate on Tribal, State, or local governments or the private sector of more than $100 million per year. The proposed rule does not have a significant or unique effect on Tribal, State, or local governments or the private sector. It addresses public use of national park lands and imposes no requirements on other agencies or governments. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings (Executive Order 12630)

This proposed rule does not effect a taking of private property or otherwise have takings implications under Executive Order 12630. A takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. This proposed rule addresses procedures governing the NPS's administration of the U.S. World Heritage Program and would not have substantial direct effects on the States, on the relationships between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. A Federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This proposed rule complies with the requirements of Executive Order 12988. This proposed rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes and ANCSA Corporations (Executive Order 13175 and Department Policy)

The Department strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. The NPS has evaluated this proposed rule under the criteria in Executive Order 13175 and under the

Department's Tribal consultation policy and has determined that Tribal consultation is not required because the proposed rule would not have a substantial direct effect on federally recognized Indian Tribes.

Paperwork Reduction Act

This proposed rule does not contain information collection requirements, and a submission to the Office of Management and Budget under the Paperwork Reduction Act is not required. The NPS may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

This rule does not constitute a major federal action significantly affecting the quality of the human environment. A detailed statement under NEPA is not required because the rule is covered by a categorical exclusion. NPS NEPA Handbook (2015) Section 3.2.H allows for the following to be categorically excluded: ''policies, directives, regulations, and guidelines that are of an administrative, financial, legal, technical, or procedural nature.'' This proposed rule addresses procedures governing the NPS's administration of the U.S. World Heritage Program. The NPS has also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Effects on the Energy Supply (Executive Order 13211)

This proposed rule is not a significant energy action under the definition in Executive Order 13211; the proposed rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy, and the proposed rule has not otherwise been designated by the Administrator of Office of Information and Regulatory Affairs as a significant energy action. A Statement of Energy Effects is not required.

Clarity of This Rule

The NPS is required by Executive Orders 12866 (section 1(b)(12)) and 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule the NPS publishes must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use common, everyday words and clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that the NPS has not met these requirements, send the NPS comments by one of the methods listed in the **ADDRESSES** section. To better help the NPS revise the rule, your comments should be as specific as possible. For example, you should identify the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Public Participation

It is the policy of the Department, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments regarding this proposed rule by one of the methods listed in the **ADDRESSES** section of this document.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask the NPS in your comment to withhold your personal identifying information from public review, the NPS cannot guarantee that it will be able to do so.

List of Subjects in 36 CFR Part 73

Foreign relations, Historic preservation.

In consideration of the foregoing, the National Park Service proposes to amend 36 CFR part 73 as set forth below:

PART 73—WORLD HERITAGE CONVENTION

■ 1. Revise the authority citation for part 73 to read as follows:

Authority: 54 U.S.C. 307101.

■ 2. Revise § 73.1 to read as follows:

§ 73.1 Purpose.

The purpose of this part is to set forth the procedures that the Department of the Interior, through the National Park Service, uses to direct and coordinate participation by the United States in the Convention Concerning the Protection of the World Cultural and Natural Heritage. The purpose of the Convention is to enhance worldwide understanding and appreciation of heritage conservation, and to recognize and preserve natural and cultural properties throughout the world that have outstanding universal value to mankind.

■ 3. Revise § 73.3 to read as follows:

§ 73.3 Definitions.

Advisory Bodies means nongovernmental organizations that are given the responsibility in the Convention for advising the Committee on technical matters relating to natural and cultural heritage. The International Union for Conservation of Nature, or IUCN, advises on natural heritage, and the International Council on Monuments and Sites, or ICOMOS, advises on cultural heritage.

Assistant Secretary means the Assistant Secretary for Fish and Wildlife and Parks, U.S. Department of the Interior, or a designee authorized to carry out the Assistant Secretary's responsibilities.

Committee means the United Nations Educational, Scientific, and Cultural Organization Intergovernmental Committee for the Protection of the World Cultural and Natural Heritage established by Article 8 of the Convention and assisted by UNESCO.

Convention means the Convention Concerning the Protection of the World Cultural and Natural Heritage.

Department means the U.S. Department of the Interior.

NPS means the office of the National Park Service assigned responsibility for the administration of the U.S. World Heritage Program.

Operational Guidelines means the Operational Guidelines for the Implementation of the World Heritage Convention adopted and periodically updated by the Committee that establish the criteria which properties must satisfy for inclusion on the World Heritage List and policy and procedures for the administration of the Convention.

Owner means an individual, entity, government, or Indian Tribe that has a fee simple interest in all or part of a property, or in the case of an Indian Tribe a restricted fee interest, or a less than fee simple interest that is integral to the entire property's outstanding universal value. For property interests held by a Federal, State, or local government, the owner is deemed to be the head of the agency responsible for administering the property, or a designee to whom such authority has been delegated. For property interests held by an Indian Tribe in fee simple or restricted fee, or held in trust by the United States for the benefit of an Indian Tribe, the owner is deemed to be the leader of the Indian Tribe or a

designee to whom such authority has been delegated.

Panel means an interagency panel consisting of representatives from the Office of the Assistant Secretary, the National Park Service, and the U.S. Fish and Wildlife Service, within the Department; the President's Council on Environmental Quality; the Smithsonian Institution; the Advisory Council on Historic Preservation; the National Oceanic and Atmospheric Administration within the Department of Commerce; and the Department of State.

Preliminary Assessment means a report prepared by one or more of the Advisory Bodies that advises a State Party on the potential of a property to have outstanding universal value.

Secretary means the Secretary of the Department, or a designee authorized to carry out the Secretary's responsibilities.

State Party means a national government that has signed, or become a party to, the Convention.

Tentative List means the list required by the Committee and maintained by the Department, of properties within the territory of the United States from which the United States may submit nominations to the World Heritage List.

UNESCO means the United Nations Educational, Scientific and Cultural Organization, which provides staff support for the Convention and its implementation.

World Heritage List means the list established by Article 11 of the Convention that includes those cultural and natural properties judged to possess outstanding universal value.

■ 4. Revise § 73.5 to read as follows:

§ 73.5 Authority.

The provisions contained in this part are based on the authority of the Secretary under title IV of the National Historic Preservation Act Amendments of 1980 (54 U.S.C. 307101) to direct and coordinate U.S. participation in the Convention, in cooperation with the Secretary of State, the Smithsonian Institution, and the Advisory Council on Historic Preservation.

■ 5. Revise § 73.7 to read as follows:

§ 73.7 World Heritage nomination process.

(a) *Overview.* (1) The Assistant Secretary is the designated official who conducts the U.S. World Heritage Program and periodically nominates properties to the World Heritage List on behalf of the United States. The NPS provides staff support to the Assistant Secretary.

(2) The Assistant Secretary periodically revises or adds properties to the Tentative List through a process that includes the advice of the NPS and members of the Panel with relevant expertise, as well as public input obtained by publishing a request for suggested additions in the **Federal Register**.

(3) The NPS identifies properties on the Tentative List that appear to be ready for the preparation of a nomination proposal or for which additional advice from one or more of the Advisory Bodies is desired. For such properties, if required by the Operational Guidelines, the NPS submits a request for a Preliminary Assessment to the UNESCO World Heritage Centre, following the procedures in the Operational Guidelines.

(4) The Assistant Secretary, with advice from the NPS and members of the Panel with relevant expertise, may authorize the preparation of a nomination of a property on the Tentative List after receiving a Preliminary Assessment, if required by the Operational Guidelines.

(5) The property owner (or owners), in cooperation with the NPS, voluntarily prepares a detailed draft nomination document for the property that has been proposed for nomination. The NPS reviews the accuracy and completeness of draft nomination documents, with the advice of members of the Panel with relevant expertise, and makes a recommendation on the nomination to the Assistant Secretary.

(6) The Assistant Secretary, after convening the Panel, decides whether to nominate the property and transmits approved nominations, through the Department of State, to the Committee to be considered for inclusion on the World Heritage List.

(b) *Requirements.* A property must satisfy the following requirements before the Assistant Secretary may consider it for nomination:

(1) The property must be nationally significant. For the purposes of this section, a property qualifies as ''nationally significant'' if it is:

(i) Designated by the Secretary as a National Historic Landmark (36 CFR part 65) or a National Natural Landmark (36 CFR part 62) under provisions of the 1935 Historic Sites Act (54 U.S.C. chapter 3201);

(ii) Established by Congressional action, or by a Federal agency under an authority provided by the United States Congress, as nationally significant; or

(iii) Proclaimed by the President of the United States as a National Monument under the Antiquities Act of 1906 (54 U.S.C. chapter 3203).

(iv) Established as a National Wildlife Refuge, National Marine Sanctuary, National Forest, of a unit of the National Park System.

(2) Except as stated below, all owners must concur in writing. Owners of private property also must certify in writing to the protection measures described in paragraph (c) of § 73.13 of this part.

(3) The nomination document must include evidence of protection measures that are necessary to ensure the preservation of the property and its environment, as described in § 73.13 of this part.

(4) In ordinary circumstances, the Preliminary Assessment should conclude that the property has potential to demonstrate outstanding universal value.

(c) *Tentative List.* (1) Article 11 of the Convention requests each State Party to submit a list of candidate sites for the World Heritage List. The NPS compiles and maintains the Tentative List for properties within the territory of the United States. A property must be on the Tentative List for at least one year to be eligible for a Preliminary Assessment and potential nomination for inclusion on the World Heritage List.

(2) The Assistant Secretary, with advice from the NPS and members of the Panel with relevant expertise, may revise or add properties to the Tentative List. Before adding a property to the Tentative List, the Assistant Secretary will consider:

(i) Whether the property appears to satisfy one or more of the criteria for inclusion on the World Heritage List, as described in the Operational Guidelines;

(ii) Whether it demonstrates a very high degree of integrity and (for cultural properties) authenticity as required by the Operational Guidelines;

(iii) Whether the property meets the requirements in paragraphs (b)(1) and (3) of this section;

(iv) How well the particular type of property is represented on the World Heritage List, both globally and in the United States. Such representation includes both geographic and thematic considerations;

(v) The balance between cultural and natural properties already on the World Heritage List, both globally and in the United States;

(vi) Opportunities that the property affords for public visitation, interpretation, and education;

(vii) Potential threats to the property's integrity or its current state of preservation; and

(viii) Other relevant factors, including public interest and awareness of the property, and the potential for the

owner(s) to effectively fund and prepare a draft nomination document.

(3) The Tentative List is not intended to be comprehensive of all types of nationally significant cultural and natural properties in the United States, but rather to focus on those that are significant in a global context.

(4) The Assistant Secretary may undertake a comprehensive update to the Tentative List when warranted, but generally every ten (10) years. When this occurs, the NPS will publish notice in the **Federal Register** that requests suggested additions from the public. The NPS will publish the new Tentative List in the **Federal Register** after the Assistant Secretary completes a comprehensive update. The NPS may publish notice in the **Federal Register** of other changes made by the Assistant Secretary at its discretion. The Assistant Secretary transmits information to the UNESCO World Heritage Centre about changes to the Tentative List as specified in the Operational Guidelines. At any time, a government agency, private organization, or individual may suggest additions to the Tentative List by contacting the NPS, preferably with accompanying documentation.

(d) *Authorizing preparation of a U.S. World Heritage nomination.* The following steps must be taken to authorize the preparation of draft nomination documents:

(1) The NPS identifies a property on the Tentative List that appears to be ready to prepare a nomination or for which the NPS desires additional advice from one or more of the Advisory Bodies. The Operational Guidelines request that countries whose heritage is already well represented on the World Heritage List voluntarily limit their nominations through actions such as refraining from annual nominations, proposing only properties in categories that are under-represented on the World Heritage List, and linking a nomination with one presented by a country whose heritage is under-represented. The NPS will consider this guidance in the identification process.

(2) If a Preliminary Assessment is required by the Operational Guidelines, the NPS submits a request for such report to the UNESCO World Heritage Centre, following the procedures in the Operational Guidelines.

(3) Upon receipt of a Preliminary Assessment, if required by the Operational Guidelines, the NPS prepares a recommendation for the Assistant Secretary as to whether the Assistant Secretary should authorize the owners to prepare a draft nomination document. The NPS will consider the content of the Preliminary Assessment and may consult with members of the Panel with relevant expertise. This recommendation also will include determination or verification of ownership of the property proposed for nomination, and a review of legal protections for the property.

(4) The Assistant Secretary, with advice from the NPS and members of the Panel with relevant expertise, may authorize the preparation of a nomination of a property on the Tentative List after receiving a Preliminary Assessment, if required by the Operational Guidelines, and a recommendation from the NPS. If the Assistant Secretary decides to authorize a nomination, the NPS will notify in writing the owner or owners of the property, the House Natural Resources Committee, and the Senate Energy and Natural Resources Committee. The NPS also may issue a press release about the proposed nomination.

(e) *Preparation of a U.S. World Heritage nomination.* The owner or owners of a property are responsible for preparing a draft nomination document. The preparation of a draft nomination document is completely voluntary. The NPS oversees the preparation of the draft nomination document and ensures that it follows the procedures in this part and the format and procedures in the Operational Guidelines.

(f) *Evaluation of a U.S. World Heritage nomination.* The draft nomination document serves as the basis for the Assistant Secretary's decision to nominate a property to the World Heritage Committee for inclusion on the World Heritage List. The NPS reviews the accuracy and completeness of draft nomination documents, with the advice of members of the Panel with relevant expertise, and makes a recommendation on the nomination to the Assistant Secretary.

(g) *Approval and submission of a U.S. World Heritage nomination.* (1) The Assistant Secretary, on behalf of the United States and based on personal evaluation of the draft nomination document and after convening the Panel, may nominate a property for inclusion on the World Heritage List if all of the requirements in paragraph (b) of this section are met.

(2) The Assistant Secretary will send an approved nomination document, through the Department of State, to the Committee so that it is received before the deadline established in the Operational Guidelines for any given year; however, if the United States is cooperating with one or more other countries to nominate thematically or geographically linked properties in a single nomination, and the United States is not the country presenting the nomination, the Assistant Secretary will not submit the nomination to the Committee but will provide documentation of the U.S. government's cooperation in the nomination as required by the Operational Guidelines.

(3) Upon a decision by the Assistant Secretary to submit a nomination, the NPS will notify in writing the owner or owners of the property, the House Natural Resources Committee, and the Senate Energy and Natural Resources Committee. The NPS also will publish notice of the nomination in the **Federal Register** and the NPS will issue a press release.

(4) Nomination by the United States does not place a property on the World Heritage List. Before a nominated property can be included on the World Heritage List it must be considered and approved by the Committee. This usually occurs at a Committee meeting in the year following the receipt of the nomination.

■ 6. Revise § 73.9 to read as follows:

§ 73.9 World Heritage criteria.

(a) The Operational Guidelines identify cultural and natural criteria for the World Heritage List. Properties must meet at least one criterion, and can meet both cultural and natural criteria, in which case the property is considered ''mixed'' heritage. The criteria are subject to revision by the Committee. The Operational Guidelines also detail requirements for integrity and authenticity, as well as for legal protection and management to ensure the conservation of the property (see § 73.13).

(b) [Reserved]

(c) [Reserved]

7. Amend § 73.11 by revising paragraph (a) introductory text, paragraph (b)(1)(ii), and paragraphs (b)(2) and (3).

The revisions read as follows:

§ 73.11 Federal Interagency Panel for World Heritage.

(a) *Responsibilities.* The Panel is established to advise the Assistant Secretary on implementation of the Convention. Among other things, the Panel or any of its members assist in the following activities:

* * * * *

(b) * * *

(1) * * *

(ii) The NPS, representing the Associate Directorships that are responsible for cultural and/or natural resources.

* * * * *

(2) Additional representatives from other Federal agencies with mandates

and expertise in the conservation of cultural or natural heritage, as those terms are defined in Articles 1 and 2 of the Convention, may be requested to participate in the Panel from time to time.

(3) The Assistant Secretary chairs meetings of the Panel, and sets its agenda and schedule. The NPS provides staff support to the Panel.

■ 8. Amend § 73.13 by:

■ a. Revising paragraphs (a) and (c); and

■ b. Removing the undesignated paragraph at the end of the section.

The revisions read as follows:

§ 73.13 Protection of U.S. World Heritage properties.

(a) *Requirements.* (1) Article 5 of the Convention, as required in more detail in the Operational Guidelines, mandates that each participating nation shall take, insofar as possible, the appropriate legal, scientific, technical, administrative, and financial measures necessary for the identification, protection, conservation, preservation, and rehabilitation of properties of outstanding universal value. This is a government-wide obligation.

(2) The nomination document for a property must include evidence of such legal protections as may be necessary to ensure preservation of the property and its environment, including, for example, restrictive covenants, easements, or other forms of protection (54 U.S.C. 307101(c)).

* * * * *

(c) *Protection Measures for Private Properties.* For properties owned by private organizations or individuals, the protection measures for each property being considered for possible nomination to the World Heritage List will be reviewed by the Assistant Secretary on a case-by-case basis to ensure that they fulfill the mandate of 54 U.S.C. 307101(c), giving consideration to what would constitute effective protection that is appropriate to the circumstances of the particular property. Such considerations may include the current and potential use of the property, the nature of its ownership, and the effectiveness of the applicable legal protection measures.

(1) One or more of the following items may satisfy the protection requirements outlined in paragraph (a) of this section, if the Assistant Secretary determines that they sufficiently prohibit any use or physical alteration that is not consistent with, or which threatens or damages the property's universally significant value:

(i) Written covenant executed by the owner(s); or

(ii) Other trust or legal arrangement, such as an easement or substantive protection under a local historic preservation ordinance.

(2) [Reserved]

§ 73.17 [Amended]

■ 9. Amend § 73.17, in paragraph (c), by removing the text ''slideshows,''.

Shannon A. Estenoz,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2024–27373 Filed 12–3–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO–P–2024–0003]

RIN 0651–AD76

Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting; Withdrawal

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Proposed rule; withdrawal.

SUMMARY: The USPTO is withdrawing the Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on May 10, 2024, that proposes to add a new requirement for an acceptable terminal disclaimer filed to obviate (that is, overcome) nonstatutory double patenting.

DATES: The proposed rule published at 89 FR 40439 on May 10, 2024, is withdrawn as of December 4, 2024.

FOR FURTHER INFORMATION CONTACT: Susy Tsang-Foster, Senior Legal Advisor, Office of Patent Legal Administration, at 571–272–7711; or Nicholas Hill, Legal Advisor, Office of Patent Legal Administration, at 571–270–1485.

SUPPLEMENTARY INFORMATION: This action withdraws a proposed rule published in the **Federal Register** on May 10, 2024 (89 FR 40439), to add a new requirement for an acceptable terminal disclaimer that is filed to obviate (that is, overcome) nonstatutory double patenting. The proposed rule's comment period was open from May 10, 2024, to July 9, 2024.

Reason for Withdrawal

During the proposed rule's 60-day comment period, the USPTO received more than 300 comments from a variety of stakeholders, including commenters both supporting and opposing the proposal. The comments are publicly available at the Federal eRulemaking Portal at *www.regulations.gov/document/PTO-P-2024-0003-0001.* Of the comments received on the proposed rule, 256 comments were unique.

In light of resource constraints, the USPTO has decided not to move forward with the proposed rule at this time and to withdraw the proposed rule.

Despite the decision not to move forward with the proposed rule at this time, the USPTO appreciates and takes seriously the thoughtful perspectives raised by commenters. The USPTO will continue engaging with its stakeholders as it works to foster a balanced, robust, and reliable intellectual property system.

Conclusion

The proposed rule to add a new requirement for an acceptable terminal disclaimer that is filed to obviate nonstatutory double patenting, published in the **Federal Register** on May 10, 2024 (89 FR 40439), is hereby withdrawn.

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2024–28263 Filed 12–3–24; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2024–0215; FRL–12351–01–R5]

Air Plan Approval; Michigan and Minnesota; Revision to Taconite Federal Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to finalize nitrogen oxide (NO_X) and/or sulfur dioxide (SO_2) limits for the indurating furnaces at five taconite facilities in accordance with the procedures set forth in the Federal implementation plan (FIP) addressing the requirement for best available retrofit technology (BART) at taconite facilities. EPA is also proposing to modify the Upper Predictive Limit (UPL) equations used to establish NO_X and SO_2 emission limits under the FIP. Finally, EPA is proposing to revise reporting provisions to require reports to be submitted to EPA electronically. EPA is proposing these actions pursuant to sections 110 and 169A of the Clean Air Act (CAA).

DATES: Comments must be received on or before January 21, 2025.

Virtual Public Hearing. EPA will hold a virtual public hearing to solicit comments on December 19, 2024. The last day to pre-register to present at the hearing will be December 16, 2024. On December 16, 2024, EPA will post a general agenda for the hearing that will list pre-registered presenters in approximate order at *https://www.epa.gov/mn/revision-taconite-regional-haze-federal-implementation-plan-mi-and-mn.* If you require the services of a translator or a special accommodation such as audio description/closed captioning, please pre-register for the hearing and describe your needs by December 11, 2024.

For more information on the virtual public hearing, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2024–0215 at *https://www.regulations.gov,* or via email to *arra.sarah@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *the docket.* EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI, PBI, or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Kathleen D'Agostino, Environmental Scientist, Air and Radiation Division (AR18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–0266, *dagostino.kathleen@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

Virtual Public Hearing

EPA is holding a virtual public hearing to provide interested parties the opportunity to present data, views, or arguments concerning the proposal. EPA will hold a virtual public hearing to solicit comments on December 19, 2024. The hearing will convene at 9:00 a.m. Central Standard Time (CST) and will conclude at 1:00 p.m. CST, or 15 minutes after the last pre-registered presenter in attendance has presented if there are no additional presenters. EPA will announce further details, including information on how to register for the virtual public hearing, on the virtual public hearing website at *https://www.epa.gov/mn/revision-taconite-regional-haze-federal-implementation-plan-mi-and-mn.*

EPA will begin pre-registering presenters and attendees for the hearing upon publication of this document in the **Federal Register**. To pre-register to attend or present at the virtual public hearing, please use the online registration form available at *https://www.epa.gov/mn/revision-taconite-regional-haze-federal-implementation-plan-mi-and-mn* or contact Mayesha Choudhury at 312–886–5909 or by email at *choudhury.mayesha@epa.gov.* The last day to pre-register to present at the hearing will be December 16, 2024. On December 16, 2024, EPA will post a general agenda for the hearing that will list pre-registered presenters in approximate order at *https://www.epa.gov/mn/revision-taconite-regional-haze-federal-implementation-plan-mi-and-mn.* Additionally, requests to present will be taken on the day of the hearing as time allows.

EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearing to run either ahead of schedule or behind schedule. Each commenter will have 5 minutes to provide oral testimony. EPA encourages commenters to provide EPA with a copy of their oral testimony electronically by including it in the registration form or emailing it to *choudhury.mayesha@epa.gov.* EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral comments and supporting information presented at the virtual public hearing.

EPA is asking all hearing attendees to pre-register, even those who do not intend to present. This will help EPA prepare for the virtual hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/mn/revision-taconite-regional-haze-federal-implementation-plan-mi-and-mn.* While EPA expects the hearing to go forward as set forth above, please monitor our website or contact Mayesha Choudhury at 312–886–5909 or *choudhury.mayesha@epa.gov* to determine if there are any updates. EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of a translator or a special accommodation such as audio description/closed captioning, please pre-register for the hearing with Mayesha Choudhury at 312–886–5909 or *choudhury.mayesha@epa.gov* and describe your needs by December 11, 2024. EPA may not be able to arrange accommodations without advance notice.

I. Background

A. Requirements of the Clean Air Act and EPA's Regional Haze Rule

In section 169A of the 1977 Amendments to the CAA, Congress created a program for protecting visibility in the nation's national parks and wilderness areas. This section of the CAA establishes as a national goal the ''prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Class I Federal areas [1] which impairment results from manmade air pollution.'' Congress added section 169B to the CAA in 1990 to address regional haze issues. EPA promulgated a rule to address regional haze on July 1, 1999

[1] Areas designated as mandatory Class I Federal areas consist of national parks exceeding 6000 acres, wilderness areas and national memorial parks exceeding 5000 acres, and all international parks that were in existence on August 7, 1977. 42 U.S.C. 7472(a). In accordance with section 169A of the CAA, EPA, in consultation with the Department of Interior, promulgated a list of 156 areas where visibility is identified as an important value. 44 FR 69122 (November 30, 1979). The extent of a mandatory Class I area includes subsequent changes in boundaries, such as park expansions. 42 U.S.C. 7472(a). Although states and Tribes may designate as Class I additional areas which they consider to have visibility as an important value, the requirements of the visibility program set forth in section 169A of the CAA apply only to ''mandatory Class I Federal areas.'' Each mandatory Class I Federal area is the responsibility of a ''Federal Land Manager.'' 42 U.S.C. 7602(i). When we use the term ''Class I area'' in this action, we mean a ''mandatory Class I Federal area.''

(64 FR 35714), codified at 40 CFR part 51, subpart P (herein after referred to as the ''Regional Haze Rule''). The Regional Haze Rule codified and clarified the BART provisions in the CAA and revised the existing visibility regulations to add provisions addressing regional haze impairment and to establish a comprehensive visibility protection program for Class I areas. The requirements for regional haze, found at 40 CFR 51.308 and 51.309, are included in EPA's visibility protection regulations at 40 CFR part 51, subpart P.

Section 169A of the CAA directs states, or EPA if developing a FIP, to evaluate the use of retrofit controls at certain larger, often uncontrolled, older stationary sources to address visibility impacts from these sources. Specifically, section 169A(b)(2)(A) of the CAA requires that implementation plans contain such measures as may be necessary to make reasonable progress toward the natural visibility goal, including a requirement that certain categories of existing major stationary sources [2] built between 1962 and 1977 procure, install, and operate BART as determined by EPA.

Under the Regional Haze Rule, states (or in the case of a FIP, EPA) are directed to conduct BART determinations for such ''BART-eligible'' sources that may reasonably be anticipated to cause or contribute to any visibility impairment in a Class I area.

On July 6, 2005, 70 FR 39104, EPA published the Guidelines for BART Determinations Under the Regional Haze Rule at appendix Y to 40 CFR part 51 (hereinafter referred to as the ''BART Guidelines'') to assist states and EPA in determining which sources should be subject to the BART requirements and in determining appropriate emission limits for each source subject to BART.

The process of establishing BART emission limitations follows three steps. First, states, or EPA if developing a FIP, must identify and list ''BART-eligible sources.'' [3] Once the state or EPA has identified the BART-eligible sources, the second step is to identify those sources that may ''emit any air pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility'' in a Class I area. (Under the Regional Haze Rule, a source which fits this description is ''subject to BART.''). Third, for each source subject to BART, the state or EPA must identify the level of control representing BART after considering the five factors set forth in CAA section 169A(g). The BART Guidelines provide a process for making BART determinations that states can use in implementing the BART requirements on a source-by-source basis. *See* 40 CFR part 51, appendix Y, at IV.D.

States, or EPA if developing a FIP, must address all visibility-impairing pollutants emitted by a source in the BART determination process. The most significant visibility impairing pollutants are SO_2, NO_X, and particulate matter (PM).

A state implementation plan (SIP) or FIP addressing regional haze must include source-specific BART emission limits and compliance schedules for each source subject to BART. Once a state or EPA has made a BART determination, the BART controls must be installed and operated as expeditiously as practicable, but no later than five years after the date of the final SIP or FIP. *See* CAA section 169A(g)(4) and 40 CFR 51.308(e)(1)(iv). In addition to what is required by the Regional Haze Rule, general SIP requirements mandate that the SIP or FIP include all regulatory requirements related to monitoring, recordkeeping, and reporting for the BART controls on the source. *See* CAA section 110(a).

B. BART FIP for Taconite Facilities in Michigan and Minnesota

EPA is proposing to finalize NO_X and/or SO_2 limits for the indurating furnaces at five taconite facilities in accordance with the procedures set forth in the FIP addressing the requirement for BART at taconite facilities. These facilities include Tilden Mining Company (Tilden) located at 101 Cci Mine Road, Ishpeming, Michigan; Hibbing Taconite Company (Hibbing) located at 4950 Highway 5 North, Hibbing, Minnesota; Minorca Mine (Minorca) located at 5950 Old Highway 53, Virginia, Minnesota; Northshore Mining Company—Silver Bay (Northshore) located at 10 Outer Drive, Silver Bay, Minnesota, and United Taconite (UTAC) located at 8470 Townline Road, Forbes, Minnesota. Tilden, Minorca, Northshore, and UTAC are owned by Cleveland-Cliffs, Inc. (Cliffs), formerly known as Cliffs Natural Resources, and Hibbing is jointly owned by Cliffs and United States Steel. The primary units identified as being subject to BART at Tilden, Hibbing, Minorca, UTAC, and Northshore include the following pelletizing, or indurating, furnaces: Tilden Grate Kiln Line 1, Hibbing Straight-Grate Lines 1–3, Minorca Straight-Grate Line 1, UTAC Grate Kiln Lines 1 and 2, and Northshore Straight-Grate Furnaces 11 and 12.[4] The U.S. taconite iron ore industry uses two types of pelletizing machines or processes: straight-grate kilns and grate kilns. In a straight-grate kiln, a continuous bed of agglomerated green pellets is carried through different temperature zones with upward draft or downward draft blown through the pellets on the metal grate. The grate kiln system consists of a traveling grate, a rotary kiln, and an annular cooler. A significant difference between these designs is that straight-grate kilns do not burn coal and therefore have a much lower potential for emitting SO_2. Further, even within the same kiln type or process, individual furnaces (referred to as indurating or pelletizing) or processes have distinct equipment and process characteristics that may affect the compatibility and performance of certain types of burners.

On February 6, 2013 (78 FR 8706), EPA promulgated a FIP that set BART limits for NO_X and SO_2 emissions from furnaces at seven taconite facilities in Michigan and Minnesota (''Original FIP''). EPA took this action because Michigan and Minnesota had failed to meet a statutory deadline to submit their Regional Haze SIPs and subsequently failed to require BART at the taconite facilities within their borders. BART limits for NO_X were based upon the performance of high stoichiometric (high-stoich) low-NO_X burners (LNBs) [5] at two of the taconite furnaces at U.S. Steel's Minntac facility, while BART for SO_2 was established as no additional controls, apart from a limit on the sulfur content of coal used in co-firing furnaces.

In a related action, EPA published a final partial disapproval of Michigan's and Minnesota's Regional Haze SIPs on September 30, 2013 (78 FR 59825), due to the states' failure to require BART for taconite facilities within these states.

ArcelorMittal USA LLC (''ArcelorMittal'') [6] and Cliffs, owners of several taconite facilities affected by the FIP, along with the State of Michigan,

[2] The set of ''major stationary sources'' potentially subject to BART is listed in CAA section 169A(g)(7) and includes ''taconite ore processing facilities.''

[3] ''BART-eligible sources'' are those sources that have the potential to emit 250 tons or more of a visibility-impairing air pollutant, were not in operation prior to August 7, 1962, but were in existence on August 7, 1977, and whose operations fall within one or more of 26 specifically listed source categories. 40 CFR 51.301.

[4] Fuel sulfur content BART limits were also set for two process boilers and a line dryer at Tilden. Those limits are not impacted by this action.

[5] Stoichiometry refers to the relationship between the actual quantity of combustion air to the theoretical minimum quantity of air needed for 100 percent combustion of the fuel.

[6] Cliffs acquired ArcelorMittal Steel Production Company in 2020. Previously, Minorca was owned by ArcelorMittal and Hibbing was jointly owned by ArcelorMittal, Cliffs and United States Steel. Currently, Minorca is owned by Cliffs and Hibbing is jointly owned by Cliffs and United States Steel.

filed timely petitions for review of the Original FIP. ArcelorMittal and Cliffs also filed a joint motion seeking a stay of the Original FIP, which was granted by the Eighth Circuit on June 14, 2013.[7] ArcelorMittal, Cliffs, the State of Michigan, and others also submitted petitions for reconsideration of the Original FIP, pursuant to CAA section 307(d)(7)(B). 42 U.S.C. 7607(d)(7)(B).

On October 22, 2015 (80 FR 64160), in response to the petitions for reconsideration and due to new information submitted to EPA after promulgation of the Original FIP, EPA proposed to revise the Original FIP to revise NO_X and SO_2 emission limits for certain taconite facilities. On April 16, 2016 (81 FR 21672), EPA promulgated the final 2016 revised FIP (''2016 FIP''). With respect to NO_X, the emission limits in the 2016 FIP were based on information submitted to EPA by Cliffs and ArcelorMittal that suggested high-stoich LNBs, which formed the basis for the NO_X limits in the Original FIP, posed serious technical hurdles. In the 2016 FIP, EPA revised the NO_X emission limits for Tilden, Hibbing, Minorca, and UTAC, and set forth a process to confirm or modify those emission limits using continuous emissions monitoring system (CEMS) data that was to be collected after the installation of the selected low-NO_X technology. Under the 2016 FIP, the NO_X emission limits do not become enforceable until EPA confirms or modifies the emission limits in accordance with procedures set forth in the FIP. The NO_X emission limits in the 2016 FIP were based upon low-stoich LNBs (for grate kilns) and LNBs that utilize a combination of water and steam injection and pre-combustion technologies (for straight-grate kilns).

With respect to SO_2, EPA granted reconsideration of the SO_2 limit for Tilden's grate kiln due to information that became available after the close of the public comment period on the 2013 FIP regarding Tilden's intent to burn mixed fuels. Cliffs' intent to burn mixed fuels at Tilden was not considered in the Original FIP and would have led to an inability to meet the established BART limit. The 2016 FIP limits the sulfur content of the coal combusted on Tilden Line 1 and sets an SO_2 emission limit for the furnace.

Cliffs and ArcelorMittal filed petitions for review of the 2016 FIP due to a dispute over the UPL equation in the final rule. The 2016 FIP requirements for each facility are set forth in 40 CFR 52.1183 for Michigan and 40 CFR 52.1235 for Minnesota and discussed further in the remainder of this action.

II. Basis for NO_X Limits

The 2016 FIP set emission limits in pounds (lbs) of NO_X per million British Thermal Unit (MMBtu), based on a 30-day (720-hour) rolling average, and established a process to either confirm or modify the NO_X emission limits within established ranges based on CEMS data that Tilden, Hibbing, Minorca, and UTAC were required to submit to EPA by dates specified in the 2016 FIP.[8] The FIP also specified that the NO_X emission limits for these facilities would become enforceable only after EPA's confirmation or modification of the NO_X emission limits reflecting EPA's expectation that the owner or operator of each facility would provide the requisite data to EPA by the dates specified in the FIP. EPA's efforts to finalize NO_X emission limits for these facilities by the deadlines established in the FIP were complicated by several implementation issues, including challenges with installation of control technology, delays in receipt of requisite data, and emission limit modification requests not conforming to the requirements set forth in the FIP.

The NO_X emission limits established for each furnace and the ranges of limits allowable under the limit modification process are set forth in Table 1. As indicated in Table 1, the emission limits for certain furnaces vary by the type of fuel being used (natural gas or ''co-fire,'' which is a combination of natural gas and coal).

TABLE 1—NO_X LIMITS AND LIMIT MODIFICATION RANGES ESTABLISHED IN THE 2016 FIP

Furnace	Emission limit (lbs NO_X/MMBtu)	Emission limit modification range (lbs NO_X/MMBtu)
Tilden Line 1:		
Natural Gas	2.8	2.8–3.0
Co-fire	1.5	1.5–2.5
Hibbing Line 1	1.2	1.2–1.8
Hibbing Line 2	1.2	1.2–1.8
Hibbing Line 3	1.2	1.2–1.8
Minorca	1.2	1.2–1.8
UTAC Line 1:		
Natural Gas	2.8	2.8–3.0
Co-fire	1.5	1.5–2.5
UTAC Line 2:		
Natural Gas	2.8	2.8–3.0
Co-fire	1.5	1.5–2.5

For Tilden, Hibbing, Minorca, and UTAC, the process specified in the 2016 FIP to either confirm or modify the NO_X emission limits within the established ranges included the installation of a CEMS, submission of an engineering report to EPA, installation of NO_X reduction control technology, submission of pellet quality analyses to EPA, and submission to EPA of a report to either confirm or modify the limit. For any furnace without CEMS already installed, CEMS installation was required for each furnace by 6 months after May 12, 2016, and the owner or operator was required to submit quarterly CEMS data to EPA after May 12, 2016, for the time periods specified

[7] On November 15, 2016, the 8th Circuit Court of Appeals terminated the June 14, 2013, stay and extended the deadlines in the Original FIP by one day for each day the court's stay was in place. From the day the 2013 FIP was effective to the day it was stayed, 98 days elapsed (March 8, 2013, to June 14, 2013). See Order dated November 15, 2016, in response to U.S. EPA's Petition to reconsider the Original FIP, EPA–R05OAR–2017–0066–0009 (8th Cir. 2016). As a result, the deadlines contained in the Original FIP still apply (*e.g.,* 6 months after March 8, 2013), only now from the date the stay was terminated, minus the number of days that elapsed prior to the stay being issued.

[8] Taconite facilities typically operate 24 hours per day and 720 is the number of hours in a 30-day period; therefore, a 720-hour average is essentially equivalent to a 30-day average.

below in Table 2. Engineering reports containing detailed engineering analyses and modeling of the selected NO_X reduction technology for each furnace demonstrating that the technology was designed to meet an emission limit equal to the lower bound of the established range were required to be submitted to EPA by the deadlines specified in Table 2. NO_X reduction technology was required to be installed two months after the engineering report submission deadline. Beginning on the earlier of six months after the installation of NO_X reduction technology or the deadline for installation of the NO_X reduction technology, the owner or operator was required to submit quarterly pellet quality analyses to EPA, including an explanation of causes for pellet samples that failed to meet the acceptable range for any pellet quality analysis factor, for the time periods specified in Table 2. At the end of the CEMS and pellet quality data collection periods, the owner or operator of each furnace may submit a report to EPA to either confirm or modify the NO_X limits within the bounds described in the 2016 FIP (and above in this section). The 2016 FIP also allows the owner or operator to submit a report proposing a single NO_X limit for all fuels. The process for confirming or modifying limits detailed in the 2016 FIP specifies that EPA's determinations shall be based on the appropriate UPL equation, using CEMS data that meet pellet quality specifications and proper furnace/burner operation. For a more detailed description of the process set forth in the 2016 FIP to confirm or modify the emission limits, *see* 40 CFR 52.1183 and 40 CFR 52.1235.

TABLE 2—TIMELINES OF PROCESSES TO CONFIRM OR MODIFY LIMITS

Furnace	Period of CEMS data required for submission to EPA	Engineering report deadline	NO_X reduction technology installation deadline	Period of pellet quality data required for submission to EPA*	Report to confirm or modify limit deadline
	Months after May 12, 2016				
Tilden Line 1	0–57	48	50	50–57	57
Hibbing Line 1	6–34	24	26	26–34	34
Hibbing Line 2	6–52	42	44	44–52	52
Hibbing Line 3	6–57	48	50	50–57	57
Minorca's Indurating Furnace	6–52	42	44	44–52	52
UTAC Line 1	0–34	24	26	26–34	34
UTAC Line 2	0–52	42	44	44–52	52

*If the owner or operator installed NO_X reduction technology more than six months before the required date, pellet quality analyses were required to be submitted to EPA beginning six months after installation.

The 2016 FIP incorporates two UPL equations to calculate emission limits. The appropriate equation is determined by the statistical distribution of the hourly CEMS data. If the data are normally distributed and statistically independent, the equation in 40 CFR 52.1183(p)(1) and 40 CFR 52.1235(f)(1) is used. If the data are not normally distributed or are normally distributed but not statistically independent, the non-parametric equation in 40 CFR 52.1183(p)(2) and 40 CFR 52.1235(f)(2) is used. None of the CEMS data submitted are normally distributed and statistically independent, therefore the non-parametric equation is the applicable equation for all limit setting in this action.[9]

The non-parametric equation in the 2016 FIP calculates a 95th percentile UPL by ranking 720-hour averages of NO_X emissions in lbs/MMBtu from lowest to highest and identifying the value at the 95th percentile of the data set as the UPL and emission limit.[10] While a 95th percentile UPL establishes an emission rate that a source is predicted to be below during at least 95 out of 100 averaging periods, it was not EPA's intent to set a limit that a source would be expected to exceed five percent of the time once the limit was in place. Rather, EPA used the 95th percentile UPL to ensure that the final emission limits would be consistent with the actual emission reduction capabilities of the BART controls, as required by 40 CFR 51.301, which defines BART as ''the degree of reduction achievable.'' [11] EPA expected that during the eight-month CEMS data collection period, furnace operators would be adjusting numerous variables to optimize control technology performance, which would result in higher emissions at times during the initial ''shakedown'' period. Once the eight-month data collection period was over, EPA expected that the operators would have gained sufficient experience to run the furnaces and control technologies with fewer adjustments, meaning less emission variations and lower emissions overall. EPA selected the 95th percentile UPL to ensure the elevated emissions expected during the initial shakedown period would not become the basis for final emission limits.

However, once continuous data collection began, the CEMS data did not show the expected elevated emissions levels during the shakedown period and emissions were not consistently lower toward the end of the data collection period as compared to the beginning of the period.[12] Therefore, EPA has

[9] Data distribution analyses are available in the docket for this action.

[10] Taconite facilities typically operate 24 hours per day and 720 is the number of hours in a 30-day period; therefore, a 720-hour average is essentially equivalent to a 30-day average. For facilities that both burn natural gas exclusively and co-fire with coal, *i.e.,* Tilden and UTAC, a 30-day period may involve operation with only natural gas as well as operation with co-firing of coal. Therefore, the 2016 FIP established UPL equations based on 720-hour averages to allow for the separation of hours when burning only natural gas from hours when co-firing with coal. When calculating an emission limit that applies only when burning natural gas, emissions are averaged over 720 successive hours in which the unit burns only natural gas. When calculating a co-firing emission limit, emissions are averaged over 720 successive hours in which the unit burns a gas/coal mix. All emission limit modifications were calculated based on 720-hour averages, consistent with the equations at 40 CFR 52.1183(p) and 40 CFR 52.1235(f). However, EPA is proposing modified emission limits in the form of a 30-day average if the facility burns only one fuel or if the modified limit applies to all fuels. In those circumstances, there is no need to be able to separate the hourly data to determine compliance with the emission limit.

[11] April 16, 2016, 81 FR 21672, 21680.

[12] See emission limit calculation files in the docket for this action.

determined that using the UPL equation at the 99th percentile is more appropriate to establish an emission limit consistent with the actual emission reduction capabilities of the BART controls and is proposing to modify the UPL equations used to calculate both the NO_X and SO_2 emission limits to reflect use of the 99th percentile. The emission limits EPA is proposing in this action were calculated using the UPL equations at 40 CFR 52.1183(p) and 40 CFR 52.1235(f) at the 99th percentile.[13]

A. Tilden

For Tilden's indurating furnace, Tilden Line 1 (EUKILN1), the 2016 FIP established a specific NO_X BART emission limit of 2.8 pounds of NO_X/MMBtu when burning natural gas, while allowing for potential modification of the limit within the range of 2.8–3.0 lbs NO_X/MMBtu. Similarly, the 2016 FIP established a specific NO_X BART emission limit of 1.5 lbs NO_X/MMBtu when co-firing coal and natural gas, with an allowance for potential modification of the limit within the range of 1.5–2.5 lbs NO_X/MMBtu.[14] The 2016 FIP also allowed for the establishment of a single NO_X limit for all fuels.[15]

Tilden submitted a partially complete engineering report on May 21, 2020, and submitted the final engineering report on July 30, 2020. Tilden implemented low-stoichiometry LNBs designed to achieve an emission rate of 2.8 lbs NO_X/MMBtu when firing exclusively natural gas and 1.5 lbs NO_X/MMBtu when co-firing with coal, as described in the engineering report submitted to EPA.

On February 12, 2021, Tilden submitted a report requesting modification of the NO_X limits for Line 1 pursuant to 40 CFR 52.1183 (k)(1)(vi). Tilden requested an emission limit of 3.0 lbs NO_X/MMBtu for all fuels. Tilden's limit modification request was accompanied by CEMS data (in 30-day rolling averages) from September 12, 2020, to February 2, 2021. On May 21, 2021, Tilden provided hourly emission data for July 1, 2020, to February 11, 2021. Approximately half of these data were collected when Tilden was co-firing with coal and half were collected when Tilden was burning exclusively natural gas. Tilden demonstrated that when burning natural gas, NO_X emission rates recorded were higher than the modeling results presented in the engineering report, and above the high end of the limit range established in the 2016 FIP (2.8–3.0 lbs/MMBtu). The CEMS data submitted to EPA when burning coal recorded emission rates within the range specified in the 2016 FIP (1.5–2.5 lbs/MMBtu). Tilden explained that the furnace is unable to achieve 3.0 lbs NO_X/MMBtu when burning exclusively natural gas and would need to burn a minimum of 80% coal when co-firing to meet a limit of 2.0 lbs NO_X/MMBtu. Tilden stated a preference to maximize natural gas usage and supplement with solid fuel as needed to meet NO_X limits.[16]

The 2016 FIP provides Tilden the option to propose, for EPA's consideration and approval, a single NO_X emission limit for all fuels based on a 30-day rolling average. Citing the CEMS data, Tilden requested a revised NO_X BART limit of 3.0 lbs NO_X/MMBtu for all fuels that would apply on a rolling 30-day average, contending that this emission limit is the most stringent limit that can be met without substantial increases in coal usage, while maintaining pellet quality standards.

Based on the equation set forth at 40 CFR 52.1183(p)(2), EPA calculated a 720-hour average NO_X emission limit of 3.8 lbs NO_X/MMBtu when burning exclusively natural gas, and separately, an emission limit of 1.9 lbs NO_X/MMBtu when burning mixed fuel.[17] While CEMS data show the installed emission control measures reduced NO_X emissions, the selected technology failed to achieve emission rates within the specified FIP ranges when burning only natural gas (2.8–3.0 lbs NO_X/MMBtu). Using the non-parametric equation with the full data set, unseparated by fuel type, EPA calculated a 720-hour average UPL of 3.7 lbs NO_X/MMBtu. EPA evaluated these CEMS data and considered Tilden's requested single NO_X emission limit of 3.0 lbs NO_X/MMBtu for all fuels based on a 30-day rolling average, as allowed at 40 CFR 52.1183(k)(1)(viii). EPA has concluded that Tilden's requested emission limit of 3.0 lbs NO_X/MMBtu for all fuels based on a 30-day rolling average is appropriate and reflects BART. It allows Tilden to select a fuel mix that maximizes natural gas usage and minimizes coal usage if the facility so chooses without exceeding the natural gas emission limit range established in the 2016 FIP. This has the duel environmental (visibility) benefit of minimizing NO_X emissions by setting an emissions limit that is below the calculated natural gas-only rate, and also potentially minimizing the use of coal and the associated SO_2 emissions from coal burning. Therefore, based on these data and as provided at 40 CFR 52.1183(k)(1)(viii), EPA is proposing that a modified limit of 3.0 lbs NO_X/MMBtu for all fuels, with compliance to be determined on a rolling 30-day average basis, reflects BART for the Tilden Line 1 indurating furnace.

B. Hibbing

For Hibbing Lines 1, 2, and 3, the 2016 FIP established NO_X BART emission limits of 1.2 lbs NO_X/MMBtu that applied to each furnace individually, with provisions allowing for potential modification of the limits within the range of 1.2–1.8 lbs NO_X/MMBtu.[18]

Hibbing implemented the NO_X reduction measures described in its engineering report, submitted to EPA on May 11, 2018, identified as LNBs in conjunction with water injection, at Hibbing Lines 1, 2, and 3. Hibbing installed CEMS on Lines 1, 2, and 3 and provided EPA with hourly NO_X emissions data on March 12, 2019, September 11, 2020, and February 12, 2021, for Lines 1, 2 and 3, respectively, documenting actual emissions after installation of LNB technology. Hibbing's submittals included CEMS data from July 12, 2018, to March 11, 2019, for Line 1; January 12, 2020, through September 1, 2020, for Line 2; and August 3, 2020, to February 11, 2021, for Line 3. The hourly CEMS data identified hours excluded from the limit-setting calculations because pellets failed to meet pellet quality specifications. Although the limit-setting period for Line 3 established in the 2016 FIP began August 3, 2020, Line 3 did not operate during the period between July 12 to August 3, 2020, due to COVID-related reasons. Line 2 did not operate from May 1, 2020, to July 31, 2020, during the limit setting period for similar reasons. On November 25, 2020, Hibbing provided additional information requested by EPA, including hourly CEMS data for Lines 1, 2, and 3 in Excel format to facilitate independent calculation of emission limits and identification of hours when the burner was not operated within the parameters modeled in the engineering report.

The requirements at 40 CFR 52.1235((b)(1)(ii)(A)(6), (B)(6), and (C)(6) set forth the process for submitting data to support limit modifications under the 2016 FIP. At the time of the initial

[13] Data analyses and emissions calculations are available in the docket for this action.

[14] 40 CFR 52.1183(k)(1).

[15] 40 CFR 52.1183(k)(1)(viii).

[16] *See* ''Tilden NO_X limit modification report (Feb. 12, 2021)_Redacted.pdf,'' available in the docket for this action.

[17] *See* Tilden Emission Limit Calculations, available in the docket for this action.

[18] *See* 40 CFR 52.1235((b)(1)(ii).

CEMS data submissions, Hibbing requested NO_X emission limits of 1.7, 1.5, and 1.6 lbs NO_X/MMBtu on Lines 1, 2, and 3, respectively. The facility cited sub-zero temperatures and other factors that may have affected the calculated emission rates and restricted production. Further, Hibbing provided regression analyses assessing the relationship between furnace feed rates and NO_X emission rates during the limit-setting periods to support the requested limit increases.

On October 22, 2021, Hibbing submitted a request to EPA to establish a crossline average emission limit for Lines 1, 2, and 3 of 1.6 lbs NO_X/MMBtu, with compliance to be determined on a 30-day rolling average basis. The submittal included hourly CEMS data for the same time periods as Hibbing's initial limit modification submittals and a regression analysis assessing the relationship between furnace feed rates and NO_X emission rates during the limit-setting periods to support the requested limit increases. The hourly CEMS data submitted to EPA included a description of the failure analyses identifying potential reasons for pellets failing to meet pellet quality specifications for hours excluded in the limit-setting calculation.

There is no basis in the FIP for adjusting emission limits to account for possible future production levels based upon an assumed correlation between feed rates and emissions. Therefore, in accordance with 40 CFR 52.1235(f)(2), EPA calculated 720-hour average NO_X emission limits of 1.5 lbs NO_X/MMBtu for Line 1, 1.4 lbs NO_X/MMBtu for Line 2, and 1.5 lbs NO_X/MMBtu for Line 3.[19] Under the BART Guidelines, a source may be permitted to '' 'average' emissions across any set of BART-eligible emission units within a fenceline, so long as the emission reductions from each pollutant being controlled for BART would be equal to those reductions that would be obtained by simply controlling each of the BART-eligible units that constitute BART-eligible sources.'' [20] EPA averaged the single line limits described above and calculated a crossline 720-hour average emission limit of 1.5 lbs NO_X/MMBtu. The NO_X controls have been installed and are being operated on all three lines. Based on EPA's analysis, this crossline average emission limit is equal to the reductions that would be obtained by controlling each line separately. Therefore, based on these data and as provided at 40 CFR 52.12335(b)(1)(ii)(A)(7), (B)(7), and (C)(7), and consistent with 40 CFR 51.308(e) and 40 CFR part 51, appendix Y, at V, EPA is proposing that a crossline average emission limit of 1.5 lbs NO_X/MMBtu for Hibbing Lines 1, 2, and 3, with compliance to be determined on a 30-day rolling average basis, reflects NO_X BART for Hibbing Lines 1, 2, and 3.

C. Minorca

For Minorca's indurating furnace, the 2016 FIP established a NO_X BART emission limit of 1.2 lbs NO_X/MMBtu, while allowing for potential modification of the limit within the range of 1.2–1.8 lbs NO_X/MMBtu.[21]

On November 12, 2019, Minorca submitted an engineering report to EPA which identified the low NO_X technology to be installed on Line 1 as an LNB, water injection, and utilization of specific operating parameters. The combined use of these measures was projected to meet an emission limit of 1.2 lbs NO_X/MMBtu based on a 30-day average. On September 11, 2020, Minorca submitted CEMS data for the period January 12, 2020, to September 10, 2020, excluding the CEMS values that did not meet pellet quality specifications, consistent with the 2016 FIP.[22]

On October 22, 2021, Minorca submitted supplemental information consisting of 720-hour averages of CEMS data from January 12, 2020, through September 30, 2021. Adding the data from September 10, 2020, through September 30, 2021, to the original data set, Minorca calculated an emission limit of 1.6 lbs NO_X/MMBtu using the equation at 40 CFR 52.1235(f)(2). Minorca then performed a regression analysis assessing the relationship between furnace pellet production rates and NO_X emission rates during the limit-setting period to support the requested limit increase. Minorca cited the climate in Minnesota and other factors that may have affected production rates in its explanation of why the emission limit should be adjusted to 1.7 lbs NO_X/MMBtu.

Based on the non-parametric equation at 40 CFR 52.1235(f)(2), EPA evaluated the 720-hour average NO_X emission data for the full data set submitted and calculated an emission limit of 1.6 lbs NO_X/MMBtu.[23] There is no basis in the FIP for adjusting emission limits to account for possible future production levels based upon an assumed correlation between feed rates and emissions. Therefore, based on these data and as provided at 40 CFR 52.1235(b)(1)(v)(7), EPA is proposing that a modified limit of 1.6 lbs NO_X/MMBtu, with compliance to be determined on a rolling 30-day average basis, reflects BART for the Minorca Line 1 indurating furnace.

D. UTAC

For UTAC's indurating furnaces, Grate Kiln Line 1 (EU040) and Grate Kiln Line 2 (EU042), the 2016 FIP established specific NO_X BART limits of 2.8 pounds of NO_X/MMBtu when burning natural gas, while allowing for potential modification of the limits within the range of 2.8–3.0 lbs NO_X/MMBtu. Similarly, the 2016 FIP established specific NO_X BART limits of 1.5 lbs NO_X/MMBtu when co-firing coal and natural gas, while allowing for potential modification of the limits within the range of 1.5–2.5 lbs NO_X/MMBtu.[24] The 2016 FIP also allowed for the establishment of a single NO_X limit for all fuels.

UTAC submitted an engineering report for Line 1 on May 11, 2018. UTAC installed and began operating the sub-stoichiometric staged combustion LNB designed to achieve an emission rate of 2.8 lbs NO_X/MMBtu when firing exclusively natural gas and 1.5 lbs NO_X/MMBtu when co-firing with coal, as described in the engineering report submitted to EPA. UTAC subsequently made modifications to the Line 1 LNB in September 2018. On March 12, 2019, UTAC submitted a report requesting modification of the co-firing NO_X limit for Line 1 to 2.5 lbs NO_X/MMBtu, based upon 720-hour averages from February 2019.

On November 12, 2019, UTAC submitted a report to EPA to address the requirement for an engineering report for Line 2. On November 12, 2021, UTAC submitted information on the LNB selected for Line 2, a modified version of the LNB installed on Line 1. This submittal included a report on computational fluid dynamics modeling demonstrating the burner was designed to achieve an emission rate of 2.8 lbs NO_X/MMBtu when firing exclusively natural gas and 1.5 lbs NO_X/MMBtu when co-firing with coal. On April 11, 2023, UTAC submitted an analysis of Line 1 and Line 2 NO_X performance

[19] *See* Hibbing Emission Limit Calculations, available in the docket for this action.

[20] 40 CFR part 51, appendix Y, at V.

[21] *See* 40 CFR 52.1235((b)(1)(v).

[22] CEMS data in the September 11, 2020, submittal was presented as 720-hour rolling averages. On November 25, 2020, Minorca provided the hourly CEMS data for the same January 12, 2020, to September 10, 2020, time period to allow for independent calculation of 720-hour averages.

[23] *See* Minorca Emission Limit Calculations, available in the docket for this action.

[24] 40 CFR 52.1235(b)(1)(iv).

post LNB installations and requested a crossline average limit of 3.0 lb NO_X/MMBtu for all fuels, based on a 30-day rolling average. Along with the analysis, UTAC submitted 720-hour averages of total lbs NO_X/MMBtu for Lines 1 and 2 combined for the time period of January 25, 2022, to March 26, 2023. UTAC also submitted hourly CEMS and process information for this time period, which UTAC claimed as confidential business information, so that EPA could verify the calculations.

Based on the equation set forth at 40 CFR 52.1235(f)(2), EPA calculated 720-hour average NO_X emission limits of 2.3 lbs NO_X/MMBtu and 3.6 lbs NO_X/MMBtu when burning exclusively natural gas for Lines 1 and 2, respectively. Separately, EPA calculated an emission limit of 3.1 lbs NO_X/MMBtu when burning mixed fuel on Line 2. There were 475 hours of co-firing data for Line 1, which is not sufficient to calculate a 720-hour average NO_X emission limit. EPA also calculated an emission limit of 3.1 lbs NO_X/MMBtu when combining hourly emissions data for both lines and all fuels.[25] While CEMS data show the installed emission control measures reduced NO_X emissions, the selected technology failed to achieve emission rates within the specified FIP ranges, particularly when evaluating separate limits for each fuel type.

As discussed in II.*B.,* under the BART Guidelines, a source may be permitted to '' 'average' emissions across any set of BART-eligible emission units within a fenceline, so long as the emission reductions from each pollutant being controlled for BART would be equal to those reductions that would be obtained by simply controlling each of the BART-eligible units that constitute BART-eligible sources.'' [26] EPA evaluated the CEMS data and considered UTAC's requested crossline average NO_X emission limit of 3.0 lbs NO_X/MMBtu for all fuels, for Lines 1 and 2, with compliance to be determined on a 30-day rolling average basis. Based on EPA's analysis, this crossline average emission limit is equal to the reductions that would be obtained by controlling each line separately and is within the natural gas NO_X emission limit range established in the 2016 FIP. A single fuel-neutral emission limit allows UTAC to select a fuel mix that maximizes natural gas usage and minimizes coal usage without exceeding the natural gas emission limit range established in the 2016 FIP. This has the dual environmental (visibility) benefit of minimizing NO_X emissions by setting an emissions limit that is below the calculated natural gas-only rate, and also potentially minimizing the use of coal and the associated SO_2 emissions from burning coal. Therefore, based on these data and as provided at 40 CFR 52.1235(b)(1)(iv)(A)(8) and (B)(8), and consistent with 40 CFR 51.308(e) and 40 CFR part 51, appendix Y, at V, EPA is proposing that a crossline emission limit of 3.0 lbs NO_X/MMBtu for all fuels for UTAC Lines 1 and 2, based on a rolling 30-day average, reflects BART for UTAC Lines 1 and 2.

III. Basis for SO_2 Limits

As previously described, the Original FIP determined that existing controls reflected SO_2 BART for Minorca, Hibbing, and Northshore, and established SO_2 emission limits for each furnace, with the option or requirement, depending on the facility, that the owner or operator submit one year of CEMS data to EPA to set a revised SO_2 emission limit calculated using the appropriate UPL equation. The 2016 FIP limited the sulfur content of the coal burned at Tilden, set an SO_2 emission limit, and required Tilden to submit one year of CEMS data to EPA to set a revised SO_2 emission limit calculated using the appropriate UPL equation. For a more detailed description of the existing SO_2 emission limits and the process set forth to modify the emission limits, *see* 40 CFR 52.1235 (Hibbing, Minorca, and Northshore) and 40 CFR 52.1183 (Tilden). As discussed above in II., EPA has calculated the emission limits using the appropriate UPL equation at the 99th percentile.

A. Tilden

For Tilden, the 2016 FIP established a specific SO_2 BART emission limit of 500 pounds of SO_2 per hour (lbs/hr) for Grate Kiln Line 1, with no more than 0.60 percent sulfur by weight based on a monthly block average for any coal usage. The 2016 FIP also required that the owner or operator of Tilden calculate an SO_2 emission limit based on one year of hourly CEMS emissions data using the appropriate UPL equation provided in 40 CFR 52.1183(p) and submit such calculations and data to EPA by 36 months after May 12, 2016. The 2016 FIP provides that EPA may revise the emission limit downward to reflect the calculated SO_2 emission rate; however, EPA may not increase the SO_2 limit above 500 lbs SO_2/hr.

On October 1, 2018, Tilden submitted SO_2 emissions data to EPA reflecting Tilden burning exclusively natural gas during the period March 28, 2017, through March 27, 2018. Citing various production-related concerns, Tilden adjusted its calculated limit to account for expected higher production capacity and higher ore sulfur content, which resulted in an adjusted expected emission rate of 568 lbs SO_2/hr. Tilden requested an SO_2 emission limit of 500 lbs/hour for all fuels, regardless of natural gas or coal fuel usage, as established in the 2016 FIP. On November 10, 2022, Tilden submitted hourly SO_2 data for Line 1 from the same time period of March 28, 2017, through March 27, 2018, during which time Tilden was exclusively burning natural gas. On March 1, 2023, Tilden provided hourly co-firing CEMS data for July 12, 2018, through July 11, 2019. On March 30, 2023, Tilden provided hourly CEMS data for the time period March 27, 2018, through March 26, 2019, which included both co-firing and natural gas-only operation.

The 2016 FIP established a single SO_2 emission limit to apply regardless of natural gas or coal fuel usage, which Tilden must meet at all times. Consistent with this approach, and because SO_2 emissions are higher when Tilden is co-firing and the emission limit must be met at all times, EPA is proposing to base the emission limit modification calculations on all co-firing data included in Tilden's March 1, 2023, and March 30, 2023, CEMS data submissions. Based on the equation set forth at 40 CFR 52.1183(p)(2), EPA calculated an emission limit of 189 lbs SO_2/hour consistent with this approach.[27] There is no basis in the FIP for adjusting emission limits to account for possible future production levels or possible higher ore sulfur content. Therefore, based on these data and as provided at 40 CFR 52.1183(k)(3), EPA is proposing that an SO_2 limit of 189 lbs SO_2/hr for the Tilden Line 1 indurating furnace, with compliance to be determined on a 30-day rolling average basis, reflects SO_2 BART for Tilden Line 1.

B. Hibbing

For Hibbing Lines 1, 2, and 3, the Original FIP set an aggregate emission limit of 247.8 lbs SO_2/hr, based on a 30-day rolling average and excluding emissions resulting from the combustion of fuel oil, and provided Hibbing the option of calculating a revised SO_2 emission limit by 20 months after March 8, 2013, based on one year of hourly CEMS emissions data and the non-parametric UPL equation. If any fuel oil is burned after the first day

[25] *See* United Taconite Emission Limit Calculations, available in the docket for this action.

[26] 40 CFR part 51, appendix Y, at V.

[27] *See* Tilden Emission Limit Calculations, available in the docket for this action.

that SO_2 CEMS were required to be operational, the 2016 FIP requires Hibbing to submit the gallons of fuel oil burned per hour, the sulfur content of the fuel oil, and the SO_2 emissions in pounds per hour, so that EPA can establish an SO_2 emissions limit for fuel oil. Hibbing chose not to calculate a revised SO_2 emission limit.[28]

C. Minorca

For Minorca, the Original FIP set an emission limit of 38.16 lbs SO_2/hour, based on a 30-day rolling average and excluding emissions when Minorca is combusting fuel oil, with an allowance for potential modification of the limit based on one year of hourly CEMS data submitted to EPA by 20 months after March 8, 2013. If any fuel oil is burned after the first day that SO_2 CEMS were required to be operational, the 2016 FIP requires Minorca to submit the gallons of fuel oil burned per hour, the sulfur content of the fuel oil, and the SO_2 emissions in pounds per hour so that EPA can establish an SO_2 emissions limit for fuel oil.

On April 6, 2018, Minorca submitted a request to modify the SO_2 limit established in the 2016 FIP. Minorca ranked hourly data from the period March 1, 2017, through March 31, 2018, adjusted the calculated limit based on potential increased production rates, and requested an emission limit of 73.79 lbs SO_2/hour. On October 14, 2019, Minorca submitted additional hourly SO_2 CEMS emission data for the time period of September 8, 2018, through September 7, 2019, revising their request to an emission limit of 208.66 lbs SO_2/hr. Minorca adjusted the calculated limit based on potential increased production rates, maximum ore sulfur content based on a ratio of maximum percent sulfur, and pellet type.

Using the equation set forth at 40 CFR 52.1235(f)(2) and the most recent CEMS data from September 8, 2018, through September 7, 2019, EPA calculated an SO_2 emission limit of 68.2 lbs SO_2/hour.[29] There is no basis in the FIP for adjusting emission limits to account for possible future production levels or possible higher ore sulfur content. Therefore, based on these data and as provided at 40 CFR 52.1235(b)(2)(v) and 40 CFR 51.308(e), EPA is proposing that an emission limit of 68.2 lbs SO_2/hr, based on a 30-day rolling average, reflects SO_2 BART for the Minorca indurating furnace.

D. Northshore

For Northshore, the Original FIP set an aggregate emission limit of 39.0 lbs SO_2/hour for Furnace 11 (EU100/EU104) and Furnace 12 (EU110/EU114), based on a 30-day rolling average and excluding emissions resulting from the combustion of fuel oil, with a requirement that the owner or operator calculate a revised limit based on one year of hourly CEMS data and submit such data and calculations to EPA by 20 months after March 8, 2013.

On April 11, 2018, Northshore submitted an SO_2 emission limit modification request which included CEMS data from January 16, 2017, through January 15, 2018. Northshore adjusted the calculated emission limit based on potential increased production rates and requested a limit of 22.1 lbs SO_2/hour.

On November 21, 2018, Northshore submitted a revised limit modification request of 49 lbs SO_2/hr. This limit modification request included data for the time period of January 16, 2017, through January 15, 2018, and adjusted the calculated limit based on potential increased production rates and potential increases in ore sulfur content. On November 10, 2022, Northshore submitted hourly SO_2 CEMS data for the period of January 16, 2017, through January 15, 2018, as requested by EPA, to allow for EPA's independent calculation of emission limits.

Using the equation set forth at 52.1235(f)(2) and the hourly SO_2 CEMS data from January 16, 2017 through January 15, 2018, EPA calculated an aggregate SO_2 emission limit of 17.0 lbs SO_2/hour for Furnaces 11 and 12.[30] There is no basis in the FIP for adjusting emission limits to account for possible future production levels or possible higher ore sulfur content. Therefore, based on these data and as provided at 40 CFR 52.1235(b)(2)(vi), EPA is proposing that an aggregate SO_2 emission limit of 17.0 lbs SO_2/hr for Northshore Furnaces 11 and 12, based on a 30-day rolling average, reflects SO_2 BART for Northshore.

IV. CAA Section 110(l)

Under CAA section 110(l) (sometimes referred to as an ''anti-backsliding'' provision), EPA cannot approve a plan revision ''if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 7501 of this title), or any other applicable requirement of this chapter.'' Based on the following analysis, we find that our revisions to the 2016 FIP are consistent with CAA section 110(l) because they will not interfere with any applicable requirement concerning attainment or reasonable further progress or any other applicable requirements of the CAA.

A. NO_X Emission Limits

When the 2016 FIP was promulgated, NO_X control technology had not yet been installed on the furnaces at Tilden, Hibbing, Minorca, and UTAC. Therefore, EPA established initial emission limitations based on the modeled (estimated) performance of the proposed technology along with a procedure to refine and modify the emission limits within a specified range based upon CEMS data collected after installation of the NO_X control technology. The 2016 FIP also allowed for the establishment of a single NO_X limit for all fuels. However, the NO_X emission limits in the 2016 FIP are not enforceable and final until EPA takes action to confirm or modify the initial emission limits established in the 2016 FIP. Because the NO_X limits established in the 2016 FIP have not been confirmed and made enforceable through the procedures set forth in the 2016 FIP, and are not currently enforceable, the proposed NO_X emission limits do not alter any existing enforceable limits, since there are no current enforceable limits. Therefore, approval of the proposed NO_X limits would not interfere with any applicable requirement concerning attainment or reasonable further progress, or any other applicable requirement of the CAA.

Additionally, even if EPA were to evaluate the proposed NO_X emission limits in relation to the relevant provisions of the 2016 FIP, we believe the FIP will not interfere with any applicable requirement concerning attainment or reasonable further progress, or any other applicable requirements of the CAA.[31] EPA's proposed action will complete the process set forth in the 2016 FIP to finalize enforceable NO_X emission limits for Tilden, Hibbing, UTAC, and Minorca within ranges previously established. The NO_X emission limits EPA is proposing reflect BART because they were calculated using the corrected UPL equation and actual emission data recorded by CEMS, after installation of the required low-NO_X technology, pursuant to the procedures set forth in

[28] While Hibbing's SO_2 BART limit is not being modified, the regulatory text at 40 CFR 52.1235(b)(2)(ii) is being revised to remove the original limit modification provisions and clarify that Hibbing's SO_2 BART limit is final.

[29] *See* Minorca Emission Limit Calculations, available in the docket for this action.

[30] *See* Northshore Emission Limit Calculations, available in the docket for this action.

[31] 40 CFR 52.1183(k)(1)(viii), 52.1235(b)(1)(iv)(A)(8) and 52.1235(b)(1)(iv)(B)(8).

the 2016 FIP. While crossline averaging was not addressed in the 2016 FIP, under the BART Guidelines, a source may be permitted to '' 'average' emissions across any set of BART-eligible emission units within a fenceline, as long as the emission reductions from each pollutant being controlled for BART would be equal to those reductions that would be obtained by simply controlling each of the BART-eligible units that constitute BART-eligible sources.'' [32] Based on EPA's analysis, the crossline average emission limits proposed for Hibbing and UTAC are equal to the reductions that would be obtained by controlling each line separately.

The proposed NO_X emission limits do not reflect a change in EPA's BART determination. Rather, the proposed limits were calculated using CEMS data and the corrected UPL equation, following the procedure set forth in the 2016 FIP, to more accurately reflect an emission limit consistent with the actual emission reduction capabilities of the BART controls and within the natural gas ranges established in the 2016 FIP. Therefore, there are no expected increases in NO_X emissions compared to the ranges set in the 2016 FIP.

B. SO_2 Emission Limits

EPA is proposing to revise the SO_2 emission limits applicable to Minorca, Northshore, and Tilden. Minorca and Northshore are straight-grate furnaces that do not co-fire with coal; SO_2 emissions from these sources result from sulfur in the ore processed in the furnaces. As discussed previously, when the Original FIP was promulgated, SO_2 BART for Minorca and Northshore was established as no further controls. EPA set initial SO_2 emission limits based on limited stack test data and established a procedure to refine those limits when CEMS data became available. EPA is proposing to modify the Minorca emission limit from 38.16 lbs SO_2/hour to 68.2 lbs SO_2/hour and the Northshore emission limit from 39.0 lbs SO_2/hour to 17.0 lbs SO_2/hour. These proposed revised emission limits do not reflect a change in EPA's BART determination or in operations at the facilities that would lead to an increase or decrease in SO_2 emissions. Rather, the emission limits EPA is proposing establish emission limits that more accurately reflect BART because they were calculated using the corrected UPL equation and actual emission data recorded by CEMS, pursuant to the procedures set forth in the Original FIP.

Similarly, the 2016 FIP established SO_2 BART for Tilden as a limit on the sulfur content of the coal and no further controls, and set an SO_2 emission limit for Tilden along with a process to modify that limit when CEMS data became available. EPA is not proposing to revise any limits on the sulfur content of coal at Tilden. EPA is only proposing to modify Tilden's emissions limit from 500 lbs SO_2/hour to 189 lbs SO_2/hour. The revised emission limit was calculated using the corrected UPL equation and actual emission data recorded by CEMS, pursuant to the procedures set forth in the 2016 FIP.

In sum, as a result of the revised SO_2 emissions limits described above, EPA does not expect changes in SO_2 emissions from these sources. The limits do not reflect a change in EPA's BART determination or in operations at the facilities. Rather, the proposed limits more accurately reflect actual emissions that were calculated using newly available CEMS data and the corrected UPL equation.

C. Regional Haze SIPs

On June 12, 2012 (77 FR 34801), EPA approved Minnesota's regional haze plan for the first implementation planning period as satisfying the applicable requirements in 40 CFR 51.308, except for BART emission limits for the taconite facilities. Among the regional haze plan elements approved were Minnesota's long-term strategy for making reasonable progress toward visibility goals. Minnesota's long-term strategy did not rely on the achievement of any particular degree of emission control from the taconite plants to achieve reasonable progress goals.

On December 3, 2012 (77 FR 71533), EPA approved Michigan's regional haze plan for the first implementation planning period as satisfying the applicable requirements in 40 CFR 51.308, except for BART emission limits for Tilden, St. Mary's Cement, and Escanaba Paper Company. Among the regional haze plan elements approved was Michigan's long-term strategy for making reasonable progress toward visibility goals. Michigan's long-term strategy did not rely on the achievement of any particular degree of emission control from the taconite plants to achieve reasonable progress goals.

On August 23, 2021, Michigan submitted a revision to their regional haze SIP for the second implementation planning period. Michigan's submittal provided a long-term strategy and reasonable progress goals that included 2028 emission projections for Tilden based on a 2016 modeling platform developed by LADCO that did not rely on emission limits or ranges in the 2016 FIP.

On December 20, 2022, Minnesota submitted a revision to its regional haze SIP for the second implementation period. Minnesota's long-term strategy included implementation of the current applicable limits and ranges in the Original FIP and 2016 FIP for Hibbing, Minorca, UTAC, and Northshore. However, in applying the long-term strategy to develop its reasonable progress goals, Minnesota used 2028 projected emissions modeling that relied on the 2016 FIP limits only for UTAC and not for Hibbing, Minorca, or Northshore. For Hibbing and Minorca, Minnesota's modeling utilized 2028 projected emissions provided by LADCO using the 2016 emissions modeling platform since CEMS data was not available at the time. For Northshore, Minnesota accounted for the facility being idled until 2031, which was incorporated into an enforceable agreement as an Administrative Order by Consent issued by the Minnesota Pollution Control Agency to Northshore and Cleveland-Cliffs, Inc. To project 2028 emissions for UTAC, Minnesota used 2017 CEMS data to convert NO_X and SO_2 emissions and associated heat input into emission rates that allowed for a comparison to the limits and ranges in the 2016 FIP. Minnesota kept heat input rates the same and assumed compliance at the least stringent end of the emission limit ranges (*e.g.,* for an emission limit range of 2.8–3.0 lbs NO_X/MMBtu, Minnesota assumed 3.0 lbs NO_X/MMBtu in the emission calculations), resulting in conservative emission projections for 2028. Using a photochemical model based on the 2028 emission projections for all selected sources in their regional haze plan, including the taconite facilities, Minnesota estimated future visibility and established their reasonable progress goals.

Although EPA has not yet taken final action on the regional haze SIP revisions submitted by Michigan and Minnesota for the second implementation period, the assumptions used in the long-term strategies and reasonable progress goals were no more stringent than the currently applicable Original FIP and 2016 FIP emission limits and ranges or the revised limits we are proposing in this action. Therefore, the revised NO_X emission limits for Tilden, Hibbing, UTAC, Minorca, and Northshore represent greater control overall than was assumed in Michigan's and Minnesota's long-term strategy and would not result in a degradation of the reasonable progress goals required by 40 CFR 51.308(d)(1).

[32] 40 CFR part 51, appendix Y, at V.

D. National Ambient Air Quality Standards (NAAQS) and Reasonable Further Progress

With respect to requirements concerning attainment of the NAAQS and reasonable further progress, EPA is proposing to finalize NO_X BART emission limits for seven subject-to-BART units at four facilities within the ranges established in the 2016 FIP. EPA is also proposing to finalize SO_2 emission limits for three facilities which will not result in an increase in SO_2 emissions. Thus, the proposed FIP revision will not interfere with attainment and reasonable further progress requirements.

E. Conclusion

We find that these revisions are consistent with CAA section 110(l). The previous sections of the notice explain how the proposed FIP revision will comply with applicable regional haze requirements and general implementation plan requirements and demonstrate that it will not interfere with any regional haze program requirements, attainment and reasonable further progress, or any other requirement of the CAA.

V. Environmental Justice Considerations

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice (EJ) part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on communities with EJ concerns.

EPA believes that the human health and environmental conditions that exist prior to this action do not result in disproportionate and adverse effects on communities with EJ concerns. To identify environmental burdens and susceptible populations in communities nearby the Tilden, Hibbing, Minorca, Northshore, and UTAC facilities, and to examine the implications of the proposed NO_X and SO_2 emission limits, EPA utilized the EJScreen tool to evaluate environmental and demographic indicators within a 3-mile buffer, a 10-mile buffer, and the county that each facility is located in (Marquette County, Michigan for Tilden; St. Louis County, Minnesota for Hibbing, Minorca, and UTAC; and Lake County, Minnesota for Northshore).

EPA's screening-level analysis indicates that communities near the facilities affected by this action score below the national average for the EJScreen ''Demographic Index'', which is the average of an area's percent minority and percent low-income populations, *i.e.,* the two demographic indicators explicitly named in Executive Order 12898. Additionally, the results indicate that these areas score below the 80th percentile (in comparison to the nation as a whole) in the 13 EJ Indexes established by EPA, which include a combination of environmental and demographic information. EPA has provided that if any of the EJ indexes for the areas under consideration are at or above the 80th percentile nationally, then further review may be appropriate. As discussed in the EPA's EJ technical guidance, communities with EJ concerns often experience greater exposure and disease burdens than the general population, which can increase their susceptibility to adverse health effects from environmental stressors.

EPA believes that this action is not likely to result in new disproportionate and adverse effects on communities with EJ concerns. This action proposes to set final NO_X and SO_2 emission limits which are not expected to result in new or increased burdens on residents, including those in communities of EJ concern, as specified in Executive Order 12898.

EPA invited the identification of EJ and other concerns during its Tribal consultations which occurred prior to proposing emission limits for all five taconite facilities. No EJ concerns were raised in the context of this action. We have determined that this rulemaking will not have disproportionately high and adverse human health or environmental effects on communities with EJ concerns. The information supporting this Executive Order review is contained in the docket for this action, including the EJSCREEN reports considering a 3-mile buffer, a 10-mile buffer, and the county that each taconite facility is in.

VI. Proposed Action

EPA is proposing to modify the UPL equations used to establish NO_X and SO_2 emission limits and to finalize NO_X and/or SO_2 limits for the indurating furnaces at five taconite facilities in accordance with the procedure set forth in the 2016 FIP. Specifically, EPA is proposing to approve the following NO_X limits, with compliance to be determined on a rolling 30-day average: 3.0 lbs NO_X/MMBtu for all fuels for Tilden Line 1; a crossline average limit of 1.5 lb NO_X/MMBtu for Hibbing Lines 1, 2, and 3; a crossline average emission limit of 3.0 lbs NO_X/MMBtu for all fuels for UTAC Lines 1 and 2; and 1.6 lbs NO_X/MMBtu for Minorca's indurating furnace. EPA is proposing to approve the following SO_2 limits, with compliance to be determined on a rolling 30-day average: 189 lbs SO_2/hr for all fuels for Tilden Line 1; an aggregate emission limit of 247.8 lbs SO_2/hr for Hibbing Lines 1, 2, and 3; 68.2 lbs SO_2/hr for Minorca's indurating furnace; and an aggregate limit of 17.0 lbs SO_2/hr for Northshore Furnaces 11 and 12.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866, as amended by Executive Order 14094, and was therefore not subject to a requirement for Executive Order 12866 review.

B. Paperwork Reduction Act

This proposed action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Because the FIP applies to just the taconite facilities in Michigan and Minnesota, the Paperwork Reduction Act does not apply. *See* 5 CFR 1320.3(c).

C. Regulatory Flexibility Act

I certify that this proposed action will not have a significant economic impact on a substantial number of small entities under the RFA. This proposed action will not impose any requirements on small entities. This action, if finalized, will add additional controls to certain sources. None of these sources are owned by small entities, and therefore are not small entities.

D. Unfunded Mandates Reform Act (UMRA)

This proposed action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The proposed action imposes no enforceable duty on any state, local or Tribal governments or the private sector.

E. Executive Order 13132: Federalism

This proposed action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed action does not have Tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on Tribal governments. Thus, Executive Order 13175 does not apply to this action. Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, EPA did discuss this action in conference calls with the Michigan and Minnesota Tribes.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not 3(f)(1) significant as defined in Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. To the extent this action, if finalized, will limit emissions of NO_X and SO_2 emissions, the rule will have a beneficial effect on children's health by reducing air pollution.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

EPA believes that the human health and environmental conditions that exist prior to this action do not result in disproportionate and adverse effects on communities with Environmental Justice concerns. This proposed FIP limits emissions of NO_X and SO_2 from five taconite facilities in Michigan and Minnesota. EPA believes that this action is not likely to result in new disproportionate and adverse effects on communities with environmental justice concerns.

EPA performed an EJ analysis, as is described above in the section titled, ''Environmental Justice Considerations.'' The analysis was done for the purpose of providing additional context and information about this rulemaking to the public, not as a basis of the action. Due to the nature of the action being taken here, this action is expected to have a neutral to positive impact on the air quality of the affected area. In addition, there is no information in the record upon which this decision is based inconsistent with the stated goal of E.O. 12898 of achieving EJ for communities with EJ concerns.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Regional haze, Reporting and recordkeeping requirements, Sulfur oxides.

Michael S. Regan,

Administrator.

For the reasons stated in the preamble, EPA proposes to amend title 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. Section 52.1183 is amended by:
■ a. in paragraph (k) revising (1), (3), (4) and (5);
■ b. in paragraph (l) revising (3), (4)(v) and (4)(xii);
■ c. in paragraph (n) revising (1) and (2); and
■ d. removing and reserving paragraph (p).

The revisions read as follows:

§ 52.1183 Visibility protection.

* * * * *

(k) Tilden Mining Company, or any subsequent owner/operator of the Tilden Mining Company facility in Ishpeming, Michigan, shall meet the following requirements:

(1) *NO_X Emission Limits.*

(i) An emission limit of 3.0 lbs NO_X/MMBTU, based on a 30-day rolling average, shall apply to Tilden Grate Kiln Line 1 (EUKILN1) beginning January 3, 2025.

(ii) Compliance with this emission limit shall be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for NO_X.

(2) *SO_2 Emission Limits.* * * *

(3) The owner or operator of the Tilden Grate Kiln Line 1 (EUKILN1) furnace shall meet an emission limit of 189.0 lbs SO_2/hr, based on a 30-day rolling average, beginning on January 3, 2025. Compliance with this emission limit shall be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for SO_2. Beginning November 12, 2016, any coal burned on Tilden Grate Kiln Line 1 shall have no more than 0.60 percent sulfur by weight based on a monthly block average. The sampling and calculation methodology for determining the sulfur content of coal must be described in the monitoring plan required for this furnace.

(4) Emissions resulting from the combustion of fuel oil are not included in the calculation of the 30-day rolling average. However, if any fuel oil is burned after the first day that SO_2 CEMS are required to be operational, then the information specified in (k)(5) must be submitted, for each calendar year, to the Regional Administrator at *R5ARDReporting@epa.gov* no later than 30 days after the end of each calendar year so that a limit can be set.

(5) Records shall be kept for any day during which fuel oil is burned as fuel (either alone or blended with other fuels) in Grate Kiln Line 1. These records must include, at a minimum, the gallons of fuel oil burned per hour, the sulfur content of the fuel oil, and the SO_2 emissions in pounds per hour. If any fuel oil is burned after the first day that SO_2 CEMS are required to be operational, then the records must be submitted, for each calendar year, to the Regional Administrator at *R5ARDReporting@epa.gov* no later than 30 days after the end of each calendar year.

(l) *Testing and monitoring.*

* * *

(3) The owner or operator shall install, certify, calibrate, maintain, and operate one or more continuous diluent monitor(s) (O_2 or CO_2) and continuous stack gas flow rate monitor(s) on Tilden Grate Kiln Line 1 to allow conversion of the NO_X and SO_2 concentrations to units of the standard (lbs/MMBTU and lbs/hr, respectively) unless a demonstration is made that a diluent monitor and/or continuous flow rate monitor are not needed for the owner or operator to demonstrate compliance with applicable emission limits in units of the standard.

(4) * * *

* * * * *

(v) The owner or operator of each CEMS must furnish the Regional Administrator a written report of the results of each quarterly performance evaluation and a data accuracy assessment pursuant to 40 CFR part 60 appendix F within 60 days after the calendar quarter in which the

performance evaluation was completed. These reports shall be submitted to the Regional Administrator at *R5AirEnforcement@epa.gov.*

* * * * *

(xii) Data substitution must not be used for purposes of determining compliance under this regulation. If CEMS data is measuring only a portion of the NO_X or SO_2 emitted during startup, shutdown, or malfunction conditions, the CEMS data may be supplemented, but not modified, by the addition of calculated emission rates using procedures set forth in the site specific monitoring plan.

* * * * *

(n) *Reporting requirements.*

(1) Unless instructed otherwise, all requests, reports, submittals, notifications, and other communications required by this section shall be submitted to the Regional Administrator at *R5AirEnforcement@epa.gov.* References in this section to the Regional Administrator shall mean the EPA Regional Administrator for Region 5.

(2) The owner or operator of each BART affected unit identified in this section and CEMS required by this section must provide to the Regional Administrator the written notifications, reports, and plans identified at paragraphs (n)(2)(i) through (viii) of this section.

* * *

* * * * *

(p) [Reserved]

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■ 3. Section 52.1235 is amended by:

■ a. in paragraph (b) revising (1)(ii), (1)(iv), (1)(v), (1)(vi), (2)(ii), (2)(v) and (2)(vi);

■ b. in paragraph (c) revising (1), (2), (3), (4)(ii), (4)(v), and (4)(xii); and

■ c. in paragraph (e) revising (1) and (2); and

■ d. revising paragraph (f).

The revisions read as follows:

§ 52.1235 Regional haze.

* * * * *

(b) * * *

(1) NO_X emission limits.

(i) * * *

(ii) Hibbing Taconite Company

(A) An aggregate emission limit of 1.5 lbs NO_X/MMBtu, based on a 30-day rolling average, shall apply to the combined NO_X emissions from the three indurating furnaces, Line 1 (EU020), Line 2 (EU021), and Line 3 (EU022), beginning on January 3, 2025. To determine the aggregate emission rate, the combined NO_X emissions from Lines 1, 2, and 3 shall be divided by the total heat input to the three lines (in MMBtu) during every rolling 30-day period.

(B) Compliance with this emission limit shall be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for NO_X.

(iii) * * *

(iv) United Taconite

(A) An aggregate emission limit of 3.0 lbs NO_X/MMBtu, based on a 30-day rolling average, shall apply to the combined NO_X emissions from the two indurating furnaces, Grate Kiln Line 1 (EU040) and Grate Kiln Line 2 (EU042), beginning on January 3, 2025. To determine the aggregate emission rate, the combined NO_X emissions from Grate Kiln Line 1 and Grate Kiln Line 2 shall be divided by the total heat input to the two lines (in MMBtu) during every rolling 30-day period.

(B) Compliance with this emission limit shall be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for NO_X.

(v) Minorca Mine

(A) An emission limit of 1.6 lbs NO_X/MMBtu, based on a 30-day rolling average, shall apply to the Minorca Mine indurating furnace (EU026). This emission limit will become enforceable on January 3, 2025.

(B) Compliance with this emission limit will be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for NO_X.

(vi) Northshore Mining Company—Silver Bay: An emission limit of 1.5 lbs NO_X/MMBtu, based on a 30-day rolling average, shall apply to Furnace 11 (EU100/EU104) beginning October 10, 2018. An emission limit of 1.5 lbs NO_X/MMBtu, based on a 30-day rolling average, shall apply to Furnace 12 (EU110/114) beginning October 11, 2019. However, for any 30, or more, consecutive days when only natural gas is used at either Northshore Mining Furnace 11 or Furnace 12, a limit of 1.2 lbs NO_X/MMBtu, based on a 30-day rolling average, shall apply. An emission limit of 0.085 lbs NO_X/MMBtu, based on a 30-day rolling average, shall apply to Process Boiler #1 (EU003) and Process Boiler #2 (EU004) beginning October 10, 2021. The 0.085 lbs NO_X/MMBtu emission limit for each process boiler applies at all times a unit is operating, including periods of start-up, shut-down and malfunction.

(2) *SO_2 Emission Limits.*

(i) * * *

(ii) Hibbing Taconite Company

(A) An aggregate emission limit of 247.8 lbs SO_2/hour, based on a 30-day rolling average, shall apply to the combined SO_2 emissions from the three indurating furnaces, Line 1 (EU020), Line 2 (EU0021), and Line 3 (EU022), beginning on February 10, 2017. To determine the aggregate emission rate, the combined SO_2 emissions from Lines 1, 2, and 3 shall be divided by the total hours of operation of the three lines during every rolling 30-day period.

(B) Compliance with this emission limit shall be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for SO_2.

(C) Emissions resulting from the combustion of fuel oil are not included in the calculation of the 30-day rolling average. However, if any fuel oil is burned after the first day that SO_2 CEMS are required to be operational, then the information specified in (b)(2)(vii) must be submitted, for each calendar year, to the Regional Administrator at *R5ARDReporting@epa.gov* no later than 30 days after the end of each calendar year so that a limit can be set.

(iii) * * *

(iv) * * *

(v) Minorca Mine

(A) An emission limit of 68.2 lbs SO_2/hr, based on a 30-day rolling average, shall apply to the indurating furnace (EU026) beginning January 3, 2025.

(B) Compliance with this emission limit shall be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for SO_2.

(C) Emissions resulting from the combustion of fuel oil are not included in the calculation of the 30-day rolling average. However, if any fuel oil is burned after the first day that SO_2 CEMS are required to be operational, then the information specified in (b)(2)(vii) must be submitted, for each calendar year, to the Regional Administrator at *R5ARDReporting@epa.gov* no later than 30 days after the end of each calendar year so that a limit can be set.

(vi) Northshore Mining Company—Silver Bay

(A) An aggregate emission limit of 17.0 lbs SO_2/hr, based on a 30-day rolling average, shall apply to Furnace 11 (EU100/EU104) and Furnace 12 (EU110/EU114) beginning January 3, 2025. To determine the aggregate emission rate, the combined SO_2 emissions from Furnace 11 and Furnace 12 shall be divided by the total hours of operation of the two furnaces during every rolling 30-day period.

(B) Compliance with these emission limits shall be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for SO_2.

(C) Emissions resulting from the combustion of fuel oil are not included in the calculation of the 30-day rolling average. However, if any fuel oil is burned after the first day that SO_2 CEMS are required to be operational, then the information specified in (b)(2)(vii) must

be submitted, for each calendar year, to the Regional Administrator at *R5ARDReporting@epa.gov* no later than 30 days after the end of each calendar year so that a limit can be set.

(D) The owner or operator may submit to EPA for approval an alternative monitoring procedure request. The request shall include at least one year of CEMS data demonstrating consistent values at or below 5 lbs SO_2/hr. The alternative monitoring procedure request shall not remove the obligation to maintain and operate a flow rate monitor in the stack. If approved, the owner or operator would not be required to operate the SO_2 CEMS and may demonstrate continuous compliance using an emission factor derived from the average of at least one year of existing SO_2 data using the procedure set forth in the site specific monitoring plan, and verified by annual stack tests using EPA approved test methods, multiplied by the daily measured flow rate as recorded by the flow rate monitor and recorded as the daily lb/hr SO_2 emission rate.

(vii) * * *

(c) Testing and monitoring.

(1) The owner or operator of the respective facility shall install, certify, calibrate, maintain and operate continuous emissions monitoring systems (CEMS) for NO_X on United States Steel Corporation, Keetac unit EU030; Hibbing Taconite Company units EU020, EU021, and EU022; United States Steel Corporation, Minntac units EU225, EU261, EU282, EU315, and EU334; United Taconite units EU040 and EU042; Minorca Mine unit EU026; and Northshore Mining Company-Silver Bay units Furnace 11 (EU100/EU104) and Furnace 12 (EU110/EU114). Compliance with the emission limits for NO_X shall be determined using data from the CEMS.

(2) The owner or operator shall install, certify, calibrate, maintain, and operate CEMS for SO_2 on United States Steel Corporation, Keetac unit EU030; Hibbing Taconite Company units EU020, EU021, and EU022; United States Steel Corporation, Minntac units EU225, EU261, EU282, EU315, and EU334; United Taconite units EU040 and EU042; Minorca Mine unit EU026; and Northshore Mining Company-Silver Bay units Furnace 11 (EU100/EU104) and Furnace 12 (EU110/EU114).

(3) The owner or operator shall install, certify, calibrate, maintain, and operate one or more continuous diluent monitor(s) (O_2 or CO_2) and continuous stack gas flow rate monitor(s) on the BART affected units to allow conversion of the NO_X and SO_2 concentrations to units of the standard (lbs/MMBTU and lbs/hr, respectively) unless a demonstration is made that a diluent monitor and/or continuous flow rate monitor are not needed for the owner or operator to demonstrate compliance with applicable emission limits in units of the standards.

(4) * * *

(i) * * *

(ii) CEMS must be installed and operational such that the operational status of the CEMS identified in paragraphs (c)(1) and (2) of this section shall be verified by, as a minimum, completion of the manufacturer's written requirements or recommendations for installation, operation, and calibration of the devices.

* * * * *

(v) The owner or operator of each CEMS must furnish the Regional Administrator a written report of the results of each quarterly performance evaluation and a data accuracy assessment pursuant to 40 CFR part 60 appendix F within 60 days after the calendar quarter in which the performance evaluation was completed. These reports shall be submitted to the Regional Administrator at *R5AirEnforcement@epa.gov.*

* * * * *

(xii) Data substitution must not be used for purposes of determining compliance under this section. If CEMS data is measuring only a portion of the NO_X or SO_2 emitted during startup, shutdown, or malfunction conditions, the CEMS data may be supplemented, but not modified, by the addition of calculated emission rates using procedures set forth in the site specific monitoring plan.

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(e) Reporting Requirements

(1) Unless instructed otherwise, all requests, reports, submittals, notifications, and other communications required by this section shall be submitted to the Regional Administrator at *R5AirEnforcement@epa.gov*. References in this section to the Regional Administrator shall mean the EPA Regional Administrator for Region 5.

(2) The owner or operator of each BART affected unit identified in this section and CEMS required by this section must provide to the Regional Administrator the written notifications, reports and plans identified at paragraphs (e)(2)(i) through (viii) of this section.

* * *

* * * * *

(f) Equations for establishing the upper predictive limit—

(1) Equation for normal distribution and statistically independent data.

$$UPL = \bar{x} + t_{[(n-1),(0.99)]}\sqrt{s^2\left(\frac{1}{n}+\frac{1}{m}\right)}$$

Where:

x = average or mean of hourly test run data;

$t_{[(n-1),(0.99)]}$ = t score, the one-tailed t value of the Student's t distribution for a specific degree of freedom (n − 1) and a confidence level (0.99, to reflect the 99th percentile)

s^2 = variance of the hourly data set;

n = number of values (*e.g.,* 5,760 if 8 months of valid lbs NO_X/MMBTU hourly values)

m = number of values used to calculate the test average (m = 720 as per averaging time)

(i) To determine if statistically independent, use the Rank von Neumann Test on p. 137 of data Quality Assessment: Statistical Methods for Practitioners EPA QA/G–9S.

(ii) Alternative to Rank von Neumann test to determine if data are dependent, data are dependent if t test value is greater than t critical value, where:

$$t\ test = \frac{\rho}{\sqrt{\frac{1-\rho^2}{n-2}}}$$

ρ = correlation between data points

t critical = $t_{[(n-2),(0.95)]}$ = t score, the two-tailed t value of the Student's t distribution for a specific degree of freedom (n − 2) and a confidence level (0.95)

(iii) The Anderson-Darling normality test is used to establish whether the data are normally distributed. That is, a distribution is considered to be normally distributed when p > 0.05.

(2) Non-parametric equation for data not normally distributed and normally distributed but not statistically independent.

m = (n+1) * α

m = the rank of the ordered data point, when data are sorted smallest to largest. The data points are 720-hour averages for establishing NO_X limits.

n = number of data points (*e.g.,* 5040 720-hourly averages for eight months of valid NO_X lbs/MMBTU values)

α = 0.99, to reflect the 99th percentile

If m is a whole number, then the limit, *UPL,* shall be computed as:

$UPL = X_m$

Where:

X_m = value of the m^{th} data point in terms of lbs SO_2/hr or lbs NO_X/MMBtu, when the data are sorted smallest to largest.

If m is not a whole number, the limit shall be computed by linear interpolation according to the following equation.

$UPL = x_m = x_{m_i} \cdot m_d = x_{m_i} + 0.m_d(x_{m_{(i+1)}} - x_{m_i})$

Where:

m_i = the integer portion of m, *i.e., m* truncated at zero decimal places, and

m_d = the decimal portion of m

[FR Doc. 2024–27635 Filed 12–3–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 10–90, 23–328, 16–271, 14–58, 09–197; WT Docket No. 10–208; FCC 24–116; FR ID 264716]

Connect America Fund, Alaska Connect Fund, Connect America Fund—Alaska Plan, ETC Annual Reports and Certifications, Telecommunications Carriers Eligible To Receive Universal Service Support, Universal Service Reform—Mobility Fund

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (FCC or Commission) adopted a Further Notice of Proposed Rulemaking (FNPRM) that seeks comment on the implementation of the Alaska Connect Fund (ACF) for mobile service from the period January 1, 2030 through December 31, 2034 for areas where more than one mobile provider had been receiving support for overlapping service areas, or duplicate-support areas (ACF Mobile Phase II). This includes comment on the methodology to determine support amounts in duplicate-support areas and the competitive or alternative mechanism to distribute support, which would result in support to a single mobile provider in duplicate-support areas after ACF Mobile Phase I (mobile support provided from January 1, 2027 to December 31, 2029) ends. The Commission also seeks comment on how to distribute support in unserved areas, Tribal consent requirements for the ACF, and other additional issues that would impact the ACF.

DATES: Comments are due on or before February 3, 2025, and reply comments are due on or before March 4, 2025.

ADDRESSES: You may submit comments, identified by WC Docket Nos. 10–90, 23–328, 16–271, 14–58, 09–197 or WT Docket No. 10–208 by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the Electronic Comment Filing System (ECFS): *https://www.fcc.gov/ecfs/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing.
- Filings can be sent by hand or messenger delivery, by commercial courier, or by the U.S. Postal Service. All filings must be addressed to the Secretary, Federal Communications Commission.
- Hand-delivered or messenger-delivered paper filings for the Commission's Secretary are accepted between 8:00 a.m. and 4:00 p.m. by the FCC's mailing contractor at 9050 Junction Drive, Annapolis Junction, MD 20701. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.
- Commercial courier deliveries (any deliveries not by the U.S. Postal Service) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- Filings sent by U.S. Postal Service First-Class Mail, Priority Mail, and Priority Mail Express must be sent to 45 L Street NE, Washington, DC 20554.

People with Disabilities. To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

FOR FURTHER INFORMATION CONTACT: For further information, please contact, Matt Warner, Competition and Infrastructure Policy Division, Wireless Telecommunications Bureau, at *Matthew.Warner@fcc.gov* or (202) 418–2419.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's FNPRM in WC Docket Nos. 10–90, 23–328, 16–271, 14–58, 09–197 and WT Docket No. 10–208; FCC 24–116, adopted on November 1, 2024 and released on November 4, 2024. The full text of this document is available at the following internet address: *https://www.fcc.gov/document/fcc-adopts-alaska-connect-fund-further-address-broadband-needs.* The Commission also concurrently adopted a Report and Order (Order) that takes important and necessary steps to ensure continued support for the advancement of modern mobile and fixed broadband service in Alaska.

Filing Requirements. Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated in this document. Comments may be filed using the Commission's ECFS or by paper. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

Ex Parte Rules. This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must: (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda, or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with Rule 1.1206(b), 47 CFR 1.1206(b). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Providing Accountability Through Transparency Act. Consistent with the Providing Accountability Through Transparency Act, Public Law 118–9, a summary of the FNPRM is available on *https://www.fcc.gov/proposed-rulemakings.*

Synopsis

I. Further Notice of Proposed Rulemaking

In this FNPRM, the Commission seeks comment on a number of issues related to the implementation of the ACF.

As an initial matter, for ACF Mobile Phase II, the Commission seeks comment on a methodology to determine a support amount for areas where more than one mobile provider had been receiving support for overlapping service areas. This mechanism may also be used to determine support amounts to claw

back for areas that the Commission deems ineligible for mobile support in the concurrently adopted Report and Order (Order) in the event that support is not shifted to a comparable area.

Additionally, the Commission seeks comment on ACF Mobile Phase II service requirements, as well as how to eliminate duplicative support in ACF Mobile Phase II so that only one provider would continue to receive funding in duplicate-support areas. First, the Commission seeks comment on a competitive mechanism for awarding support to one provider in duplicate-support areas. Second, the Commission seeks comment on an alternative mechanism to address duplicate-support areas that would designate one provider that would continue receiving support in the same area, and would allow other providers to choose different areas to serve to continue receiving the previous support levels.

In addition, the Commission seeks to update the record on how best to deploy mobile service to areas that remain unserved with the $162 million from the Alaska Plan that has been reallocated toward this purpose. Further, the Commission seeks comment on conducting a reverse auction to award support to competitive Eligible Telecommunication Carriers (ETCs) to deploy advanced communications networks in these areas.

The Commission seeks comment on additional issues for implementation of the mobile portion of the ACF, for both the two support-area plan established in the concurrently adopted Order and the ACF Mobile Phase II as described in this document. The Commission seeks comment on retail consumer conditions, including seeking comment on a proposal to impose a minimum subscriber requirement for ACF mobile participants, as well as seeking comment on marketing on Tribal lands. The Commission also seeks further comment on offering incentives to deploy networks with Open Radio Access Network (Open RAN). Finally, the Commission seeks further comment on Tribal consent under both the mobile and fixed portions of the ACF.

The Commission seeks comment on how to determine support amounts by area for purposes of the mobile portion of the ACF—for example, to determine the support amounts for duplicate-support areas and single-support areas, as well as previously supported areas that are no longer eligible. In the Alaska Plan, providers were awarded funding based on statewide commitments. Because the Commission adopts an area-based approach for the mobile portion of the ACF, it must establish a way to disaggregate total support across smaller geographic areas. Specifically, in order to address issues involving providers serving areas that are ineligible in the ACF but were eligible in the Alaska Plan (*e.g.,* areas which have an unsubsidized provider of 5G–NR at 7/1 Mbps in an outdoor stationary environment or three or more mobile providers offering at least 4G LTE at 5/1 Mbps in an outdoor stationary environment—with at least one of those providers being unsubsidized—based on Broadband Data Collection (BDC) coverage data as of December 31, 2024), the Commission must calculate how much support has been allocated to these ineligible areas. In the *Alaska Connect Fund Notice,* 88 FR 80238, November 17, 2023, the Commission asked if duplicate funds could be redistributed ''by calculating the support that eligible providers are receiving per hexagon across all of that provider's service areas and subtracting the support that the provider receives per hexagon in a particular service area?'' As no commenters directly addressed this question, the Commission seeks comment on the methodology in the following to calculate Alaska Plan support in specific areas, at the hex-9 level.

Because mobile providers have statewide buildout requirements under the Alaska Plan, calculating a provider's rate of support in any given area is particularly complicated, since providers that receive support to cover multiple areas are not required to spend that money in any particular area. A provider's average rate of support over all areas is likely not to reflect the amount of support it uses to cover any particular area. However, the average support rate for a provider that receives support for a more targeted area is more likely to reflect the amount of support that the provider needs to cover that area. Based on that assumption, the Commission seeks comment on whether to iterate through the Alaska Plan participants, from smallest footprint to largest, using the smaller providers' support as proxies for the support for larger providers in areas where they overlap.

To provide a detailed example of the information in this document, the Commission would first consider the support of the provider covering the fewest number of hex-9s located in Alaska Plan eligible census blocks (Provider A). Specifically, the Commission would divide Provider A's annual support by the total number of hex-9s that the provider covers in Alaska Plan eligible census blocks to calculate an average value for each covered hex-9. A hex-9 would be considered covered by a provider if 70% of the grandchild hex-11s were covered at the centroid, using the union of December 2024 BDC mobile broadband and mobile voice coverage for that provider. For example, if Provider A receives $100,000 in annual support and covers 1,000 hex-9s in Alaska Plan eligible blocks, each such hex-9 it covers would be said to receive $100 in annual support.

The Commission would then evaluate the support of the provider covering the second fewest hex-9s in Alaska Plan eligible census blocks (Provider B). The Commission would first determine if Provider B covered any of the same hex-9s as Provider A. If so, the value of those hex-9s would be the same as for Provider A; in this example, $100 per hex-9. The Commission would subtract the funding of these duplicate hex-9s from Provider B's total annual support, and divide the remaining annual support by the remaining covered hex-9s to calculate the funding for each hex-9 that is not duplicated by Provider A. To continue the example, suppose Provider B receives $150,000 in annual support and covers 2,500 hex-9s in Alaska Plan eligible blocks, and that 500 of these hex-9s are also covered by Provider A. In this case, the Commission would say that 500 of its hex-9s would each be assigned a value of $100, for a total of $50,000. The Commission would then calculate that the remaining $100,000 of support spread across the remaining 2,000 hex-9s results in each non-duplicate hex-9 receiving $50 of support. Alternatively, if there were no overlap between Providers A and B, the calculation for Provider B would follow the same process as Provider A, distributing $150,000 across the 2,500 hex-9s, resulting in each hex-9 covered by Provider B receiving $60 of support.

This process would be repeated with the provider covering the next largest area, or Provider C, such that its hex-9s that overlap with Provider A would be valued the same as for Provider A ($100 in the above example), the hex-9s that overlap with Provider B would be valued the same as for Provider B ($50 in the above example), and the remaining hex-9s as the average of the remaining support. (Note that if Providers A, B, and C all overlap in some hex-9s, the value would be at Provider A's average, or $100 in this example). The process would then iterate through the remaining providers, smallest to largest in terms of covered hex-9s in eligible Alaska Plan blocks, until a value has been assigned for every covered hex-9. Note that it would

theoretically be possible for the largest of the eight Alaska Plan providers to have hex-9s valued at each of the smaller seven provider's averages, and then have its own average for its remaining hex-9s.

Further, the Commission would also use these values to determine the amount of ACF support at stake in areas no longer eligible in the ACF. Continuing the example in this document, if 100 of Provider B's non-duplicate hex-9s were no longer eligible, the value of those hex-9s would be $5,000. If Provider B were not able to commit to cover comparable hex-9s in its performance plan, its annual ACF support would be reduced by $5,000. Similarly, if the 100 ineligible hex-9s were covered by both Providers A and B, the value of each hex-9 would be $100, and the at-stake ACF support would be $10,000 for each provider.

The Commission seeks comment on the methodology in this document. Should hex-9s covered by more than one provider have the same value to each provider, or should the Commission adopt a different method that allows for heterogenous support levels for such hex-9s? Should the Commission instead apportion support based on another metric, such as covered BSLs or population? Should hex-9s within the same geographic area, such as a census tract or borough, all be assigned the same value, regardless of whether or not a given hex-9 is covered by more than one provider?

The Commission also seeks comment on whether to use this methodology to determine support amounts by area for use in a competitive—or alternative—mechanism for addressing duplicate support in ACF Mobile Phase II. The Commission seeks comment on whether this would be an effective methodology for determining duplicate support amounts. Additionally, the Commission seeks comment on the effectiveness of this methodology to calculate the amount of support to be clawed back in the event that a provider serving areas deemed ineligible for ACF, as set forth in the concurrently adopted Order, is not able to—or chooses not to—serve comparable areas. Further, the Commission asks whether it should use this or a similar hex-9-based methodology to calculate the value of ACF Phase I commitments. Are there other uses for this methodology in the mobile portion of the ACF? Finally, if commenters have concern about this methodology, the Commission seeks comment on alternative methodologies to calculate support amounts for these particular areas. The Commission seeks comment generally regarding how to determine the support amounts per area.

The Commission seeks comment on the level of service that it should expect from mobile providers that receive support under ACF Mobile Phase II of the ACF. Since the adoption of the *Alaska Plan Order,* 81 FR 69696, October 7, 2016, mobile wireless technologies have advanced significantly, and the Commission has moved toward supporting 5G–NR as the standard for high-cost mobile-wireless deployment. Despite this, the current Alaska Plan still supports 2G, 3G, and 4G LTE networks. While the Commission recognizes that Alaska presents unique challenges when deploying mobile networks, it also must recognize the advances in mobile wireless technologies that have been made since the adoption of the Alaska Plan; therefore the Commission tentatively concludes that continuing to fund such obsolete technologies would be both inefficient and contrary to the Commission's statutory mandate that consumers in rural and high-cost areas ''should have access to'' advanced communications ''that are reasonably comparable to those services provided in urban areas.'' As such, for ACF Mobile Phase II, the Commission seeks comment on whether to set a goal of 5G–NR 7/1 Mbps or whether to make this a requirement of ACF Mobile Phase II. Given that 4G LTE at 5/1 Mbps is already available in many parts of Alaska, particularly in areas with duplicate support, the Commission believes that this service level is achievable, and it seeks comment on this. However, the Commission provides a preference for higher deployment speeds when selecting winners in the competitive mechanisms, and therefore it expects that providers will be incentivized to offer 5G–NR 35/3 Mbps services in areas where it is technically and financially feasible. The Commission seeks comment on this approach. Alternatively, should the Commission make 5G–NR 35/3 Mbps the technology and speed goal (consistent with its approach for single-support areas by 2034, as in the concurrently adopted Order)? Should the Commission make this a requirement?

Additionally, if the Commission were to adopt a 5G–NR goal or minimum standard, should there be areas where providers are allowed to meet a lesser speed standard? For example, should areas with high middle-mile costs be required to deploy 5G–NR but only be required to meet a lower speed threshold, and if so, how would the Commission determine areas with high transport costs? Should the goal or minimum service requirements be lower for providers seeking to deploy in unserved areas? In the alternative, should the Commission continue to fund 4G LTE networks, and if so, under what conditions? If the Commission adopts 5G–NR 7/1 Mbps as the goal or minimum performance standard, how much time should it give carriers to upgrade their networks to meet this new standard? Should the adopted service goal or minimum deployment standard evolve over time to a higher standard so that it does not become outdated?

The Commission seeks comment on the appropriate mechanism to eliminate duplicate support in the mobile portion of the ACF. It is generally not the policy of the Universal Service Fund (USF) to subsidize competition in high-cost areas. Therefore, in the high-cost program, the Commission has sought to eliminate duplicate support—the provision of support to more than one competitive ETC in the same area. In the *Alaska Connect Fund Notice,* the Commission expressed concern that many areas were receiving duplicate support under the Alaska Plan. To address the issue of duplicate support, in this document, the Commission seeks comment on whether to adopt a competitive mechanism to decide which competitive ETC should be awarded the support for a given geographic area based on which provider proposes the best combination of coverage and service offerings for each community. Under this proposal, providers seeking to be chosen as the provider for a given community will submit proposed coverage maps for the areas where more than one provider currently receives support, as well as the surrounding community where no provider currently offers service (*i.e.,* unserved hex-9s within a larger geography that contains the duplicate support hex-9s). Based on these coverage map offers, the competitive mechanism would then determine which competitive ETC to support based on which provider proposes to deploy the 5G network with the best combination of speed and coverage to the duplicate-support areas and surrounding unserved areas. The Commission seeks comment on this approach.

As discussed in the concurrently adopted Order, in ACF Mobile Phase I, the Commission limits support to mobile ETCs that participated in the Alaska Plan, subject to other eligibility requirements. However, for ACF Mobile Phase II, in order to maximize competition in the competitive mechanism, the Commission seeks comment on whether to permit any

competitive ETC, including competitive ETCs that do not already receive support for mobile service in remote Alaska, to be eligible to participate. The Commission believes that this approach would encourage new mobile providers to emerge in Alaska, including those that are not currently ETCs or that were not eligible for the Alaska Plan. The Commission sees no reason why a mobile provider that meets all other criteria to participate in a competitive process should be deemed ineligible solely because it is not currently receiving Alaska Plan support. The Commission tentatively concludes that this approach will stretch its scarce universal service dollars further and result in better service for Alaskans, and it seeks comment on this tentative conclusion. The Commission seeks comment on whether these are the appropriate eligibility criteria and whether any additional factors should be considered.

As mentioned in this document, several current participants in the Alaska Plan have failed to meet their commitments. In the concurrently adopted Order, the Commission determined that an Alaska Plan mobile provider participant may have its ACF support delayed, reduced, or may be deemed ineligible from the ACF, if the Wireless Telecommunications Bureau (WTB) determines that the provider has failed to comply with the public interest obligations or other terms and conditions of the Alaska Plan or its Alaska Plan commitments, or failed to meet a build-out milestone. This determination—and delegation to WTB—extends to eligibility to participate in the mechanisms the Commission discusses in this document. In short, Alaska Plan providers that have been deemed ineligible for ACF will be ineligible for ACF Mobile Phase II support. The Commission seeks comment on this approach. Should there be a process by which an ineligible provider under these criteria could be once again deemed eligible?

As discussed in the concurrently adopted Order, the Commission will determine whether an area is ineligible, a duplicate-support area, a single-support area, or unserved at the hex-9 level. The Commission seeks comment on whether only eligible duplicate support and unserved hex-9s should be eligible for support in the competitive mechanism. Under this proposal, single support hex-9s and ineligible hex-9s will both be ineligible for support in the competitive mechanism. The Commission also seeks comment on whether to aggregate eligible hex-9s into census tracts as the minimum geographic unit for which it will accept competing offers. Should the Commission use an alternative Census geography for accepting competing offers? Alternatively, should eligible hex-9s be aggregated into a lower resolution (larger) hexagon such as a hex-7? The Commission seeks comment on these proposals.

Based on the previously discussed methodology for determining the amount of support associated with each hex-9, the Commission seeks comment on whether to establish a budget for each census tract with duplicate support areas as follows. After determining the support for each duplicate support hex-9, based on the disaggregation of statewide support methodology the Commission adopts, it seeks comment on whether to establish a total duplicate support amount for each census tract with duplicate support areas that is equal to the sum, over all duplicate support hex-9s, of the calculated support amount for each duplicate support hex-9. If the duplicate support amount associated with each hex-9 is different by provider based on the adopted disaggregation methodology, the Commission seeks comment on whether the total support amount associated with a tract with duplicate support areas should be equal to the sum of the maximum amounts of duplicate support any provider receives for the eligible duplicate support hex-9s. In this case, the Commission seeks comment on whether to use the sum of these maximum amounts so that it ensures support is sufficient to maintain the existing available coverage within the duplicate support areas. Would this approach provide sufficient support to, at a minimum, maintain existing coverage? Would this level of support allow the awarded provider to enhance its coverage within the supported hex-9s to provide 5G–NR services? Would an alternative budget such as the total support associated with all supported providers in the duplicate support areas be a more appropriate amount, and if so, why?

For each census tract with duplicate support areas, the Commission seek comment on whether an eligible ETC could submit a proposal to be the sole recipient of the duplicate support amount for the census tract. Under this approach, a competitive ETC's proposal would consist of a proposed coverage map for a census tract that complies with the BDC mobile coverage data requirements and must predict 5G–NR coverage in an outdoor stationary environment. The Commission seeks comment on whether eligible ETCs may propose to cover a subset of the eligible areas within a tract with 5G–NR 7/1 Mbps service or 5G–NR 35/3 Mbps service, and that they would be required to submit separate coverage maps for each proposed service. The Commission seeks comment on these proposals. In order to ensure that coverage map proposals are comparable, should the Commission set uniform propagation model parameters for all submitted coverage maps? Alternatively, could an eligible ETC's bid be more general within a biddable area, such that it promises to deploy to a certain number of hex-9s with a specified level of service, but does not specify exactly which hex-9s?

For each census tract receiving coverage offers, the Commission seeks comment on whether to evaluate the proposals and determine a single winner for each area based on a combination of the scope of proposed geographic coverage and service levels to the eligible areas within the tract, as determined by submitted coverage maps. The Commission seeks comment on this approach. Specifically, based on the coverage maps submitted, the Commission seeks comment on whether it should calculate a weighted percent coverage of the eligible hex-9s in the census tract for each proposal received and award the entire duplicate support amount for the tract to the ETC that proposes the highest weighted percent coverage of eligible hex-9s. In this calculation, hex-9s would receive different weights depending on whether they would be covered with 7/1 Mbps or 35/3 Mbps 5G–NR service under a proposal. For the weights, the Commission seeks comment on whether 35/3 Mbps 5G–NR service should receive a weight equal to 1 and 7/1 Mbps 5G–NR service should receive a weight equal to .9 when calculating the weighted coverage percentage used to evaluate competing proposals.

For example, suppose that there are ten hex-9s in a tract with a total land area of approximately 1 square mile—eight eligible hex-9s and two ineligible hex-9s, one of which is served at 5G–NR at 7/1 Mbps minimum speed by an unsubsidized provider and one of which is a single support area. Suppose that two ETCs submit coverage maps for this tract and the first ETC proposes to serve 2 of the eligible hex-9s at 5G–NR 35/3 Mbps minimum speed service, and 3 of the eligible hex-9s at 5G–NR at 7/1 Mbps minimum speed service. In this case, under the weighting scheme, the weighted coverage percentage for this offer would be approximately equal to 47%. Further suppose that the second ETC proposes to serve 6 eligible hex-9s

with 5G–NR at 7/1 Mbps minimum speed. The approximate score for this second proposal would be 54%, and therefore, this second ETC would be the winner of the budget assigned to this tract in the competitive mechanism.

Minimum Acceptable Offers. The Commission also seeks comment on the minimum acceptable weighted coverage percentage for an offer and whether it should be the weighted coverage percentage that would be implied by the current combined service areas of all the supported ETCs in the eligible hex-9s assuming 5G–NR 7/1 Mbps service in the hex-9s where such services are currently unavailable, and the actual 5G–NR deployed service in hex-9s where 5G–NR 7/1 Mbps or 35/3 Mbps services are deployed. For example, in the previous example, if two eligible hex-9s had 4G LTE 5/1 Mbps service, one had 5G–NR 7/1 Mbps and one had 5G–NR 35/3 Mbps, then the minimum acceptable coverage percentage for an offer would be approximately 37%. The Commission seeks comment on whether, if a provider submits an offer below the minimum coverage percentage or any other minimum criteria the Commission establishes, WTB should notify the provider and provide one opportunity for the provider to correct its bid. After this process, offers that remain below this minimum coverage percentage would be rejected. The Commission seeks comment on this approach.

Tie Breaker. Finally, in the event that more than one proposal should tie when calculating the highest weighted coverage percentage, the Commission seeks comment on what procedure should be used to break such a tie. Should the provider with the current highest weighted coverage percentage be awarded the support given that this provider has demonstrated a willingness and ability to serve the broader community with the most advanced mobile wireless services? Should the tie be broken at random? Should offers also include the lowest support amount below the available budget that the provider would be willing to accept in order to deploy the proposed service and, only in the case of ties for highest weighted coverage percentage, the provider with the lowest support amount would win and receive the support amount requested? To the extent a provider already receives support in the ACF, should the Commission consider the progress carriers have made in their single-support areas as indicated in the December 31, 2029 progress reports?

The Commission seeks comment on these proposals for accepting and evaluating competing offers in order to resolve duplicate support. Should the scoring of offers include other criteria besides proposed geographic coverage and service levels? For example, should the number of covered BSLs and road miles be explicitly included in the scoring formula? Are the weights the Commission seeks comment on for the two service levels appropriate? Should more weight be given to 5G–NR 35/3 Mbps service? Should other service levels be considered? Should providers be allowed to submit multiple offers that include a minimum support amount the provider would be willing to accept to deploy the proposed service level of the offer, and if so, how should the Commission trade off coverage and requested support when determining winners? Should the minimum coverage percentage in a census tract instead be set at the highest weighted coverage percentage of any single provider in the duplicate-support area under a minimum 5G–NR 7/1 Mbps service level assumption? Should the Commission also impose a minimum acceptable criterion on offers that all areas that currently have service (*e.g.,* a hex-9) would need to still have service under any proposal that it would accept as a valid proposal? Instead of only evaluating offers based on the eligible duplicate support and unserved areas within a tract, should the Commission also include ineligible single support areas within the tract when calculating the score in order to ensure that service is maintained to these areas? The Commission seeks comment on these questions and on any modifications that should be made to the methodology for evaluating competing offers and determining winners.

Support Phase-Down. The Commission seeks comment on whether providers that are not chosen as the sole recipient of the duplicate-support amount within a tract should have their support phased down over two years. Specifically, the Commission seeks comment on whether losing providers should receive two-thirds of their support for the first twelve months following the announcement of winners, one-third of their support for the next twelve months, and zero support for the tract thereafter. The Commission seeks comment on this approach and any alternatives. Is a phase-down of support appropriate? Is two years a sufficient length of time for the phase-down?

The Commission also seeks comment on an alternative mechanism that would assign support to only a single provider if an eligible area is covered by two or more Alaska Plan mobile provider participants. At a high level, this approach would take into consideration the existing coverage of each supported provider within a potentially larger area that includes the duplicate-support area—balancing various factors—and award support for the duplicate-support area to the provider that demonstrates the ''best'' coverage. Unlike the competitive mechanism, this approach would look at past service deployments rather than evaluating offers for future service deployments. For a currently supported provider that is not selected to continue receiving support for an area under the alternative mechanism, the Commission would make available an option to negotiate a revised plan with WTB that would allow it to continue to receive the same or similar level of support in exchange for serving different, but comparable, currently unserved areas. The Commission seeks comment on various aspects of this approach.

Evaluation Areas. In the concurrently adopted *Order,* the Commission defines duplicate-support areas as eligible areas covered by two or more Alaska Plan participants. For this alternative mechanism, the Commission seeks comment on criteria for deeming a potentially larger and more standardized area as the basis for evaluating the service provided by each of multiple supported carriers and selecting a single carrier to receive support for the eligible duplicate-support hex-9s within that area. Specifically, the Commission would consider a census tract as the evaluation area, and it seeks comment on whether census tracts would be large enough to provide sufficient scale for the selected provider but not so large as to create overlaps with areas where other providers may be receiving duplicate support. Would census blocks be a more reasonable size as evaluation areas? Alternatively, should the evaluation area be constructed based on the particular duplicate support situation, such as an aggregation of smaller adjacent census geographies, such as blocks? The Commission seeks comment on these options and generally on the criteria to be considered when determining an evaluation area that includes the hex-9s deemed to have duplicate support and the adjacent coverage areas of the supported providers.

Evaluating Mobile Technology. The Commission also seeks comment on how to evaluate a subsidized provider's service in a covered hex-9 with respect to mobile technology. For example, should the Commission differentiate among four categories of service in a hex-9: 2G and 3G service; 4G–LTE; 5G–

NR at 7/1 Mbps; and 5G–NR at 35/3 Mbps or better? If the component hex-11s in a hex-9 indicate service of different mobile technologies, should the Commission deem the hex-9 as covered by the most frequently indicated technology in the covered hex-11s, or in the case of an equal split between mobile technologies, of the more advanced technology offered by the provider? Should the Commission instead not differentiate between mobile technologies in evaluating coverage, and consider an area either served or not? Alternatively, should the Commission differentiate among fewer than four mobile technologies, and if so, what should they be? Should the Commission use a different method to assign a technology to a hex-9 when the component hex-11s show different mobile technologies?

The Commission seeks comment on whether and, if so, how to weight differently the hex-9s in an evaluation area that are deemed to show coverage by different technologies. For example, if half of the hex-9s in a provider's footprint in an area show coverage at 3G speeds, and the other half receive 4G LTE service, should the Commission weight the 4G–LTE areas more heavily when evaluating the overall coverage of a supported provider? For this purpose, the Commission suggests weighting 2G and 3G service as .75, 4G LTE service at 1, 5G–NR at 7/1 Mbps at 1.15; and 5G–NR at 35/3 Mbps and higher speeds of service at 1.25. These weights would essentially use 4G LTE service as a benchmark, with slower service carrying less weight while faster service would count more heavily in the evaluation of a provider's existing coverage. If commenters disagree with this approach or with the suggested weights, the Commission asks that they suggest a different approach or different weights and explain why they believe their alternative approach is preferable. As an additional weight, should the Commission evaluate progress of upgraded deployments demonstrated in the December 31, 2029 progress reports for single-support areas, and if so, how should it do so?

Superior Coverage Calculation. In order to compare two or more supported providers that serve an area, this approach—on which the Commission seeks comment—would consider their technology-weighted service performance and the geographic extent of their footprint. The Commission would, for each provider, determine an area-specific score calculated as the sum of the weighted hex-9s that they serve. As a simple example, a provider that serves 1000 hex-9s in an evaluation area at 3G speeds would have a score of 1000*.75, or 750. Another provider that serves 800 hex-9s in the evaluation area with 4G–LTE would have a score of 800. The Commission suggests these two criteria—coverage within the geographic evaluation area and technology—because they provide for a simple, measurable, and transparent method for comparing coverage that captures essential components of a provider's service offering. How should the Commission select a single provider if two or more providers cover 100% of the evaluation area at the same technology, or otherwise have a tied score? Should the Commission then look to a broader area to evaluate the providers' coverage, such as the census block group, census tract level, or an alternate geographic area?

The Commission is mindful, however, that there are other aspects of a supported provider's performance that also matter to consumers. Should other factors, such as price or reliability, be considered in a supported provider's score? Would it be feasible to find standardized, measurable, and transparent ways to incorporate these or other factors? Would consideration of any such factors contribute significantly to the fairness of the comparison across duplicate supported providers? Will the requirements in ACF Mobile Phase I serve to ensure that a provider receiving support as of the start of ACF Mobile Phase II already meets basic price and/or reliability (or other) criteria, mitigating any need to incorporate the criteria explicitly into the scoring approach? The Commission seeks comment on these aspects of the approach.

Under this approach, the provider with the highest score in the evaluation area would be selected to continue to receive support for the previously duplicate support area. The Commission would calculate the support amount as set forth in this document, where generally support for a provider would be based on the support rate of the provider with the smaller footprint. Under this approach, the single winner of support for hex-9s that it and another provider both previously covered would receive a support amount based on the number of previous duplicate support hex-9s in the evaluation area. Its support amount for areas within the evaluation area for which it was a single-supported provider—for which it has guaranteed support through December 31, 2034—would not be affected. That is, the winning provider would receive support at a new rate for the previous duplicate support areas and continue to receive support at its existing rate for any hex-9s for which it has been receiving support as a single provider.

Alternative Evaluation Criteria. Rather than evaluate a provider's current performance based on the extent of coverage within the geographic evaluation area and the technology and speed that it offers, the Commission seeks comment on alternative means of evaluation that would select a single supported provider based solely on which of the duplicate support recipients offers service to the largest number of hex-9s within the evaluation area. The Commission seeks comment on this and other possible approaches that are consistent with the actions of the concurrently adopted Order.

Performance Requirements. Once selected as the winning provider for the evaluation area, the Commission would require that the provider meet the minimum standard of deployment for support under ACF Mobile Phase II of 5G–NR 7/1 Mbps measured in an outdoor stationary environment.

Loss of Support. Under this approach, on which the Commission seeks comment, providers that lose their support in a duplicate-support area would be subject to phase down of support. Providers would lose support subject to a phase down schedule of 2/3 support for the first twelve months, 1/3 support for the next twelve months, and zero support thereafter. In the alternative, the Commission seeks comment on allowing providers that lose duplicate support to deploy to comparable unserved hex-9s in other areas of Alaska. Under this approach, providers that have their performance plans approved by providing comparable service to hex-9s in an uncovered location would have their lost support resume from the date that the performance plan is approved. The Commission seeks comment on this approach. Should there be any differences in the loss of support approach depending on how the provider loses support between the competitive and alternative mechanism?

In the *Alaska Plan Order,* 81 FR 69696, October 7, 2016, the Commission reallocated funds going to support the provision of mobile service in unserved remote areas in Alaska and decided to distribute those reallocated funds through a reverse auction process. In the *Alaska Plan Order,* unserved areas were defined as ''those census blocks where less than 15% of the population within the census block was within any mobile carrier's coverage area.'' By December 31, 2026, that allocation will amount to $162 million. The Commission provided that support for unserved areas would

be distributed through a reverse auction process, subject to the competitive bidding rules codified at Part 1 Subpart AA of the Commission's rules. The *Alaska Plan Order* stated that ''[a]ny competitive ETC, including competitive ETCs that do not otherwise receive support for mobile service in remote Alaska, may bid in the auction to receive annual support through the remainder of the Plan term to extend service to areas that do not have commercial mobile radio service as of December 31, 2014.'' The Commission wishes to refresh the record on this approach and update the definition of unserved areas. The Commission seeks comment on a potential auction mechanism for assigning support to provide service in areas that are currently unserved by any provider. The Commission first addresses several high-level program elements and then describe a reverse auction mechanism, which would use competitive bidding to determine how best to apportion the available budget to maximize new service to Alaskans in places where they live, work, and travel that have heretofore been ignored. The auction mechanism on which the Commission seeks comment would leverage competition across areas to determine the areas that will receive support through the auction and, in areas where more than one bidder is competing, the auction would additionally leverage competition between bidders to determine a single winner of support.

The Commission seeks comment on continuing with the prior decision to open up the unserved areas auction to any competitive ETC certified in Alaska at the commencement of the auction, including competitive ETCs that do not already receive support for mobile service in remote Alaska. The Commission suggests this broad eligibility requirement in order to attract a wide pool of potential service providers, recognizing that the technical and business approaches consistent with providing service to areas that have remained unserved may require expertise and technology different than that of the carriers that traditionally have provided service in Alaska. In addition, the potential availability of new middle-mile capacity may make it feasible for new entities to enter the market in these (and potentially other) eligible areas.

The Commission seeks comment on a term of support of eight years, which is the same period of time that mobile providers will receive support in single-support areas. This will allow time for mobile-support recipients to buildout and maintain a communications network for remote communities and reassess any ongoing support needs to these areas. After that eight-year period, the Commission would reassess any ongoing support needs.

The Commission also seeks comment on the public-interest obligations that a winning bidder will have in exchange for receiving ACF support for serving a previously unserved area. For example, the Commission would require the winning provider to offer 5G–NR service at 7/1 Mbps to at least 85% of the eligible unserved hex-9s in the area by December 31, 2034. The Commission seeks comment on these standards with respect to technology and speed, geographic coverage, and timing. Should the Commission instead establish performance obligations in stages, for example, requiring less geographic coverage at a 2- or 3-year benchmark, more coverage at 5 years, with full coverage required by year 6, or other staged requirements? Should the Commission require a greater or lower technology and speed, or allow a mix of such? Should obligations vary according to the type of service to be provided, such as requiring greater coverage if provided by satellite, or less coverage depending upon access to middle-mile?

The *Alaska Plan Order* defined an unserved area as ''[a] census block [ ] where less than 15% of the population within the census block was within any mobile carrier's coverage area,'' as of December 31, 2014. The Commission finds this definition to be out of date. The Commission seeks comment on an alternative approach whereby it would first determine an area's eligibility at the hex-9 level, rather than at the census-block level, consistent with the concurrently adopted Order regarding areas receiving support. In order to determine that a hex-9 is unserved for purposes of the auction, BDC data would have to indicate that no carrier provides mobile data service as shown at the centroids of 70% of the component hex-11s that comprise the hex-9. The Commission would also determine whether an area includes at least one BSL (as defined by the Fabric) for the hex-9. If a hex-9 is deemed uncovered, contains at least one BSL and is otherwise eligible for ACF support, then the hex-9 would be deemed unserved.

However, because hex-9s are very small relative to the size of mobile deployment areas, the Commission intends that participants in a reverse auction would bid at the level of a larger geographic area, such as a census block, census block group, or census tract. For the larger geographic area to be considered unserved, the Commission would require that 85% of the eligible hex-9s in the larger geographic area be deemed unserved. The Commission seeks comment on the use of census block, census block group, or census tract as the biddable area for the auction. Is there another well-defined geographic area that would be more appropriate for an auction to assign support to currently unserved areas in Alaska? Would a larger hexagonal area in the H3 system, such as a hex-5 (approximately 253 sq. kms) or hex-6 (approximately 36 sq. kms.) be preferred? Biddable areas based on a larger H3 system hexagon would be of a more uniform size than census tracts or blocks. Would potential bidders consider that an advantage? Is it important that the geographic areas used in this reverse auction be the same as those used for any support mechanism for areas that are currently served by at least one subsidized provider? Are there any classes of hex-9s without at least one BSL that should be considered eligible for support if uncovered?

Second, the Commission seeks comment on whether there is a minimum speed or technology level above which a hex-9 would be deemed served. In the *5G Fund Second Report and Order,* an area is eligible if there is not an unsubsidized 5G provider of 7/1 Mbps service in an outdoor stationary environment; however, the *5G Fund Second Report and Order*'s goal is to bring 5G to areas without 5G, instead of bringing 5G to unserved areas. Given that the Alaska Plan's goal was to get to 4G LTE, the Commission thinks a number of otherwise served areas will be defined as unserved if it uses the threshold from the *5G Fund Second Report and Order.* Rather, the Commission suggests that eligible areas with no service, not even voice service, will be deemed unserved for the unserved areas auction in Alaska. The Commission seeks comment on the speed and technology threshold that, if unavailable, should be considered for an area to be deemed unserved.

Are there other approaches to determining eligible areas and biddable areas for the reverse auction that would allow for an accurate, transparent, and careful evaluation of an area's suitability to be considered for support through a reverse auction? Should the Commission consider criteria other than those it has laid out to determine whether an area is considered eligible for the unserved areas auction? More specifically, are there alternatives to certain elements of the means of defining eligible unserved areas that would be preferable?

In the *Alaska Plan Order,* the Commission reallocated funds for use in an auction for support to unserved areas. By December 31, 2026 that allocation will amount to approximately $162 million. The Commission seeks comment on whether this amount should be the maximum amount of support that can be assigned in the reverse auction. The reverse auction format that the Commission sets forth would assign support so as to maximize the additional coverage that can be supported with the budget. The Commission seeks comment on whether this amount will achieve the intended purpose. If commenters contend that additional support is needed, the Commission seeks comment on that amount and if there is support going to mobile wireless in Alaska that can be reallocated for unserved areas.

In the *Alaska Plan Order,* the Commission stated that the reverse auction will be subject to the competitive bidding rules codified at Part 1 Subpart AA of the Commission's rules. Consistent with this, under the competitive bidding approach, the Commission would use a multi-round, descending clock (reverse) auction to identify the areas that would receive support, the providers that would receive support and the amount of support that each winning bidder would be eligible to receive. The descending clock auction would consist of sequential bidding rounds according to an announced schedule providing the start time and closing time of each bidding round. The Commission would use a reverse auction format similar to that used for the Rural Digital Opportunity Fund and the Connect America Fund Phase II auctions.

Bidding and Support Metric. Under this approach, bids in the reverse auction would be accepted and winning bids would be determined based on a price per eligible hex-9. Accordingly, the price clock would be denominated in terms of dollars per eligible hex-9. Each biddable area would be associated with a number of eligible hex-9s, and support amounts would be determined by multiplying the number of eligible hex-9s in the area by the relevant price per hex-9. The opening clock price times the number of eligible hex-9s in a biddable area would indicate the highest support amount that a bidder could receive for the area. The same clock price would apply to all eligible areas.

The Commission also seeks comment on whether an alternative bidding and support metric, such as the number of BSLs in the eligible hex-9s in the biddable area, would be preferable to using the number of eligible hex-9s in the area. Under this approach, the Commission would use the number of hex-9s because hex-9s are a standard unit of area coverage (equal to .105 square kilometers) and are small enough to enable a granular evaluation of whether there are locations—indications that mobile coverage would be used—in the area. Moreover, using the number of hex-9s in a biddable area as a metric is consistent with the approach the Commission adopts in this document for ACF Mobile Phase I and also seeks comment on for other elements of the ACF.

Accepting Bids and Identifying Winning Bids. In the initial round of the auction mechanism, each bidder would indicate the biddable areas to which it is willing to provide service meeting the specified performance requirements in exchange for a support amount implied by the opening clock price. In each subsequent bidding round, the price clock would be decremented and each bidder would indicate the areas to which it is willing to provide service at the lower implied support amount.

Under this reverse auction mechanism on which the Commission seeks comment, after every bidding round, the bidding system would calculate the total requested implied support for the areas that have bids at the current clock price (counting each area with a bid only once). If this amount is greater than the budget, then the price clock would be decremented again, and another bidding round would follow. After the first bidding round in which the total requested support is equal to or less than the budget—that is, the budget ''clearing round''—the bidding system would begin to assign support using a ''second-price rule.'' A second-price rule would ensure that each winning bidder receives a support amount for an area that is at least as great as the support amount implied by its bid price. Bidding would continue with a new bidding round at a decremented clock price for areas that receive more than one bid at the clock price in the clearing round, since at least two bidders are still competing for support to that area. Such rounds would continue until, for each such area, there is at most one bid at the clock price. The lowest bid for the area would be the winning bid, and support amounts again would be determined using a second-price rule.

The Commission seeks comment on this general approach to a multiple-round, descending clock auction to assign support to areas in Alaska that are currently deemed unserved. If the Commission moves forward with this approach, as is the typical procedure for Commission auctions, it would delegate authority to WTB and the Office of Economics and Analytics to release a further Public Notice specifying in more detail the proposed rules and procedures of an auction mechanism that follows the general format the Commission sets forth here. At that point, the Commission would seek comment on the specific elements of the reverse auction. After taking into account the submitted comments, the Commission would release another Public Notice that lays out the specific rules and procedures to be used in the auction and announces the availability of bidder education materials.

The Commission notes that the reverse auction could establish a level of support for unserved eligible areas through competition among bidders based on their assessment of the costs to deploy mobile service in these areas. Could the results of this reverse auction to assign support to unserved areas in Alaska help the Commission consider a more appropriate level of support for participants already serving existing areas in Alaska (single support areas or duplicative support areas), given that this support was initially established based on frozen costs of wireline deployment?

Noncompetitive Alternative. Is there a reason to deviate from this reverse auction approach? Are there considerations that would argue in favor of another approach, and if so, what are they and how would they affect the determinations of eligible areas?

Retail Consumer Subscribership. In the Alaska Plan, the Commission has found instances where some mobile provider participants had very few customers, and in one example, a provider claimed to have only one mobile data subscriber. In such instances, the Commission is concerned that it has been providing support in areas where subscribers are not subscribing to the services.

The Commission seeks comment on whether it should require that all ACF mobile providers receiving support must have a minimum of five mobile data subscribers per census designated place and be able to provide proof of those subscribers upon request by WTB, starting with the due date of the first milestone. For this purpose, each subscriber would be one person, not directly employed by the provider, paying the publicly advertised rate for the mobile data service. Providers unable to provide address-level data of these subscribers upon demand after December 31, 2029, may have a proportional amount of support

withheld as not having effective service in the area. Providers may not take more than 14 days to satisfy any subscribership requests by WTB. Census designated places with fewer than 20 people, based on most recent census estimates, are exempt from this requirement. The Commission seeks comment on this proposal. Would this approach help guard against waste, fraud, and abuse in the mobile portion of the ACF? Would, and if so, how would this approach materially affect the goal to ensure that mobile providers are covering where Alaskans travel? How much of the census designated place would need to be covered before such a condition would be applicable?

In the *Alaska Connect Fund Notice,* the Commission sought comment on whether it should use the ACF to encourage the deployment of Open RAN in mobile networks, and if so how. The Commission has previously noted that networks deploying Open RAN ''have the potential to address national security and other concerns that the Commission and other federal stakeholders have raised in recent years about network integrity and supply chain reliability.'' In its comments, Alaska Telecom Association, the only commenter on this issue, argued that the Commission should avoid any mandates and that providers should have flexibility in deploying such network technologies in Alaska. The Commission has since concluded that it is in the public interest and serves national priorities to use universal service funds to incentivize the voluntary inclusion of Open RAN in mobile networks deployed with 5G Fund support. In the *5G Fund Second Report and Order,* the Commission, recognizing the significant public interest benefits of Open RAN networks, and to encourage the voluntary inclusion of Open RAN in networks that are deployed with 5G Fund support, offered 5G Fund support recipients additional support and an extension of time to deploy networks with Open RAN technologies. The Commission seeks comment on whether it should consider similar incentives for ACF recipients deploying 5G networks. Based on what the Commission adopted in the concurrently adopted Order for single-support areas and duplicate-support areas under ACF Mobile Phase I and are proposing to adopt for ACF Mobile Phase II, should the Commission adopt similar incentives to provide additional funding and extension of build-out obligations for providers that voluntarily agree to deploy Open RAN in Alaska for all ACF mobile provider recipients?

In this document, the Commission seeks comment on whether ACF providers of mobile or fixed service must obtain the consent of the relevant Tribal government(s) for new deployments, prior to being authorized to receive support for those areas. The Tribal consent requirement is exclusively predicated on a government-to-government relationship, based on the Tribes recognized from the Tribe Act of 1994. To promote and support Tribal sovereignty and self-determination, the Commission tentatively concludes that adopting a Tribal consent requirement in ACF rules is consistent with its long-standing recognition that engagement between Tribal governments and communications providers, and the Commission recognizes particularly that early engagement is an important element to promote the successful deployment and provision of service on Tribal lands. The Commission seeks comment generally on this tentative conclusion and how it may be implemented.

In the *Alaska Connect Fund Notice,* the Commission reiterated its commitment to working with Tribes and Tribal leaders, and sought comment on considerations with respect to participation in the ACF by Indian Tribes, Tribal governments, and residents on Tribal lands. In recognition of the fact that engagement between Tribal nations and service providers ''is vitally important to the successful deployment and provision of service,'' the Commission has reaffirmed the importance of its obligation that all high-cost recipients serving Tribal lands demonstrate annually that they have meaningfully engaged with Tribal governments in their supported areas. Several commenters support additional Tribal consultation and Tribal engagement, and others argue the Commission should require Alaska high-cost recipients to obtain written authorizing resolutions from a Tribal government or Tribal entity under the Alaska Native Claims Settlement Act of 1971 (ANCSA) prior to receiving support for projects proposed to be built on Tribal lands.

In the recent *5G Fund Second Report and Order and Second Further Notice,* 89 FR 76016, September 17, 2024, the Commission explored the idea of requiring a winning bidder in the 5G Fund Phase I auction to demonstrate during the long-form application process, and prior to being authorized to receive support, that it has obtained the consent of the relevant Tribal government(s) for any necessary access to deploy network facilities using its 5G Fund support on Tribal lands within the area(s) of its winning bid(s). The Commission tentatively concluded that adopting a Tribal consent requirement in its 5G Fund rules is consistent with its long-standing recognition that engagement between Tribal governments and communications providers, particularly early engagement, is an important element to promote the successful deployment and provision of service on Tribal lands. The Commission envisioned a Tribal consent requirement for the 5G Fund as a continuation of its commitment to ensuring Tribal engagement by service providers that receive high-cost universal service support and in furtherance of the Commission's *Policy Statement* establishing a government-to-government relationship with Tribes. Additionally, in the *5G Fund Second Report and Order and Second Further Notice,* the Commission looked to the Tribal consent requirements of its Tribal Lands Bidding Credit (TLBC) as a guide and discussed including a requirement that applicants for 5G Fund support to provide service on Tribal lands submit a certification from the Tribal government(s) that it has granted any required consent.

The Commission tentatively concludes that it should require Tribal consent for deployment of new facilities for mobile providers participating in the ACF and any new deployments that may be authorized under Fixed ACFs and seeks comment on how it could implement this requirement. The Commission seeks comment on what it should consider as deployment of new facilities for Tribal consent purposes. Should the Commission use any of the existing high-cost universal service Tribal engagement requirements to develop the criteria necessary to evidence Tribal consent in order to provide more consistency and predictability for both Tribal governments and service providers? The Commission seeks comment on any other consent requirements that will help provide equitable provision of ACF support for mobile and fixed broadband service using new facilities located on Tribal lands and that would benefit Tribal communities in Alaska.

In the *Alaska Connect Fund Report and Order,* 89 FR 25147, April 10, 2024, *supra,* the Commission reminded recipients of high-cost support serving Tribal Lands that they are required to have annual discussions with Tribal governments that include feasibility and sustainability planning and compliance with applicable Tribal requirements. The Commission seeks comment on

whether it should consider additional or different Tribal engagement requirements under § 54.313(a)(5) of the Commission's rules for ACF fixed and mobile support recipients.

The Commission seeks comment on how compliance with a Tribal consent requirement may be demonstrated and verified by the Commission. In the *5G Fund Second Report Order and Second Further Notice,* the Commission also sought comment on whether it should include parameters similar to the those that the Commission includes for a winning bidder that is applying for a TLBC to demonstrate its compliance with any Tribal consent requirement, including a requirement for submission of a certification from the Tribal government(s) that it has granted any required Tribal consent. Such a required certification of Tribal consent could include: the signature of an official of the Tribal Government and their title; a statement that the Tribal government has not and will not enter into an exclusive contract with the applicant to preclude entry by other carriers and will not unreasonably discriminate among wireless carriers seeking to provide service on the eligible Tribal land; and a statement that the Tribal government will, as applicable, permit the applicant to locate and deploy facilities on the Tribal land consistent with ACF public interest obligations and performance requirements. Would using the TLBC certification model adequately reflect the contours of Tribal government consent in this context? Under this model, once the certifications from the applicant and the consent of the Tribal government(s) being served are received and reviewed by the Commission and determined to be consistent with the ACF rules, support may be authorized. What adjustments to this model should be made if it is used? Should a process such as the TLBC certification process be adopted? The Commission seeks comment on how it might be able to incorporate flexibility in such a process.

If the Commission does adopt a Tribal consent requirement, when should that consent be obtained for the purposes of the ACF? How would the Commission's requirement be impacted by the Broadband Equity Access and Deployment (BEAD) requirement? Would the Commission need to adopt a specific Tribal consent dispute resolution process? How could the Commission assist in the Tribal consent dispute resolution process? Did any issues arise with respect to Tribal engagement or access to Tribal lands for deployments during the course of the Alaska Plan that can be improved upon? Given Tribal sovereignty, how should the Commission address circumstances in which a Tribal government neither declines nor provides consent? What are the costs and burdens of such requirements to providers? Should different requirements be made for mobile support in Alaska versus fixed support?

In terms of who must provide consent, the Commission recognizes that the question of Tribal land management and sovereignty in Alaska is unique in many respects. All of Alaska is considered Tribal land for purposes of the universal service fund programs. Unlike the lower 48 states, Alaska's Tribal lands are not held and managed by the Bureau of Indian Affairs (BIA). Rather, its Tribal lands are held and managed by Alaska Native Regional Corporations. Twelve years after Alaska was granted statehood in 1959, the ANCSA was passed into law. ANCSA sought to address the ''immediate need for a fair and just settlement of all claims by Natives and Native groups of Alaska.'' ANCSA did this by extinguishing all ''aboriginal titles'' and divided Alaska into twelve distinct regions and for-profit corporations. Each Native Alaskan was enrolled in one of the corporations; enrollment was determined in a tiered manner using the Native's region of residency as of 1970, region of birth, or region of ancestor birth; and through this enrollment the Native Alaskan was listed as a shareholder of a corporation. In other words, much of the land claims of the Alaska Native Villages are managed by the for-profit Alaska corporations, whose shareholders are often comprised by many different federally recognized Tribes. Deployment of advanced communications services provided by the ACF will cross and cover these lands, as they did in the Alaska Plan.

Given these unique aspects of Tribal land management in Alaska, the Commission tentatively concludes that an ACF recipient seeking to deploy new facilities on Tribal lands must obtain consent from the appropriate Tribal entity. Is the appropriate Tribal entity the relevant Alaska Native Village(s) recognized by the BIA? The Commission notes that federally recognized Tribes have a government-to-government relationship with the United States and are eligible to receive certain protections, services, and benefits by virtue of their federally recognized status. While the Commission's rules with respect to Tribal eligibility in various contexts vary somewhat, they universally limit eligibility to those Tribes that are ''federally-recognized.'' The Commission also seeks comment regarding the role of the Alaska Native Corporations as they relate to Tribal consent requirements of it.

In addition, the Commission seeks comment on how to address the fact that many Alaska Native Villages do not have defined boundaries but are assigned into Alaska Native Village Statistical Areas (ANVSA) by the Census Bureau, and that much of Alaska lies outside these areas, which opens the possibility to multiple claims of sovereignty. In § 54.5, the Commission defines Tribal lands for the purposes of the high-cost support as including ''Alaska Native regions established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688).'' However, Alaska Native regions often contain many different Tribal entities, and given the size of the Alaska Native regions, several of the Tribal entities in the respective Alaska Native region may not be physically located near the deployment in a region. Should the Tribal consent process be limited to new deployments or buildouts where the facilities placement occurs within the census boundaries of an ANVSA, as this situation would clearly identify that a particular Tribal entity is directly affected by a deployment? The Commission seeks comment generally on these issues.

The Commission, as part of its continuing effort to advance digital equity for all, including people of color, persons with disabilities, persons who live in rural or Tribal areas, and others who are or have been historically underserved, marginalized, or adversely affected by persistent poverty or inequality, invites comment on any equity-related considerations, and invites comment on any benefits (if any) that may be associated with the proposals and issues discussed herein. Specifically, the Commission seeks comment on how its proposals may promote or inhibit advances in diversity, equity, inclusion, and accessibility, as well as the scope of the Commission's relevant legal authority.

II. Procedural Matters

Paperwork Reduction Act

The FNPRM contains possible new or modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, will invite the general public and the Office of Management and Budget to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public

Law 107–198, *see* 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies in this document. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments provided in this document. The Commission will send a copy of the FNPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

In the FNPRM, the Commission seeks comment on several issues pertaining to the implementation of the ACF. In doing so, the Commission continues to work towards its objectives of providing service to rural and high-cost areas of Alaska, which historically are some of the most difficult and costliest areas to serve in the country and where many residents continue to lack access to the high-quality, affordable broadband service enjoyed by other parts of our nation. Specifically, the Commission seeks comment on ACF Mobile Phase II service goals or requirements, as well as on a methodology to determine a single support amount for areas where more than one provider had been receiving support for overlapping service areas, as well as for use in determining support amounts for areas that the Commission deems ineligible in the concurrently adopted Order. Additionally, the Commission seeks comment on how to resolve duplicative funding so that only one provider would continue receiving support in the area, in particular proposing two possible mechanisms to address this issue. Further comment is also sought to update the record on how best to deploy service to unserved areas using the approximately $162 million collected from the Alaska Plan. Finally, the Commission seeks comment on additional issues, such as retail consumer conditions, Open RAN, and Tribal consent under the ACF. In further developing the record in this proceeding, the Commission relies on the experiences of carriers with operations in Alaska, many of which are small business entities, to build a record on how best to implement the ACF.

The proposed action is authorized pursuant to sections 4(i), 214, 254, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 201, 205, 214, 254, 303(r), 403, and §§ 1.1 and 1.421 of the Commission's rules, 47 CFR 1.1, 1.421.

Small entities potentially affected by the rules herein include Wired Telecommunications Carriers, LECs, Incumbent LECs, Competitive LECs, Interexchange Carriers (IXC's), Local Resellers, Toll Resellers, Other Toll Carriers, Prepaid Calling Card Providers, Fixed Microwave Services, Cable and Other Subscription Programming, Cable Companies and Systems (Rate Regulation), Cable System Operators (Telecom Act Standard), Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, Satellite Telecommunications, Wireless Telecommunications Carriers (except Satellite), All Other Telecommunications, Wired Broadband internet Access Service Providers (Wired ISPs), Wireless Broadband internet Access Service Providers (Wireless ISPs or WISPs), internet Service Providers (Non-Broadband), and All Other Information Services.

Potential rules resulting from comments in the FNPRM, could impose new or additional recordkeeping and reporting requirements for small and other entities, if adopted. Specifically, in the FNPRM, the Commission seeks comment on a number of issues related to the implementation of the ACF. For example, the FNPRM seeks comment on setting a minimum goal of deployment of 5G–NR 7/1 Mbps for all mobile providers participating in ACF Mobile Phase II, as well as whether any exemptions should be made for certain areas. Under the competitive mechanism, providers seeking to participate would submit proposals including coverage maps for the areas where more than one provider currently receives support, as well as the surrounding community where no provider or only a single provider may currently offer service. The coverage map would comply with BDC mobile coverage data requirements and would predict 5G–NR coverage in an outdoor stationary environment. An ETC may propose to cover a tract with 5G–NR 7/1 Mbps service or 5G–NR 35/3 Mbps service, but separate coverage maps must be submitted for each proposed service. For the alternative mechanism, the Commission seeks comment on whether to set a minimum goal of deployment for support under ACF Mobile Phase II of 5G–NR 7/1 Mbps measured in an outdoor stationary environment.

The RFA requires an agency to describe any significant alternatives that could minimize impacts to small entities that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): ''(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.''

The FNPRM also takes the step of outlining an alternative mechanism that would allow a provider to retain its funding if it provides comparable service in a nonduplicate-support area, as well as consider alternative approaches from small and other entities on how best to achieve an outcome that dovetails both the Commission's policy goals and the minimization of substantial economic impact to small entities.

III. Ordering Clauses

It is further ordered that, pursuant to the authority contained in sections 4(i), 201, 205, 214, 254, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 201, 205, 214, 254, 303(r), 403, and §§ 1.1 and 1.421 of the Commission's rules, 47 CFR 1.1, 1.421, the FNPRM *is adopted.* The FNPRM will be *effective* upon publication in the **Federal Register,** with comment dates indicated therein.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–28170 Filed 12–3–24; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 383

[Docket No. FMCSA–2024–0121]

RIN 2126–AC59

Transportation of Fuel for Agricultural Aircraft Operations

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This proposed rule would amend the Federal Motor Carrier Safety Regulations (FMCSRs) to allow States to waive the hazardous materials (HM) endorsement requirement for holders of Class A commercial driver's licenses (CDL) who transport no more than 1,000 gallons of aviation grade jet fuel in support of seasonal agricultural operations.

DATES: Comments must be received on or before February 3, 2025.

ADDRESSES: You may submit comments identified by Docket Number FMCSA-2024–0121 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov/docket/FMCSA-2024-0121/document*. Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.
- *Fax:* (202) 493–2251.

FOR FURTHER INFORMATION CONTACT: Ms. Rebecca Rehberg, Transportation Specialist, CDL Division, Office of Safety Programs, FMCSA; (850)-728–2034; *rebecca.rehberg@dot.gov*. If you have questions on viewing or submitting material to the docket, call Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION: FMCSA organizes this NPRM as follows:

I. Public Participation and Request for Comments

A. Submitting Comments

If you submit a comment, please include the docket number for this NPRM (FMCSA–2024–0121), indicate the specific section of this document to which your comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *https://www.regulations.gov/docket/FMCSA-2024-0121/document,* click on this NPRM, click ''Comment,'' and type your comment into the text box on the following screen.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing.

FMCSA will consider all comments and material received during the comment period.

Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the NPRM, it is important that you clearly designate the submitted comments as CBI.Please mark each page of your submission that constitutes CBI as ''PROPIN'' to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the NPRM. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 or via email at *brian.g.dahlin@dot.gov*. At this time, you need not send a duplicate hardcopy of your electronic CBI submissions to FMCSA headquarters. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this rulemaking.

B. Viewing Comments and Documents

To view any documents mentioned as being available in the docket, go to *https://www.regulations.gov/docket/FMCSA-2024-0121/document* and choose the document to review. To view comments, click this NPRM, then click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its regulatory process. DOT posts these comments, including any personal information the commenter provides, to *www.regulations.gov* as described in the system of records notice DOT/ALL 14 (Federal Docket Management System (FDMS)), which can be reviewed at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices*. The comments are posted without edit and are searchable by the name of the submitter.

II. Executive Summary

A. Purpose and Summary of the Regulatory Action

FMCSA proposes to amend the commercial driver's license (CDL) regulations to allow States additional flexibility to waive the hazardous materials (HM) endorsement [1] requirement for certain drivers transporting aviation fuel in furtherance of agricultural aviation operations. Many farm operations rely on aircraft to apply pesticides or fertilizers to their

[1] *Endorsement* as defined in § 383.5 means an authorization to an individual's commercial learner's permit (CLP) or CDL required to permit the individual to operate certain types of commercial motor vehicles.

crops. Agricultural aviation companies often deliver aircraft fuel to staging areas some distance from their headquarters. These companies, particularly in remote, rural areas, have difficulty finding CDL holders with HM endorsements to complete these deliveries. Under the current regulations, most CDL holders must obtain an HM endorsement before transporting fuels. However, 49 CFR 383.3(i) provides a limited exception to this requirement and allows States to waive the requirement of an HM endorsement if the holder of a Class A CDL is transporting diesel fuel in the CDL holder's State of domicile as an employee of four specific agriculture-related businesses. FMCSA proposes to give States authority to waive the HM endorsement requirement for Class A CDL holders who transport up to 1,000 gallons of aviation grade jet fuel (often called Jet A, referred to as *jet fuel* for the purposes of this preamble) in the CDL holder's State of domicile and in support of agricultural aircraft operations.

B. Costs and Benefits

This proposal could result in costs to States and their State driver licensing agencies (SDLAs) and may result in cost savings to drivers and to agricultural aviation operators. States and their SDLAs may incur costs for updating their websites and other informational materials to reflect the changes in requirements for Class A CDL holders transporting hazardous materials and for training roadside officers. The proposal would result in cost savings for agricultural aviation operators and the drivers these operators hire to mix, load, and transport jet fuel in quantities of 1,000 gallons or less in participating States. Class A CDL holders would avoid approximately $261 in costs associated with each driver obtaining an HM endorsement, and agricultural aviation operators would be able to run their businesses more efficiently by making use of satellite airstrips. FMCSA does not expect that this proposed rule would negatively impact CMV safety. For various reasons, drivers who transport jet fuel operate in low-risk safety conditions and rarely experience crashes. More in depth discussion of the potential impacts resulting from this rule are found in the regulatory analyses section below.

III. Abbreviations

ANPRM Advanced notice of proposed rulemaking
BLS Bureau of Labor Statistics
CBI Confidential business information
CDL Commercial driver's license
CFR Code of Federal Regulations
CE Categorical exclusion
CLP Commercial learner's permit
CMV Commercial motor vehicle
CMVSA Commercial Motor Vehicle Safety Act
DOT Department of Transportation
ELOS Equivalent level of safety
FAST Act Fixing America's Surface Transportation Act
FHWA Federal Highway Administration
FMCSA Federal Motor Carrier Safety Administration
FMCSRs Federal Motor Carrier Safety Regulations
FR Federal Register
HM Hazardous materials
HMRs Hazardous materials regulations
IRFA Initial regulatory flexibility analysis
MCMIS Motor Carrier Management Information System
NAAA National Agricultural Aviation Association
NAICS North American Industry Classification System
NEPA National Environmental Policy Act
NHTSA National Highway Traffic Safety Administration
NPRM Notice of proposed rulemaking
OMB Office of Management and Budget
PHMSA Pipeline and Hazardous Materials Safety Administration
PIA Privacy impact assessment
PTA Privacy threshold assessment
RFA Regulatory Flexibility Act
SBA Small Business Administration
SBREFA Small Business Regulatory Enforcement Fairness Act
SDLA State driver's licensing agency
STA Security Threat Assessment
TPR Training Provider Registry
TSA Transportation Security Administration
UMRA Unfunded Mandates Reform Act
U.S.C. United States Code

IV. Legal Basis

The CDL regulations are based on the authority of the Commercial Motor Vehicle Safety Act of 1986 (CMVSA). Section 12013 of the CMVSA allowed the Federal Highway Administration (FHWA), FMCSA's predecessor agency, to ''waive, in whole or in part, application of any provision of this title or any regulation issued under this title with respect to class of persons or class of commercial motor vehicles if the Secretary of Transportation (the Secretary) determines that such waiver is not contrary to the public interest and does not diminish the safe operation of commercial motor vehicles'' (Pub. L. 99–570, Title XII, 100 Stat. 3207–170, 3207–186, Oct. 27, 1986, codified at 49 U.S.C. app. 2711).

On the basis of section 12013, FHWA authorized the States to waive the knowledge and skills tests otherwise required to obtain a CDL for employees of custom harvesters, farm retail outlets and suppliers, agrichemical businesses, and livestock feeders (57 FR 13650, Apr. 17, 1992). CDL applicants in States that exercised this waiver option were required to meet certain conditions, including a prohibition on carrying any placarded quantities of HM, except for diesel fuel in quantities of 1,000 gallons or less (57 FR 13650, 13654). The 1992 CDL waiver option, with the 1,000-gallon restriction on the transportation of diesel fuel, was codified originally as 49 CFR 383.3(f)(3)(v) (61 FR 9546, March 8, 1996).

Following statutory amendments,[2] the language of the CMVSA's section 12013—that a waiver must be ''not contrary to the public interest'' and ''not diminish the safe operation of commercial motor vehicles''—has been replaced by the standard that a waiver or exemption must ''likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved in the absence of the waiver'' (49 U.S.C. 31315(a)) or ''absent such exemption'' (49 U.S.C. 31315d(b)(1)).

Section 7208 of the Fixing America's Surface Transportation (FAST) Act (Pub. L. 114–94, Dec. 4, 2015, 129 Stat. 1312, 1593) allowed the States to waive the requirement that a holder of a Class A CDL obtain the HM endorsement required by 49 CFR 383.93(b)(4), provided the Class A CDL holder is an employee of one of the four categories of business specified in FHWA's 1992 waiver who transports diesel fuel in quantities of 1,000 gallons or less. As thus amended, the State waiver authority is now codified at 49 CFR 383.3(i).

FMCSA believes that the equivalent-level-of-safety (ELOS) standard required by the waiver and exemption provisions in 49 U.S.C. 31315 and 49 CFR part 381 is the appropriate standard for this NPRM. The 1992 rule required that the State waiver option not diminish the safe operation of CMVs, and all subsequent versions of the statute and regulation have retained that ELOS concept. Congress itself clearly embraced that standard when section 7208 was explicitly limited to the same four agriculture-related businesses covered by the 1992 exemption.

Pursuant to 49 U.S.C. 31305(a), which sets forth the general standards for the CDL rules, also provides that FMCSA ''shall prescribe regulations on minimum standards for testing and ensuring the fitness of an individual

[2] Title 49, United States Code, was recodified in 1994, the waiver authority in 49 U.S.C. app. 2711 was redesignated as 49 U.S.C. 31315 (Pub. L. 103–272, 108 Stat. 745, 1029, July 5, 1994), and the Transportation Equity Act for the 21st Century (TEA–21) revised 49 U.S.C. 31315 as ''Waivers, exemptions, and pilot programs'' (Pub. L. 105–178, 112 Stat. 107, 401, June 9, 1998).

operating a commercial motor vehicle.'' Implicit in that provision is the authority to decide whether certain CDL holders may meet the ''fitness'' requirement without complying with every part of the CDL regulations. FMCSA believes that exempting employees of agricultural aviation companies who hold Class A CDLs and transport jet fuel from the requirement to obtain an HM endorsement is consistent both with the standard of the CMVSA's section 12013 and with the current ELOS and ''fitness'' standards enacted by Congress. A waiver granted by a State under this proposal, as under section 7208 of the FAST Act, would also exempt eligible drivers from the Transportation Security Administration's (TSA) background records check in 49 CFR part 1572, subpart B.

V. Background

A. Commercial Driver's License

Since April 1, 1992, drivers have been required to obtain and hold a CDL if they operate in interstate, intrastate, or foreign commerce and drive a vehicle that meets one or more of the classifications of a CMV in 49 U.S.C. 31301(4).[3] The physical requirements and knowledge and skills testing are intended to help to ensure safe operations of CMVs. FHWA and, since 2000, FMCSA have developed and issued standards for State licensing and testing of CDL applicants. Under § 383.133(c)(6) of the FMCSRs, States must administer a three-part CDL skills test to CDL applicants in the following order: (1) pre-trip inspection, (2) basic vehicle control skills, and (3) on-road skills. Drivers who operate special types of CMVs, such as school buses, vehicles carrying HM, double/triple trailers, tank vehicles, and combination vehicles, must pass additional tests to obtain the relevant endorsement for their CDLs. Endorsement testing requirements are found in § 383.93(c). The HM endorsement requires a knowledge test.

B. National Agricultural Aviation Association Interactions With FMCSA

The National Agricultural Aviation Association (NAAA) is a trade association that represents over 1,900 members in 46 States. NAAA member operators/pilots are licensed as commercial applicators who use aircraft to enhance food and fiber production and control health-threatening pests. According to NAAA's petition for rulemaking, aircraft operations are often the only, or the only economical, method to apply pesticides or fertilizers. Almost 28 percent of crop protection product applications to commercial farmland are made aerially. As a result, NAAA estimates that 127 million acres of cropland are treated via aerial application in the U.S. each year.[4]

While fueling, mixing, and loading of crop-protection products (*e.g.,* fertilizers, insecticides, fungicides, or herbicides) are normally conducted at a location where agriculture aviation operators have permanent fuel tanks and mixing and loading facilities, at times operators and pilots work so far from their permanent facility that it is cost-effective to use a satellite landing strip and an on-site fuel truck. In such scenarios, fuel is pumped from the fixed-base tanks into the fuel truck that transports it to the satellite landing strip. Additional trips are made to the satellite strip as needed, and the CMV returns to the fixed-base location at the end of the day. Some CMVs may also be loaded with crop-protection products (*e.g.,* insecticides, fungicides, or herbicides). The driver may serve both as a ''mixer loader'' of the fertilizers or pesticides and of the aircraft fuel.

2005 Exemption Request

On June 17, 2005, NAAA requested an exemption [5] under 49 CFR 381.310 on behalf of its members. NAAA asked that CMV drivers supporting agricultural aircraft operations be exempted from the required knowledge and skills tests required for a CDL and that they be eligible to receive restricted CDLs allowed for certain drivers in farm-related service industries, as described in § 383.3(f). In addition, NAAA sought an exemption from § 383.3(f)(3)(v) to allow these restricted CDL holders to transport fuel used to power crop-sprayer aircraft, if transported in quantities of 1,000 gallons or less. NAAA argued that the exemptions would provide parity with the CDL regulations for other, nearly identical farm-related services. NAAA did not offer any countermeasures to ensure an ELOS, as required by 49 U.S.C. 31315(b)(5)(D), but it argued that compliance with all other DOT requirements would ensure safe CMV operations.

2007 Federal Register Notice

On July 5, 2007, FMCSA issued a **Federal Register** notice (72 FR 36748) soliciting comments on the NAAA application. The Agency received a total of 17 comments, 9 supporting and 6 opposing the exemption. Two comments were out of scope. All comments that supported the request were from agricultural entities. Opponents included a safety association and State safety agencies.

Supporters of the request noted that they were experiencing the same shortage of qualified CDL drivers as NAAA members, creating a hardship for the industry. Commenters also mentioned CMVs transporting jet fuel and pesticides operate primarily in rural areas, where low population and traffic density reduced crash risk. These trips usually occur within a 50-mile radius or less of their permanent facilities. One farmer indicated that agriculture relies on crop spraying operations.

The NAAA's application was opposed by Advocates for Highway and Auto Safety and safety agencies of Missouri, Virginia, and Ohio. The commenters pointed out that, if this exemption were in place, NAAA drivers would be transporting HM more dangerous than that permitted by § 383.3(f)(3)(v) and would be doing so without demonstrating basic competency in CMV operations. The drivers would also avoid two requirements for the HM endorsement: successful completion of the written HM test required by § 383.135, and a determination by the TSA pursuant to § 383.141(b) that the driver is ''not a security threat.'' The commenters also pointed out that NAAA failed to propose an alternative method of assessing the knowledge and skills of these CMV drivers, as required by § 381.415(c)(6) through (c)(8).

2010 Denial

After reviewing NAAA's request for exemption and the public comments received, FMCSA concluded that NAAA had failed to demonstrate how it would ensure that the operations of its members under the exemption would achieve an ELOS. The Agency published the notice of denial in the **Federal Register** on June 10, 2010 (75 FR 32983).

FAST Act Implementation

Section 7208 of the FAST Act directed the Secretary to allow a State, at its discretion, to waive the requirement that a Class A CDL holder obtain an HM endorsement when that individual is transporting 3,785 liters (1,000 gallons) or less of diesel fuel, marked ''flammable'' or ''combustible,'' as appropriate, as an employee of a custom harvester operation,

[3] Commercial Motor Vehicle Safety Act of 1986, Public Law 99–570, Title XII, 100 Stat. 3207–170, 49 U.S.C. chapter 313.

[4] Industry Facts, Environmental Benefits and FAQs—National Agricultural Aviation Association (agaviation.org) *(accessed June 11, 2024).*

[5] The request for exemption and other associated documents may be found at *https://www.regulations.gov/docket/FMCSA-2007-28480.*

agrichemical business, farm retail outlet and supplier, or livestock feeder.

On July 22, 2016, FMCSA implemented this and other provisions of the FAST Act (81 FR 47714). The final rule amended § 383.3 by adding a new paragraph (i), providing that a State may waive the requirement that a driver obtain a HM endorsement to transport diesel fuel under certain circumstances.

2018 NAAA Petition

In April of 2018, NAAA submitted a petition to amend § 383.3(i), which FMCSA treated as a petition for rulemaking under § 389.31. NAAA argued that expanding the exemption options allowed by section 7208 of the FAST Act to include an HM exception for drivers with a Class A CDL transporting 1,000 gallons or less of jet fuel would provide an economic benefit to agriculture aviation operators while keeping America's roads safe. NAAA asserted that the similar chemical properties of jet fuel and diesel fuel, along with infrequency of trips involving aviation fuel, the rural environments in which these trips typically occur, and exceptional weather conditions would provide an ELOS while reducing regulatory burdens on agriculture aviation operators.

NAAA emphasized the cost to agriculture aviation operators, almost all of them small businesses, of paying drivers to obtain an HM endorsement when they already have the knowledge and skills required to hold a CDL. NAAA noted that retaining drivers with an HM endorsement is extremely difficult due to the seasonal nature of agriculture aviation work. NAAA indicated that a shortage of available drivers with such an endorsement may block the transportation of jet fuel to a satellite airstrip closer to the application site. In December of 2022, after review of the petition and consultation with technical staff from the Pipeline and Hazardous Materials Safety Administration (PHMSA), FMCSA granted NAAA's petition for rulemaking to amend § 383.3(i).[6]

VI. Discussion of Proposed Rulemaking

Pursuant to §§ 383.93(a)(1) and (b)(4), a CDL holder may not drive a vehicle used to transport HM without obtaining a State-issued HM endorsement. The term *hazardous materials* is defined in § 383.5 to include materials for which placarding is required under subpart F of 49 CFR part 172. Current regulations generally require a CDL holder to obtain an HM endorsement in order to transport fuel, including jet fuel.

This NPRM would amend § 383(i) to allow States to waive the HM requirement for Class A CDL holders who are employed by agricultural aviation operators in their State of domicile and drive a vehicle transporting up to 3,785 liters (1,000 gallons) of jet fuel (clearly marked with a ''flammable'' or ''combustible'' placard) for use in agricultural aviation operations. The Agency also proposes to add a definition of *jet fuel* to mean ''fuel, aviation, turbine engine'' as listed in the Hazardous Materials Table in 49 CFR 172.101 that is reclassed as a combustible liquid in accordance with 49 CFR part 173.

FMCSA developed the proposal in this NPRM based on evaluation and review of available data relating to the similarity of jet fuel and diesel fuel, the safety of the trucking operations of the agricultural aviation industry, NAAA's petition content, existing exemptions to subpart H of 49 CFR part 383, potential impact on the States, and the ELOS for an addition of a jet fuel exemption. These topic areas are discussed individually below. In addition to the specific areas detailed below, FMCSA also requests comment on other questions regarding the agricultural aviation industry transport of fuel in general which can be found in Section VI.6. Issues on Which the Agency Seeks Further Comment.

1. Jet Fuel and Diesel Fuel

Both diesel and jet fuel are kerosene-based fuels and have similar chemical characteristics, transportation requirements, and related exceptions. Under the HM regulations, both diesel fuel and jet fuel are classified as flammable liquids in the hazardous materials table (§ 172.101), but in most instances, may be reclassed as combustible liquids if they have a flash point at or above 100 °F (38°C). If properly reclassed as *combustible liquids* and transported in *non-bulk packaging,* as defined in § 171.8, diesel and jet fuel are not subject to the requirements of Subchapter C of the HM regulations unless the combustible liquid is a hazardous substance, a hazardous waste, or a marine pollutant. This exception allows drivers to potentially transport more than 1,000 gallons of diesel or jet fuel in multiple non-bulk packagings without an HM endorsement. However, when diesel or jet fuel are properly reclassed as combustible liquids but transported in a bulk packaging, as defined in § 171.8, they are subject to some of the HM regulations including the placarding requirements of subpart F of 49 CFR part 172 and the HM endorsement. Additionally, PHMSA's Emergency Response Guidebook provides emergency responders the same guidance on what to do during the initial stages of a HM transportation incident.

2. Safety of the Trucking Operations of the Agricultural Aviation Industry

FMCSA reviewed the supporting evidence provided by NAAA in its petition. NAAA indicated that several factors support the safety of its proposed HM exemption, primarily the similarity of jet fuel to diesel fuel, for which an exemption option is already available. Additionally, agriculture aviation operations typically take place in rural areas with minimal traffic and during fair weather conditions. In many cases, driving occurs only once or twice a week to a satellite facility. These factors, in addition to the knowledge and skills required to obtain a Class A CDL, create low-risk safety conditions. FMCSA agrees diesel fuel is similar to jet fuel, as defined in this NPRM, and that agricultural aviation transport of jet fuel generally occurs in lower traffic areas which are linked to lower incident rates. In the FAST Act, Congress implicitly determined that allowing States the option to waive the HM endorsement for drivers transporting diesel fuel for the four agriculture-related businesses now listed in § 383.3(i), would not adversely affect safety. Because jet fuel is chemically very similar to diesel fuel and because agricultural aviation companies transport jet fuel in the same rural areas, on roads with low traffic density, as drivers transporting diesel fuel for the four agricultural businesses listed in the FAST Act, FMCSA concludes that the ELOS determination underlying the FAST Act waiver option is equally valid and applicable to the option for a State waiver of the HM endorsement proposed by this rulemaking.

3. Impact on the States

FMCSA is aware that States may have concerns if the HM knowledge test were allowed to be waived. These concerns could include undermining the purpose of a CDL and its intended level of safety, opening the possibility for other industries to request such exemptions, and inconsistency across the States that exercise discretion with the proposed *jet fuel* exemption.

The Agency notes that, regardless of whether any State exercises its discretion, a driver may still be required to obtain an HM endorsement when

[6] The grant letter and all other correspondence with NAAA related to this rulemaking can be found in the docket for this rule.

operating a CMV in a State that has not opted to waive the requirement. This scenario could occur when jet fuel is transported across a State line. As detailed earlier in the section V. B. Background, most satellite locations utilizing exempted CMVs are expected to be within a 50-mile radius of the permanent facility. FMCSA therefore believes that such discrepancies in endorsement requirements would be uncommon.

The Agency's experience with SDLAs' responses to codification of the diesel fuel exemption indicate that 16 of 50 [7] States choose to grant the exemption. FMCSA believes that States with economies heavily dependent on agriculture would be most likely to exercise a jet fuel exemption. The Agency expects a similar level of use if this proposal were to be made final, but requests comment on that assumption.

States utilizing the exemption would need to provide training to roadside officers on the application of the new rule. The added development cost of the training would be minimal, however, due to the similarity of the existing diesel fuel exemption.

4. Equivalent Level of Safety

As part of evaluating the NAAA petition, FMCSA considered whether granting the exemption for jet fuel would likely maintain a level of safety equivalent to, or greater than, the level achieved by the current regulations. The Agency reviewed available safety records, reports, and statistics to evaluate the safety of the proposal presented in this NPRM.

In addition to other analysis, FMCSA evaluated the existing diesel fuel exemption to determine if jet fuel has similar risk characteristics. FMCSA reviewed the conference report that accompanied the FAST Act, and found no indication that Congress intentionally excluded the transportation of kerosene-based fuels other than diesel fuels, such as fuels used in support of agriculture aviation operations.[8]

FMCSA analyzed existing data sources available in the National Highway Traffic Safety Administration's (NHTSA) Fatality Analysis Reporting System and FMCSA's Motor Carrier Management Information System (MCMIS) as well completing a 47-question survey of Agency field staff directly involved in the enforcement of, and compliance with, Federal regulations. The study did not return evidence of safety or enforcement impacts directly attributable to the FAST Act provisions, which include the HM endorsement exemption for diesel fuel.[9]

NAAA indicated that agricultural aviation fuel transportation occurs most commonly in rural agricultural areas where there is less traffic. This is supported by research which indicates, for example, that 16.4 percent of crashes are on roads with 10,000 vehicles/day or fewer, compared to 36.9 percent of crashes on roads with 10,000–50,000 vehicles, and 46.7 percent of crashes on roads with 50,000+ vehicles.[10] Likewise, the 2005 FMCSA Report to Congress on the Large Truck Crash Causation Study reviewed crashes by roadway type and indicated the following: Interstate (25.1 percent), U.S. highway (24.2 percent), State highway (30.3 percent), country road (9.1 percent), township (1.5 percent), municipality (6.8 percent), and other (2.6 percent).[11]

Finally, the FAST Act addition of § 383.3(i) does not provide exemptions from additional regulatory requirements related to the transportation of diesel fuel and, for the purposes of this rulemaking, jet fuel. Because drivers transporting jet fuel are hazmat employees as defined in 49 CFR 171.8, hazmat training is still required under parts 172 and 177 for the agricultural aviation industry.

PHMSA initial and recurring HM training requirements, found in § 172.704, include general awareness/familiarization with HM, function specific training, safety training including emergency response, and security awareness. Additionally, § 177.816 requires driver training that is very similar to the training required to obtain the HM endorsement.

FMCSA finds that initiation of a rulemaking to provide States the option to grant relief from the HM endorsement for agriculture aviation operators seeking a Class A CDL to be reasonable, given the similarity of diesel fuel to jet fuel and the available research.

5. Issues on Which the Agency Seeks Further Comment

The Agency requests comment on certain aspects of the agriculture aviation industry and the use of CMVs to transport jet fuel.

a. FMCSA believes that States with economies heavily dependent on agriculture would be most likely to exercise a jet fuel exemption. Is this an accurate assumption?

b. Will this proposal lead to additional burden or costs to SDLAs and/or roadside officers and any other law enforcement officials responsible for enforcing CDL and HM endorsement compliance?

c. How many Class A CDL holders with HM endorsements are currently involved in transporting jet fuel in quantities of 1,000 gallons or less for agriculture aviation operations?

d. How many CMV drivers will enter the market for transporting jet fuel in quantities of 1,000 gallons or less in participating States due to relaxed requirements?

e. As part of the initial petition for rulemaking, the NAAA claimed that a shortage of available drivers may prevent the use of a satellite airstrip closer to the application site. How many satellite airstrips would be available for use if this proposal were to be finalized? How many refueling trips from application sites back to operational bases (mixing-loading sites) do aircraft currently make, and how much fuel do these trips require?

f. How much revenue do agriculture aviation operators lose as a result of not having an available CMV driver with a Class A CDL and HM endorsement? In a survey from 2005 cited in its initial petition for rulemaking, the NAAA mentioned that one operator claimed that he loses $2,500 to $5,000 per day as a result of not having an available CDL holder and loses work as a result of this shortage. FMCSA is seeking an estimate of the revenue the typical (average) agriculture aviation operator loses per day by not having an available CMV driver to transport jet fuel and therefore occasionally being unable to work.

[7] FMCSA contacted the States, 50 of which responded as of July 25, 2024, to determine which States choose to grant the exemption for diesel. The 16 States that grant the diesel exemption are: Alabama, Connecticut, Iowa, Kansas, Kentucky, Minnesota, Mississippi, Nebraska, North Dakota, New Mexico, New Jersey, Oklahoma, Pennsylvania, South Dakota, Texas, and Wisconsin.

[8] FAST Act Conference Report to Accompany H.R. 22. Dec. 1, 2015. *https://www.congress.gov/114/crpt/hrpt357/CRPT-114hrpt357.pdf* (accessed June 21, 2024).

[9] FMCSA *Congress Safety and Enforcement Impacts Report to Congress.* Feb. 2023. This document is available at: *https://www.fmcsa.dot.gov/sites/fmcsa.dot.gov/files/2023-03/Safety%20and%20Enforcement%20Impacts%20Report%20Final%20February%202023.pdf* and in the docket for this rulemaking (last accessed May 24, 2024).

[10] Dong, Chunjiao, Qiao Dong, Baoshan Huang, Wei Hu, and Shashi S. Nambisan. ''Estimating factors contributing to frequency and severity of large truck-involved crashes.'' 2017. *Journal of Transportation Engineering,* Part A: Systems 143, no. 8: 04017032.

[11] *Report to Congress on the Large Truck Crash Causation Study.* Federal Motor Carrier Safety Administration, U.S. Department of Transportation: Washington, DC, USA (2005).

VII. International Impacts

Motor carriers and drivers are subject to the laws and regulations of the countries that they operate in, unless an international agreement states otherwise. Drivers and carriers should be aware of the regulatory differences between nations.

VIII. Section-by-Section Analysis

This section-by-section analysis describes the proposed changes in numerical order. Part 383 ''Applicability'' would be amended in five locations. Paragraph (i) of § 383.3 would be amended to add ''or jet fuel'' to the commodities States may exempt from the subpart H CDL requirement. Paragraph (i)(1) would be amended by adding ''agriculture aviation operation'' to the list of industries to which the hazardous material endorsement exemption applies. Paragraph (i)(2)(i) would be amended to add operators of vehicles transporting jet fuel in a quantity of 1,000 or less gallons to the conditions of the hazardous material exemption. Paragraph (i)(2)(ii) would be revised to indicate that jet fuel or diesel fuel transported under this hazardous material endorsement exemption must be clearly placarded in accordance with Part 172 subpart F and all other applicable HMRs.

Finally, section 383.5 ''Definitions'' would be amended to add a definition for *jet fuel*. The definition includes all classes of fuel, aviation, turbine engine as listed in the Hazardous Materials Table in 49 CFR 172.101, including Jet A, that are reclassed as a combustible liquid in accordance with 49 CFR part 173.

IX. Regulatory Analyses

A. Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), E.O. 14094 (Modernizing Regulatory Review), and DOT Regulatory Policies and Procedures

FMCSA has considered the impact of this NPRM under E.O. 12866 (58 FR 51735, Oct. 4, 1993), Regulatory Planning and Review, E.O. 13563 (76 FR 3821, Jan. 21, 2011), Improving Regulation and Regulatory Review, and E.O. 14094 (88 FR 21879, Apr. 11, 2023) Modernizing Regulatory Review. The Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB) determined that this NPRM is not a significant regulatory action under section 3(f) of E.O. 12866, as supplemented by E.O. 13563 and E.O. 14094, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. Accordingly, OMB has not reviewed it under that E.O.

This proposal would amend the CDL regulations to allow States additional flexibility to waive the HM endorsement requirement for holders of a Class A CDL who are transporting aviation fuel in quantities of 1,000 gallons or less in service of agricultural aviation operations. Under the current regulations, before undertaking this task, drivers working for agricultural aviation operators must obtain an HM endorsement, which requires training, testing, and a TSA background check. This proposal would allow flexibility for a limited population of drivers while operating within their State of domicile to provide services to agricultural aviation operations without obtaining an HM endorsement.

This proposed rule is voluntary in nature and does not require that States adopt any flexibilities contained herein. This proposed rule could impact States, SDLAs, agricultural aviation operators, and drivers. The analysis below discusses these affected entities, the need for the regulation, and the costs and benefits that could result from the proposed rule.

Affected Entities

States

States could be impacted by this proposal; however, FMCSA does not know how many States would opt to waive the HM endorsement for agricultural aviation businesses and their drivers under this proposal. In response to Section 7208 of the FAST Act, 16 of 50 States chose to grant the exemption for diesel fuel, which is similar to the jet fuel exemption specified in this proposal. FMCSA assumes that there would be a similar level of adoption for this proposal, and that the majority of participating States would be those with agriculture-dependent economies.

SDLAs

This proposal would impact SDLAs in States that choose to waive the requirement for HM endorsements for Class A CDL holders employed by agricultural aviation operators. SDLAs are responsible for administering CDLs and endorsements for the motor carrier driver population. SDLAs in participating States would need to become familiar with these new requirements and update information on requirements for CDL holders.

Drivers

This proposal would impact Class A CDL holders who are employed by agricultural aviation operators in participating States and are responsible for transporting jet fuel in quantities of 1,000 gallons or less. Drivers serve as ''mixer-loaders'' for crop protection products and load agricultural aircrafts with these products and fuel. Drivers pump fuel from fixed base tanks into the fuel truck then transport it to the satellite airstrip to load into agricultural aircraft. Under this proposal, drivers operating Group A vehicles would still need to hold a Class A CDL since this proposal would only allow States to waive the HM endorsement requirement. These drivers would still be required to obtain an HM endorsement when transferring jet fuel across State lines.

FMCSA anticipates that any impacted drivers would work in the same North American Industry Classification System (NAICS) industry as agricultural aviation operators; 11511—support activities for crop production. As of May 2023, Bureau of Labor Statistics (BLS) reports that there are 5,430 heavy tractor-trailer drivers working in the 1151 industry.[12] The 1151 industry is broader than agricultural aviation operations, and as such drivers impacted by this rule would be a subset of the 5,430 within this industry. Further, FMCSA does not know how many drivers are employed by agricultural aviation operators in the States that would waive the HM endorsement requirement. FMCSA requests comment on the size of this population.

Agricultural Aviation Operators

According to the NAAA, there are approximately 1,560 agricultural aviation businesses and 3,400 agricultural pilots (approximately 2,000 are hired pilots and 1,400 are owner/operators) operating in the United States.[13] FMCSA does not know how many agricultural aviation businesses would be impacted by this rule.

Need for the Regulation

While both fueling and mixing and loading of crop-protection products (*e.g.,* fertilizers, insecticides, fungicides, or herbicides) are normally conducted at a location where agriculture aviation operators have permanent fuel tanks and mixing and loading facilities, at times operators and pilots work so far from their permanent facility that it is cost-effective to use a satellite landing strip and an on-site fuel truck. When on-site fuel trucks or drivers are not available, pilots must fly agricultural

[12] BLS, date extracted: July 11, 2024.

[13] *https://www.agaviation.org/about/about-ag-aviation/industry-facts-faqs/.*

aircraft back to their permanent mixing and loading facilities, which limits the amount of land pilots can spray on a given day and increases fuel costs, leading to reduced revenue for businesses.

Agricultural aviation businesses face a shortage of qualified drivers because for a Class A CDL an HM endorsement is a marketable asset, and these drivers are likely to find consistent, non-seasonal work. Furthermore, these businesses tend to operate in remote, rural areas that may be hundreds of miles away from the nearest SDLA. These factors limit agricultural aviation businesses from meeting their workforce needs.

Costs and Benefits

Costs

This proposal could result in costs to States and their licensing agencies and may result in cost savings to drivers and to agricultural aviation operators. Under this proposal, States and their SDLAs may incur costs. SDLAs in participating States may need to update their websites to reflect the changes in requirements for Class A CDL holders transporting hazardous materials. Also, roadside officers in participating States would need to undergo training to be able to determine which drivers are operating under the waiver. FMCSA anticipates that States would update their biannual training to include a module on any changes to the CDL regulations and model any changes resulting from this rule after the training for the diesel fuel exemption. Because this training is ongoing, FMCSA anticipates that any additional costs related to this change would be de minimis. The Agency does not have data with which to estimate these potential State and SDLA costs and requests comments on the scope and magnitude of costs in participating States as a result of this proposal.

The proposal would result in cost savings for agricultural aviation operators and the drivers these operators hire to mix, load, and transport jet fuel in quantities of 1,000 gallons or less in participating States. Under the proposal, Class A CDL holders would not need to undergo the 4-step process of obtaining an HM endorsement: completing a theory training module, passing a written exam, passing a TSA Security Threat Assessment (STA), and paying an SDLA fee, if applicable. As outlined below, the total cost per driver to obtain an HM endorsement is $261.

Drivers must take theory training from training providers listed on the FMCSA Training Provider Registry (TPR). FMCSA anticipates that drivers impacted by this rule would opt to take online theory training because they live in remote areas. There are over 1,000 providers listed on the TPR that provide online HM endorsement training. FMCSA took a random sample of approximately 180 providers and researched websites to develop estimates of training cost and time. Based on those websites that provided information, FMCSA found that the theory training cost ranges from $16 to $200, with a mean cost of $96 and a median cost of $99. These trainings tend to be self-paced, so few companies advertise the average length of time to complete the training. From those companies that provided information, the time ranges from 1 hour to 16 hours, with a mean of 5 and a median of 2 hours. For estimation purposes, FMCSA anticipates that drivers impacted by this rule would save a $99 theory training fee and 2 hours of training, valued at $61.50. The opportunity cost of training time is valued at the rate at which drivers would accept in exchange for it, $30.75 per hour ($20.75 median hourly wage × 48.19 percent fringe benefit rate).[14] [15]

Drivers seeking an HM endorsement must complete a background investigation through the TSA HM Endorsement Threat Assessment Program on-line application, visiting an application center, and paying a non-refundable fee of $86.50. This process must be completed every 5 years in order to maintain the HM endorsement. Drivers operating under the waiver provided in the proposed rule would not be required to complete this process.

Lastly, Class A CDL holders operating under the waiver provided in the proposed rule would not need to return to the SDLA to obtain an HM endorsement and would not be required to pay the associated SDLA fee. The SDLA HM endorsement fee changes by jurisdiction, ranging from $0 to over $40. For illustrative purposes, FMCSA estimates the average SDLA fee to be $14. As displayed in the table below, the total per driver cost to obtain an HM endorsement is $261.

[14] Department of Labor (DOL), BLS. *Occupational Employment Statistics (OES).* May 2023. Median hourly wage for Heavy and Tractor-Trailer truck drivers in the 115110 occupation is $20.75. Available at: *http://www.bls.gov/oes/tables.htm* (accessed July 11, 2024).

[15] DOL, BLS. *Employer Cost for Employee Compensation for Transportation and Warehousing, Table 4: Table 4: Employer Costs for Employee Compensation for private industry workers by occupational and industry group. March 17, 2023.* Available at: *https://www.bls.gov/news.release/pdf/ecec.pdf* (accessed Apr. 22, 2024).

TABLE 1—COSTS TO OBTAIN HM ENDORSEMENT

Component	Value
Theory Training Fee	$99.00
Driver Opportunity Cost of Training	61.50
TSA Background Fee	86.50
SDLA HM Endorsement Fee	14.00
Total Cost Savings for each Class A CDL Holder	261.00

FMCSA does not expect this proposal would immediately impact drivers who currently hold a Class A CDL and HM endorsement. The proposal could impact these drivers at the time of renewal by eliminating the fees for the HM endorsement.

These estimates do not include the costs associated with traveling to a TSA appointment center for the STA or traveling to the SDLA to take an HM knowledge test or obtain the HM endorsement. In rural areas where aerial agricultural operations are based, an SDLA may be several hundred miles away. FMCSA does not have data on how far drivers must travel to a TSA appointment center or an SDLA to pass the requirements to operate a vehicle transporting jet fuel but welcomes comment on the costs associated with this process.

Agricultural aviation operators would gain efficiencies from this proposal because pilots working for operators in participating States would not need to expend time and fuel to travel back to their home bases to refuel. Instead, they would rely on CMV drivers with Class A CDLs to transport jet fuel and crop protection products from permanent facilities, which are often far from the agricultural fields, to satellite airstrips. According to an NAAA survey from 2005, operators shared that in many cases they could not work because drivers were not available. The NAAA maintains that a shortage of available drivers with HM endorsements prevents the use of satellite airstrips, limiting the amount of land that can be sprayed on a given day and resulting in increased jet fuel costs. FMCSA does not know the current fuel or time (opportunity) costs these trips entail. In addition, FMCSA does not know how many more satellite facilities would be available as a result of this proposal and how many trips to mixing-loading facilities would be avoided by agricultural pilots. As such, FMCSA cannot estimate the cost savings that could result from this provision but requests comment on the impact of this proposed change as well as any data that the Agency can use to quantify the impact of this provision.

Benefits

FMCSA does not expect this proposed rule would negatively impact CMV safety. For various reasons, drivers who transport jet fuel operate in low-risk safety conditions and rarely experience crashes. According to the previously mentioned survey from 2005 cited in the NAAA's initial application for endorsement, 95.3 percent of agricultural aviation operations had never been involved in any type of accident, and 92.9 percent travel on rural roads with minimal traffic. The NAAA also noted in this survey that drivers transporting fuel and chemicals travel an average of 57.81 miles per day, although they drive only once or twice a week to a satellite facility. Furthermore, the NAAA currently provides highway safety education for a large portion of the small business owners of agricultural aircraft operations throughout the country through its Professional Agricultural Aviation Support System.

The Agency has not identified any other benefits to society that would result from the proposed change to § 383.3(i).

B. Advance Notice of Proposed Rulemaking

Under 49 U.S.C. 31136(g), FMCSA is required to publish an advance notice of proposed rulemaking (ANPRM) or proceed with a negotiated rulemaking if a proposed rule is likely to lead to the promulgation of a major rule.[16] As this proposed rule is not likely to result in the promulgation of a major rule, the Agency is not required to issue an ANPRM or to proceed with a negotiated rulemaking.

C. Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act of 1980, Public Law 96–354, 94 Stat. 1164 (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (Pub. L. 104–121, 110 Stat. 857, March 29, 1996) and the Small Business Jobs Act of 2010 (Pub. L. 111–240, 124 Stat. 2504 September 27, 2010), requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term ''small entities'' comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities, and mandates that agencies strive to lessen any adverse effects on these businesses. Therefore, FMCSA is publishing this initial regulatory flexibility analysis (IRFA) to aid the public in commenting on the potential small business impacts of the proposals in this NPRM.

An IRFA must contain the following:

1. A description of the reasons why the action is being considered;
2. A succinct statement of the objectives of, and legal basis for, the proposed rule;
3. A description—and where feasible, an estimate of the number of small entities to which the rule will apply;
4. A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
5. An identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule.

(1) A description of the reasons why the action is being considered.

FMCSA proposes to amend the CDL regulations to allow States additional flexibility to waive the HM endorsement[17] requirement for certain drivers transporting aviation fuel in furtherance of agricultural aviation operations. Many such operations rely on aircraft to apply pesticides or fertilizers to their crops. Agricultural aviation operators often deliver aircraft fuel to staging areas some distance from their headquarters. These companies, particularly in remote, rural areas, have difficulty finding CDL holders with HM endorsements to complete these deliveries.

(2) A succinct statement of the objectives of, and legal basis for, the proposed rule.

The CDL regulations are based on the authority of CMVSA. Section 12013 of the CMVSA allowed the FHWA, FMCSA's predecessor agency, to ''waive, in whole or in part, application of any provision of this title or any regulation issued under this title with respect to class of persons or class of commercial motor vehicles if the Secretary determines that such waiver is not contrary to the public interest and does not diminish the safe operation of commercial motor vehicles'' (Pub. L. 99–570, Title XII, 100 Stat. 3207–170, 3207–186, Oct. 27, 1986, codified at 49 U.S.C. app. 2711). Following statutory amendments,[18] the language of the CMVSA's section 12013—that a waiver must be ''not contrary to the public interest'' and ''not diminish the safe operation of commercial motor vehicles''—has been replaced by the standard that a waiver or an exemption must ''likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved in the absence of the waiver'' (49 U.S.C. 31315(a) or ''absent such exemption'' (49 U.S.C. 31315(b)(1)).

FMCSA believes that the ELOS standard required by the waiver and exemption provisions is the appropriate standard for this NPRM. The 1992 FHWA rule authorized the States to waive the knowledge and skills tests otherwise required to obtain a CDL for employees of custom harvesters, farm retail outlets and suppliers, agrichemical businesses, and livestock feeders (57 FR 13650, Apr. 17, 1992) and required that the State waiver option not diminish the safe operation of CMVs, and all subsequent versions of the statute and regulation have retained that ELOS concept. Congress itself clearly embraced that standard when section 7208 was explicitly limited to the same four agriculture-related businesses covered by the 1992 exemption.

Pursuant to 49 U.S.C. 31305(a), which sets forth the general standards for the CDL rules, FMCSA ''shall prescribe regulations on minimum standards for testing and ensuring the fitness of an individual operating a commercial motor vehicle.'' Implicit in that provision is the authority to decide whether certain CDL holders may meet the ''fitness'' requirement without complying with every part of the CDL regulations. FMCSA believes that exempting employees of agricultural aviation companies who hold Class A CDLs and transport jet fuel from the

[16] A *major rule* means any rule that the Office of Management and Budget finds has resulted in or is likely to result in (a)an annual effect on the economy of $100 million or more; (b)a major increase in costs or prices for consumers, individual industries, geographic regions, Federal, State, or local government agencies; or (c)significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets (5 U.S.C. 802(4)).

[17] *Endorsement* as defined in § 383.5 means an authorization to an individual's CLP or CDL required to permit the individual to operate certain types of commercial motor vehicles.

[18] Title 49, United States Code, was recodified in 1994, the waiver authority in 49 U.S.C. app. 2711 was redesignated as 49 U.S.C. 31315 (Pub. L. 103–272, 108 Stat. 745, 1029, July 5, 1994), and the Transportation Equity Act for the 21st Century (TEA–21) revised 49 U.S.C. 31315 as ''Waivers, exemptions, and pilot programs'' (Pub. L. 105–178, 112 Stat. 107, 401, June 9, 1998).

requirement to obtain a HM endorsement is consistent, both with the standard of the CMVSA's section 12013 and with the current ELOS and ''fitness'' standards enacted by Congress. A waiver granted by a State under this proposal, as under section 7208 of the FAST Act, would also exempt eligible drivers from the TSA background records check in 49 CFR part 1572, subpart B.

(3) A description—and, where feasible, an estimate of the number—of small entities to which the proposed rule will apply.

Under the standards of the RFA, as amended by SBREFA, the participating States are not small entities. States are not considered small entities because they do not meet the definition of a small entity in section 601 of the RFA. Specifically, States are not considered small governmental jurisdictions under section 601(5) of the RFA, both because State government is not included among the various levels of government listed in section 601(5), and because, even if this were the case, no State or the District of Columbia has a population of less than 50,000, which is the criterion by which a governmental jurisdiction is considered small under section 601(5) of the RFA.

Drivers are not considered small entities because they do not meet the definition of a small entity in section 601 of the RFA. Specifically, drivers are considered neither a small business under section 601(3) of the RFA, nor are they considered a small organization under section 601(4) of the RFA.

The Small Business Administration (SBA) defines the size standards used to classify entities as small. SBA establishes separate standards for each industry, as defined by the NAICS. FMCSA expects that CMV drivers transporting jet fuel would largely be employed by aerial application operators that operate within the Agriculture, Forestry, Fishing and Hunting sector (NAICS sector 11), and more specifically, within NACIS industry 115110 (support activities for crop production). Industry groups within the 1151 NAICS industry have size standards based on the amount of annual revenue and ranging from $8.5 million in revenue to $34 million in revenue. There is not a specific NAICS national industry for aerial application operators, and therefore it is not possible to narrow down the Census data to determine the number of small entities that are potentially impacted by this rule. Based on the NAAA membership, FMCSA estimates that, if adopted in all jurisdictions, this rule could impact up to 1,900 aerial application operators.[19] FMCSA requests comment on how many of these entities would be considered small based on the SBA size standards.

(4) A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirements and the types of professional skills necessary for preparation of the report or record.

This proposal would not result in reporting, recordkeeping, or other compliance requirements. This proposed rule is voluntary in nature and does not require that States adopt any flexibilities provided in the proposed rule. Further, the Agency did not identify significant alternatives that would lessen the burden on small entities beyond the proposed exemption in § 383.3(i).

(5) An identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule.

FMCSA is not aware of any relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule.

D. Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857), FMCSA wants to assist small entities in understanding this proposed rule so they can better evaluate its effects on themselves and participate in the rulemaking initiative. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's Small Business and Agriculture Regulatory Enforcement Ombudsman (Office of the National Ombudsman, see *https://www.sba.gov/about-sba/oversight-advocacy/office-national-ombudsman*) and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of FMCSA, call 1–888–REG–FAIR (1–888–734–3247). DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

E. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) requires Federal agencies to assess the effects of their discretionary regulatory actions. The Act addresses actions that may result in the expenditure by a State, local, or Tribal government, in the aggregate, or by the private sector of $200 million (which is the value equivalent of $100 million in 1995, adjusted for inflation to 2023 levels) or more in any 1 year. Though this NPRM would not result in such an expenditure, and the analytical requirements of UMRA do not apply as a result, the Agency discusses the effects of this rule elsewhere in this preamble.

F. Paperwork Reduction Act

This proposed rule contains no new information collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

G. E.O. 13132 (Federalism)

A rule has implications for federalism under section 1(a) of E.O. 13132 if it has ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

FMCSA has determined that this rule would not have substantial direct costs on or for States, nor would it limit the policymaking discretion of States. Nothing in this document preempts any State law or regulation. Therefore, this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Impact Statement.

H. Privacy

The Consolidated Appropriations Act, 2005,[20] requires the Agency to assess the privacy impact of a regulation that will affect the privacy of individuals. This NPRM would not require the collection of personally identifiable information (PII).

The Privacy Act (5 U.S.C. 552a) applies only to Federal agencies and any non-Federal agency that receives records contained in a system of records from a Federal agency for use in a matching program.

[19] National Agricultural Aviation Association (NAAA), *https://www.agaviation.org/about/*. Accessed: July 18, 2024

[20] Public Law 108–447, 118 Stat. 2809, 3268, note following 5 U.S.C. 552a (Dec. 4, 2014).

The E-Government Act of 2002,[21] requires Federal agencies to conduct a Privacy Impact Assessment (PIA) for new or substantially changed technology that collects, maintains, or disseminates information in an identifiable form. No new or substantially changed technology would collect, maintain, or disseminate information as a result of this rule. Accordingly, FMCSA has not conducted a PIA.

In addition, the Agency submitted a Privacy Threshold Assessment (PTA) to evaluate the risks and effects the proposed rulemaking might have on collecting, storing, and sharing personally identifiable information. The PTA has been submitted to FMCSA's Privacy Officer for review and preliminary adjudication and to DOT's Privacy Officer for review and final adjudication.

I. E.O. 13175 (Indian Tribal Governments)

This rule does not have Tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

J. National Environmental Policy Act of 1969

FMCSA analyzed this proposed rule pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321, *et seq.*) and determined this action is categorically excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1 (69 FR 9680), Appendix 2, paragraph (6)(t)(2). The categorical exclusion (CE) in paragraph (6)(t)(2) covers requirements ensuring that States have the appropriate regulations concerning the qualification and licensing of persons who apply and are issued a commercial driver's license. The proposed requirements in this rule are covered by this CE.

K. Rulemaking Summary

As required by 5 U.S.C. 553(b)(4), a summary of this rule can be found in the Abstract section of the Department's Unified Agenda entry for this rulemaking at *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202310&RIN=2126-AC59.*

List of Subjects in 49 CFR Part 383

Administrative practice and procedure, Alcohol abuse, Drug abuse, Drug testing, Highway safety, Motor carriers, Penalties, Safety, Transportation.

Accordingly, FMCSA proposes to amend 49 CFR chapter III, part 383 as follows:

PART 383—COMMERCIAL DRIVER'S LICENSE STANDARDS; REQUIREMENTS AND PENALTIES

■ 1. The authority citation for part 383 continues to read as follows:

Authority: 49 U.S.C. 521, 31136, 31301, *et seq.,* and 31502; secs. 214 and 215 of Pub. L. 106–159, 113 Stat. 1748, 1766, 1767; sec. 1012(b) of Pub. L. 107–56, 115 Stat. 272, 297, sec. 4140 of Pub. L. 109–59, 119 Stat. 1144, 1746; sec. 32934 of Pub. L. 112–141, 126 Stat. 405, 830; sec. 23019 of Pub. L. 117–58, 135 Stat. 429, 777; and 49 CFR 1.87.

■ 2. Amend § 383.3 by revising paragraph (i) to read as follows:

§ 383.3 Applicability.

* * * * *

(i) *Hazardous materials endorsement exemption for certain drivers transporting diesel or jet fuel.* A State may waive the requirement for a holder of a Class A commercial driver's license to obtain a hazardous materials endorsement under this part, if the license holder is:

(1) Acting within the scope of the license holder's employment, and within the State of domicile (or another State with a hazardous materials endorsement exemption) as an employee of a custom harvester operation, agrichemical business, farm retail outlet and supplier, livestock feeder, or agriculture aviation operation; and

(2) Operating a service vehicle that is:

(i) Transporting diesel or jet fuel in a quantity of 3,785 liters (1,000 gallons) or less; and

(ii) Clearly placarded in accordance with 49 CFR part 172 subpart F and all other applicable HMRs.

* * * * *

■ 3. Amend § 383.5 by adding in alphabetical order a definition for *jet fuel* to read as follows:

§ 383.5 Definitions.

* * * * *

Jet fuel means ''fuel, aviation, turbine engine'' as listed in the Hazardous Materials Table in § 172.101 of this title that is reclassed as a combustible liquid in accordance with part 173 of this title.

* * * * *

Issued under authority delegated in 49 CFR 1.87.

Vincent G. White,

Deputy Administrator.

[FR Doc. 2024–28097 Filed 12–3–24; 8:45 am]

BILLING CODE 4910–EX–P

[21] Public Law 107–347, sec. 208, 116 Stat. 2899, 2921 (Dec. 17, 2002).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 241127–0305; RTID 0648–XE346]

Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands; Proposed 2025 and 2026 Harvest Specifications for Groundfish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; harvest specifications and request for comments.

SUMMARY: NMFS proposes 2025 and 2026 harvest specifications, apportionments, and prohibited species catch allowances for the groundfish fisheries of the Bering Sea and Aleutian Islands (BSAI) management area. This action is necessary to establish harvest limits for groundfish during the 2025 and 2026 fishing years and to accomplish the goals and objectives of the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP). The 2025 harvest specifications supersede those previously set in the final 2024 and 2025 harvest specifications, and the 2026 harvest specifications will be superseded in early 2026 when the final 2026 and 2027 harvest specifications are published. The intended effect of this action is to conserve and manage the groundfish resources in the BSAI in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Comments must be received by January 3, 2025.

ADDRESSES: A plain language summary of this proposed rule is available at *https://www.regulations.gov/docket/NOAA-NMFS-2024-0116.* You may submit comments on this document, identified by NOAA–NMFS–2024–0116, by any of the following methods:

• *Electronic Submission:* Submit all electronic public comments via the

Federal e-Rulemaking Portal. Visit *https://www.regulations.gov* and type NOAA–NMFS–2024–0116 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit written comments to Gretchen Harrington, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Records Office. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.
- *Fax:* (907) 586–7465; Attn: Gretchen Harrington.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of the Alaska Groundfish Harvest Specifications Final Environmental Impact Statement (Final EIS), Record of Decision (ROD) for the Final EIS, and the annual Supplementary Information Reports (SIR) to the Final EIS prepared for this action are available from *https://www.regulations.gov.* An updated 2025 SIR for the final 2025 and 2026 harvest specifications will be available from the same source.

The final 2023 Stock Assessment and Fishery Evaluation (SAFE) report for the groundfish resources of the BSAI, dated November 2023, is available from the North Pacific Fishery Management Council (Council) at 1007 West 3rd Ave., Suite 400, Anchorage, Alaska 99501, phone 907–271–2809, or from the NMFS Alaska Region website at *https://www.fisheries.noaa.gov/alaska/population-assessments/north-pacific-groundfish-stock-assessments-and-fishery-evaluation.* The 2024 SAFE report for the BSAI will be available from the same sources.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: Federal regulations at 50 CFR part 679 implement the FMP and govern the groundfish fisheries in the BSAI. The Council prepared the FMP, and NMFS approved it, under the Magnuson-Stevens Act. General regulations governing U.S. fisheries also appear at 50 CFR part 600.

The FMP and its implementing regulations require that NMFS, after consultation with the Council, specify annually the total allowable catch (TAC) for target species. The sum of TACs for all groundfish target species in the BSAI must be within the optimum yield (OY) range of 1.4 million to 2.0 million metric tons (mt) (see § 679.20(a)(1)(i)(A) and 679.20(a)(2)). Section 679.20(c)(1) further requires that NMFS publish proposed harvest specifications in the **Federal Register** and solicit public comments on proposed annual TACs for each target species and apportionments thereof; prohibited species catch (PSC) allowances; prohibited species quota (PSQ) reserves established by § 679.21; seasonal allowances of pollock, Pacific cod, and Atka mackerel TAC; American Fisheries Act allocations; Amendment 80 allocations; Community Development Quota (CDQ) reserve amounts established by § 679.20(b)(1)(ii); and acceptable biological catch (ABC) surpluses and reserves for CDQ groups and Amendment 80 cooperatives for flathead sole, rock sole, and yellowfin sole. The proposed harvest specifications set forth in tables 1 through 15 of this proposed rule satisfy these requirements.

In accordance with § 679.20(c)(3), NMFS will publish the final 2025 and 2026 harvest specifications after (1) considering comments received within the comment period (see **DATES**), (2) consulting with the Council at its December 2024 meeting, (3) considering information presented in the 2025 SIR to the Final EIS that assesses the need to prepare a Supplemental EIS (see **ADDRESSES**), and (4) considering information presented in the final 2024 SAFE report, including the 2024 Ecosystem Status Reports for both the Bering Sea and Aleutian Islands.

Other Actions Affecting or Potentially Affecting the 2025 and 2026 Harvest Specifications

Amendment 125 to the FMP: Pacific Cod Small Boat Access

NMFS is developing a proposed rule to implement Amendment 125 to the FMP, which, if approved, would redefine the BSAI Pacific cod jig sector during the A-season (January 1–April 30) to include hook-and-line or pot catcher vessels (CV) less than or equal to 55 feet (ft) (16.8 meters (m)) length overall (LOA). All harvest from the redefined A-season jig sector would be deducted from the jig sector's 1.4 percent allocation currently set in regulation (§ 679.20(a)(7)(ii)). In addition, the current hook-and-line or pot CV less than 60 feet (ft) (18.3 m) LOA sector would be redefined from January 1 to April 30 so that harvest only from hook-and-line or pot CVs with a LOA of 55 ft (16.8 m) and less than 60 ft LOA (55–59 ft) (16.8–18.0 m) would be deducted from the hook-and-line or pot CV less than 60 feet (ft) (18.3 m) LOA sector's 2.0 percent allocation currently set in regulation (§ 679.20(a)(7)(ii)). If amendment 125 and its implementing regulations are approved by the Secretary of Commerce, NMFS would incorporate the changes in a future harvest specifications action, and any such changes are anticipated for the 2026 and 2027 harvest specifications.

State of Alaska Guideline Harvest Levels

For 2025 and 2026, the State of Alaska Board of Fisheries (BOF) established the guideline harvest level (GHL) for vessels using pot, longline, jig, and hand troll gear in State waters in the State's Aleutian Islands subarea (AI) State-waters sablefish registration area that includes all State waters west of Scotch Cap Light (164°44.72′ W longitude) and south of Cape Sarichef (54°36′ N latitude). The AI GHL is set at 5 percent of the combined proposed Bering Sea (BS) subarea and AI ABC (1,233 mt). The State's AI sablefish registration area includes areas adjacent to parts of the Federal BS subarea. Since most of the State's 2025 and 2026 GHL sablefish fishery is expected to occur in State waters adjacent to the Federal BS subarea, the Council and its BSAI Groundfish Plan Team (Plan Team), Scientific and Statistical Committee (SSC), and Advisory Panel (AP) recommended that the sum of all State and Federal sablefish removals from the BS and AI not exceed the proposed ABC recommendations for sablefish in the BS and AI. Accordingly, the Council recommended, and NMFS proposes, that the 2025 and 2026 sablefish TACs in the BS and AI be reduced by at least 5 percent to account for the State's GHLs for sablefish caught in State waters.

For 2025 and 2026, the BOF established the GHL for vessels using pot gear in State waters in the BS equal to 13 percent of the Pacific cod ABC in the BS. The BS GHL will increase by one percent if 90 percent of the GHL is harvested by November 15 of the preceding year for 2 consecutive years but may not exceed 15 percent of the BS ABC. If 90 percent of the GHL is not harvested by November 15 of the preceding year for 2 consecutive years, the GHL will decrease by 1 percent, but

the GHL may not decrease below 10 percent of the BS ABC. Based on harvest in 2023 and 2024, the GHL will be 13 percent in 2025. 13 percent of the proposed BS ABC is 19,614 mt. NMFS will account for any adjustment to the 2026 GHL in the final 2026 and 2027 harvest specifications. Also, for 2025 and 2026, the BOF established an additional GHL for vessels using jig gear in State waters in the BS equal to 45 mt of Pacific cod in the BS. The Council and its Plan Team, SSC, and AP recommended that the sum of all State and Federal waters Pacific cod removals from the BS not exceed the ABC recommendations for Pacific cod in the BS. Accordingly, the Council recommended, and NMFS proposes, that the 2025 and 2026 Pacific cod TACs in the BS account for the State's GHLs for Pacific cod caught in State waters in the BS.

For 2025 and 2026, the BOF established the GHL in State waters in the AI equal to 35 percent of the Pacific cod ABC in the AI. The AI GHL will increase annually by 4 percent of the AI ABC if 90 percent of the GHL is harvested by November 15 of the preceding year but may not exceed 39 percent of the AI ABC or 15 million pounds (6,804 mt). If 90 percent of the GHL is not harvested by November 15 of the preceding year for 2 consecutive years, the GHL will decrease by 4 percent, but the GHL may not decrease below 15 percent of the AI ABC. Based on harvest in 2023 and 2024, the GHL likely will remain at 35 percent in 2025. Thirty-five percent of the proposed AI ABC is 4,350 mt. NMFS will account for any adjustment to the 2025 GHL in the final 2025 and 2026 harvest specifications. The GHL for 2026 may change based on harvest during the preceding fishing years, and NMFS will account for any adjustment to the 2026 GHL in the final 2026 and 2027 harvest specifications. The Council and its Plan Team, SSC, and AP recommended that the sum of all State and Federal waters Pacific cod removals from the AI not exceed the ABC recommendations for Pacific cod in the AI. Accordingly, the Council recommended, and NMFS proposes, that the 2025 and 2026 Pacific cod TACs in the AI account for the State's GHL for Pacific cod caught in State waters in the AI.

Proposed ABC and TAC Harvest Specifications

In October 2024, the Council's SSC, its AP, and the Council reviewed the most recent biological and harvest information on the condition of the BSAI groundfish stocks. The Plan Team compiled and presented this information in the final 2023 SAFE report for the BSAI groundfish fisheries, dated November 2023 (see **ADDRESSES**). The final 2024 SAFE report, including individual stock assessments, will be available on the NMFS Alaska Region website (see **ADDRESSES**).

The proposed 2025 and 2026 harvest specifications are based on the final 2025 harvest specifications published in March 2024 (89 FR 17287, March 11, 2024), which were set after consideration of the most recent 2023 SAFE report that was presented at the November 2023 Plan Team meeting.

The SAFE report contains a review of the latest scientific analyses and estimates of each species' biomass and past, present, and possible future condition of the stocks and groundfish fisheries off Alaska. The SAFE report also contains an economic summary informed by the Economic SAFE and ecosystem information summarized from the Ecosystem Status Reports (ESR). The SAFE report provides information to the Council and NMFS for recommending and setting, respectively, annual harvest levels for each stock and documenting significant trends or changes in the resource, marine ecosystems, and fisheries over time.

The ESRs are combined into an appendix to the SAFE reports. The ESRs compile and summarize information about the status of the Alaska marine ecosystems for the Plan Team, SSC, AP, Council, NMFS, and the public, and they are updated annually. These ESRs include ecosystem report cards, ecosystem assessments, and ecosystem status indicators (*i.e.,* climate indices, sea surface temperature), which together provide context for ecosystem-based fisheries management in Alaska. The ESRs inform stock assessments and are integrated into the annual harvest recommendations, primarily through inclusion in stock assessment-specific risk tables that inform the specification of ABC for target species. Also, the ESRs provide context for the SSC's recommendations for overfishing levels (OFL) and ABCs, as well as for the Council's TAC recommendations. The SAFE reports and the ESRs are presented at the October and December Council meetings before the SSC, AP, and the Council make groundfish harvest recommendations, and they aid NMFS in implementing these annual groundfish harvest specifications. An ESR is prepared for both the Eastern BS ecosystem and the AI ecosystem (as well as for the Gulf of Alaska ecosystem).

In addition to the 2023 SAFE report, the Plan Team, SSC, and Council also reviewed preliminary survey data from 2024 surveys, updates on ecosystem and socioeconomic profiles (ESPs) for certain species, initial updates on climate and oceanography for Alaska ecosystems, and summaries of potential changes to models and methodologies. From these data and analyses, the Plan Team and SSC recommend the proposed OFL and ABC for each species and species group. The proposed 2025 and 2026 harvest specifications in this action are subject to change in the final harvest specifications to be published by NMFS following the Council's December 2024 meeting.

In November 2024, the Plan Team will update the 2023 SAFE report to include new information collected during 2024, such as NMFS stock surveys, revised stock assessments, and catch data. The Plan Team will compile this information and present the draft 2024 SAFE report at the December 2024 Council meeting. At that meeting, the SSC and the Council will review the 2024 SAFE report, and the Council will approve the 2024 SAFE report for use in informing the Council's final recommendations to NMFS. The Council will consider information in the 2024 SAFE report, recommendations from the November 2024 Plan Team meeting and December 2024 SSC and AP meetings, public testimony, and relevant written comments in making its recommendations to NMFS for the final 2025 and 2026 harvest specifications. Pursuant to § 679.20(a)(2) and (3), the Council could recommend that NMFS adjust the final TACs if warranted based on the biological condition of groundfish stocks or a variety of socioeconomic considerations, or if required to cause the sum of TACs to fall within the OY range.

Potential Changes Between Proposed and Final Specifications

In previous years, the most significant changes (relative to the amount of assessed tonnage of fish) to the OFLs and ABCs from the proposed to the final harvest specifications have been based on the most recent NMFS stock surveys. These surveys provide updated estimates of stock biomass and spatial distribution, and inform changes to the models or the models' results used for producing stock assessments. Any changes to models used in stock assessments will be recommended by the Plan Team in November 2024, reviewed by the SSC in December 2024, and then included in the final 2024 SAFE report. Model changes can result in changes to final OFLs, ABCs, and TACs. The final 2024 SAFE report will include the most recent information, such as catch data.

The final harvest specification amounts for these stocks are not expected to vary greatly from these proposed harvest specification amounts. If the 2024 SAFE report indicates that the stock biomass trend is increasing for a species, then the final 2025 and 2026 harvest specifications may reflect an increase from the proposed harvest specifications. Conversely, if the 2024 SAFE report indicates that the stock biomass trend is decreasing for a species, then the final 2025 and 2026 harvest specifications may reflect a decrease from the proposed harvest specifications. In addition to changes driven by biomass trends, there may be changes in TACs due to the constraint of the OY for the BSAI. Under regulations and the FMP, TAC may not exceed ABC, but can be set equal to ABC. The regulations require the sum of all TACs for target species in the BSAI to be set to an OY between 1.4 and 2 million mt. Thus, the Council may be required to recommend TACs that are lower than the ABCs recommended by the Plan Team and the SSC, if setting all TACs equal to ABCs would cause the sum of TACs to exceed an OY of 2 million mt. Generally, total ABCs greatly exceed 2 million mt in years with a large pollock biomass. For both 2025 and 2026, NMFS anticipates that the sum of the final ABCs will exceed 2 million mt, and therefore TACs for some species likely will have to be set lower than ABCs to ensure the sum of TACs is between 1.4 and 2 million mt. Historically, the sum of the final TACs has been close to or equal to 2 million mt.

The proposed 2025 and 2026 OFLs and ABCs are based on the best available biological and scientific information, including projected biomass trends, information on assumed distribution of stock biomass, and revised technical methods used to calculate stock biomass. The FMP specifies a series of six tiers to define OFLs and ABCs based on the level of reliable information available to fishery scientists. Tier 1 represents the highest level of information quality available, while Tier 6 represents the lowest. The proposed 2025 and 2026 TACs are also based on the best available biological and socioeconomic information.

In October 2024, the SSC adopted the proposed 2025 and 2026 OFLs and ABCs recommended by the Plan Team for all groundfish. In making its recommendations, the Council adopted the SSC's OFL and ABC recommendations. The OFL and ABC amounts are unchanged from the final 2025 harvest specifications published in the **Federal Register** on March 11, 2024 (89 FR 17287). The sum of the proposed 2025 and 2026 ABCs for all assessed groundfish is 3,550,691 mt. The sum of the proposed TACs is 1,998,491 mt. NMFS has reviewed the recommendations of the SSC and Council for OFLs, ABCs, and TACs for target species and species groups in the BSAI as well as any other relevant information. Based on that review, NMFS is proposing the OFLs, ABCs, and TACs set forth in the tables of this proposed rule. NMFS concludes that these specifications are consistent with the Magnuson-Stevens Act, the FMP, and other applicable law, subject to further review and consideration after public comment.

Specification and Apportionment of TAC Amounts

The Council recommended proposed 2025 and 2026 TACs that are equal to the proposed ABCs for 2025 and 2026 BS and AI Greenland turbot, BSAI Kamchatka flounder, Central AI Atka mackerel, BS Pacific ocean perch, Central AI Pacific ocean perch, Eastern AI Pacific ocean perch, BS and Eastern AI blackspotted and rougheye rockfish, Central AI and Western AI blackspotted and rougheye rockfish, BSAI shortraker rockfish, and BS and AI ''other rockfish.'' The Council recommended proposed TACs less than the respective proposed ABCs for all other species and species groups. TACs for some species and species groups are reduced so that the overall TAC does not exceed the BSAI OY.

The proposed groundfish OFLs, ABCs, and TACs are subject to change pending the completion of the final 2024 SAFE report, public comment, and the Council's recommendations for the final 2025 and 2026 harvest specifications during its December 2024 meeting. These proposed amounts are consistent with the biological condition of groundfish stocks as described in the 2023 SAFE report. The proposed ABCs reflect harvest amounts that are less than the specified overfishing levels. The proposed TACs have been adjusted for other biological information and socioeconomic considerations, including maintaining the overall TAC within the required OY range. Pursuant to section 3.2.3.4.1 of the FMP, the Council could recommend that NMFS adjust the final TACs, if warranted on the basis of bycatch considerations, management uncertainty, or socioeconomic considerations; or if required in order to cause the sum of the TACs to fall within the OY range. Table 1 lists the proposed 2025 and 2026 OFL, ABC, TAC, initial TAC (ITAC), CDQ amounts, and nonspecified reserves for groundfish for the BSAI. The proposed apportionment of TAC amounts among fisheries and seasons is discussed below.

TABLE 1—PROPOSED 2025 AND 2026 OVERFISHING LEVEL (OFL), ACCEPTABLE BIOLOGICAL CATCH (ABC), TOTAL ALLOWABLE CATCH (TAC), INITIAL TAC (ITAC), CDQ RESERVE ALLOCATION, AND NONSPECIFIED RESERVES OF GROUNDFISH IN THE BSAI [1]

[Amounts are in metric tons]

Species	Area	Proposed 2025 and 2026					
		OFL	ABC	TAC	ITAC [2]	CDQ [3 4]	Nonspecified reserves
Pollock [4]	BS	3,449,000	2,401,000	1,325,000	1,192,500	132,500	
	AI	53,030	43,863	19,000	17,100	1,900	
	Bogoslof	115,146	86,360	250	250		
Pacific cod [5]	BS	180,798	150,876	131,217	117,177	14,040	
	AI	18,416	12,431	8,080	7,216	865	
Sablefish [6]	Alaska-wide	55,317	47,350	n/a	n/a	n/a	
	BS	n/a	11,499	9,500	4,038	356	356
	AI	n/a	13,156	8,440	1,794	158	158
Yellowfin sole	BSAI	317,932	276,917	195,000	174,135	20,865	
Greenland turbot	BSAI	3,185	2,740	2,740	2,329	n/a	
	BS	n/a	2,310	2,310	1,964	247	99
	AI	n/a	430	430	366		65
Arrowtooth flounder	BSAI	104,270	88,548	14,000	11,900	1,498	602
Kamchatka flounder	BSAI	8,687	7,360	7,360	6,256		1,104

TABLE 1—PROPOSED 2025 AND 2026 OVERFISHING LEVEL (OFL), ACCEPTABLE BIOLOGICAL CATCH (ABC), TOTAL ALLOWABLE CATCH (TAC), INITIAL TAC (ITAC), CDQ RESERVE ALLOCATION, AND NONSPECIFIED RESERVES OF GROUNDFISH IN THE BSAI [1]—Continued

[Amounts are in metric tons]

Species	Area	Proposed 2025 and 2026					
		OFL	ABC	TAC	ITAC [2]	CDQ [3 4]	Nonspecified reserves
Rock sole [7]	BSAI	264,789	122,535	66,000	58,938	7,062	
Flathead sole [8]	BSAI	82,699	68,203	35,500	31,702	3,799	
Alaska plaice	BSAI	45,182	37,560	20,000	17,000		3,000
Other flatfish [9]	BSAI	22,919	17,189	4,500	3,825		675
Pacific ocean perch	BSAI	48,139	40,366	37,181	32,711	n/a	
	BS	n/a	11,430	11,430	9,716		1,715
	EAI	n/a	7,828	7,828	6,990	838	
	CAI	n/a	5,423	5,423	4,843	580	
	WAI	n/a	15,685	12,500	11,163	1,338	
Northern rockfish	BSAI	22,838	18,685	15,000	12,750		2,250
Blackspotted/Rougheye rockfish [10]	BSAI	813	607	607	516		91
	BS/EAI	n/a	412	412	350		62
	CAI/WAI	n/a	195	195	166		29
Shortraker rockfish	BSAI	706	530	530	451		80
Other rockfish [11]	BSAI	1,680	1,260	1,260	1,071		189
	BS	n/a	880	880	748		132
	AI	n/a	380	380	323		57
Atka mackerel	BSAI	99,723	84,676	66,165	59,085	7,080	
	BS/EAI	n/a	37,049	30,000	26,790	3,210	
	CAI	n/a	14,877	14,877	13,285	1,592	
	WAI	n/a	32,750	21,288	19,010	2,278	
Skates	BSAI	44,203	36,625	30,361	25,807		4,554
Sharks	BSAI	689	450	400	340		60
Octopuses	BSAI	6,080	4,560	400	340		60
Total		4,946,241	3,550,691	1,998,491	1,779,229	193,125	15,058

[1] These amounts apply to the entire BSAI management area unless otherwise specified. With the exception of pollock, and for the purpose of these harvest specifications, the BS subarea includes the Bogoslof District.

[2] Except for pollock, the portion of the sablefish TAC allocated to fixed gear, and the Amendment 80 species (Atka mackerel, flathead sole, rock sole, yellowfin sole, Pacific cod, and Aleutian Islands Pacific ocean perch), 15 percent of the TAC for each species and species group is put into a nonspecified reserve. The ITAC for these species is the remainder of the TAC after subtraction of the reserves. For pollock and Amendment 80 species, ITAC is the non-CDQ allocation of TAC (see footnote 3 and 4).

[3] For the Amendment 80 species (Atka mackerel, flathead sole, rock sole, yellowfin sole, Pacific cod, and Aleutian Islands Pacific ocean perch), 10.7 percent of the TAC is reserved for use by CDQ participants (see § 679.20(b)(1)(ii)(C)). Twenty percent of the sablefish TAC allocated to fixed gear, 7.5 percent of the sablefish TAC allocated to trawl gear, and 10.7 percent of the TACs for Bering Sea Greenland turbot and BSAI arrowtooth flounder are reserved for use by CDQ participants (see § 679.20(b)(1)(ii)(B) and (D)). The 2026 fixed gear portion of the sablefish ITAC and CDQ reserve will not be specified until the final 2026 and 2027 harvest specifications. Aleutian Islands Greenland turbot, ''other flatfish,'' Alaska plaice, Bering Sea Pacific ocean perch, Kamchatka flounder, northern rockfish, shortraker rockfish, blackspotted and rougheye rockfish, ''other rockfish,'' skates, sharks, and octopuses are not allocated to the CDQ Program.

[4] Under § 679.20(a)(5)(i)(A), the annual BS pollock TAC, after subtracting first for the CDQ directed fishing allowance (10 percent) and second for the incidental catch allowance (46,000 mt), is further allocated by sector for a pollock directed fishery as follows: inshore–50 percent; catcher/processor–40 percent; and motherships–10 percent. Section 679.20(a)(5)(iii)(B)(1) requires the AI pollock TAC to be set at 19,000 mt when the AI pollock ABC equals or exceeds 19,000 mt. Under § 679.20(a)(5)(iii)(B)(*2*), the annual AI pollock TAC, after subtracting first for the CDQ directed fishing allowance (10 percent) and second for the incidental catch allowance (3,000 mt), is allocated to the Aleut Corporation for a pollock directed fishery. The Bogoslof pollock TAC is set to accommodate incidental catch amounts.

[5] The proposed BS Pacific cod TAC is set to account for the 13 percent of the BS ABC, plus 45 mt, for the State of Alaska's (State) guideline harvest levels in State waters of the BS. The proposed AI Pacific cod TAC is set to account for 35 percent of the AI ABC for the State guideline harvest level in State waters of the AI.

[6] The sablefish OFL and ABC are Alaska-wide and include the Gulf of Alaska. The Alaska-wide sablefish OFL and ABC are included in the total OFL and ABC. The BS and AI sablefish TACs are set to account for the 5 percent of the BS and AI ABC for the State of Alaska's (State) guideline harvest level in State waters of the BS and AI.

[7] ''Rock sole'' includes *Lepidopsetta polyxystra* (Northern rock sole).

[8] ''Flathead sole'' includes *Hippoglossoides elassodon* (flathead sole) and *Hippoglossoides robustus* (Bering flounder).

[9] ''Other flatfish'' includes all flatfish species, except for halibut (a prohibited species), Alaska plaice, arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.

[10] ''Blackspotted/Rougheye rockfish'' includes *Sebastes melanostictus* (blackspotted) and *Sebastes aleutianus* (rougheye).

[11] ''Other rockfish'' includes all *Sebastes* and *Sebastolobus* species except for Pacific ocean perch, dark rockfish, northern rockfish, shortraker rockfish, and blackspotted/rougheye rockfish.

Note: Regulatory areas and districts are defined at § 679.2 (BSAI = Bering Sea and Aleutian Islands management area, BS = Bering Sea subarea, AI = Aleutian Islands subarea, EAI = Eastern Aleutian district, CAI = Central Aleutian district, WAI = Western Aleutian district.)

Groundfish Reserves and the Incidental Catch Allowance for Pollock, Atka Mackerel, Flathead Sole, Rock Sole, Yellowfin Sole, and AI Pacific Ocean Perch

Section 679.20(b)(1)(i) requires NMFS to reserve 15 percent of the TAC for each target species (except for pollock, fixed gear allocation of sablefish, and Amendment 80 species) in a nonspecified reserve. Section 679.20(b)(1)(ii)(B) requires that NMFS allocate 20 percent of the fixed gear allocation of sablefish to the fixed gear sablefish CDQ reserve for each subarea. Section 679.20(b)(1)(ii)(D) requires that NMFS allocate 7.5 percent of the trawl gear allocation of sablefish for each subarea from the nonspecified reserve and 10.7 percent of BS Greenland turbot and BSAI arrowtooth flounder TACs to the respective CDQ reserves. Section 679.20(b)(1)(ii)(C) requires that NMFS allocate 10.7 percent of the TACs for Atka mackerel, AI Pacific ocean perch, yellowfin sole, rock sole, flathead sole, and Pacific cod (the Amendment 80 allocated species) to the respective CDQ reserves.

Sections 679.20(a)(5)(i)(A) and 679.31(a) require allocation of 10 percent of the BS pollock TAC to the pollock CDQ directed fishing allowance (DFA). Sections 679.20(a)(5)(iii)(B)(*2*)(*i*) and 679.31(a) require 10 percent of the AI pollock TAC be allocated to the pollock CDQ DFA. The entire Bogoslof District pollock TAC is allocated as an incidental catch allowance (ICA) pursuant to § 679.20(a)(5)(ii) because the Bogoslof District is closed to directed

fishing for pollock by regulation (§ 679.22(a)(7)(B)). With the exception of the fixed gear sablefish CDQ reserve, the regulations do not further apportion the CDQ reserves by gear.

Pursuant to § 679.20(a)(5)(i)(A)(*1*), NMFS proposes a pollock ICA of 46,000 mt of the BS pollock TAC after subtracting the 10 percent CDQ DFA. This allowance is based on NMFS's examination of the pollock incidentally retained and discarded catch, including the incidental catch by CDQ vessels, in target fisheries other than pollock in recent years. Pursuant to § 679.20(a)(5)(iii)(B)(*2*)(*i*) and (*ii*), NMFS proposes a pollock ICA of 3,000 mt of the AI pollock TAC after subtracting the 10 percent CDQ DFA. This allowance is based on NMFS's examination of the pollock incidental catch, including the incidental catch by CDQ vessels, in target fisheries other than pollock in recent years.

After subtracting the 10.7 percent CDQ reserve and pursuant to § 679.20(a)(8) and (10), NMFS proposes ICAs of 2,000 mt of flathead sole, 3,000 mt of rock sole, 2,000 mt of yellowfin sole, 10 mt of Western Aleutian district Pacific ocean perch, 60 mt of Central Aleutian district Pacific ocean perch, 100 mt of Eastern Aleutian district Pacific ocean perch, 20 mt of Western Aleutian district Atka mackerel, 100 mt of Central Aleutian district Atka mackerel, and 800 mt of Eastern Aleutian district and BS Atka mackerel. These ICAs are based on NMFS's examination of the incidental catch in other target fisheries in recent years.

The regulations do not designate the remainder of the nonspecified reserve by species or species group. Any amount of the reserve may be apportioned to a target species that contributed to the nonspecified reserve during the year, provided that such apportionments are consistent with § 679.20(a)(3) and do not result in overfishing (see § 679.20(b)(1)(i)). In the final 2025 and 2026 harvest specifications, NMFS will evaluate whether any apportionments are necessary and may apportion from the nonspecified reserve to increase the ITAC for any target species that contributed to the reserve.

Allocations of Pollock TAC Under the American Fisheries Act

Section 679.20(a)(5)(i)(A) requires that BS pollock TAC be apportioned as a DFA, after subtracting 10 percent for the CDQ Program and 46,000 mt for the ICA, as follows: 50 percent to the inshore sector, 40 percent to the catcher/processor (CP) sector, and 10 percent to the mothership sector. In the BS, 45 percent of the DFAs are allocated to the A season (January 20 to June 10), and 55 percent of the DFAs are allocated to the B season (June 10 to November 1) (§§ 679.20(a)(5)(i)(B)(*1*) and 679.23(e)(2)). The AI directed pollock fishery allocation to the Aleut Corporation is the amount of pollock TAC remaining in the AI after subtracting 1,900 mt for the CDQ DFA (10 percent), and 3,000 mt for the ICA (§ 679.20(a)(5)(iii)(B)(*2*)). In the AI, the total A season apportionment of the pollock TAC (including the AI directed fishery allocation, the CDQ DFA, and the ICA) may not exceed 40 percent of the ABC for AI pollock, and the remainder of the pollock TAC is allocated to the B season (§ 679.20(a)(5)(iii)(B)(*3*)). Table 2 lists these proposed 2025 and 2026 amounts. Within any fishing year, any underharvest of a seasonal allowance may be added to a subsequent seasonal allowance (§ 679.20(a)(5)(i)(B)(*2*) and 679.20(a)(5)(iii)(B)(*3*)(*iii*)).

Section 679.20(a)(5)(iii)(B)(*6*) sets harvest limits for pollock in the A season (January 20 to June 10) in Areas 543, 542, and 541. In Area 543, the A season pollock harvest limit is no more than 5 percent of the AI pollock ABC. In Area 542, the A season pollock harvest limit is no more than 15 percent of the AI pollock ABC. In Area 541, the A season pollock harvest limit is no more than 30 percent of the AI pollock ABC.

Section 679.20(a)(5)(i)(A)(*4*) includes several specific requirements regarding BS pollock allocations. First, it requires that 8.5 percent of the pollock allocated to the CP sector be available for harvest by American Fisheries Act (AFA) catcher vessels (CVs) with CP sector endorsements, unless the Regional Administrator receives a cooperative contract that allows the distribution of harvest among AFA CPs and AFA CVs in a manner agreed to by all members of the CP sector cooperative(s). Second, AFA CPs not listed in the AFA are limited to harvesting no more than 0.5 percent of the pollock allocated to the CP sector. Table 2 lists the proposed 2025 and 2026 allocations of pollock TAC. Tables 13, 14, and 15 list the AFA CP and CV harvesting sideboard limits. The BS inshore pollock cooperative and open access sector allocations are based on the submission of AFA inshore cooperative applications due to NMFS on December 1 of each calendar year. Because AFA inshore cooperative applications for 2025 have not been submitted to NMFS, and NMFS therefore cannot calculate 2025 allocations, NMFS has not included inshore cooperative tables in these proposed harvest specifications. NMFS will include the 2025 AFA inshore pollock cooperative and open access sector allocations in the final harvest specifications. NMFS also will post the 2025 AFA inshore pollock cooperative and open access sector allocations on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/alaska-fisheries-management-reports* prior to the start of the fishing year, based on the harvest specifications effective on that date.

Table 2 also lists proposed seasonal apportionments of pollock and harvest limits within the Steller Sea Lion Conservation Area (SCA). The harvest of pollock within the SCA, as defined at § 679.22(a)(7)(vii), is limited to no more than 28 percent of the annual pollock DFA before 12 p.m. (noon), April 1, as provided in § 679.20(a)(5)(i)(C). The A season pollock SCA harvest limit will be apportioned to each sector in proportion to each sector's allocated percentage of the DFA.

TABLE 2—PROPOSED 2025 AND 2026 ALLOCATIONS OF POLLOCK TACS TO THE DIRECTED POLLOCK FISHERIES AND TO THE CDQ DIRECTED FISHING ALLOWANCES (DFA) [1]

[Amounts are in metric tons]

Area and sector	2025 and 2026 allocations	A season [1]		B season [1]
		A season DFA	SCA harvest limit [2]	B season DFA
Bering Sea subarea TAC	1,325,000	n/a	n/a	n/a
CDQ DFA	132,500	59,625	37,100	72,875
ICA [1]	46,000	n/a	n/a	n/a
Total Bering Sea DFA (non-CDQ)	1,146,500	515,925	321,020	630,575

TABLE 2—PROPOSED 2025 AND 2026 ALLOCATIONS OF POLLOCK TACS TO THE DIRECTED POLLOCK FISHERIES AND TO THE CDQ DIRECTED FISHING ALLOWANCES (DFA) [1]—Continued

[Amounts are in metric tons]

Area and sector	2025 and 2026 allocations	A season [1]		B season [1]
		A season DFA	SCA harvest limit [2]	B season DFA
AFA Inshore	573,250	257,963	160,510	315,288
AFA Catcher/Processors [3]	458,600	206,370	128,408	252,230
Catch by CPs	419,619	188,829	n/a	230,790
Catch by CVs [3]	38,981	17,541	n/a	21,440
Unlisted CP Limit [4]	2,293	1,032	n/a	1,261
AFA Motherships	114,650	51,593	32,102	63,058
Excessive Harvesting Limit [5]	200,638	n/a	n/a	n/a
Excessive Processing Limit [6]	343,950	n/a	n/a	n/a
Aleutian Islands subarea ABC	43,863	n/a	n/a	n/a
Aleutian Islands subarea TAC	19,000	n/a	n/a	n/a
CDQ DFA	1,900	1,900	n/a	.....
ICA	3,000	1,500	n/a	1,500
Aleut Corporation	14,100	14,100	n/a	.....
Area harvest limit [7]	n/a	n/a	n/a	n/a
541	13,159	n/a	n/a	n/a
542	6,579	n/a	n/a	n/a
543	2,193	n/a	n/a	n/a
Bogoslof District ICA [8]	300	n/a	n/a	n/a

[1] Pursuant to § 679.20(a)(5)(i)(A), the annual Bering Sea subarea pollock TAC, after subtracting the CDQ DFA (10 percent) and the ICA (46,000 mt), is allocated as a DFA as follows: inshore sector–50 percent, CPs–40 percent, and mothership sector–10 percent. In the Bering Sea subarea, 45 percent of the DFA and CDQ DFA are allocated to the A season (January 20–June 10) and 55 percent of the DFA and CDQ DFA are allocated to the B season (June 10–November 1). Pursuant to § 679.20(a)(5)(iii)(B)(*2*), the annual Aleutian Islands subarea pollock TAC, after subtracting first for the CDQ DFA (10 percent) and second for the ICA (3,000 mt), is allocated to the Aleut Corporation for a directed pollock fishery. In the Aleutian Islands subarea, the A season is allocated up to 40 percent of the AI pollock ABC.

[2] In the Bering Sea subarea, pursuant to § 679.20(a)(5)(i)(C), no more than 28 percent of each sector's annual DFA may be taken from the SCA before noon, April 1. The SCA is defined at § 679.22(a)(7)(vii).

[3] Pursuant to § 679.20(a)(5)(i)(A)(*4*), 8.5 percent of the DFA allocated to listed CPs shall be available for harvest only by eligible catcher vessels with a CP endorsement delivering to listed CPs, unless there is a cooperative contract for the year.

[4] Pursuant to § 679.20(a)(5)(i)(A)(*4*)(*iii*), the AFA unlisted CPs are limited to harvesting not more than 0.5 percent of the C/P sector's allocation of pollock.

[5] Pursuant to § 679.20(a)(5)(i)(A)(*6*), NMFS establishes an excessive harvesting share limit equal to 17.5 percent of the sum of the non-CDQ pollock DFAs.

[6] Pursuant to § 679.20(a)(5)(i)(A)(*7*), NMFS establishes an excessive processing share limit equal to 30 percent of the sum of the non-CDQ pollock DFAs.

[7] Pursuant to § 679.20(a)(5)(iii)(B)(*6*), NMFS establishes harvest limits for pollock in the A season in Area 541 no more than 30 percent, in Area 542 no more than 15 percent, and in Area 543 no more than 5 percent of the Aleutian Islands pollock ABC.

[8] Pursuant to § 679.22(a)(7)(B), the Bogoslof District is closed to directed fishing for pollock. The amounts specified are therefore for incidental catch only and are not apportioned by season or sector (§ 679.20(a)(5)(ii)).

Allocation of the Atka Mackerel TACs

Section 679.20(a)(8) allocates the Atka mackerel TACs to the Amendment 80 and BSAI trawl limited access sectors, after subtracting the CDQ reserves, ICAs for the BSAI trawl limited access sector and non-trawl gear sector, and the jig gear allocation (table 3). The percentage of the ITAC for Atka mackerel allocated to the Amendment 80 and BSAI trawl limited access sectors is listed in table 33 to 50 CFR part 679 and in § 679.91. Pursuant to § 679.20(a)(8)(i), up to 2 percent of the Eastern Aleutian district and BS subarea Atka mackerel TAC may be allocated to vessels using jig gear. The percent of this allocation is recommended annually by the Council based on several criteria, including the anticipated harvest capacity of the jig gear fleet. The Council recommended, and NMFS proposes, a 0.5 percent allocation of the Atka mackerel TAC in the Eastern Aleutian district and BS subarea to the jig sector gear in 2025 and 2026.

Section 679.20(a)(8)(ii)(A) apportions the Atka mackerel TAC, after subtraction of the jig gear allocation, into two equal seasonal allowances. Section 679.23(e)(3) sets the first seasonal allowance for directed fishing with trawl gear from January 20 through June 10 (A season), and the second seasonal allowance from June 10 through December 31 (B season). Section 679.23(e)(4)(iii) applies Atka mackerel trawl seasons to trawl CDQ Atka mackerel fishing. Within any fishing year, any underharvest or overharvest of a seasonal allowance may be added to or subtracted from a subsequent seasonal allowance (§ 679.20(a)(8)(ii)(B)). The ICA and jig gear allocations are not apportioned by season.

Sections 679.20(a)(8)(ii)(C)(*1*)(*i*) and (*ii*) limit Atka mackerel catch within waters 0 nautical miles (nmi) to 20 nmi of Steller sea lion sites listed in table 6 to 50 CFR part 679 and located west of 178° W longitude to no more than 60 percent of the annual TACs in Areas 542 and 543, and equally divides that annual harvest limit between the A and B seasons as defined at § 679.23(e)(3). Section 679.20(a)(8)(ii)(C)(*2*) requires that the annual TAC in Area 543 will be no more than 65 percent of the ABC in Area 543. Section 679.20(a)(8)(ii)(D) requires that any unharvested Atka mackerel A season allowance that is added to the B season be prohibited from being harvested within waters 0 nmi to 20 nmi of Steller sea lion sites listed in table 6 to 50 CFR part 679 and located in Areas 541, 542, and 543.

Table 3 lists the proposed 2025 and 2026 Atka mackerel seasonal allowances, area allowances, and the sector allocations. One Amendment 80 cooperative has formed for the 2025 fishing year. Because all Amendment 80 vessels are part of the sole cooperative,

no allocation to the Amendment 80 limited access sector is required for 2025. The 2026 allocations for Atka mackerel between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2025. NMFS will post the 2026 Amendment 80 cooperatives and Amendment 80 limited access sector allocations on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/sustainable-fisheries-alaska* prior to the start of the fishing year, based on the harvest specifications effective on that date.

TABLE 3—PROPOSED 2025 AND 2026 SEASONAL AND SPATIAL ALLOWANCES, GEAR SHARES, CDQ RESERVE, INCIDENTAL CATCH ALLOWANCE (ICA), AND AMENDMENT 80 ALLOCATIONS OF THE BSAI ATKA MACKEREL TAC

[Amounts are in metric tons]

Sector [1]	Season [2 3 4]	2025 and 2026 allocation by area		
		Eastern Aleutian District/Bering Sea	Central Aleutian District [5]	Western Aleutian District [5]
TAC	n/a	30,000	14,877	21,288
CDQ reserve	Total	3,210	1,592	2,278
	A	1,605	796	1,139
	Critical habitat [5]	n/a	478	683
	B	1,605	796	1,139
	Critical habitat [5]	n/a	478	683
non-CDQ TAC	n/a	26,790	13,285	19,010
ICA	Total	800	100	20
Jig [6]	Total	130	.....	.....
BSAI trawl limited access	Total	2,586	1,319	.....
	A	1,293	659	.....
	Critical habitat [5]	n/a	396	.....
	B	1,293	659	.....
	Critical habitat [5]	n/a	396	.....
Amendment 80 [7]	Total	23,274	11,867	18,990
	A	11,637	5,933	9,495
	Critical habitat [5]	n/a	3,560	5,697
	B	11,637	5,933	9,495
	Critical habitat [5]	n/a	3,560	5,697

[1] Section 679.20(a)(8)(ii) allocates the Atka mackerel TACs, after subtracting the CDQ reserves, ICAs, and the jig gear allocation, to the Amendment 80 and BSAI trawl limited access sectors. The allocation of the ITAC for Atka mackerel to the Amendment 80 and BSAI trawl limited access sectors is established in table 33 to 50 CFR part 679 and § 679.91. The CDQ reserve is 10.7 percent of the TAC for use by CDQ participants (see § 679.20(b)(1)(ii)(C)).

[2] Sections 679.20(a)(8)(ii)(A) and 679.22(a) establish temporal and spatial limitations for the Atka mackerel fishery.

[3] The seasonal allowances of Atka mackerel for the CDQ reserve, BSAI trawl limited access sector, and Amendment 80 sector are 50 percent in the A season and 50 percent in the B season.

[4] Section 679.23(e)(3) authorizes directed fishing for Atka mackerel with trawl gear during the A season from January 20 to June 10, and the B season from June 10 to December 31.

[5] Section 679.20(a)(8)(ii)(C)(*1*)(*i*) limits no more than 60 percent of the annual TACs in Areas 542 and 543 to be caught inside of Steller sea lion critical habitat; § 679.20(a)(8)(ii)(C)(*1*)(*ii*) equally divides the annual harvest limits between the A and B seasons as defined at § 679.23(e)(3); and § 679.20(a)(8)(ii)(C)(*2*) requires that the TAC in Area 543 shall be no more than 65 percent of ABC in Area 543.

[6] Sections 679.2 and 679.20(a)(8)(i) require that up to 2 percent of the Eastern Aleutian District and Bering Sea subarea TAC be allocated to jig gear after subtraction of the CDQ reserve and ICA. The proposed amount of this allocation is 0.5 percent. The jig gear allocation is not apportioned by season.

[7] The 2026 allocations for Atka mackerel between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2025.

Allocation of the Pacific Cod TAC

The Council separated the BSAI OFL, ABC, and TAC into BS and AI subarea OFLs, ABCs, and TACs for Pacific cod in 2014 (79 FR 12108, March 4, 2014). Section 679.20(b)(1)(ii)(C) allocates 10.7 percent of the BS TAC and the AI TAC to the CDQ Program. After CDQ allocations have been deducted from the respective BS and AI Pacific cod TACs, the remaining BS and AI Pacific cod TACs are combined for calculating further BSAI Pacific cod sector allocations and seasonal allowances. If the non-CDQ Pacific cod TAC is or will be reached in either the BS or the AI subareas, NMFS will prohibit directed fishing for non-CDQ Pacific cod in that subarea, as provided in § 679.20(d)(1)(iii).

Section 679.20(a)(7)(ii) allocates to the non-CDQ sectors the combined BSAI Pacific cod TAC, after subtracting 10.7 percent for the CDQ Program, as follows: 1.4 percent to vessels using jig gear, 2.0 percent to hook-and-line or pot CVs less than 60 feet (ft) (18.3 m) LOA, 0.2 percent to hook-and-line CVs greater than or equal to 60 ft (18.3 m) LOA, 48.7 percent to hook-and-line CPs, 8.4 percent to pot CVs greater than or equal to 60 ft (18.3 m) LOA, 1.5 percent to pot CPs, 2.3 percent to AFA trawl CPs, 13.4 percent to the Amendment 80 sector, and 22.1 percent to trawl CVs. The BSAI ICA for the hook-and-line and pot sectors will be deducted from the aggregate portion of BSAI Pacific cod TAC allocated to the hook-and-line and pot sectors (§ 679.20(a)(7)(ii)(B)). For 2025 and 2026, the Regional Administrator proposes a BSAI ICA of 500 mt, based on anticipated incidental catch by these sectors in other fisheries. During the fishing year, NMFS may reallocate unharvested Pacific cod among sectors, consistent with the reallocation hierarchy set forth at § 679.20(a)(7)(iii).

The BSAI ITAC allocation of Pacific cod to the Amendment 80 sector is established in table 33 to 50 CFR part 679 and § 679.91. One Amendment 80 cooperative has formed for the 2025 fishing year. Because all Amendment 80 vessels are part of the sole cooperative, no allocation to the Amendment 80 limited access sector is required for

2025. The 2026 allocations for Pacific cod between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2025. NMFS will post the 2026 Amendment 80 cooperatives and Amendment 80 limited access fishery allocations on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/sustainable-fisheries-alaska* prior to the start of the fishing year, based on the harvest specifications effective on that date.

The BSAI ITAC allocation of Pacific cod to the Pacific Cod Trawl Cooperative Program (PCTC) Program is established in § 679.131(b). Section 679.131(b)(1)(i) also requires NMFS to establish an ICA for incidental catch of Pacific cod by trawl CVs engaged in directed fishing for groundfish other than PCTC Program Pacific cod during the A and B seasons. In the annual harvest specification process, NMFS determines the Pacific cod trawl catcher vessel TAC and the annual apportionment of Pacific cod in the A and B seasons between the PCTC Program DFA and the ICA (§ 679.131(b)(2)) (table 4 below). The allocations to PCTC Program cooperatives are not included in these proposed harvest specifications. PCTC Program cooperative applications are not due to NMFS until November 1, 2024; therefore, NMFS cannot calculate 2025 and 2026 allocations in conjunction with these proposed harvest specifications (§ 679.131(b)). After receiving the PCTC Program applications, NMFS will calculate the 2025 allocations for PCTC Program cooperatives, as set forth in in § 679.131(b), and will include the 2025 PCTC Program cooperative allocations in the final harvest specifications. NMFS also will post the 2025 PCTC Program cooperative allocations on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/alaska-fisheries-management-reports* prior to the start of the fishing year, based on the harvest specifications effective on that date. The 2026 allocations for Pacific cod for PCTC Program cooperatives will not be known until eligible participants apply for participation in the program by November 1, 2025.

The sector allocations of Pacific cod are apportioned into seasonal allowances to disperse the Pacific cod fisheries over the fishing year (see §§ 679.20(a)(7)(i)(B) (CDQ), 679.20(a)(7)(iv)(A) (non-CDQ), and 679.23(e)(5) (seasons)). Table 4 lists the non-CDQ sector and seasonal allowances. In accordance with § 679.20(a)(7)(iv)(B) and (C), any unused portion of a non-CDQ Pacific cod seasonal allowance for any sector, except the jig sector, will become available at the beginning of that sector's next seasonal allowance. Section 679.20(a)(7)(i)(B) sets forth the CDQ Pacific cod gear allowances by season, and CDQ groups are prohibited from exceeding those seasonal allowances (§ 679.7(d)(6)).

Section 679.20(a)(7)(vii) requires that the Regional Administrator establish an Area 543 Pacific cod harvest limit based on Pacific cod abundance in Area 543 as determined by the annual stock assessment process. Based on the 2023 stock assessment, the Regional Administrator has preliminarily determined for 2025 and 2026 that the estimated amount of Pacific cod abundance in Area 543 is 15.7 percent of total AI abundance. To calculate the Area 543 Pacific cod harvest limit, NMFS first subtracts the State GHL Pacific cod amount from the AI Pacific cod ABC. Then NMFS determines the harvest limit in Area 543 by multiplying the percentage of Pacific cod estimated in Area 543 (15.7 percent) by the remaining ABC for AI Pacific cod. Based on these calculations, which rely on the 2023 stock assessment, the proposed Area 543 harvest limit is 1,269 mt. However, the final Area 543 harvest limit could change if the Pacific cod abundance in Area 543 changes based on the stock assessment in the final 2024 SAFE report.

Under the PCTC Program, PCTC cooperatives are required to collectively set aside up to 12 percent of the PCTC Program A-season allocation for delivery to an AI shoreplant established through the process set forth at § 679.132 in years in which an AI community representative notifies NMFS of their intent to process PCTC Program Pacific cod in Adak or Atka. A notice of intent to process PCTC Program Pacific cod for 2025 must be submitted in writing to the Regional Administrator by a representative of the City of Adak or the City of Atka no later than October 15. A notice of intent was not received in 2024, and accordingly the AI set-aside will not be in effect for 2025. The 2026 set-aside will be determined after the October 15, 2025, deadline in conjunction with the 2026 and 2027 harvest specifications process.

Based on the proposed 2025 and 2026 Pacific cod TACs, table 4 lists the CDQ and non-CDQ TAC amounts; non-CDQ seasonal allowances by gear; the sector allocations of Pacific cod; and the seasons set forth at § 679.23(e)(5).

TABLE 4—PROPOSED 2025 AND 2026 SECTOR ALLOCATIONS AND SEASONAL ALLOWANCES OF THE BSAI [1] PACIFIC COD TAC

[Amounts are in metric tons]

Sector	Percent	2025 and 2026 share of gear sector total	2025 and 2026 share of sector total	2025 and 2026 seasonal allowances	
				Season	Amount
Total Bering Sea TAC	n/a	131,217	n/a	n/a	n/a
Bering Sea CDQ	n/a	14,040	n/a	See § 679.20(a)(7)(i)(B)	n/a
Bering Sea non-CDQ TAC	n/a	117,177	n/a	n/a	n/a
Total Aleutian Islands TAC	n/a	8,080	n/a	n/a	n/a
Aleutian Islands CDQ	n/a	865	n/a	See § 679.20(a)(7)(i)(B)	n/a
Aleutian Islands non-CDQ TAC	n/a	7,215	n/a	n/a	n/a
Western Aleutians Islands Limit	n/a	1,269	n/a	n/a	n/a
Total BSAI non-CDQ TAC [1]	100.0	124,392	n/a	n/a	n/a
Total hook-and-line/pot gear	60.8	75,630	n/a	n/a	n/a
Hook-and-line/pot ICA [2]	n/a	n/a	500	n/a	n/a
Hook-and-line/pot sub-total	n/a	75,130	n/a	n/a	n/a
Hook-and-line catcher/processors	48.7	n/a	60,179	n/a	n/a
A-season				Jan-1–Jun 10	30,691
B-season				Jun 10–Dec 31	29,487
Hook-and-line catcher vessels ≥60 ft LOA	0.2	n/a	247	n/a	n/a
A-season				Jan 1–Jun 10	126
B-season				Jun 10–Dec 31	121
Pot catcher/processors	1.5	n/a	1,854	n/a	n/a

TABLE 4—PROPOSED 2025 AND 2026 SECTOR ALLOCATIONS AND SEASONAL ALLOWANCES OF THE BSAI [1] PACIFIC COD TAC—Continued

[Amounts are in metric tons]

Sector	Percent	2025 and 2026 share of gear sector total	2025 and 2026 share of sector total	2025 and 2026 seasonal allowances	
				Season	Amount
Pot catcher/processors A-season				Jan 1–Jun 10	945
Pot catcher/processors B-season				Sept 1–Dec 31	908
Pot catcher vessels ≥60 ft LOA	8.4	n/a	10,380	n/a	n/a
A-season				Jan 1–Jun 10	5,294
B-season				Sept-1–Dec 31	5,086
Catcher vessels <60 ft LOA using hook-and-line or pot gear	2.0	n/a	2,471	n/a	n/a
Trawl catcher vessels [3]	22.1	27,491	n/a	n/a	n/a
A-Season ICA				Jan 20–Apr 1	1,500
A-season PCTC				Jan 20–Apr 1	18,843
B-season ICA				Apr 1–Jun 10	700
B-season PCTC				Apr 1–Jun 10	2,324
C-season trawl catcher vessels				Jun 10–Nov 1	4,124
AFA trawl catcher/processors	2.3	2,861	n/a	n/a	n/a
A-season				Jan 20–Apr 1	2,146
B-season				Apr 1–Jun 10	715
C-season				Jun 10–Nov 1	.....
Amendment 80	13.4	16,669	n/a	n/a	n/a
A-season				Jan 20–Apr 1	12,501
B-season				Apr 1–Jun 10	4,167
C-season				Jun 10–Dec 31	.....
Jig	1.4	1,741	n/a	n/a	n/a
A-season				Jan 1–Apr 30	1,045
B-season				Apr 30–Aug 31	348
C-season				Aug 31–Dec 31	348

[1] The sector allocations and seasonal allowances for BSAI Pacific cod TAC are based on the sum of the BS and AI Pacific cod TACs, after subtraction of the reserves for the CDQ Program. If the TAC for Pacific cod in either the BS or AI is or will be reached, then directed fishing will be prohibited for non-CDQ Pacific cod in that subarea, even if a BSAI allowance remains (§ 679.20(d)(1)(iii)).

[2] The ICA for the hook-and-line and pot sectors will be deducted from the aggregate portion of Pacific cod TAC allocated to the hook-and-line and pot sectors. The Regional Administrator proposes an ICA of 500 mt based on anticipated incidental catch by these sectors in other fisheries.

[3] The A and B season trawl CV Pacific cod allocation will be allocated to the PCTC Program after subtraction of the A and B season ICAs (§ 679.131(b)(1)). The Regional Administrator proposes for the A and B seasons, ICAs of 1,500 mt and 700 mt, respectively, to account for projected incidental catch of Pacific cod by trawl catcher vessels engaged in directed fishing for groundfish other than PCTC Program Pacific cod.

Note: Seasonal or sector apportionments may not total precisely due to rounding.

Sablefish Gear Allocation

Section 679.20(a)(4)(iii) and (iv) require allocation of sablefish TAC for the BS and AI between trawl gear and fixed gear. Gear allocations of the sablefish TAC for the BS are 50 percent for trawl gear and 50 percent for fixed gear. Gear allocations of the TAC for the AI are 25 percent for trawl gear and 75 percent for fixed gear. Section 679.20(b)(1)(ii)(B) requires that NMFS apportion 20 percent of the fixed gear allocation of sablefish TAC to the CDQ reserve for each subarea. Also, § 679.20(b)(1)(ii)(D)(*1*) requires that 7.5 percent of the trawl gear allocation of sablefish TAC from the nonspecified reserve, established under § 679.20(b)(1)(i), be apportioned to the CDQ reserve. The Council recommended that only trawl gear allocations of sablefish TACs be established biennially and that fixed gear allocations of sablefish TACs be established for 1 year. NMFS concurs, and the proposed harvest specifications for the fixed gear sablefish Individual Fishing Quota (IFQ) fisheries are limited to the 2025 fishing year to ensure those fisheries are conducted concurrently with the halibut IFQ fishery. Concurrent sablefish and halibut IFQ fisheries reduce the potential for discards of halibut and sablefish in those fisheries. The sablefish IFQ fisheries remain closed at the beginning of each fishing year until the final harvest specifications for the sablefish IFQ fisheries are in effect. Table 5 lists the proposed 2025 and 2026 gear allocations of the sablefish TAC and CDQ reserve amounts.

TABLE 5—PROPOSED 2025 AND 2026 GEAR SHARES AND CDQ RESERVE OF BSAI SABLEFISH TACS

[Amounts are in metric tons]

Subarea and gear	Percent of TAC	2025 Share of TAC	2025 ITAC [1]	2025 CDQ reserve	2026 Share of TAC	2026 ITAC	2026 CDQ reserve
Bering Sea:							
Trawl gear	50	4,750	4,038	356	4,750	4,038	356
Fixed gear [2]	50	4,750	n/a	950	n/a	n/a	n/a
Total	100	9,500	4,038	1,306	4,750	4,038	356
Aleutian Islands:							
Trawl gear	25	2,110	1,794	158	2,110	1,794	158
Fixed gear [2]	75	6,330	n/a	1,266	n/a	n/a	n/a

TABLE 5—PROPOSED 2025 AND 2026 GEAR SHARES AND CDQ RESERVE OF BSAI SABLEFISH TACS—Continued

[Amounts are in metric tons]

Subarea and gear	Percent of TAC	2025 Share of TAC	2025 ITAC [1]	2025 CDQ reserve	2026 Share of TAC	2026 ITAC	2026 CDQ reserve
Total	100	8,440	1,794	1,424	2,110	1,794	158

[1] For the sablefish TAC allocated to vessels using trawl gear, 15 percent of TAC is apportioned to the nonspecified reserve (§ 679.20(b)(1)(i)). The ITAC for vessels using trawl gear is the remainder of the TAC after subtracting this reserve. In the BS and AI, 7.5 percent of the trawl gear allocation of the TAC is assigned from the nonspecified reserve to the CDQ reserve (§ 679.20(b)(1)(ii)(D)(*1*)).

[2] For the portion of the sablefish TAC allocated to vessels using fixed gear, 20 percent of the allocated TAC for the BS and AI is reserved for use by CDQ participants (§ 679.20(b)(1)(ii)(B)). The ITAC for vessels using fixed gear is the remainder of the TAC after subtracting the CDQ reserve for each subarea. The Council recommended, and NMFS proposes, that specifications for the fixed gear sablefish IFQ fisheries be limited to 1 year.

Note: Seasonal or sector apportionments may not total precisely due to rounding.

Allocation of the AI Pacific Ocean Perch, and BSAI Flathead Sole, Rock Sole, and Yellowfin Sole TACs

Section 679.20(a)(10)(i) and (ii) require that NMFS allocate AI Pacific ocean perch, and BSAI flathead sole, rock sole, and yellowfin sole TACs between the Amendment 80 sector and the BSAI trawl limited access sector, after subtracting 10.7 percent for the CDQ reserves and amounts for ICAs for the BSAI trawl limited access sector and vessels using non-trawl gear. The allocation of the ITACs for AI Pacific ocean perch, and BSAI flathead sole, rock sole, and yellowfin sole to the Amendment 80 sector is established in accordance with tables 33 and 34 to 50 CFR part 679 and in § 679.91.

One Amendment 80 cooperative has formed for the 2025 fishing year. Because all Amendment 80 vessels are part of the sole cooperative, no allocation to the Amendment 80 limited access sector is required for 2025. The 2026 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program and the deadline for applying for participation is November 1, 2025. NMFS will post the 2026 Amendment 80 cooperatives and Amendment 80 limited access sector allocations on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/sustainable-fisheries-alaska* prior to the start of the fishing year, based on the harvest specifications effective on that date. Table 6 lists the proposed 2025 and 2026 allocations of the AI Pacific ocean perch, and BSAI flathead sole, rock sole, and yellowfin sole TACs.

TABLE 6—PROPOSED 2025 AND 2026 COMMUNITY DEVELOPMENT QUOTA (CDQ) RESERVES, INCIDENTAL CATCH AMOUNTS (ICAS), AND AMENDMENT 80 ALLOCATIONS OF THE ALEUTIAN ISLANDS PACIFIC OCEAN PERCH, AND BSAI FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE TACS

[Amounts are in metric tons]

Sector	2025 and 2026 allocations					
	Pacific ocean perch			Flathead sole	Rock sole	Yellowfin sole
	Eastern Aleutian District	Central Aleutian District	Western Aleutian District	BSAI	BSAI	BSAI
TAC	7,828	5,423	12,500	35,500	66,000	195,000
CDQ	838	580	1,338	3,799	7,062	20,865
ICA	100	60	10	2,000	3,000	2,000
BSAI trawl limited access	689	478	223	.....	.....	33,796
Amendment 80 [1]	6,201	4,304	10,929	29,702	55,938	138,339

[1] The 2026 allocations between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by the deadline of November 1, 2025.

Section 679.2 defines the ABC surplus for flathead sole, rock sole, and yellowfin sole as the difference between the annual ABC and TAC for each species. Section 679.20(b)(1)(iii) establishes ABC reserves for flathead sole, rock sole, and yellowfin sole. The ABC surpluses and the ABC reserves are necessary to mitigate the operational variability, environmental conditions, and economic factors that may constrain the CDQ groups and the Amendment 80 cooperatives from fully harvesting their allocations and to improve the likelihood of achieving and maintaining, on a continuing basis, the optimum yield in the BSAI groundfish fisheries. NMFS, after consultation with the Council, may set the ABC reserve at or below the ABC surplus for each species, thus maintaining the TAC at or below ABC limits. An amount equal to 10.7 percent of the ABC reserves will be allocated as CDQ ABC reserves for flathead sole, rock sole, and yellowfin sole. Section 679.31(b)(4) establishes the annual allocations of CDQ ABC reserves among the CDQ groups. The Amendment 80 ABC reserves are the ABC reserves minus the CDQ ABC reserves. Section 679.91(i)(2) establishes each Amendment 80 cooperative ABC reserves to be the ratio of each cooperatives' quota share units and the total Amendment 80 quota share units, multiplied by the Amendment 80 ABC reserve for each respective species. Table 7 lists the proposed 2025 and 2026 ABC surplus and ABC reserves for BSAI flathead sole, rock sole, and yellowfin sole.

TABLE 7—PROPOSED 2025 AND 2026 ABC SURPLUS, ABC RESERVES, COMMUNITY DEVELOPMENT QUOTA (CDQ) ABC RESERVES, AND AMENDMENT 80 ABC RESERVES IN THE BSAI FOR FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE

[Amounts are in metric tons]

Sector	Flathead sole	Rock sole	Yellowfin sole
ABC	68,203	122,535	276,917
TAC	35,500	66,000	195,000
ABC surplus	32,703	56,535	81,917
ABC reserve	32,703	56,535	81,917
CDQ ABC reserve	3,499	6,049	8,765
Amendment 80 ABC reserve [1]	29,204	50,486	73,152

Note: The 2026 allocations between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by the deadline of November 1, 2025.

Proposed PSC Limits for Halibut, Salmon, Crab, and Herring

Sections 679.21(b), (e), (f), and (g) set forth the BSAI PSC limits. Section 679.21(b)(1) establishes three fixed halibut PSC limits totaling 1,770 mt, and assigns 315 mt of the halibut PSC limit as the PSQ reserve for use by the groundfish CDQ Program, 745 mt of the halibut PSC limit for the BSAI trawl limited access sector, and 710 mt of the halibut PSC limit for the BSAI non-trawl sector. Under amendment 123 to the FMP and implementing regulations (88 FR 82740, November 24, 2023), an additional amount for the halibut PSC limit for the Amendment 80 sector is determined annually based on the most recent halibut biomass estimates from the International Pacific Halibut Commission (IPHC) setline survey index and the NMFS Alaska Fisheries Science Center (AFSC) Eastern Bering Sea shelf trawl survey index. In accordance with § 679.21(b)(1)(i)(B), NMFS applies both halibut biomass estimates such that the value at the intercept of those survey indices from table 58 to 50 CFR part 679 is the Amendment 80 sector halibut PSC limit for the following year.

The 2024 AFSC Eastern Bering Sea shelf trawl survey index estimate of halibut abundance is 125,145 mt and is below the threshold level of 150,000 mt. The IPHC setline survey index is unknown at this time but is anticipated to be available by December 2024. Based on the 2024 AFSC Eastern Bering Sea shelf trawl survey index indicating a low biomass state, the final Amendment 80 sector halibut PSC limit will be one of the following—1,134 mt, 1,309 mt, 1,396 mt, or 1,745 mt—depending on the IPHC setline survey index. Since both survey indices are not yet available, NMFS is unable to calculate the Amendment 80 sector halibut PSC limit for next year in these proposed 2025 and 2026 harvest specifications and therefore proposes a roll-over from last year's 2024 and 2025 harvest specifications of 1,396 mt. NMFS will calculate the final Amendment 80 sector halibut PSC limit and the total halibut PSC limit for the BSAI in the final 2025 and 2026 harvest specifications.

Section 679.21(b)(1)(iii)(A) and (B) require apportionment of the BSAI non-trawl halibut PSC limit into PSC allowances among six fishery categories, and § 679.21(b)(1)(ii)(A) and (B), (e)(3)(i)(B), and (e)(3)(iv) require apportionment of the BSAI trawl limited access sector's halibut and crab PSC limits into PSC allowances among seven fishery categories. Tables 9 and 10 list the proposed fishery PSC allowances for the BSAI trawl limited access sector fisheries, and table 11 lists the proposed fishery PSC allowances for the non-trawl fisheries.

Pursuant to section 3.6 of the FMP, the Council recommends, and NMFS proposes, that certain specified non-trawl fisheries be exempt from the halibut PSC limit. As in past years, after consultation with the Council, NMFS proposes to exempt the pot gear fishery, the jig gear fishery, and the sablefish IFQ fixed gear fishery categories from halibut bycatch restrictions for the following reasons: (1) the pot gear fisheries have low halibut bycatch mortality; (2) NMFS estimates halibut mortality for the jig gear fleet to be negligible because of the small size of the fishery and the selectivity of the gear; and (3) the sablefish and halibut IFQ fisheries have low halibut bycatch mortality because the IFQ Program requires legal-size halibut to be retained by vessels using fixed gear if a halibut IFQ permit holder or a hired master is aboard and is holding unused halibut IFQ for that vessel category and the IFQ regulatory area in which the vessel is operating (§ 679.7(f)(11)).

As of November 8, 2024, total groundfish catch for the pot gear fishery in the BSAI was 13,278 mt, with an associated halibut bycatch mortality of 9 mt. The 2024 jig gear fishery harvested 0 mt of groundfish. Most vessels in the jig gear fleet are exempt from observer coverage requirements. As a result, observer data are not available on halibut bycatch in the jig gear fishery. As mentioned above, NMFS estimates a negligible amount of halibut bycatch mortality because of the selective nature of jig gear and the low mortality rate of halibut caught with jig gear and released.

Under § 679.21(f)(2), NMFS annually allocates portions of either 33,318, 45,000, 47,591, or 60,000 Chinook salmon PSC limits among the AFA sectors, depending on past bycatch performance, on whether Chinook salmon bycatch incentive plan agreements (IPA) are approved, and on whether NMFS determines it is a low Chinook salmon abundance year. NMFS will determine that it is a low Chinook salmon abundance year when abundance of Chinook salmon in western Alaska is less than or equal to 250,000 Chinook salmon. The State provides to NMFS an estimate of Chinook salmon abundance using the 3-System Index for western Alaska, based on the Kuskokwim, Unalakleet, and Upper Yukon aggregate stock grouping.

If an AFA sector participates in an approved IPA and has not exceeded its performance standard under § 679.21(f)(6), and if it is not a low Chinook salmon abundance year, then NMFS will allocate a portion of the 60,000 Chinook salmon PSC limit to that sector as specified in § 679.21(f)(3)(iii)(A). If no IPA is approved, or if the sector has exceeded its performance standard under § 679.21(f)(6), and if it is not a low abundance year, then NMFS will allocate a portion of the 47,591 Chinook salmon PSC limit to that sector as specified in § 679.21(f)(3)(iii)(C). If an AFA sector participates in an approved IPA and has not exceeded its performance standard under § 679.21(f)(6) in a low abundance year, then NMFS will allocate a portion of the 45,000 Chinook salmon PSC limit to that sector as specified in § 679.21(f)(3)(iii)(B). If no IPA is approved, or if the sector has exceeded

its performance standard under § 679.21(f)(6), and if in a low abundance year, then NMFS will allocate a portion of the 33,318 Chinook salmon PSC limit to that sector as specified in § 679.21(f)(3)(iii)(D).

NMFS has determined that 2024 was a low Chinook salmon abundance year, based on the State's estimate that Chinook salmon abundance in western Alaska is less than 250,000 Chinook salmon. In addition, all AFA sectors are participating in NMFS-approved IPAs, and no sector has exceeded the sector's annual Chinook salmon bycatch performance standard in any three of seven consecutive years. Therefore, in 2025, the Chinook salmon PSC limit is 45,000 Chinook salmon, allocated to each sector as specified in § 679.21(f)(3)(iii)(B). In 2025, the Chinook salmon bycatch performance standard under § 679.21(f)(6) is 33,318 Chinook salmon, allocated to each sector as specified in § 679.21(f)(3)(iii)(D). If a sector exceeds its Chinook salmon bycatch performance standard in any three of seven consecutive years, that sector's allocation is reduced to the amount allocated under the Chinook salmon bycatch performance standard at § 679.21(f)(3)(iii)(C)–(D). The AFA sector Chinook salmon PSC limits are also seasonally apportioned with 70 percent for the A season pollock fishery and 30 percent for the B season pollock fishery (§§ 679.21(f)(3)(i) and 679.23(e)(2)). NMFS publishes the approved IPAs and the Chinook salmon PSC allocations and reports at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/sustainable-fisheries-alaska.*

Section 679.21(g)(2)(i) specifies 700 fish as the 2025 and 2026 Chinook salmon PSC limit for the AI pollock fishery. Section 679.21(g)(2)(ii) allocates 7.5 percent, or 53 Chinook salmon, as the AI PSQ reserve for the CDQ Program and allocates the remaining 647 Chinook salmon to the non-CDQ fisheries.

Section 679.21(f)(14)(i) specifies 42,000 fish as the 2025 and 2026 non-Chinook salmon PSC limit for vessels using trawl gear from August 15 through October 14 in the Catcher Vessel Operational Area (CVOA). Section 679.21(f)(14)(ii) allocates 10.7 percent, or 4,494 non-Chinook salmon, in the CVOA as the PSQ reserve for the CDQ Program and allocates the remaining 37,506 non-Chinook salmon in the CVOA to the non-CDQ fisheries. Section 679.21(f)(14)(iv) exempts from closures in the Chum Salmon Savings Area trawl vessels participating in directed fishing for pollock and operating under an IPA approved by NMFS.

PSC limits for crab and herring are specified annually based on abundance and spawning biomass.

Based on the most recent (2024) survey data, the red king crab mature female abundance is estimated at 11.7 million red king crabs, and the effective spawning biomass is estimated at 22.47 million lbs (10,190 mt). Based on the criteria set out at § 679.21(e)(1)(i), the calculated 2025 and 2026 PSC limit of red king crab in Zone 1 for trawl gear is 97,000 animals. This limit derives from the mature female abundance estimate above 8.4 million mature red king crab and an effective spawning biomass between 14.5 and 55 million lbs (6,577 and 24,947 mt).

Section 679.21(e)(3)(ii)(B)(*2*) establishes criteria under which NMFS must specify, after consultation with the Council, an annual red king crab bycatch limit for the Red King Crab Savings Subarea (RKCSS) if the State has established a GHL fishery for red king crab in the Bristol Bay area in the previous year. The regulations limit the RKCSS red king crab bycatch limit to 25 percent of the red king crab PSC limit, based on the need to optimize the groundfish harvest relative to red king crab bycatch. In October 2024, the Council recommended and NMFS proposes that the RKCSS red king crab bycatch limit for 2025 and 2026 be equal to 25 percent of the red king crab PSC limit (table 9).

Based on the most recent (2024) survey data from the NMFS annual bottom trawl survey, Tanner crab (*Chionoecetes bairdi*) abundance is estimated at 1,216 million animals. Pursuant to criteria set out at § 679.21(e)(1)(ii), the calculated 2025 and 2026 *C. bairdi* crab PSC limit for trawl gear is 980,000 animals in Zone 1 and 2,970,000 animals in Zone 2. The limit in Zone 1 is based on the total abundance of *C. bairdi* (estimated at 1,216 million animals), which is greater than 400 million animals. The limit in Zone 2 is based on the total abundance of *C. bairdi* (estimated at 1,216 million animals), which is greater than 400 million animals.

Pursuant to § 679.21(e)(1)(iii), the PSC limit for trawl gear for snow crab (*C. opilio*) is based on total abundance as indicated by the NMFS annual bottom trawl survey. The *C. opilio* crab PSC limit in the *C. opilio* bycatch limitation zone (COBLZ) is set at 0.1133 percent of the Bering Sea abundance index minus 150,000 crabs, unless a minimum or maximum PSC limit applies. Based on the most recent (2024) survey estimate of 13.37 billion animals, the calculated *C. opilio* crab PSC limit is 14,998,210 animals. Because 0.1133 percent multiplied by the total abundance is greater than 13 million animals, the maximum PSC limit applies and the PSC limit will be 12.85 million animals.

Pursuant to § 679.21(e)(1)(v), the PSC limit of Pacific herring caught while conducting any trawl operation for BSAI groundfish is 1 percent of the annual eastern Bering Sea herring biomass. Due to the lack of new information as of October 2024 regarding herring PSC limits and apportionments, the Council recommended, and NMFS proposes, basing the proposed 2025 and 2026 herring PSC limits and apportionments on the 2023 survey data. Based on the 2023 survey data, the best current estimate of 2025 and 2026 herring biomass is 253,511 mt. This amount was developed by the Alaska Department of Fish and Game based on biomass for spawning aggregations. Therefore, the herring PSC limit proposed for 2025 and 2026 is 2,535 mt for all trawl gear as listed in tables 8 and 9. The Council and NMFS will reconsider the herring PSC limit for the final harvest specifications when updated survey data and information on biomass becomes available.

Section 679.21(e)(3)(i)(A)(*1*) apportions 10.7 percent of each trawl gear PSC limit specified for crab as a PSQ reserve for use by the groundfish CDQ Program. Section 679.21(e)(3)(i)(A) requires that crab PSQ reserves be subtracted from the total trawl PSC limits. The crab and halibut PSC limits assigned to the Amendment 80 and BSAI trawl limited access sectors are listed in table 35 to 50 CFR part 679. The resulting proposed 2025 and 2026 apportionments of crab and halibut PSC limits to CDQ PSQ, the Amendment 80 sector, and the BSAI trawl limited access sector are listed in table 8. Pursuant to §§ 679.21(b)(1)(i), 679.21(e)(3)(vi), and 679.91(d) through (f), crab and halibut trawl PSC limits assigned to the Amendment 80 sector are then further issued to Amendment 80 cooperatives as cooperative quotas. Crab and halibut PSC cooperative quotas assigned to Amendment 80 cooperatives are not assigned to specific fishery categories.

One Amendment 80 cooperative has formed for the 2025 fishing year. Because all Amendment 80 vessels are part of the sole cooperative, no PSC limit assigned to the Amendment 80 limited access sector is required for 2025. The 2026 PSC limits assigned between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in

the program by the deadline of November 1, 2025. NMFS will post the 2026 Amendment 80 cooperatives and Amendment 80 limited access sector limits on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/sustainable-fisheries-alaska* prior to the start of the fishing year, based on the harvest specifications effective on that date.

The BSAI allocation of halibut and crab PSC limits to the PCTC Program is established in § 679.131(c) and (d). The halibut PSC apportioned to the trawl CV sector is 98 percent of the halibut PSC limit apportioned to the BSAI trawl limited access sector's Pacific cod fishery category, and the remaining 2 percent is apportioned to the AFA CP sector. The trawl CV sector apportionment is further assigned to the A and B seasons (95 percent) and the C season (5 percent), and the A and B season trawl CV halibut PSC limit is reduced by 25 percent to determine the overall PCTC Program halibut PSC limit. The crab PSC apportioned to the trawl CV sector is 90.6 percent of the crab PSC limit apportioned to the BSAI trawl limited access sector's Pacific cod fishery category, and the remaining 9.4 percent is apportioned to the AFA CP sector. The trawl CV sector apportionment is further assigned to the A and B seasons (95 percent) and the C season (5 percent), and the A and B season trawl CV crab PSC limit is reduced by 35 percent to determine the overall PCTC Program crab PSC limit.

Pursuant to § 679.131(c) and (d), the halibut and crab trawl PSC limits assigned to the PCTC Program are then further issued to PCTC Program cooperatives as cooperative quotas. The halibut and crab PSC limits issued to PCTC Program cooperatives are not included in these proposed harvest specifications. PCTC Program cooperative applications are not due to NMFS until November 1, 2024; therefore, NMFS cannot calculate 2025 PSC limits in conjunction with these proposed harvest specifications (§ 679.131(c) and (d)). After receiving the PCTC Program cooperative applications, NMFS will calculate the 2025 halibut and crab PSC limits for PCTC Program cooperatives, as set forth in in § 679.131(c) and (d), and will include the 2025 halibut and crab PSC limits for PCTC Program cooperatives in the final harvest specifications. NMFS also will post them on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/alaska-fisheries-management-reports* prior to the start of the fishing year, based on the harvest specifications effective on that date. The 2026 allocations of halibut and crab PSC limits for PCTC Program cooperatives will not be known until eligible participants apply for participation in the program by the deadline of November 1, 2025.

Sections 679.21(b)(2) and (e)(5) authorize NMFS, after consulting with the Council, to establish seasonal apportionments of halibut and crab PSC amounts for the BSAI non-trawl, BSAI trawl limited access, and Amendment 80 limited access sectors to maximize the ability of the fleets to harvest the available groundfish TAC and to minimize bycatch. The factors considered are (1) seasonal distribution of prohibited species, (2) seasonal distribution of target groundfish species relative to prohibited species distribution, (3) prohibited species bycatch needs on a seasonal basis relevant to prohibited species biomass and expected catches of target groundfish species, (4) expected variations in bycatch rates throughout the year, (5) expected changes in directed groundfish fishing seasons, (6) expected start of fishing effort, and (7) economic effects of establishing seasonal prohibited species apportionments on segments of the target groundfish industry. Based on these criteria, the Council recommended, and NMFS proposes, the seasonal PSC apportionments in tables 10 and 11 to maximize harvest among gear types, fisheries, and seasons, while minimizing bycatch of PSC.

TABLE 8—PROPOSED 2025 AND 2026 APPORTIONMENT OF PROHIBITED SPECIES CATCH ALLOWANCES TO NON-TRAWL GEAR, THE CDQ PROGRAM, AMENDMENT 80, AND THE BSAI TRAWL LIMITED ACCESS SECTORS

PSC species, areas, and zones [1]	Total PSC [4]	Non-trawl PSC	CDQ PSQ reserve [2]	Trawl PSC remaining after CDQ PSQ	Amendment 80 sector [3 4]	BSAI trawl limited access sector	BSAI PSC limits not allocated [2]
Halibut mortality (mt) BSAI	3,166	710	315	n/a	1.396	745	n/a
Herring (mt) BSAI	2,535	n/a	n/a	n/a	n/a	n/a	n/a
Red king crab (animals) Zone 1	97,000	n/a	10,379	86,621	43,293	26,489	16,839
C. opilio (animals) COBLZ	12,850,000	n/a	1,374,950	11,475,050	5,639,987	3,688,081	2,146,982
C. bairdi crab (animals) Zone 1	980,000	n/a	104,860	875,140	368,521	411,228	95,390
C. bairdi crab (animals) Zone 2	2,970,000	n/a	317,790	2,652,210	627,778	1,241,500	782,932

[1] Refer to § 679.2 for definitions of areas and zones.
[2] The PSQ reserve for the CDQ Program for crab species is 10.7 percent of each crab PSC limit.
[3] The Amendment 80 program reduced apportionment of the trawl PSC limits for crab below the total PSC limit. These reductions are not apportioned to other gear types or sectors.
[4] Under Amendment 123 and implementing regulations (88 FR 82740, November 24, 2023), the halibut PSC limit for the Amendment 80 sector is determined annually based on the most recent halibut biomass estimates from the IPHC setline survey index and the NMFS AFSC Eastern Bering Sea shelf trawl survey index (§ 679.21(b)(1)(i)(A)–(C)). Since both survey indices are not yet available, NMFS is unable to calculate the Amendment 80 sector halibut PSC limit for the proposed 2025 and 2026 harvest specifications and therefore proposes a roll-over from last year's 2024 and 2025 harvest specifications of 1,396 mt. NMFS will update the final halibut PSC limit for the Amendment 80 sector, as well as the total halibut PSC limit for the BSAI, in the final 2025 and 2026 harvest specifications.

TABLE 9—PROPOSED 2025 AND 2026 HERRING AND RED KING CRAB SAVINGS SUBAREA PROHIBITED SPECIES CATCH ALLOWANCES FOR ALL TRAWL SECTORS

Fishery categories	Herring (mt) BSAI	Red king crab (animals) Zone 1
Yellowfin sole	147	n/a
Rock sole/flathead sole/Alaska plaice/other flatfish [1]	73	n/a
Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish	7	n/a
Rockfish	7	n/a
Pacific cod	13	n/a
Midwater trawl pollock	2,257	n/a
Pollock/Atka mackerel/other species [2 3]	30	n/a

TABLE 9—PROPOSED 2025 AND 2026 HERRING AND RED KING CRAB SAVINGS SUBAREA PROHIBITED SPECIES CATCH ALLOWANCES FOR ALL TRAWL SECTORS—Continued

Fishery categories	Herring (mt) BSAI	Red king crab (animals) Zone 1
2024 Red king crab savings subarea non-pelagic trawl gear [4]	n/a	24,250
Total trawl PSC	2,535	97,000

[1] "Other flatfish" for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), Alaska plaice, arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.
[2] Pollock other than midwater trawl pollock, Atka mackerel, and "other species" fishery category.
[3] "Other species" for PSC monitoring includes skates, sharks, and octopuses.
[4] In October 2024, the Council recommended and NMFS proposes that the red king crab bycatch limit within the RKCSS be limited to 25 percent of the red king crab PSC limit (see § 679.21(e)(3)(ii)(B)(*2*)).
Note: Species apportionments may not total precisely due to rounding.

TABLE 10–PROPOSED 2025 PROHIBITED SPECIES BYCATCH ALLOWANCES FOR THE BSAI TRAWL LIMITED ACCESS SECTORS AND PACIFIC COD TRAWL COOPERATIVE PROGRAM

BSAI trawl limited access sector fisheries	Prohibited species and area [1]				
	Halibut mortality (mt) BSAI	Red king crab (animals) Zone 1	*C. opilio* (animals) COBLZ	*C. bairdi* (animals)	
				Zone 1	Zone 2
Yellowfin sole	265	23,337	3,521,726	346,228	1,185,500
Rock sole/flathead sole/other flatfish [2]			0		
Greenland turbot/arrowtooth flounder/Kamchatka flounder/ sablefish			0		
Rockfish, April 15–December 31	5		2,971		1,000
Total Pacific cod [3]	300	2,955	148,531	60,000	50,000
AFA CP Pacific cod	6	278	13,962	5,640	4,700
PCTC Program Pacific cod, A and B season	209	1,653	83,097	33,567	27,973
Trawl CV Pacific cod, C season	15	134	6,728	2,718	2,265
PCTC Program unallocated reduction	70	890	44,744	18,075	15,062
Pollock/Atka mackerel/other species [4]	175	197	14,854	5,000	5,000
Total BSAI trawl limited access sector PSC	745	26,489	3,688,082	411,228	1,241,500

[1] Refer to § 679.2 for definitions of areas and zones.
[2] "Other flatfish" for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), Alaska plaice, arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.
[3] With the implementation of the PCTC Program, the BSAI trawl limited access sector Pacific cod PSC limits for halibut and crab are split between AFA CPs, PCTC A and B-season for trawl CVs, and open access C-season. NMFS will apply a 25 percent reduction to the A and B season trawl CV sector halibut PSC limit in the annual harvest specifications after the Council recommends and NMFS approves the BSAI trawl limited access sector's PSC limit apportionments to fishery categories including the Pacific cod fishery category. In addition, NMFS will apply a 35 percent reduction to the A and B season trawl CV sector crab PSC limit. Any amount of the PCTC Program halibut or crab PSC limits remaining after the B season may be reapportioned to the trawl CV open access fishery in the C season. Because the annual PSC limits for the PCTC Program are not a fixed amount established in regulation and, instead, are determined annually through the harvest specification process, NMFS must apply the reduction to the A and B season apportionment of the trawl CV sector apportionment to implement the overall PSC reductions under the PCTC Program.
[4] "Other species" for PSC monitoring includes skates, sharks, and octopuses.
Note: Species apportionments may not total precisely due to rounding.

TABLE 11—PROPOSED 2025 AND 2026 HALIBUT PROHIBITED SPECIES BYCATCH ALLOWANCES FOR NON-TRAWL FISHERIES

		Halibut mortality (mt) BSAI		
Non-trawl fisheries	Seasons	Catcher/processor	Catcher vessel	All non-trawl
Pacific cod	Annual Pacific cod	648	13	661
	January 1–June 10	388	9	n/a
	June 10–August 15	162	2	n/a
	August 15–December 31	98	2	n/a
Non-Pacific cod non-trawl-Total	May 1–December 31	n/a	n/a	49
Groundfish pot and jig	n/a	n/a	n/a	Exempt
Sablefish hook-and-line	n/a	n/a	n/a	Exempt
Total for all non-trawl PSC	n/a	n/a	n/a	710

Halibut Discard Mortality Rates

To monitor halibut bycatch mortality allowances and apportionments, the Regional Administrator uses observed halibut incidental catch rates, halibut discard mortality rates (DMRs), and estimates of groundfish catch to project when a fishery's halibut bycatch mortality allowance or seasonal apportionment is reached. Halibut incidental catch rates are based on observed estimates of halibut incidental catch in the groundfish fishery. DMRs are estimates of the proportion of incidentally caught halibut that do not survive after being returned to the sea. The cumulative halibut mortality that accrues to a particular halibut PSC limit is the product of a DMR multiplied by the estimated halibut PSC. DMRs are estimated using the best scientific information available in conjunction with the annual BSAI stock assessment process. The DMR methodology and findings are included as an appendix to the annual BSAI groundfish SAFE report (see **ADDRESSES**).

In 2016, the DMR estimation methodology underwent revisions per the Council's recommendation. A halibut working group (IPHC, Council, and NMFS staff) developed improved estimation methods that have undergone review by the Plan Team, SSC, and the Council. A summary of the revised methodology is included in the BSAI proposed 2017 and 2018 harvest specifications (81 FR 87863, December 6, 2016), and the comprehensive discussion of the working group's statistical methodology is available from the Council (see **ADDRESSES**). The DMR working group's revised methodology is intended to improve estimation accuracy, transparency, and transferability used for calculating DMRs. The working group will continue to consider improvements to the methodology used to calculate halibut mortality, including potential changes to the reference period (the period of data used for calculating the DMRs). The methodology will continue to ensure that NMFS is using DMRs that more accurately reflect halibut mortality, which will inform the different sectors of their estimated halibut mortality and allow specific sectors to respond with methods that could reduce mortality and, eventually, the DMR for that sector.

At the October 2024 meeting, the SSC, AP, and Council recommended halibut DMRs derived from the revised methodology, and NMFS proposes DMRs calculated under the revised methodology. Comparing the proposed 2025 and 2026 DMRs to the final DMRs from the 2024 and 2025 harvest specifications, the DMR for pelagic trawl gear remained at 100 percent, the DMR for motherships and CPs using non-pelagic trawl gear increased 1 percent, the DMR for CVs using non-pelagic trawl gear increased 4 percent, the DMR for CPs using hook-and-line gear increased 2 percent, the DMR for CVs using hook-and-line gear increased 2 percent, and the DMR for pot gear decreased 5 percent. Table 12 lists the proposed 2025 and 2026 DMRs.

TABLE 12—PROPOSED 2025 AND 2026 PACIFIC HALIBUT DISCARD MORTALITY RATES (DMR) FOR THE BSAI

Gear	Sector	Halibut discard mortality rate (percent)
Pelagic trawl	All	100
Non-pelagic trawl	Mothership and catcher/processor	86
Non-pelagic trawl	Catcher vessel	67
Hook-and-line	Catcher vessel	9
Hook-and-line	Catcher/processor	9
Pot	All	21

Listed AFA CP Sideboard Limits

Pursuant to § 679.64(a), the Regional Administrator is responsible for restricting the ability of listed AFA CPs to engage in directed fishing for groundfish species other than pollock to protect participants in other groundfish fisheries from adverse effects resulting from the AFA fishery and from fishery cooperatives in the directed pollock fishery. These restrictions are set as sideboard limits on catch. On February 8, 2019, NMFS published a final rule (84 FR 2723) that implemented regulations to prohibit non-exempt AFA CPs from directed fishing for all groundfish species or species groups subject to sideboard limits (see § 679.20(d)(1)(iv)(D) and table 54 to 50 CFR part 679). NMFS proposes to exempt AFA CPs from a yellowfin sole sideboard limit pursuant to § 679.64(a)(1)(v) because the proposed 2025 and 2026 aggregate ITAC of yellowfin sole assigned to the Amendment 80 sector and BSAI trawl limited access sector is greater than 125,000 mt.

Section 679.64(a)(2) and tables 40 and 41 to 50 CFR part 679 establish a formula for calculating PSC sideboard limits for halibut and crab caught by listed AFA CPs. The basis for these sideboard limits is described in detail in the final rules implementing the major provisions of the AFA (67 FR 79692, December 30, 2002) and Amendment 80 (72 FR 52668, September 14, 2007). PSC species listed in table 13 that are caught by listed AFA CPs participating in any groundfish fishery other than pollock will accrue against the proposed 2025 and 2026 PSC sideboard limits for the listed AFA CPs. Section 679.21(b)(4)(iii), (e)(3)(v), and (e)(7) authorize NMFS to close directed fishing for groundfish other than pollock for listed AFA CPs once a 2025 or 2026 PSC sideboard limit listed in table 13 is reached. Pursuant to § 679.21(b)(1)(ii)(C) and (e)(3)(ii)(C), halibut or crab PSC by listed AFA CPs while fishing for pollock will accrue against the PSC allowances annually specified for the pollock/Atka mackerel/''other species'' fishery categories, according to § 679.21(b)(1)(ii)(B) and (e)(3)(iv).

TABLE 13—PROPOSED 2025 AND 2026 BSAI AMERICAN FISHERIES ACT LISTED CATCHER/PROCESSOR PROHIBITED SPECIES SIDEBOARD LIMITS

PSC species and area [1]	Ratio of PSC to total PSC	Proposed 2025 and 2026 PSC available to trawl vessels after subtraction of PSQ [2]	Proposed 2025 and 2026 CP sideboard limit [2]
Halibut mortality BSAI	n/a	n/a	286
Red king crab Zone 1	0.007	86,621	606
C. opilio (COBLZ)	0.153	11,475,050	1,755,683
C. bairdi Zone 1	0.140	875,140	122,520
C. bairdi Zone 2	0.050	2,652,210	132,611

[1] Refer to § 679.2 for definitions of areas.
[2] Halibut amounts are in metric tons of halibut mortality. Crab amounts are in numbers of animals.

AFA CV Sideboard Limits

The Regional Administrator is responsible for restricting the ability of listed AFA CVs to engage in directed fishing for groundfish species other than pollock to protect participants in other groundfish fisheries from adverse effects resulting from the AFA and from fishery cooperatives in the pollock directed fishery. These restrictions are set out as sideboard limits on catch. Section 679.64(b)(3) and (b)(4) and tables 40 and 41 to 50 CFR part 679 establish formulas for setting AFA CV groundfish and halibut and crab PSC sideboard limits for the BSAI. The basis for these sideboard limits is described in detail in the final rules implementing the major provisions of the AFA (67 FR 79692, December 30, 2002), Amendment 80 (72 FR 52668, September 14, 2007), and amendment 122 (88 FR 53704, August 8, 2023). NMFS proposes to exempt AFA CVs from a yellowfin sole sideboard limit pursuant to § 679.64(b)(6) because the proposed 2025 and 2026 aggregate ITAC of yellowfin sole assigned to the Amendment 80 sector and BSAI trawl limited access sector is greater than 125,000 mt.

On February 8, 2019, NMFS published a final rule (84 FR 2723) that implemented regulations to prohibit non-exempt AFA CVs from directed fishing for a majority of the groundfish species or species groups subject to sideboard limits (see § 679.20(d)(1)(iv)(D) and table 55 to 50 CFR part 679). The only remaining sideboard limit for non-exempt AFA CVs is for Pacific cod. Pursuant to amendment 122 to the FMP, the Pacific cod sideboard limit is no longer necessary in the A and B seasons because directed fishing in the BSAI for Pacific cod by trawl CVs is now managed under the PCTC Program, and accordingly the sideboard limit is in effect in the C season only (§ 679.64(b)(3)(ii)). Table 14 lists the proposed 2025 and 2026 AFA CV Pacific cod sideboard limits.

TABLE 14—PROPOSED 2025 AND 2026 BSAI PACIFIC COD SIDEBOARD LIMITS FOR AMERICAN FISHERIES ACT CATCHER VESSELS (CVS)

[Amounts are in metric tons]

Fishery by area/gear/season	Ratio of 1997 AFA CV catch to TAC	2025 and 2026 initial TAC for C Season	2025 and 2026 AFA catcher vessel sideboard limits
BSAI	n/a	n/a	n/a
Trawl gear CV	n/a	n/a	n/a
C Season Jun 10–Nov 1	0.8609	4,124	3,550

Note: As proposed, § 679.64(b)(6) would exempt AFA CVs from a yellowfin sole sideboard limit because the proposed 2025 and 2026 aggregate ITAC of yellowfin sole assigned to the Amendment 80 sector and BSAI trawl limited access sector is greater than 125,000 mt.

Halibut and crab PSC limits listed in table 15 that are caught by AFA CVs participating in any groundfish fishery other than pollock will accrue against the 2025 and 2026 PSC sideboard limits for the AFA CVs. Section 679.21(b)(4)(iii), (e)(3)(v), and (e)(7) authorize NMFS to close directed fishing for groundfish other than pollock for AFA CVs once a 2025 or 2026 PSC sideboard limit listed in table 15 is reached. Pursuant to § 679.21(b)(1)(ii)(C) and (e)(3)(ii)(C), halibut or crab PSC by AFA CVs while fishing for pollock will accrue against the PSC allowances annually specified for the pollock/Atka mackerel/''other species'' fishery categories, according to § 679.21(b)(1)(ii)(B) and (e)(3)(iv).

TABLE 15—PROPOSED 2025 AND 2026 AMERICAN FISHERIES ACT CATCHER VESSEL PROHIBITED SPECIES CATCH SIDEBOARD LIMITS FOR THE BSAI [1]

PSC species and area [1]	Target fishery category [2]	AFA catcher vessel PSC sideboard limit ratio	Proposed 2025 and 2026 PSC limit after subtraction of PSQ reserves [3]	Proposed 2025 and 2026 AFA catcher vessel PSC sideboard limit [3]
Halibut	Pacific cod trawl	n/a	n/a	n/a
	Pacific cod hook-and-line or pot.	n/a	n/a	2

TABLE 15—PROPOSED 2025 AND 2026 AMERICAN FISHERIES ACT CATCHER VESSEL PROHIBITED SPECIES CATCH SIDEBOARD LIMITS FOR THE BSAI [1]—Continued

PSC species and area [1]	Target fishery category [2]	AFA catcher vessel PSC sideboard limit ratio	Proposed 2025 and 2026 PSC limit after subtraction of PSQ reserves [3]	Proposed 2025 and 2026 AFA catcher vessel PSC sideboard limit [3]
	Yellowfin sole total	n/a	n/a	101
	Rock sole/flathead sole/Alaska plaice/other flatfish [4].	n/a	n/a	228
	Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish.	n/a	n/a	
	Rockfish	n/a	n/a	2
	Pollock/Atka mackerel/other species [5].	n/a	n/a	5
Red king crab Zone 1	n/a	0.2990	86,621	25,900
C. opilio COBLZ	n/a	0.1680	11,475,050	1,927,808
C. bairdi Zone 1	n/a	0.3300	875,140	288,796
C. bairdi Zone 2	n/a	0.1860	2,652,210	493,311

[1] Refer to § 679.2 for definitions of areas and zones.
[2] Target fishery categories are defined at § 679.21(b)(1)(ii)(B) and (e)(3)(iv).
[3] Halibut amounts are in metric tons of halibut mortality. Crab amounts are in numbers of animals.
[4] "Other flatfish" for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), Alaska plaice, arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.
[5] "Other species" for PSC monitoring includes skates, sharks, and octopuses.

Classification

NMFS is issuing this proposed rule pursuant to section 305(d) of the Magnuson-Stevens Act. Through previous actions, the FMP and regulations authorize NMFS to take this action (see 50 CFR part 679). The NMFS Assistant Administrator has preliminarily determined that the proposed harvest specifications are consistent with the FMP, the Magnuson-Stevens Act, and other applicable laws, subject to further review and consideration after public comment.

This action is authorized under 50 CFR 679.20 and is exempt from review under Executive Order 12866 because it only implements annual catch limits in the BSAI.

NMFS prepared an EIS for the Alaska groundfish harvest specifications and alternative harvest strategies (see **ADDRESSES**) and made it available to the public on January 12, 2007 (72 FR 1512). On February 13, 2007, NMFS issued the ROD for the Final EIS. A SIR is being prepared for the final 2025 and 2026 harvest specifications to address the need to prepare a Supplemental EIS (40 CFR 1502.9(d)(1)). Copies of the Final EIS, ROD, and annual SIRs for this action are available from NMFS (see **ADDRESSES**). The Final EIS analyzes the environmental, social, and economic consequences of alternative harvest strategies on resources in the action area. Based on the analysis in the Final EIS, NMFS concluded that the preferred alternative (Alternative 2) provides the best balance among relevant environmental, social, and economic considerations and allows for continued management of the groundfish fisheries based on the most recent, best scientific information.

Initial Regulatory Flexibility Analysis

This Initial Regulatory Flexibility Analysis (IRFA) was prepared for this proposed rule, as required by Section 603 of the Regulatory Flexibility Act (RFA) (5 U.S.C. 603), to describe the economic impact this proposed rule, if adopted, would have on small entities. The IRFA describes the action; the reasons why this proposed rule is proposed; the objectives and legal basis for this proposed rule; the estimated number and description of directly regulated small entities to which this proposed rule would apply; the recordkeeping, reporting, and other compliance requirements of this proposed rule; and the relevant Federal rules that may duplicate, overlap, or conflict with this proposed rule. The IRFA also describes significant alternatives to this proposed rule that would accomplish the stated objectives of the Magnuson-Stevens Act, and any other applicable statutes, and that would minimize any significant economic impact of this proposed rule on small entities. The description of the proposed action, its purpose, and the legal basis are explained earlier in the preamble and are not repeated here.

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (North American Industry Classification System (NAICS) code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual gross receipts not in excess of $11 million for all its affiliated operations worldwide. A shoreside and mothership processor primarily involved in seafood processing (NAICS code 311710) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual employment, counting all individuals employed on a full-time, part-time, or other basis, not in excess of 750 employees for all its affiliated operations worldwide.

Number and Description of Small Entities Regulated by This Proposed Rule

The entities directly regulated by the groundfish harvest specifications include: (a) entities operating vessels with groundfish Federal fisheries permits (FFPs) catching FMP groundfish in Federal waters (including those receiving direction allocations of groundfish); (b) all entities operating vessels, regardless of whether they hold groundfish FFPs, catching FMP groundfish in the State-waters parallel fisheries; and (c) all entities operating vessels fishing for halibut inside 3 nautical miles of the shore (whether or not they have FFPs). In 2023 (the most

recent year of complete data), there were 119 individual CVs and CPs with gross revenues less than or equal to $11 million as well as 6 CDQ groups. This represents the potential suite of directly regulated small entities. This includes an estimated 116 small CV and 3 small CP entities in the BSAI groundfish sector. The determination of entity size is based on vessel revenues and affiliated group revenues. This determination also includes an assessment of fisheries cooperative affiliations, although actual vessel ownership affiliations have not been completely established. However, the estimate of these 116 CVs may be an overstatement of the number of small entities, as some of these vessels may be affiliated with large entities. This latter group of vessels had average gross revenues that varied by gear type. Average gross revenues for hook-and-line CVs, pot gear CVs, and trawl gear CVs are estimated to be $910,000, $1.5 million, and $2.3 million, respectively. Average gross revenues for CP entities are confidential. There are 3 AFA cooperative affiliated motherships, which appear to fall under the 750 worker threshold and are therefore small entities. The average gross revenues for the AFA motherships are confidential.

Description of Significant Alternatives That Minimize Adverse Impacts on Small Entities

The action under consideration is comprised of the proposed 2025 and 2026 harvest specifications, apportionments, and prohibited species catch limits for the groundfish fishery of the BSAI. This action is necessary to establish harvest limits for groundfish during the 2025 and 2026 fishing years and is taken in accordance with the FMP prepared and recommended by the Council pursuant to the Magnuson-Stevens Act. The establishment of the proposed harvest specifications is governed each year by the harvest strategy for the catch of groundfish in the BSAI. This strategy was selected from among five alternatives, with the preferred alternative harvest strategy being one in which the TACs are set to levels that fall within the range of ABCs recommended by the SSC through the harvest specifications process, and the sum of the TACs must achieve the OY specified in the FMP and in regulation. While the specific numbers that the harvest strategy produces may vary from year to year, the methodology used for the preferred harvest strategy remains constant.

The TACs associated with the preferred harvest strategy are those recommended by the Council in October 2024. OFLs and ABCs for the species were based on recommendations prepared by the Council's Plan Team in September 2024 and reviewed by the Council's SSC in October 2024. The Council based its TAC recommendations on those of its AP, which were consistent with the SSC's OFL and ABC recommendations. The sum of all TACs remains within the OY for the BSAI consistent with § 679.20(a)(1)(i)(A). Because setting all TACs equal to ABCs would cause the sum of TACs to exceed an OY of 2 million mt, TACs for some species or species groups are lower than the ABCs recommended by the Plan Team and the SSC.

The proposed 2025 and 2026 OFLs and ABCs are based on the best available biological information, including projected biomass trends, information on assumed distribution of stock biomass, and revised technical methods to calculate stock biomass. The proposed 2025 and 2026 TACs are based on the best available biological and socioeconomic information. The proposed 2025 and 2026 OFLs, ABCs, and TACs are consistent with the biological condition of groundfish stocks as described in the 2023 SAFE report, which is the most recent, completed SAFE report.

Under this action, the proposed ABCs reflect harvest amounts that are less than the specified overfishing levels. The proposed TACs are within the range of proposed ABCs recommended by the SSC and do not exceed the biological limits recommended by the SSC (the ABCs and OFLs). For some species and species groups in the BSAI, the Council recommended, and NMFS proposes, proposed TACs equal to proposed ABCs, which is intended to maximize harvest opportunities in the BSAI.

However, NMFS cannot set TACs for all species in the BSAI equal to their ABCs due to the constraining OY limit of 2 million mt. For this reason, some proposed TACs are less than the proposed ABCs. The specific reductions were reviewed and recommended by the Council's AP, and the Council in turn adopted the AP's TAC recommendations in making its own recommendations for the proposed 2025 and 2026 TACs.

Based upon the best scientific data available, and in consideration of the objectives of this action, it appears that there are no significant alternatives to the proposed rule that have the potential to accomplish the stated objectives of the Magnuson-Stevens Act and any other applicable statutes and that have the potential to minimize any significant adverse economic impact of the proposed rule on small entities. This action is economically beneficial to entities operating in the BSAI, including small entities. The action proposes TACs for commercially-valuable species in the BSAI and allows for the continued prosecution of the fishery, thereby creating the opportunity for fishery revenue. After public process during which the Council solicited input from stakeholders, the Council recommended the proposed harvest specifications, which NMFS determines would best accomplish the stated objectives articulated in the preamble for this proposed rule, and in applicable statutes, and would minimize to the extent practicable adverse economic impacts on the universe of directly regulated small entities.

This action does not modify recordkeeping or reporting requirements, or duplicate, overlap, or conflict with any Federal rules.

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

Adverse impacts on marine mammals or endangered or threatened species resulting from fishing activities conducted under these harvest specifications are discussed in the Final EIS and its accompanying annual SIRs (see **ADDRESSES**).

Authority: 16 U.S.C. 773 *et seq.;* 16 U.S.C. 1540(f); 16 U.S.C. 1801 *et seq.;* 16 U.S.C. 3631 *et seq.;* Pub. L. 105–277; Pub. L. 106–31; Pub. L. 106–554; Pub. L. 108–199; Pub. L. 108–447; Pub. L. 109–241; Pub. L. 109–479.

Dated: November 29, 2024.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2024–28414 Filed 12–3–24; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 89, No. 233
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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FSIS–2024–0021]

Food Date Labeling

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA); Food and Drug Administration (FDA), U.S. Department of Health and Human Services (HHS).

ACTION: Request for Information.

SUMMARY: FSIS and FDA (we, the agencies) are seeking public input on food date labeling. This Request for Information seeks information on industry practices and preferences for date labeling, research results on consumer perceptions of date labeling, and any impact date labeling may have on food waste.

DATES: Submit comments on or before February 3, 2025.

ADDRESSES: FSIS invites interested persons to submit information. Submit comments by one of the following methods:

- *Federal eRulemaking Portal:* This website allows commenters to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to *https://www.regulations.gov.* Follow the online instructions at that site for submitting comments.
- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.
- *Hand- or Courier-Delivered Submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2024–0021. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *https://www.regulations.gov.*

Docket: For access to background documents or comments received, call 202–720–5046 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT:

FSIS: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205–0495.

FDA: Peter Koufopoulos; Deputy Director for Animal Derived Food; Human Foods Program; Telephone: (240) 252–9709.

SUPPLEMENTARY INFORMATION:

Background

USDA and FDA jointly have broad jurisdiction and oversight over the U.S. food supply. FSIS and FDA have responsibility for ensuring that food labels on products over which they each have jurisdiction are truthful and not misleading. This applies to foods produced domestically, as well as foods imported from foreign countries. FSIS has the authority to regulate the labeling of most meat (including Siluriformes fish) and poultry products, and egg products. FDA has authority over all other foods, including seafood (except Siluriformes fish), game meat and shell eggs. Accordingly, some foods, such as eggs and meat, are regulated by both agencies.

FSIS is responsible for ensuring that meat, poultry, and egg products are safe, wholesome, and properly labeled and packaged. The Agency administers a regulatory program for meat products under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), for poultry products under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and for egg products under the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*).

Under the FMIA, PPIA, and EPIA, any meat, poultry, or egg product is misbranded if its labeling, including date labeling, is false or misleading in any particular (21 U.S.C. 601(n)(1); 21 U.S.C. 453(h)(1); 21 U.S.C. 1036(b)). In particular, no product or any of its wrappers, packaging, or other containers shall bear any false or misleading marking, label, or other labeling, and no statement, word, picture, design, or device which conveys any false impression or gives any false indication of origin or quality or is otherwise false or misleading shall appear in any marking or other labeling (9 CFR 317.8(a)), 381.129(b), 590.411(f)(1)).

For meat, poultry, and egg products under FSIS jurisdiction, dates may be voluntarily applied to product labels provided the products are labeled in a manner that is truthful and not misleading and in compliance with FSIS regulations (see 9 CFR 317.8, 381.129, and 590.411). To comply, a calendar date, if shown on labeling, must express both the month and day of the month. In the case of shelf-stable (including thermally processed, commercially sterile products) and frozen products, the year must also be displayed. Additionally, immediately adjacent to the date must be a phrase explaining the meaning of that date such as ''Best if Used By.''

FDA regulates a significant portion of the nation's food supply, including fruits, vegetables, dairy (*e.g.,* milk, cheese, yogurt), grain (*e.g.,* breads, cereals, rice), packaged foods (*e.g.,* canned foods, frozen foods, ready-to-eat foods), shell eggs (*i.e.,* whole eggs that are still in the shell), seafood (except Siluriformes fish), infant formula, dietary supplements, beverages, and game meat. FDA helps ensure that such foods are safe, sanitary, wholesome, and that their labeling is truthful and non-misleading. To achieve this, FDA administers regulatory programs under various authorities, including the Federal Food, Drug, and Cosmetic Act (FD&C Act)(21 U.S.C. 9), the Fair Packaging and Labeling Act(FPLA)(15 U.S.C. 39), and the Nutrition Labeling and Education Act (NLEA)(21 U.S.C. 9 343–1).[1]

Under section 403(a)(1) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular (21 U.S.C. 343(a)). Accordingly, a food would be deemed misbranded under

[1] Under section 201(ff) of the FD&C Act, dietary supplements are deemed ''food'' for most purposes, and thus the labeling requirements that apply to foods generally also apply to dietary supplements, with some exceptions (*e.g.,* nutrition labeling).

section 403(a)(1) of the FD&C Act if it has a date label that is false or misleading.

The FPLA requires specific information (*e.g.,* the net quantity of contents) to be provided on the label of consumer commodities, including food, to prevent unfair or deceptive packaging and labeling. The NLEA, which amended the FD&C Act, requires most foods to bear nutrition labeling, among other requirements. Section 403(w) of the FD&C Act requires foods (other than a raw agricultural commodity) that contain or are a major food allergen to be specifically labeled with the name of the allergen source.

The Dietary Supplement Health and Education Act (DSHEA) amended the FD&C Act to define the term ''dietary supplement'' and establish requirements for dietary supplements. Under section 201(ff) of the FD&C Act, dietary supplements are deemed ''food'' for most purposes, and thus the labeling requirements that apply to foods generally also apply to dietary supplements, with some exceptions. For example, specific nutrition labeling requirements apply to dietary supplements.

FDA regulates infant formula under the FD&C Act and FDA's implementing regulations, which require, among other things, that infant formula labels include a ''Use by'' date (21 CFR 107.20(c)). Accordingly, infant formula date labeling is outside the scope of this Request for Information.

Food Loss and Waste

On June 12, 2024, the Biden-Harris Administration released the final National Strategy for Reducing Food Loss and Waste and Recycling Organics (the National Strategy).[2] The National Strategy lays out a path for the U.S. to meet its national goal of reducing food loss and waste by 50 percent by 2030.

The U.S. Environmental Protection Agency (EPA) estimates that in 2019, 66 million tons of wasted food was generated in the food retail, food service, and residential sectors, and most of this waste (about 60 percent) was sent to landfills. An additional 40 million tons of wasted food was generated in the food and beverage manufacturing and processing sectors.[3] Wasted food is the single largest category of material placed in municipal landfills. Wasted wholesome and safe food represents nourishment that could have helped feed families in need. Additionally, water, energy, arable land, and labor used to produce wasted food could have been used for other purposes. Effectively reducing food waste will require cooperation among federal, state, tribal, territory, and local governments, food manufacturers, agriculture producers, faith-based institutions, environmental organizations, communities, and others, all along the entire supply chain.

In response to the draft National Strategy for Reducing Food Loss and Waste and Recycling Organics, FSIS and FDA received comments encouraging an update of the Federal date labeling requirements, including standardizing date labeling. Commenters noted that food manufacturers use a variety of phrases such as ''Sell By,'' ''Use By,'' and ''Best By'' on product labels to describe dates on a voluntary basis. According to commenters, the use of different phrases to describe dates may cause consumer confusion and lead to the premature disposal of wholesome and safe food, because it is past the date printed on the package.

As explained in the final National Strategy, both FSIS and FDA recommend that food industry members voluntarily apply the ''Best if Used By'' food date label, which notes the date after which quality may decline but the product may still be consumed. The ''Best if Used By'' label aims to lessen consumer confusion and reduce wasted food.[4] In addition, the ''Best if Used By'' label was the most frequently perceived by consumers as communicating quality, among the food date labels assessed by researchers at Johns Hopkins Center for a Livable Future (CLF), which supports standardizing this label.[5] Although FSIS and FDA encourage the use of the phrase ''Best if Used By'', current federal regulations do not prohibit industry from using other date labeling phrases, such as ''Sell By'' or ''Use By,'' if they are truthful and not misleading. It should be noted that industry groups have taken steps to address consumer confusion.[6] However, the number, diversity, and complexity of food products in the marketplace along with significant variability in the environmental, storage, and distribution conditions of food create challenges for standardization of food safety or quality date labels.

FSIS and FDA are requesting additional information on industry practices and barriers for standardizing food date labeling, research results on consumer perceptions of food date labeling, and any impact date labeling may have on food loss and waste. The information may be used to inform future policy decisions, guidance, or consumer education campaigns on food date labels intended to help reduce the premature discard of wholesome and safe food. Commenters should provide any data, studies, or other evidence that supports their response. To help FSIS and FDA review comments efficiently, please identify the question to which you are responding by its associated category and number (*e.g. Industry Practices and Preferences for Date Labeling* 1).

Questions for Commenters

Industry Practices and Preferences for Date Labeling

1. Which products contain date labels, and which do not? Why do some products contain date labels and others do not?

2. What standards or criteria do manufacturers and producers consider when deciding which food date label phrase to use? Are different phrases used for different products or categories of products, and if so, why? Are there legal or trade requirements or marketing standards that impact which phrases are used (*i.e.,* local or state requirements, industry best practice standards, etc.)? If so, please describe.

3. What standards or criteria do manufacturers and producers consider when deciding what date to use?

4. Would a particular product have a different date depending on the phrase used (*e.g.,* would the date be the same or different if the phrase were ''Best if Used By'' versus ''Use By'' or ''Freeze By'')? If so, please explain.

5. What challenges or limitations do food manufacturers have when establishing or changing food date labels?

6. Are there costs associated with changing the date label phrase or date used in addition to the costs associated with any label change? If so, please explain what those are. What data are available on the use of certain food date label phrases and cost to manufacturers, retailers, or consumers?

7. How do grocery retailers determine that a food item is no longer sellable? Do

[2] *https://www.usda.gov/sites/default/files/documents/NATIONAL-STRATEGY-FOR-REDUCING-FOOD-LOSS-AND-WASTE-AND-RECYCLING-ORGANICS.pdf.*

[3] Food: Material-Specific Data | US EPA.

[4] See also *https://www.fsis.usda.gov/food-safety/safe-food-handling-and-preparation/food-safety-basics/food-product-dating* and *https://www.fda.gov/news-events/fda-voices/working-food-industry-reduce-confusion-over-date-labels.*

[5] Johns Hopkins Bloomberg School of Public Health. (2019). Survey: Misunderstanding Food Date Labels Linked with Higher Food Discards—Confusion about when to worry about food safety is widespread. *https://publichealth.jhu.edu/2019/survey-misunderstanding-food-datelabels-linked-with-higher-food-discards.*

[6] See *https://www.fmi.org/docs/default-source/Industry-Topics-Doc/fact-sheet-product-code-dating-initiative.pdf?sfvrsn=59de6c6e_2.*

the considerations differ depending on the food item? Do the considerations take into account the phrase and/or date on the label, and if so, how?

Research on Consumer Perception of Date Labeling

8. What studies or data are available on consumer understanding of current date labeling on food that FSIS and FDA regulate, and why are these studies or data important for FSIS and FDA to consider? Are there data and studies that demonstrate that consumers are confused by date labels and believe the dates determine whether food is safe? Are there any available studies or data on whether and how consumers consider food date labels when grocery shopping or when deciding to discard food at the home?

9. What data are available on the most effective ways for presenting food date labels on food items so that consumers can easily access and clearly understand the information?

10. What studies exist on the factors that should be considered in a national education campaign aimed at reducing consumer confusion about date labels? Please explain your reasoning as to why a study should be considered.

Food Loss and Waste Research

11. What studies detailing the effects of date labeling on food waste should FSIS and FDA consider and why?

12. What factors do firms (*e.g.,* manufacturers, retailers, food banks) and individuals consider when determining which food items to donate or discard? Specifically, do firms or individuals use food date labels to inform decisions to donate or discard food items? Please provide supporting studies or data.

13. What estimates are available concerning the value of food that is discarded due to date labels, including any studies regarding the value discarded due to confusion of date labels?

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at *http://www.fsis.usda.gov/federal-register.* FSIS will also make copies of this publication available through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service that provides automatic and customized access to selected food safety news and information. This service is available at: *https://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password-protect their accounts.

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(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; or

(2) *Fax:* (833) 256–1665 or (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

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Done at Washington, DC.

Paul Kiecker,

Administrator.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs, Food and Drug Administration.

[FR Doc. 2024–27810 Filed 12–3–24; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–557–830]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From Malaysia: Affirmative Preliminary Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells) from Malaysia are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is April 1, 2023, through March 31, 2024. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable December 4, 2024.

FOR FURTHER INFORMATION CONTACT: Patrick Barton or Elizabeth Talbot Russ, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0012 or (202) 482–5516 respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce initiated this

investigation on May 14, 2024.[1] On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[2] On September 17, 2024, Commerce postponed the preliminary determination of this investigation until November 27, 2024.[3]

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[4] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The products covered by this investigation are solar cells from Malaysia. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the *Preamble* to Commerce's regulations,[5] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[6] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memoranda.[7] Commerce is preliminarily modifying the scope language as it appeared in the *Initiation Notice,* provided in Appendix I to this notice. The deadline for scope-related case and rebuttal briefs is established in the Preliminary Scope Decision Memoranda.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value is calculated in accordance with section 773 of the Act. In addition, pursuant to section 776(a) and (b) of the Act, Commerce has preliminarily relied upon facts otherwise available, with adverse inferences, for Baojia New Energy Manufacturing Sdn., CRC Solar Cell Joint Stock Company, Lynter Enterprise, and Mega PP Sdn. Bhd. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that, in the preliminary determination, Commerce shall determine an estimated weighted-average dumping margin, *i.e.,* all-others rate, for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

In this investigation, Commerce preliminarily calculated a zero rate for Hanwha Q Cells Malaysia Sdn. Bhd (Hanwha Q Cells). Therefore, the only rate that is not zero, *de minimis,* or based entirely on facts otherwise available is the rate calculated for Jinko Solar Technology Sdn. Bhd. (Jinko Solar). Consequently, the rate calculated for Jinko Solar is also assigned as the rate for all other producers and exporters.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset(s)) (percent)
Hanwha Q Cells Malaysia Sdn. Bhd	0.00	[8] 0.00
Jinko Solar Technology Sdn. Bhd	21.31	[9] 17.84
Baojia New Energy Manufacturing Sdn	* 81.24	* 81.24
CRC Solar Cell Joint Stock Company	* 81.24	* 81.24
Lynter Enterprise	* 81.24	* 81.24
Mega PP Sdn. Bhd	* 81.24	* 81.24
All Others	21.31	17.84

* Rates based on facts available with adverse inferences.

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations,* 89 FR 43809 (May 20, 2024) (*Initiation Notice*).

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[3] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 89 FR 77473 (September 23, 2024).

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Determination in the Less-Than-Fair-Value Investigation of Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Malaysia,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[6] *See Initiation Notice,* 89 FR 43810.

[7] *See* Memoranda, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Cambodia, Malaysia, and Thailand: Preliminary Scope Decision Memorandum,'' dated concurrently with this notice and ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from Vietnam,'' dated concurrently with this notice (collectively, Preliminary Scope Decision Memoranda).

[8] *See* Memorandum, ''Countervailing Duty Investigation of Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Malaysia: Preliminary Determination Calculations for Hanwha Q Cells Malaysia Sdn. Bhd.,'' dated September 30, 2024.

[9] *See* Memorandum, ''Countervailing Duty Investigation of Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Malaysia: Amended Preliminary Determination Calculations for Jinko Solar Technology Sdn. Bhd.,'' dated October 31, 2024.

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption, on or after the date of publication of this notice in the **Federal Register**, except as noted below for Hanwha Q Cells. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin, as adjusted for export subsidies, as follows: (1) the cash deposit rate for the respondents listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

Commerce normally adjusts cash deposits for estimated antidumping duties by the amount of export subsidies countervailed in a companion countervailing duty (CVD) proceeding. Accordingly, where Commerce preliminarily made an affirmative determination for countervailable export subsidies, Commerce has offset the estimated weighted-average dumping margin by the appropriate CVD rate. Any such adjusted cash deposit rate may be found in the ''Preliminary Determination'' section above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting estimated antidumping duty cash deposits unadjusted for countervailed export subsidies at the time that the provisional CVD measures expire. These suspension of liquidation instructions will remain in effect until further notice.

Because the estimated weighted-average dumping margin for Hanwha Q Cells is zero, entries of subject merchandise produced and exported by Hanwha Q Cells will not be subject to suspension of liquidation or cash deposit requirements. In such situations, Commerce applies the exclusion to the provisional measures to the producer/exporter combination that was examined in the investigation. Accordingly, Commerce is directing CBP not to suspend the liquidation of entries of subject merchandise that was exported and produced by Hanwha Q Cells. Entries of shipments of subject merchandise from this company in any other producer/exporter combination, or by third parties that sourced subject merchandise from the excluded producer/exporter combination, are subject to the provisional measures at the all-others rate.

Should the final estimated weighted-average dumping margin be zero or *de minimis* for the producer/exporter combination identified above, entries of shipments of subject merchandise from this producer/exporter combination will be excluded from the potential antidumping duty order. Such exclusions are not applicable to merchandise exported to the United States by this respondent in any other producer/exporter combination or by third parties that sourced subject merchandise from the excluded producer/exporter combination.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address or do not satisfy the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination if the ministerial error allegation is included with issues raised in the case briefs or other written comments.

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

All interested parties will have the opportunity to submit scope case and rebuttal briefs, to allow interested parties to comment on our preliminary scope decision at that time. For all scope case and rebuttal briefs, parties must file identical documents simultaneously on the records of the ongoing LTFV and CVD investigations of solar cells from Cambodia, Malaysia, the Socialist Republic of Vietnam, and Thailand. No new factual information or business proprietary information may be included in either scope case or rebuttal briefs.

Case briefs or other written comments regarding non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation.[10] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[11] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[12]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[13] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[14]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant

[10] *See* 19 CFR 351.309(c)(1)(i); *see also* 19 CFR 351.303 (for general filing requirements).

[11] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[12] *See* 19 CFR 351.309(c)(2) and (d)(2).

[13] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[14] *See APO and Service Final Rule.*

Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On November 8, 2024, pursuant to 19 CFR 351.210(e), Jinko Solar requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[15] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

[15] *See* Jinko Solar's Letter, ''Jinko's Request for Postponement of Final Determination,'' dated November 8, 2024.

U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: November 27, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by these investigations is crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels and building integrated materials.

These investigations cover crystalline silicon photovoltaic cells of thickness equal to or greater than 20 micrometers, having a p/n junction formed by any means, whether or not the cell has undergone other processing, including, but not limited to, cleaning, etching, coating, and/or addition of materials (including, but not limited to, metallization and conductor patterns) to collect and forward the electricity that is generated by the cell.

Merchandise under consideration may be described at the time of importation as parts for final finished products that are assembled after importation, including, but not limited to, modules, laminates, panels, building-integrated modules, building-integrated panels, or other finished goods kits. Such parts that otherwise meet the definition of merchandise under consideration are included in the scope of the investigations.

Excluded from the scope of the investigations are thin film photovoltaic products produced from amorphous silicon (a-Si), cadmium telluride (CdTe), or copper indium gallium selenide (CIGS).

Also excluded from the scope of the investigations are crystalline silicon photovoltaic cells, not exceeding 10,000 mm^2 in surface area, that are permanently integrated into a consumer good whose function is other than power generation and that consumes the electricity generated by the integrated crystalline silicon photovoltaic cell. Where more than one cell is permanently integrated into a consumer good, the surface area for purposes of this exclusion shall be the total combined surface area of all cells that are integrated into the consumer good.

Additionally, excluded from the scope of the investigations are panels with surface area from 3,450 mm^2 to 33,782 mm^2 with one black wire and one red wire (each of type 22 AWG or 24 AWG not more than 206 mm in length when measured from panel extrusion), and not exceeding 2.9 volts, 1.1 amps, and 3.19 watts. For the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Also excluded from the scope of the investigations are:

1. Off grid CSPV panels in rigid form with a glass cover, with the following characteristics: (A) a total power output of 100 watts or less per panel; (B) a maximum surface area of 8,000 cm^2 per panel; (C) do not include a built-in inverter; (D) must include a permanently connected wire that terminates in either an 8 mm male barrel connector, or a two-port rectangular connector with two pins in square housings of different colors; (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features, and foam for transport); and

2. Off grid CSPV panels without a glass cover, with the following characteristics: (A) a total power output of 100 watts or less per panel; (B) a maximum surface area of 8,000 cm^2 per panel; (C) do not include a built-in inverter; (D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and (E) each panel is (1) permanently integrated into a consumer good; (2) encased in a laminated material without stitching, or (3) has all of the following characteristics: (i) the panel is encased in sewn fabric with visible stitching, (ii) includes a mesh zippered storage pocket, and (iii) includes a permanently attached wire that terminates in a female USB–A connector.

In addition, the following CSPV panels are excluded from the scope of the investigations: off-grid CSPV panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water: (A) a total power output of no more than 80 watts per panel; (B) a surface area of less than 5,000 square centimeters (cm^2) per panel; (C) do not include a built-in inverter; (D) do not have a frame around the edges of the panel; (E) include a clear glass back panel; and (F) must include a permanently connected wire that terminates in a twoport rectangular connector.

Additionally excluded from the scope of these investigations are off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (1) a total power output of 200 watts or less per panel; (2) a maximum surface area of 16,000 cm^2 per panel; (3) no built-in inverter; (4) an

integrated handle or a handle attached to the package for ease of carry; (5) one or more integrated kickstands for easy installation or angle adjustment; and (6) a wire of not less than 3 meters either permanently connected or attached to the package that terminates in an 8 mm diameter male barrel connector.

Also excluded from the scope of these investigations are off-grid crystalline silicon photovoltaic panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water: (A) a total power output of no more than 180 watts per panel at 155 degrees Celsius; (B) a surface area of less than 16,000 square centimeters (cm^2) per panel; (C) include a keep-out area of approximately 1,200 cm^2 around the edges of the panel that does not contain solar cells; (D) do not include a built-in inverter; (E) do not have a frame around the edges of the panel; (F) include a clear glass back panel; (G) must include a permanently connected wire that terminates in a two-port rounded rectangular, sealed connector; (H) include a thermistor installed into the permanently connected wire before the twoport connector; and (I) include exposed positive and negative terminals at opposite ends of the panel, not enclosed in a junction box.

Further excluded from the scope of the investigations are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 10,500 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure, (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 16,000 cm^2 per panel, (C) no built-in inverter, (D) an integrated handle or a handle attached to the package for ease of carry, (E) one or more integrated kickstands for easy installation or angle adjustment, and (F) a wire either permanently connected or attached to the package terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure.

Also excluded from the scope of the investigations are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 10,500 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure, (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Small off-grid panels with glass cover, with the following characteristics: (A) surface area from 3,450 mm^2 to 33,782 mm^2, (B) with one black wire and one red wire (each of type 22AWG or 28 AWG not more than 350 mm in length when measured from panel extrusion), (C) not exceeding 10 volts, (D) not exceeding 1.1 amps, (E) not exceeding 6 watts, and (F) for the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Additionally excluded from the scope of the investigations are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 175 watts or less per panel, (B) a maximum surface area of 9,000 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure; (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Off grid CSPV panels without a glass cover, with the following characteristics, (A) a total power output of 220 watts or less per panel, (B) a maximum surface area of 16,000 cm^2 per panel, (C) do not include a built-in inverter, (D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (E) each panel is encased in a laminated material without stitching.

Also excluded from the scope of these investigations are off-grid CSPV panels in rigid form, with or without a glass cover, permanently attached to an aluminum extrusion that is an integral component of an automation device that controls natural light, whether or not assembled into a fully completed automation device that controls natural light, with the following characteristics:

1. a total power output of 20 watts or less per panel;
2. a maximum surface area of 1,000 cm^2 per panel;
3. does not include a built-in inverter for powering third party devices

Modules, laminates, and panels produced in a third-country from cells produced in a subject country are covered by the investigations; however, modules, laminates, and panels produced in a subject country from cells produced in a third-country are not covered by the investigations.

Also excluded from the scope of these investigations are all products covered by the scope of the antidumping and countervailing duty orders on *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 77 FR 73018 (December 7, 2012); *and Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Countervailing Duty Order,* 77 FR 73017 (December 7, 2012).

Merchandise covered by the investigations is currently classified in the Harmonized Tariff System of the United States (HTSUS) under subheadings 8541.42.0010 and 8541.43.0010. Imports of the subject merchandise may enter under HTSUS subheadings 8501.71.0000, 8501.72.1000, 8501.72.2000, 8501.72.3000, 8501.72.9000, 8501.80.1000, 8501.80.2000, 8501.80.3000, 8501.80.9000, 8507.20.8010, 8507.20.8031, 8507.20.8041, 8507.20.8061, and 8507.20.8091. These HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of the investigations is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–28401 Filed 12–3–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–501, A–489–822, A–489–816, A–489–833]

Circular Welded Carbon Steel Standard Pipe and Tube Products From the Republic of Türkiye; Welded Line Pipe From the Republic of Türkiye; Certain Oil Tubular Goods From the Republic of Türkiye; and Large Diameter Welded Pipe From the Republic of Türkiye: Final Results of Antidumping Duty Changed Circumstances Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On September 10, 2024, the U.S. Department of Commerce (Commerce) published the preliminary results of the changed circumstances reviews (CCRs) of the antidumping duty

orders on circular welded carbon steel standard pipe and tube products (standard pipe), welded line pipe (WLP), certain oil tubular goods (OCTG), and large diameter welded pipe (LDWP) from the Republic of Türkiye (Türkiye). For these final results, Commerce continues to find that Borusan Birleşik Boru Fabrikalari Sanayi ve Ticaret A.S. (Borusan Boru) is the successor-in-interest to Borusan Mannesmann Boru Sanayi ve Ticaret A.S. (BMB).

DATES: Applicable December 4, 2024.

FOR FURTHER INFORMATION CONTACT: Ajay K. Menon, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0208.

SUPPLEMENTARY INFORMATION:

Background

On September 10, 2024, Commerce published the *Preliminary Results,* determining that Borusan Boru is the successor-in-interest to BMB and provided interested parties with an opportunity to comment.[1] On October 10, 2024, Borusan Boru filed comments regarding the effective date of Commerce's successor-in-interest determinations.[2] For a summary of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[3]

Scope of the Orders [4]

The merchandise covered by these *Orders* is standard pipe, WLP, OCTG, and LDWP from Türkiye. For a complete description of the scope of each of these *Orders, see* the *Preliminary Results*.[5]

Analysis of Comments Received

We addressed the comments received in these CCRs in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is included in the Appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade/gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on our analysis of the comments received, we revised the effective date of these CCRs. For further discussion, *see* the Issues and Decision Memorandum.

Final Results of Changed Circumstances Reviews

For the reasons stated in the *Preliminary Results,* Commerce continues to find that Borusan Boru is the successor-in-interest to BMB. As a result, we determine that Borusan Boru should receive the cash deposit rate previously assigned to the Borusan Mannesmann for merchandise subject to the *Standard Pipe AD Order* and *Welded Line Pipe AD Order.* Consequently, Commerce will instruct U.S. Customs and Border Protection (CBP) to collect cash deposits and suspend liquidation of all shipments of subject merchandise subject to the *Standard Pipe AD Order* and *Welded Line Pipe AD Order* produced or exported by Borusan Boru and entered, or withdrawn from warehouse, for consumption on or after November 13, 2023, at the rate assigned to BMB.[6]

Further, Commerce will instruct CBP that Borusan Boru is entitled to its predecessor's exclusions from the *OCTG AD Order* and *LDWP AD Order* for entries of subject merchandise produced and exported by Borusan Boru. Lastly, these cash deposit requirements shall remain in effect until further notice.

Notification to Interested Parties

We are issuing this determination and publishing these final results and notice in accordance with sections 751(b)(1) and 777(i)(1) and (2) of the Act and 19 CFR 351.216(e), 351.221(b), and 351.221(c)(3).

Dated: November 26, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2024–28394 Filed 12–3–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–489–502, C–489–823, C–489–817, C–489–834]

Circular Welded Carbon Steel Standard Pipe and Tube Products From the Republic of Türkiye; Welded Line Pipe From the Republic of Türkiye; Certain Oil Tubular Goods From the Republic of Türkiye; and Large Diameter Welded Pipe From the Republic of Türkiye: Final Results of Countervailing Duty Changed Circumstances Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On September 10, 2024, the U.S. Department of Commerce (Commerce) published the preliminary results of the changed circumstances reviews (CCRs) of the countervailing duty orders on circular welded carbon steel standard pipe and tube products (standard pipe), welded line pipe (WLP), certain oil tubular goods (OCTG), and large diameter welded pipe (LDWP) from the Republic of Türkiye (Türkiye). For these final results, Commerce continues to find that Borusan Birleşik Boru Fabrikalari

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[1] *See Circular Welded Carbon Steel Standard Pipe and Tube Products from the Republic of Türkiye; Welded Line Pipe from the Republic of Türkiye; Certain Oil Tubular Goods From the Republic of Türkiye; and Large Diameter Welded Pipe from the Republic of Türkiye: Preliminary Results of Antidumping Duty Changed Circumstances Review,* 89 FR 67669 (September 10, 2024).

[2] *See* Borusan Boru's Letter, ''Case Brief,'' dated October 10, 2024.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Changed Circumstances Reviews of Circular Welded Carbon Steel Standard Pipe and Tube Products from the Republic of Türkiye; Welded Line Pipe from the Republic of Türkiye; Certain Oil Tubular Goods from the Republic of Türkiye; and Large Diameter Welded Pipe from the Republic of Türkiye,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Antidumping Duty Order; Welded Carbon Steel Standard Pipe and Tube Products from Turkey,* 51 FR 17784 (May 15, 1986) (*Standard Pipe AD Order*); *Welded Line Pipe from the Republic of Korea and the Republic of Turkey: Antidumping Duty Orders,* 80 FR 75056 (December 1, 2015) (*Welded Line Pipe AD Order*); *Certain Oil Country Tubular Goods from India, the Republic of Korea, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam: Antidumping Duty Orders; and Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam: Amended Final Determination of Sales at Less Than Fair Value,* 79 FR 53691, 53693 (September 10, 2014) (*OCTG AD Order*); and *Large Diameter Welded Pipe from the Republic of Turkey: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Order,* 84 FR 18799 (May 2, 2019) (*LDWP AD Order*) (collectively, the *Orders*).

[5] *See Preliminary Results,* 89 FR at 73376–73377.

[6] The current rate for BMB in the *Standard Pipe AD Order* is 5.27 percent. *See Circular Welded Carbon Steel Standard Pipe and Tube Products from Turkey: Final Results of Antidumping Duty Administrative Review; 2021–2022,* 88 FR 85592, 85593 (December 9, 2023). The current rate for BMB in the *Welded Line Pipe AD Order* is zero percent. *See Welded Line Pipe from the Republic of Korea and the Republic of Turkey: Antidumping Duty* Orders, 80 FR 75056, 75057 (December 1, 2015).

Sanayi ve Ticaret A.S. (Borusan Boru) is the successor-in-interest to Borusan Mannesmann Boru Sanayi ve Ticaret A.S. (BMB).

DATES: Applicable December 4, 2024.

FOR FURTHER INFORMATION CONTACT: Ajay K. Menon, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0208.

SUPPLEMENTARY INFORMATION:

Background

On September 10, 2024, Commerce published the *Preliminary Results* of these CCRs, determining that Borusan Boru is the successor-in-interest to BMB and provided interested parties with an opportunity to comment.[1] On October 10, 2024, Borusan Boru filed comments regarding the effective date of Commerce's successor-in-interest determinations.[2] For a summary of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[3]

Scope of the Orders [4]

The merchandise covered by these *Orders* is standard pipe, WLP, OCTG, and LDWP from Türkiye. For a complete description of the scope of each of these orders, *see* the *Preliminary Results*.[5]

Analysis of Comments Received

We addressed the comments received in these CCRs in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is included in the Appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade/gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on our analysis of the comments received, we revised the effective date of these CCRs. For further discussion, *see* the Issues and Decision Memorandum.

Final Results of Changed Circumstances Reviews

For the reasons stated in the *Preliminary Results,* we continue to find that Borusan Boru is the successor-in-interest to BMB. As a result, we determine that Borusan Boru is entitled to receive the cash deposit rate previously assigned to Borusan Mannesmann for merchandise subject to the *Standard Pipe CVD Order, Welded Line Pipe CVD Order,* and *OCTG CVD Order.* Consequently, will Commerce instruct U.S. Customs and Border Protection (CBP) to collect cash deposits and suspend liquidation of all shipments of merchandise subject to the *Standard Pipe CVD Order, Welded Line Pipe CVD Order,* and *OCTG CVD Order* produced and/or exported by Borusan Boru and entered, or withdrawn from warehouse, for consumption on or after November 13, 2023, at the rate assigned to BMB.[6] Further, Commerce will instruct CBP that Borusan Boru is entitled to its predecessor's exclusion from the *LDWP CVD Order* for entries of subject merchandise produced and exported by Borusan Boru. Lastly, these cash deposit requirements shall remain in effect until further notice.

Notification to Interested Parties

We are issuing this determination and publishing these final results and notice in accordance with sections 751(b)(1) and 777(i)(1) and (2) of the Act and 19 CFR 351.216(e), 351.221(b), and 351.221(c)(3).

Dated: November 26, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2024–28395 Filed 12–3–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–820]

Fresh Tomatoes From Mexico: Final Results of the Expedited Sunset Review of Suspended Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this sunset review, the U.S. Department of Commerce (Commerce) finds that termination of the 2019 Agreement Suspending the Antidumping Duty Investigation on Fresh Tomatoes from Mexico would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Review'' section of this notice.

DATES: Applicable December 4, 2024.

FOR FURTHER INFORMATION CONTACT: Sally C. Gannon or Walter Schaub, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0162 or (202) 482–0907, respectively.

SUPPLEMENTARY INFORMATION:

Background

On August 1, 2024, Commerce initiated the sunset review of the suspended antidumping duty

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[1] *See Circular Welded Carbon Steel Standard Pipe and Tube Products from the Republic of Türkiye; Welded Line Pipe from the Republic of Türkiye; Certain Oil Tubular Goods from the Republic of Türkiye; and Large Diameter Welded Pipe from the Republic of Türkiye: Preliminary Results of Countervailing Duty Changed Circumstances Reviews,* 89 FR 73361 (September 10, 2024).

[2] *See* Borusan Boru's Letter, ''Case Brief,'' dated October 10, 2024.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Countervailing Duty Changed Circumstances Reviews of Circular Welded Carbon Steel Standard Pipe and Tube Products from the Republic of Türkiye; Welded Line Pipe from the Republic of Türkiye; Certain Oil Tubular Goods from the Republic of Türkiye; and Large Diameter Welded Pipe from the Republic of Türkiye,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Countervailing Duty Order: Certain Welded Carbon Steel Pipe and Tube Products from Turkey,*51 FR 7984 (March 7, 1986) (*Standard Pipe CVD Order*); *Welded Line Pipe from the Republic of Turkey: Countervailing Duty Order,*80 FR 75054 (December 1, 2015) (*Welded Line Pipe CVD Order*); *Certain Oil Country Tubular Goods from India and the Republic of Turkey: Countervailing Duty Orders and Amended Affirmative Final Countervailing Duty Determination for India,* 79 FR 53688 (September 10, 2014) (*OCTG CVD Order*); and *Large Diameter Welded Pipe from the Republic of Turkey: Countervailing Duty Order,* 84 FR 18771 (May 2, 2019) (*LDWP CVD Order*) (collectively, the *Orders*).

[5] *See Preliminary Results,* 89 FR 73363–73364.

[6] The current rate for BMB under the *Standard Pipe CVD Order* is 0.83 percent. *See Circular Welded Carbon Steel Pipes and Tubes from the Republic of Turkey: Final Results and Rescission, in Part, of Countervailing Duty Administrative Review; Calendar Year 2019,* 86 FR 67681, 67682 (November 29, 2021). The current rate for BMB under the *Welded Line Pipe CVD Order* 0.78 percent. *See Welded Line Pipe from the Republic of Turkey: Final Results of Countervailing Duty Administrative Review; 2015,* 83 FR 34113, 34114 (July 19, 2018). The current rate for BMB under the *OCTG CVD Order* is 0.38 percent (*de minimis*). *See Oil Country Tubular Goods from the Republic of Turkey: Final Results and Partial Rescission of Countervailing Duty Administrative Review; 2018,* 86 FR 24842 (May 10, 2021).

investigation on fresh tomatoes from Mexico, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[1] Commerce received notices of intent to participate in this sunset review from the Florida Tomato Exchange (FTE) on August 15, 2024, and from NS Brands, Ltd. and NatureSweet Invernaderos S. de R.L. de C.V./ NatureSweet Comercializadora, S. de R.L. de C.V. (collectively, NatureSweet) on August 16, 2024, within the applicable deadline specified in section 351.218(d)(1)(i) of Commerce's regulations.

Commerce received an adequate substantive response from FTE within the 30-day deadline specified in Commerce's regulations under section 351.218(d)(3)(i). In its submission, FTE claimed interested party status under section 771(9)(E) of the Act as a trade or business association a majority of whose members manufacture, produce, or wholesale a domestic like product in the United States. NatureSweet also filed a response in which it claimed interested party status under sections 771(9)(C) and 771(9)(A) of the Act, *i.e.,* both as a domestic and foreign producer of subject merchandise, respectively; however, the response did not meet the requirements of 19 CFR 351.218(d)(3)(iii) and 351.218(e)(1)(ii). Thus, Commerce did not receive an adequate substantive response from any respondent interested party. As a result, Commerce conducted an expedited (120-day) sunset review, in accordance with 19 CFR 351.218(e)(1)(ii)(C)(2).

Scope of the Suspension Agreement [2]

The merchandise subject to the suspension agreement is all fresh or chilled tomatoes (fresh tomatoes) which have Mexico as their origin, except for those tomatoes which are for processing. For purposes of this suspension agreement, processing is defined to include preserving by any commercial process, such as canning, dehydrating, drying, or the addition of chemical substances, or converting the tomato product into juices, sauces, or purees. In Appendix F of this *2019 Agreement,* Commerce has outlined the procedure that Signatories must follow for selling subject merchandise for processing. Fresh tomatoes that are imported for cutting up, not further processing (*e.g.,* tomatoes used in the preparation of fresh salsa or salad bars), are covered by this suspension agreement.

Commercially grown tomatoes, both for the fresh market and for processing, are classified as Lycopersicon esculentum. Important commercial varieties of fresh tomatoes include common round, cherry, grape, plum, greenhouse, and pear tomatoes, all of which are covered by this suspension agreement. Tomatoes imported from Mexico covered by this suspension agreement are classified under the following subheading of the Harmonized Tariff Schedules of the United States (HTSUS), according to the season of importation: 0702. Although this HTSUS number is provided for convenience and customs purposes, the written description of the scope of this Agreement is dispositive.

A full description of the scope of the *2019 Agreement* is also contained in the Issues and Decision Memorandum.[3]

Analysis of Comments Received

All issues raised in this sunset review, including the likelihood of continuation or recurrence of dumping and the magnitude of the margin of dumping likely to prevail if the *2019 Agreement* is terminated, are addressed in the Issues and Decision Memorandum. A list of topics included in the Issues and Decision Memorandum is included in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. A complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Review

Pursuant to section 752(c) of the Act, we determine that the termination of the *2019 Agreement* would likely lead to continuation or recurrence of dumping at weighted-average margins up to 30.48 percent.

Administrative Protective Order (APO)

This notice also serves as the only reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

Commerce is issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218(e)(1)(ii)(C)(2) and 351.221(c)(5)(ii).

Dated: November 27, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2024–28396 Filed 12–3–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–851]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From Thailand: Preliminary Affirmative Determination of Sales at Less-Than-Fair-Value, Affirmative Determination of Critical Circumstances, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells), from Thailand are being, or are likely to be, sold in the United States at less-than-fair-value (LTFV). The period of investigation (POI) is April 1, 2023, through March 31, 2024. Interested

[1] *See Initiation of Five-Year (Sunset) Reviews,* 89 FR 62717 (August 1, 2024).

[2] *See Fresh Tomatoes From Mexico: Suspension of Antidumping Duty Investigation,* 84 FR 49987 (September 24, 2019) (*2019 Agreement*).

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Fifth Sunset Review of the Suspended Investigation of Fresh Tomatoes from Mexico,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

parties are invited to comment on this preliminary determination.

DATES: Applicable December 4, 2024.

FOR FURTHER INFORMATION CONTACT: Drew Jackson, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4406.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce initiated this investigation on May 14, 2024.[1] On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[2] On September 17, 2024, Commerce postponed the preliminary determination of this investigation until November 27, 2024.[3]

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[4] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The products covered by this investigation are solar cells from Thailand. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the *Preamble* to Commerce's regulations,[5] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[6] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memoranda.[7] Commerce is preliminarily modifying the scope language as it appeared in the *Initiation Notice,* provided in Appendix I to this notice. The deadline for scope-related case and rebuttal briefs is established in the Preliminary Scope Decision Memoranda.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value is calculated in accordance with section 773 of the Act. In addition, pursuant to sections 776(a) and (b) of the Act, Commerce preliminarily relied upon facts otherwise available with adverse inferences for certain companies. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Affirmative Determination of Critical Circumstances

In accordance with section 733(e) of the Act and 19 CFR 351.206, Commerce preliminarily finds that critical circumstances exist for Trina Solar Science & Technology (Thailand) Ltd. (TTL). Commerce also preliminarily finds that critical circumstances exist for all other exporters and producers of the subject merchandise as well as for Sunshine Electrical Energy and Taihua New Energy (Thailand) Co. Ltd. For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* the Preliminary Decision Memorandum and Preliminary Analysis of Critical Circumstances.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that, in the preliminary determination, Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

In this investigation, Commerce calculated an individual estimated weighted-average dumping margin for TTL, the only individually examined exporter/producer in this investigation. Because the only individually calculated dumping margin is not zero, *de minimis,* or based entirely on facts otherwise available, the estimated weighted-average dumping margin calculated for TTL is the margin assigned to all other producers and exporters, pursuant to section 735(c)(5)(A) of the Act. For this preliminary determination, Commerce has determined the rates for Sunshine Electrical Energy and New Energy (Thailand) Co. Ltd. entirely under facts available with an adverse inference.[8]

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations,* 89 FR 43809 (May 20, 2024) (*Initiation Notice*).

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[3] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 89 FR 77473 (September 23, 2024).

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Determination in the Less-Than-Fair-Value Investigation of Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Thailand,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[6] *See Initiation Notice,* 89 FR 43810.

[7] *See* Memoranda, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Cambodia, Malaysia, and Thailand: Preliminary Scope Decision Memorandum,'' dated concurrently with this notice and ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from Vietnam,'' dated concurrently with this notice (collectively, Preliminary Scope Decision Memoranda).

[8] *See* Preliminary Decision Memorandum at ''Application of Facts Available and Use of Adverse Inferences.''

Exporter/producer	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset(s)) (percent)
Trina Solar Science & Technology (Thailand) Ltd	77.85	N/A
Sunshine Electrical Energy	*154.68	N/A
Taihua New Energy (Thailand) Co. Ltd	*154.68	N/A
All Others	77.85	[9]57.66

*Rates based on facts available with adverse inferences.

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption, as discussed below. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) The cash deposit rate for the respondents listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.[9]

Section 733(e)(2) of the Act provides that, given an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the later of (a) the date which is 90 days before the date on which the suspension of liquidation was first ordered, or (b) the date on which notice of initiation of the investigation was published. Commerce preliminarily finds that critical circumstances exist for imports of subject merchandise produced or exported by TTL, firms subject to the all others rate, Sunshine Electrical Energy, and Taihua New Energy (Thailand) Co. Ltd. In accordance with section 733(e)(2)(A) of the Act, the suspension of liquidation shall apply to unliquidated entries of shipments of subject merchandise from the producer(s) or exporter(s) identified in this paragraph that were entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the publication of this notice.

Commerce normally adjusts cash deposits for estimated antidumping duties by the amount of export subsidies countervailed in a companion countervailing duty (CVD) proceeding, when CVD provisional measures are in effect. Accordingly, where Commerce preliminarily made an affirmative determination for countervailable export subsidies, Commerce has offset the estimated weighted-average dumping margin by the appropriate CVD rate. Any such adjusted cash deposit rate may be found in the ''Preliminary Determination'' section above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting estimated antidumping duty cash deposits unadjusted for countervailed export subsidies at the time that the provisional CVD measures expire.

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

All interested parties will have the opportunity to submit scope case and rebuttal briefs to allow interested parties to comment on our preliminary scope decision at that time. For all scope case and rebuttal briefs, parties must file identical documents simultaneously on the records of the ongoing LTFV and CVD investigations of solar cells from Cambodia, Malaysia, the Socialist Republic of Vietnam, and Thailand. No new factual information or business proprietary information may be included in either scope case or rebuttal briefs.

Case briefs or other written comments regarding non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation.[10] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[11] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[12]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public,

[9] *Id.* at 25.

[10] *See* 19 CFR 351.309(c)(1)(i); *see also* 19 CFR 351.303 (for general filing requirements).

[11] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[12] *See* 19 CFR 351.309(c)(2) and (d)(2).

executive summary for each issue raised in their briefs.[13] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[14]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On November 15, 2024, pursuant to 19 CFR 351.210(e), TTL requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[15] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: November 27, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels and building integrated materials.

This investigation covers crystalline silicon photovoltaic cells of thickness equal to or greater than 20 micrometers, having a p/n junction formed by any means, whether or not the cell has undergone other processing, including, but not limited to, cleaning, etching, coating, and/or addition of materials (including, but not limited to, metallization and conductor patterns) to collect and forward the electricity that is generated by the cell.

Merchandise under consideration may be described at the time of importation as parts for final finished products that are assembled after importation, including, but not limited to, modules, laminates, panels, building-integrated modules, building-integrated panels, or other finished goods kits. Such parts that otherwise meet the definition of merchandise under consideration are included in the scope of the investigations.

Excluded from the scope of the investigation are thin film photovoltaic products produced from amorphous silicon (a-Si), cadmium telluride (CdTe), or copper indium gallium selenide (CIGS).

Also excluded from the scope of the investigation are crystalline silicon photovoltaic cells, not exceeding 10,000 mm^2 in surface area, that are permanently integrated into a consumer good whose function is other than power generation and that consumes the electricity generated by the integrated crystalline silicon photovoltaic cell. Where more than one cell is permanently integrated into a consumer good, the surface area for purposes of this exclusion shall be the total combined surface area of all cells that are integrated into the consumer good.

Additionally, excluded from the scope of the investigation are panels with surface area from 3,450 mm^2 to 33,782 mm^2 with one black wire and one red wire (each of type 22 AWG or 24 AWG not more than 206 mm in length when measured from panel extrusion), and not exceeding 2.9 volts, 1.1 amps, and 3.19 watts. For the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Also excluded from the scope of the investigation are:

1. Off grid CSPV panels in rigid form with a glass cover, with the following characteristics: (A) a total power output of 100 watts or less per panel; (B) a maximum surface area of 8,000 cm^2 per panel; (C) do not include a built-in inverter; (D) must include a permanently connected wire that terminates in either an 8 mm male barrel connector, or a two-port rectangular connector with two pins in square housings of different colors; (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features, and foam for transport); and

2. Off grid CSPV panels without a glass cover, with the following characteristics: (A) a total power output of 100 watts or less per panel; (B) a maximum surface area of 8,000 cm^2 per panel; (C) do not include a built-in inverter; (D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and (E) each panel is (1) permanently integrated into a consumer good; (2) encased in a laminated material without stitching, or (3) has all of the following characteristics: (i) the panel is encased in sewn fabric with visible stitching, (ii) includes a mesh zippered storage pocket, and (iii) includes a permanently attached wire that terminates in a female USB–A connector.

[13] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[14] *See APO and Service Final Rule.*

[15] *See* TTL's Letter, ''Request to Extend the Deadline for the Final Determination,'' dated November 15, 2024.

In addition, the following CSPV panels are excluded from the scope of the investigation: off-grid CSPV panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water: (A) a total power output of no more than 80 watts per panel; (B) a surface area of less than 5,000 square centimeters (cm^2) per panel; (C) do not include a built-in inverter; (D) do not have a frame around the edges of the panel; (E) include a clear glass back panel; and (F) must include a permanently connected wire that terminates in a two-sport rectangular connector.

Additionally excluded from the scope of this investigation are off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (1) a total power output of 200 watts or less per panel; (2) a maximum surface area of 16,000 cm^2 per panel; (3) no built-in inverter; (4) an integrated handle or a handle attached to the package for ease of carry; (5) one or more integrated kickstands for easy installation or angle adjustment; and (6) a wire of not less than 3 meters either permanently connected or attached to the package that terminates in an 8 mm diameter male barrel connector.

Also excluded from the scope of this investigation are off-grid crystalline silicon photovoltaic panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water: (A) a total power output of no more than 180 watts per panel at 155 degrees Celsius; (B) a surface area of less than 16,000 square centimeters (cm^2) per panel; (C) include a keep-out area of approximately 1,200 cm^2 around the edges of the panel that does not contain solar cells; (D) do not include a built-in inverter; (E) do not have a frame around the edges of the panel; (F) include a clear glass back panel; (G) must include a permanently connected wire that terminates in a two-port rounded rectangular, sealed connector; (H) include a thermistor installed into the permanently connected wire before the two-port connector; and (I) include exposed positive and negative terminals at opposite ends of the panel, not enclosed in a junction box.

Further excluded from the scope of the investigation are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 10,500 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure, (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 16,000 cm^2 per panel, (C) no built-in inverter, (D) an integrated handle or a handle attached to the package for ease of carry, (E) one or more integrated kickstands for easy installation or angle adjustment, and (F) a wire either permanently connected or attached to the package terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure.

Also excluded from the scope of the investigation are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 10,500 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure, (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Small off-grid panels with glass cover, with the following characteristics: (A) surface area from 3,450 mm^2 to 33,782 mm^2, (B) with one black wire and one red wire (each of type 22 AWG or 28 AWG not more than 350 mm in length when measured from panel extrusion), (C) not exceeding 10 volts, (D) not exceeding 1.1 amps, (E) not exceeding 6 watts, and (F) for the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Additionally excluded from the scope of the investigation are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 175 watts or less per panel, (B) a maximum surface area of 9,000 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure; (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Off grid CSPV panels without a glass cover, with the following characteristics, (A) a total power output of 220 watts or less per panel, (B) a maximum surface area of 16,000 cm^2 per panel, (C) do not include a built-in inverter, (D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (E) each panel is encased in a laminated material without stitching.

Also excluded from the scope of this investigation are off-grid CSPV panels in rigid form, with or without a glass cover, permanently attached to an aluminum extrusion that is an integral component of an automation device that controls natural light, whether or not assembled into a fully completed automation device that controls natural light, with the following characteristics:

1. a total power output of 20 watts or less per panel;

2. a maximum surface area of 1,000 cm^2 per panel;

3. does not include a built-in inverter for powering third party devices

Modules, laminates, and panels produced in a third-country from cells produced in a subject country are covered by the investigations; however, modules, laminates, and panels produced in a subject country from cells produced in a third-country are not covered by the investigations.

Also excluded from the scope of this investigation are all products covered by the scope of the antidumping and countervailing duty orders on *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 77 FR 73018 (December 7, 2012); *and Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Countervailing Duty Order,* 77 FR 73017 (December 7, 2012).

Merchandise covered by the investigation is currently classified in the Harmonized Tariff System of the United States (HTSUS) under subheadings 8541.42.0010 and 8541.43.0010. Imports of the subject merchandise may enter under HTSUS subheadings 8501.71.0000, 8501.72.1000, 8501.72.2000, 8501.72.3000, 8501.72.9000, 8501.80.1000, 8501.80.2000, 8501.80.3000, 8501.80.9000, 8507.20.8010, 8507.20.8031, 8507.20.8041, 8507.20.8061, and 8507.20.8091. These HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of the investigations is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–28404 Filed 12–3–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–841]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules From the Socialist Republic of Vietnam: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Affirmative Determination of Critical Circumstances, in Part, and Postponement of Final Determination and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells) from the Socialist Republic of Vietnam (Vietnam) are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2023, through March 31, 2024. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable December 4, 2024.

FOR FURTHER INFORMATION CONTACT: Laurel LaCivita or Deborah Cohen, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4243 or (202) 482–4521, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce initiated this investigation on May 14, 2024.[1] On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[2] On September 17, 2024, Commerce postponed the preliminary determination of this investigation until November 27, 2024.[3]

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[4] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The products covered by this investigation are solar cells from Vietnam. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the *Preamble* to Commerce's regulations,[5] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[6] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memoranda.[7] Commerce is preliminarily modifying the scope language as it appeared in the *Initiation Notice,* provided in Appendix I to this notice. The deadline for scope-related case and rebuttal briefs is established in the Preliminary Scope Decision Memoranda.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated constructed export prices in accordance with section 772(b) of the Act. Because Vietnam is a non-market economy, within the meaning of section 771(18) of the Act, Commerce has calculated normal value in accordance with section 773(c) of the Act. Furthermore, pursuant to sections 776(a) and (b) of the Act, Commerce preliminarily relied upon facts otherwise available, with adverse inferences, for the Vietnam-wide entity. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Affirmative Determination of Critical Circumstances, in Part

In accordance with section 733(e) of the Act and 19 CFR 351.206, Commerce preliminarily determines that critical circumstances exist with respect to imports of solar cells from Vietnam for the non-selected companies eligible for a separate rate and the Vietnam-wide entity, but that critical circumstances do not exist for mandatory respondents JA Solar Vietnam Co. Ltd (JA Solar) and Jinko Solar (Vietnam) Industries Company Limited (Jinko Vietnam). For a full description of the methodology and results of Commerce's analysis, *see* the Preliminary Decision Memorandum.

Combination Rates

In the *Initiation Notice,*[8] Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation. Policy Bulletin 05.1 describes this practice.[9]

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

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[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations,* 89 FR 43809 (May 20, 2024) (*Initiation Notice*).

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[3] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 89 FR 77473 (September 23, 2024).

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Determination in the Less-Than-Fair-Value Investigation of Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from the Socialist Republic of Vietnam,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

[6] *See Initiation Notic*e, 89 FR 43810.

[7] *See* Memoranda, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Cambodia, Malaysia, and Thailand: Preliminary Scope Decision Memorandum,'' dated concurrently with this notice, and ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from Vietnam,'' dated concurrently with this notice (collectively, Preliminary Scope Decision Memoranda).

[8] *See Initiation Notice,* 89 FR 43814.

[9] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' (April 5, 2005) (Policy Bulletin 05.1), available on Commerce's website at *https://enforcement.trade.gov/policy/bull05-1.pdf.*

Producer	Exporter	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
JA Solar Vietnam Co. Ltd./JA Solar PV [10]	JA Solar Vietnam Co. Ltd	53.30	53.19
Jinko Solar (Vietnam) Industries Company Limited.	Jinko Solar (Vietnam) Industries Company Limited.	56.51	56.40
Blue Moon Vina Co	Blue Moon Vina Co	54.46	54.35
Boviet Solar Technology Co., Ltd	Boviet Solar Technology Co., Ltd	54.46	54.46
Elite Solar Technology (Vietnam) Company Limited.	Elite SNG	54.46	54.35
Letsolar Vietnam Company Limited	Letsolar Vietnam Company Limited	54.46	54.35
Mecen Solar Vina Co., Ltd	Mecen Solar Vina Co., Ltd	54.46	54.35
Nexuns Vietnam Company Limited	Nexuns Vietnam Company Limited	54.46	54.35
Trina Solar Energy Development Company Ltd	Trina Solar Energy Development Company Ltd	54.46	54.35
Vietnergy Co., Ltd. and Tainergy Tech Co., Ltd. (collectively, Vietnergy).	Vietnergy Co., Ltd. and Tainergy Tech Co., Ltd. (collectively, Vietnergy).	54.46	54.35
Vietnam Sunergy Joint Stock Company (f.k.a. Vietnam Sunergy Company Limited).	Vietnam Sunergy Joint Stock Company (f.k.a. Vietnam Sunergy Company Limited).	54.46	54.35
Vietnam-Wide Entity		*271.28	271.28

*This rate is based on facts available with adverse inferences.

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin, as adjusted for export subsidies, as follows: (1) for the producer/exporter combinations listed in the table above, the cash deposit rate is equal to the estimated weighted-average dumping margin listed for that combination in the table; (2) for all combinations of Vietnam producers/exporters of merchandise under consideration that have not established eligibility for their own separate rates, the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the Vietnam-wide entity; and (3) for all third-county exporters of merchandise under consideration not listed in the table above, the cash deposit rate is the cash deposit rate applicable to the Vietnam producer/exporter combination (Vietnam-wide entity) that supplied that third-country exporter.

Should the final estimated weighted-average dumping margin be zero or *de minimis* for the producer/exporter combinations identified above, entries of merchandise from these producer/exporter combinations will be excluded from the order. Such exclusion(s) will not be applicable to merchandise exported to the United States by any other producer/exporter combinations or by third-country exporters that sourced from the excluded producer/exporter combinations.

Section 733(e)(2) of the Act provides that, given an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of merchandise entered, or withdrawn from warehouse, for consumption on or after the later of: (a) the date which is 90 days before the date on which the suspension of liquidation was first ordered; or (b) the date on which notice of initiation of the investigation was published. Commerce preliminarily finds that critical circumstances exist for imports of subject merchandise from the non-selected companies eligible for a separate rate and the Vietnam-wide entity. In accordance with section 733(e)(2)(A) of the Act, the suspension of liquidation shall apply to all unliquidated entries of merchandise from the producer/exporter combinations identified in this paragraph that were entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the publication of this notice.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion countervailing duty (CVD) proceeding when CVD provisional measures are in effect. Accordingly, where Commerce has made a preliminary affirmative determination for domestic subsidy pass-through or export subsidies, Commerce has offset the calculated estimated weighted-average dumping margin by the appropriate rate(s). Any such adjusted rates may be found in the ''Preliminary Determination'' section's chart of estimated weighted-average dumping margins above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting cash deposits at a rate equal to the estimated weighted-average dumping margins calculated in this preliminary determination unadjusted for the passed-through domestic subsidies or for export subsidies at the time the CVD provisional measures expire.

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent

[10] We preliminarily find that JA Solar and JA Solar PV Vietnam Company Limited (JAPV) are affiliated and should be treated as a single entity pursuant to 19 CFR 351.401(f)(1) for the purposes of this preliminary determination. *See* Preliminary Decision Memorandum at Section IV. ''Single Entity Analysis'' for further discussion of the preliminary collapsing determination.

with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify information relied upon in making its final determination.

Public Comment

All interested parties will have the opportunity to submit scope case and rebuttal briefs to allow interested parties to comment on our preliminary scope decision at that time. For all scope case and rebuttal briefs, parties must file identical documents simultaneously on the records of the ongoing LFTV and CVD investigations of solar cells from Cambodia, Malaysia, Vietnam, and Thailand. No new factual information or business proprietary information may be included in either scope case or rebuttal briefs.

Case briefs or other written comments regarding non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last final verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[11] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[12]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[13] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[14]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On November 5 and 8, 2024, pursuant to 19 CFR 351.210(e), JA Solar and Jinko, respectively, requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[15] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporters account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act, and 19 CFR 351.205(c).

Dated: November 27, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels and building integrated materials.

This investigation covers crystalline silicon photovoltaic cells of thickness equal to or greater than 20 micrometers, having a p/n junction formed by any means, whether or not the cell has undergone other processing, including, but not limited to, cleaning, etching, coating, and/or addition of materials (including, but not limited to, metallization and conductor patterns) to collect and forward the electricity that is generated by the cell.

Merchandise under consideration may be described at the time of importation as parts for final finished products that are assembled after importation, including, but not limited

[11] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[12] *See* 19 351.309(c)(2) and (d)(2).

[13] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[14] *See APO and Service Final Rule.*

[15] *See* JA Solar's Letter, ''Postponement of Final Determination and Extension of Provisional Measures Period,'' dated November 5, 2024; and, Jinko's Letter, ''Jinko's Request for Postponement of Final Determination,'' dated November 8, 2024.

to, modules, laminates, panels, building-integrated modules, building-integrated panels, or other finished goods kits. Such parts that otherwise meet the definition of merchandise under consideration are included in the scope of the investigation.

Excluded from the scope of the investigation are thin film photovoltaic products produced from amorphous silicon (a–Si), cadmium telluride (CdTe), or copper indium gallium selenide (CIGS).

Also excluded from the scope of this investigation are crystalline silicon photovoltaic cells, not exceeding 10,000 mm^2 in surface area, that are permanently integrated into a consumer good whose function is other than power generation and that consumes the electricity generated by the integrated crystalline silicon photovoltaic cell. Where more than one cell is permanently integrated into a consumer good, the surface area for purposes of this exclusion shall be the total combined surface area of all cells that are integrated into the consumer good.

Additionally, excluded from the scope of the investigation are panels with surface area from 3,450 mm^2 to 33,782 mm^2 with one black wire and one red wire (each of type 22 AWG or 24 AWG not more than 206 mm in length when measured from panel extrusion), and not exceeding 2.9 volts, 1.1 amps, and 3.19 watts. For the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Also excluded from the scope of the investigation are:

1. Off grid CSPV panels in rigid form with a glass cover, with the following characteristics: (A) a total power output of 100 watts or less per panel; (B) a maximum surface area of 8,000 cm^2 per panel; (C) do not include a built-in inverter; (D) must include a permanently connected wire that terminates in either an 8 mm male barrel connector, or a two-port rectangular connector with two pins in square housings of different colors; (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features, and foam for transport); and

2. Off grid CSPV panels without a glass cover, with the following characteristics: (A) a total power output of 100 watts or less per panel; (B) a maximum surface area of 8,000 cm^2 per panel; (C) do not include a built-in inverter; (D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and (E) each panel is (1) permanently integrated into a consumer good; (2) encased in a laminated material without stitching, or (3) has all of the following characteristics: (i) the panel is encased in sewn fabric with visible stitching, (ii) includes a mesh zippered storage pocket, and (iii) includes a permanently attached wire that terminates in a female USB–A connector.

In addition, the following CSPV panels are excluded from the scope of the investigation: off-grid CSPV panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water: (A) a total power output of no more than 80 watts per panel; (B) a surface area of less than 5,000 square centimeters (cm^2) per panel; (C) do not include a built-in inverter; (D) do not have a frame around the edges of the panel; (E) include a clear glass back panel; and (F) must include a permanently connected wire that terminates in a twoport rectangular connector.

Additionally excluded from the scope of this investigation are off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (1) a total power output of 200 watts or less per panel; (2) a maximum surface area of 16,000 cm^2 per panel; (3) no built-in inverter; (4) an integrated handle or a handle attached to the package for ease of carry; (5) one or more integrated kickstands for easy installation or angle adjustment; and (6) a wire of not less than 3 meters either permanently connected or attached to the package that terminates in an 8 mm diameter male barrel connector.

Also excluded from the scope of this investigation are off-grid crystalline silicon photovoltaic panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water: (A) a total power output of no more than 180 watts per panel at 155 degrees Celsius; (B) a surface area of less than 16,000 square centimeters (cm^2) per panel; (C) include a keep-out area of approximately 1,200 cm^2 around the edges of the panel that does not contain solar cells; (D) do not include a built-in inverter; (E) do not have a frame around the edges of the panel; (F) include a clear glass back panel; (G) must include a permanently connected wire that terminates in a two-port rounded rectangular, sealed connector; (H) include a thermistor installed into the permanently connected wire before the twoport connector; and (I) include exposed positive and negative terminals at opposite ends of the panel, not enclosed in a junction box.

Further excluded from the scope of the investigation are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 10,500 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure, (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 16,000 cm^2 per panel, (C) no built-in inverter, (D) an integrated handle or a handle attached to the package for ease of carry, (E) one or more integrated kickstands for easy installation or angle adjustment, and (F) a wire either permanently connected or attached to the package terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure.

Also excluded from the scope of the investigation are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 10,500 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure, (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Small off-grid panels with glass cover, with the following characteristics: (A) surface area from 3,450 mm^2 to 33,782 mm^2, (B) with one black wire and one red wire (each of type 22AWG or 28 AWG not more than 350 mm in length when measured from panel extrusion), (C) not exceeding 10 volts, (D) not exceeding 1.1 amps, (E) not exceeding 6 watts, and (F) for the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Additionally excluded from the scope of the investigation are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 175 watts or less per panel, (B) a maximum surface area of 9,000 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure; (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Off grid CSPV panels without a glass cover, with the following characteristics, (A) a total power output of 220 watts or less per panel, (B) a maximum surface area of 16,000 cm^2 per panel, (C) do not include a built-in inverter, (D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (E) each panel is encased in a laminated material without stitching.

Also excluded from the scope of this investigation are off-grid CSPV panels in

rigid form, with or without a glass cover, permanently attached to an aluminum extrusion that is an integral component of an automation device that controls natural light, whether or not assembled into a fully completed automation device that controls natural light, with the following characteristics:

1. a total power output of 20 watts or less per panel;

2. a maximum surface area of 1,000 cm^2 per panel;

3. does not include a built-in inverter for powering third party devices.

Additionally excluded from the scope of the investigation are off-grid greenhouse shade tracking systems with between 3 and 30 flexible CSPV panels, each permanently affixed to an outer aluminum frame, with (A) no glass cover, (B) no back sheet, (C) no built-in inverter, (D) power output of 220 watts or less per panel, (E) surface area of 10,000 cm squared or less per panel, (F) two clear plastic trusses per panel permanently attached running lengthwise on the same side as the junction boxes, (G) visible parallel grid collector metallic wire lines every 1–4 mm per each cell on same side as junction box, (H) two rectangular plastic junction boxes per panel with at least 16 diodes per panel, and (I) encased in an aluminum frame and laminated without stitching.

Modules, laminates, and panels produced in a third-country from cells produced in a subject country are covered by the investigation; however, modules, laminates, and panels produced in a subject country from cells produced in a third-country are not covered by the investigation.

Also excluded from the scope of this investigation are all products covered by the scope of the antidumping and countervailing duty orders on *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 77 FR 73018 (December 7, 2012); and *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Countervailing Duty Order,* 77 FR 73017 (December 7, 2012).

Merchandise covered by the investigation is currently classified in the Harmonized Tariff System of the United States (HTSUS) under subheadings 8541.42.0010 and 8541.43.0010. Imports of the subject merchandise may enter under HTSUS subheadings 8501.71.0000, 8501.72.1000, 8501.72.2000, 8501.72.3000, 8501.72.9000, 8501.80.1000, 8501.80.2000, 8501.80.3000, 8501.80.9000, 8507.20.8010, 8507.20.8031, 8507.20.8041, 8507.20.8061, and 8507.20.8091. These HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of the investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–28403 Filed 12–3–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–168]

Certain Alkyl Phosphate Esters From the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that certain alkyl phosphate esters (alkyl phosphate esters) from the People's Republic of China (China) are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2023, through March 31, 2024. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable December 4, 2024.

FOR FURTHER INFORMATION CONTACT: Robert Palmer or Dennis McClure, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9068 or (202) 482–5973, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on May 20, 2024.[1] On August 8, 2024, Commerce tolled certain deadlines in this investigation by seven days.[2] On September 17, 2024, Commerce postponed the preliminary determination of this investigation and the revised deadline is now November 26, 2024.[3]

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[4] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The product covered by this investigation is alkyl phosphate esters from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the *Preamble* to Commerce's regulations,[5] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[6] No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice.*[7] Commerce is not preliminarily modifying the scope language as it appeared in the *Initiation Notice. See* the scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with section

[1] *See Certain Alkyl Phosphate Esters from the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 89 FR 43801 (May 20, 2024) (*Initiation Notice*).

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[3] *See Certain Alkyl Phosphate Esters from the People's Republic of China: Postponement of Preliminary Determinations of Less-Than-Fair-Value Investigations,* 89 FR 76087 (September 17, 2024).

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Determination in the Less-Than-Fair-Value Investigation of Certain Alkyl Phosphate Esters from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

[6] *See Initiation Notice.*

[7] *See* Shanghai Yongxiangshun International Trade Co., Ltd.'s Letter, ''Scope of Order Comments,'' dated May 30, 2024. Although Shanghai Yongxiangshun International Trade Co., Ltd. (Shanghai Yongxiangshun) submitted a letter entitled, ''Scope Order Comments,'' the letter did not include comments opposing the scope as published in the *Initiation Notice.*

731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act and constructed export prices in accordance with section 772(b) of the Act. Because China is a non-market economy (NME), within the meaning of section 771(18) of the Act, Commerce has calculated normal value (NV) in accordance with section 773(c) of the Act. Furthermore, pursuant to sections 776(a) and (b) of the Act, Commerce preliminarily has relied upon facts otherwise available, with adverse inferences, for (1) Icool Chemical Co., Ltd., (2) Isochem Australia Pty Ltd., (3) Jiangsu Victory Chemical Co., Ltd., (4) Shanghai Chenhua International Trade Co., Ltd., (5) Taian Tayong Biotechnology Co., Ltd., (6) Unibrom Corp., (7) Unibrom Pte. Ltd., (8) Xing Fa (Hongkong) Imp. & Exp. Limited, and (9) Yangzhou Chenhua New Material Co., Ltd. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Combination Rates

In the *Initiation Notice*,[8] Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation. Policy Bulletin 05.1 describes this practice.[9]

Separate Rates

We have preliminarily granted a separate rate to certain separate rate respondents that we did not select for individual examination.[10] In calculating the rate for non-individually examined separate rate respondents in an NME LTFV investigation, Commerce normally looks to section 735(c)(5)(A) of the Act, which pertains to the calculation of the all-others rate in a market economy LTFV investigation, for guidance. Pursuant to section 735(c)(5)(A) of the Act, normally this rate shall be an amount equal to the weighted-average of the estimated weighted-average dumping margins established for those companies individually examined, excluding zero and *de minimis* dumping margins, and any dumping margins based entirely under section 776 of the Act. Commerce calculated individual estimated weighted-average dumping margins for Anhui RunYue Technology Co., Ltd. (Anhui RunYue) and Zhejiang Wansheng Co., Ltd. (Zhejiang Wansheng) that are not zero, *de minimis,* or based entirely on facts otherwise available. Thus, the weighted-average dumping margins calculated for Anhui RunYue and Zhejiang Wansheng are the basis to determine the weighted-average dumping margin for the non-examined, separate rate companies in this investigation.[11] *See* the table below in the ''Preliminary Determination'' section of this notice.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Anhui RunYue Technology Co., Ltd	Anhui RunYue Technology Co., Ltd	247.52	175.82
Zhejiang Wansheng Co., Ltd	Zhejiang Wansheng Co., Ltd	164.29	141.98
ACETO (SHANGHAI) LTD	Xinji Hongzheng Chemical Co., Ltd	182.22	135.22
Anhui Shengli Import and Export Co., Ltd	Anhui Shengli Pesticide & Chemistry Co., Ltd	182.22	135.22
Anhui Shengli Import and Export Co., Ltd	Ningguo Long Day Chemical Co., Ltd	182.22	135.22
Fujian Wynca Technology Co., Ltd	Fujian Wynca Technology Co., Ltd	182.22	135.22
Fujian Wynca Technology Co., Ltd	Anhui RunYue Technology Co., Ltd	182.22	135.22
Fujian Wynca Technology Co., Ltd	Shandong Yarong Chemical Co., Ltd	182.22	135.22
Shandong Yarong Chemical Co., Ltd	Shandong Yarong Chemical Co., Ltd	182.22	135.22
Shanghai Iroyal Chemical Co., Ltd	Futong Chemical Co., Ltd	182.22	135.22
Shanghai Iroyal Chemical Co., Ltd	Fujian Wynca Technology Co., Ltd	182.22	135.22
Shanghai Iroyal Chemical Co., Ltd	Zhejiang Hong Hao Technology Co., Ltd	182.22	135.22
Shanghai Iroyal Chemical Co., Ltd	Shandong Yarong Chemical Co., Ltd	182.22	135.22
Shanghai Iroyal Chemical Co., Ltd	Xuancheng City Trooyawn Refined Chemical Industry Co., Ltd.	182.22	135.22
Shanghai Yongxiangshun International Trade Co., Ltd.	Hebei Zhenxing Chemical and Rubber Co., Ltd	182.22	135.22
Xuancheng City Trooyawn Refined Chemical Industry Co., Ltd.	Xuancheng City Trooyawn Refined Chemical Industry Co., Ltd.	182.22	135.22
Yoke Chemicals and New Materials (Shanghai) Co. Ltd.	Jiangsu Yoke Technology Co., Ltd	182.22	135.22
Zhangjiagang Fortune Chemical Co., Ltd	Nantong Jiangshan Agrochemical & Chemicals Limited Liability Co., Ltd.	182.22	135.22
Zhangjiagnag Fortune Chemical Co., Ltd	Shandong Yarong Chemical Co., Ltd	182.22	135.22
China Wide-Entity		*269.60	247.29

*This rate is based on facts available with adverse inferences.

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as discussed below. Further, pursuant to section 733(d)(1)(B) of the

[8] *See Initiation Notice,* 89 FR 43805.

[9] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' (April 5, 2005) (Policy Bulletin 05.1), available on Commerce's website at *https://enforcement.trade.gov/policy/bull05-1.pdf.*

[10] *See* the Preliminary Decision memorandum for additional details.

[11] *See* Memorandum, ''Calculation of the Dumping Margin for Respondents Not Selected for Individual Examination,'' dated November 26, 2024.

Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the weighted average amount by which NV exceeds U.S. price, as indicated in the chart above as follows: (1) for the producer/exporter combinations listed in the table above, the cash deposit rate is equal to the estimated weighted-average dumping margin listed for that combination in the table; (2) for all combinations of Chinese producers/exporters of merchandise under consideration that have not established eligibility for their own separate rates, the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the China-wide entity; and (3) for all third-county exporters of merchandise under consideration not listed in the table above, the cash deposit rate is the cash deposit rate applicable to the Chinese producer/exporter combination (or the China-wide entity) that supplied that third-country exporter.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion countervailing duty (CVD) proceeding when CVD provisional measures are in effect. Accordingly, where Commerce has made a preliminary affirmative determination for domestic subsidy pass-through or export subsidies, Commerce has offset the calculated estimated weighted-average dumping margin by the appropriate rate(s). Any such adjusted rates may be found in the chart of estimated weighted-average dumping margins, above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting cash deposits at a rate equal to the estimated weighted-average dumping margins calculated in this preliminary determination unadjusted for the passed-through domestic subsidies or for export subsidies at the time the CVD provisional measures expire.

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last final verification report is issued in this investigation. A timeline for the submission of case briefs and written comments will be notified to interested parties at a later date. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[12] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[13]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[14] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[15]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants and whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Pursuant to 19 CFR 351.210(e)(2), Commerce requires that requests by respondents for postponement of a final antidumping determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On October 24 and November 1, 2024, Anhui RunYue and ICL–IP America, Inc. (the petitioner) requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months, respectively.[16] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii),

[12] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[13] *See* 19 351.309(c)(2) and (d)(2).

[14] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[15] *See APO and Service Final Rule.*

[16] *See* Anhui RunYue's Letter, ''Request for Postponement of Final AD Determination,'' dated October 24, 2024; *see also* Petitioner's Letter, ''Request to Postpone Final Determination,'' dated November 1, 2024.

because: (1) the preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

U.S. International Trade Commission (ITC) Notification

In accordance with section 733(f) of the Act, Commerce will notify the ITC of its preliminary determination of sales at LTFV. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of the subject merchandise are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act, and 19 CFR 351.205(c).

Dated: November 26, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The products covered by this investigation are alkyl phosphate esters, which are halogenated and non-halogenated phosphorus-based esters with a phosphorus content of at least 6.5 percent (per weight) and a viscosity between 1 and 2000 mPa.s (at 20–25 °C).

Merchandise subject to this investigation primarily includes Tris (2-chloroisopropyl) phosphate (TCPP), Tris(1,3-dichloroisopropyl) phosphate (TDCP), and Triethyl Phosphate (TEP).

TCPP is also known as Tris (1-chloro-2-propyl) phosphate, Tris (1-chloropropan-2-yl) phosphate, Tris (monochloroisopropyl) phosphate (TMCP), and Tris (2-chloroisopropyl) phosphate (TCIP). TCPP has the chemical formula C9H18Cl3O4P and the Chemical Abstracts Service (CAS) Nos. 1244733–77–4 and 13674–84–5. It may also be identified as CAS No. 6145–73–9.

TDCP is also known as Tris (1,3-dichloroisopropyl) phosphate, Tris (1,3-dichloro-2-propyl) phosphate, Chlorinated tris, tris {2- chloro-1-(chloromethyl ethyl)} phosphate, TDCPP, and TDCIPP. TDCP has the chemical formula C9H15Cl6O4P and the CAS No. 13674–87–8.

TEP is also known as Phosphoric acid triethyl ester, phosphoric ester, flame retardant TEP, Tris(ethyl) phosphate, Triethoxyphosphine oxide, and Ethyl phosphate (neutral). TEP has the chemical formula (C2H5O)3PO and the CAS No. 78–40–0.

Imported alkyl phosphate esters are not excluded from the scope of this investigation even if the imported alkyl phosphate ester consists of a single isomer or combination of isomers in proportions different from the isomers ordinarily provided in the market.

Also included in this investigation are blends including one or more alkyl phosphate esters, with or without other substances, where the alkyl phosphate esters account for 20 percent or more of the blend by weight.

Alkyl phosphate esters are classified under subheading 2919.90.5050, Harmonized Tariff Schedule of the United States (HTSUS). Imports may also be classified under subheadings 2919.90.5010 and 3824.99.5000, HTSUS. The HTSUS subheadings and CAS registry numbers are provided for convenience and customs purposes. The written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–28397 Filed 12–3–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–555–003]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From Cambodia: Affirmative Preliminary Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells) from Cambodia are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is April 1, 2023, through March 31, 2024. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable December 4, 2024.

FOR FURTHER INFORMATION CONTACT: Hermes Pinilla or Joshua Weiner, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3477 or (202) 482–3902 respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce initiated this investigation on May 14, 2024.[1] On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[2] On September 17, 2024, Commerce postponed the preliminary determination of this investigation until November 27, 2024.[3]

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[4] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The products covered by this investigation are solar cells from Cambodia. For a complete description of

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations,* 89 FR 43809 (May 20, 2024) (*Initiation Notice*).

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[3] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 89 FR 77473 (September 23, 2024).

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Determination in the Less-Than-Fair-Value Investigation of Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Cambodia,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the *Preamble* to Commerce's regulations,[5] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[6] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[7] Commerce is preliminarily modifying the scope language as it appeared in the *Initiation Notice,* provided in Appendix I to this notice. The deadline for scope-related case and rebuttal briefs is established in the Preliminary Scope Decision Memoranda

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Pursuant to section 776(a) of the Act, Commerce preliminarily relied upon facts otherwise available to determine estimated weighted-average dumping margins for Hounen Solar Inc. Co. Ltd. (Hounen) and Solar Long PV Tech Cambodia Co. (Solar Long), the mandatory respondents in this investigation because both Hounen and Solar Long withdrew their participation in this investigation. Further, Commerce preliminarily determines that Hounen and Solar Long failed to cooperate by not acting to the best of each of their ability to comply with Commerce's request for information, and Commerce is using an adverse inference in selecting from among the facts otherwise available (*i.e.,* applying adverse facts available (AFA) to each respondent) in accordance with section 776(b) of the Act. For a full description of the methodology underlying our preliminary determination, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that, in the preliminary determination, Commerce shall determine an estimated weighted-average dumping margin, *i.e.,* all-others rate, for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters or producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

The estimated weighted-average dumping margins in this preliminary determination was determined entirely under section 776 of the Act. In cases where no estimated weighted-average dumping margins other than zero, *de minimis,* or those determined entirely under section 776 of the Act have been established for individually examined companies, in accordance with section 735(c)(5)(B) of the Act, Commerce typically calculates a simple average of the dumping margins alleged in the petition, and applies the results as the estimated weighted-average dumping margin for all other producers and exporters not individually examined.[8]

In the Petition,[9] the American Alliance for Solar Manufacturing Trade Committee (the petitioner) alleged a single estimated dumping margin for Cambodia, 125.37 percent.[10] Therefore, consistent with our practice, for the all-others rate in this investigation, the simple average of the dumping margins alleged in the Petition is 125.37 percent.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter or producer	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset(s)) (percent)
Hounen Solar Inc. Co. Ltd	* 125.37	117.12
Solar Long PV Tech Cambodia Co	* 125.37	117.12
All Others	125.37	117.12

* Rate is based on AFA.

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption, on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin, as adjusted for export subsidies, as follows: (1) the cash deposit rate either produced or exported by Hounen or Solar Long will be equal to the company-specific, adjusted, estimated weighted-average dumping margin determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the adjusted, all-others estimated weighted-average dumping margin.

Commerce normally adjusts cash deposits for estimated antidumping duties by the amount of export subsidies countervailed in a companion countervailing duty (CVD) proceeding. Accordingly, where Commerce preliminarily made an affirmative determination for countervailable export subsidies, Commerce has offset the estimated weighted-average dumping margin by the appropriate CVD rate. Any such adjusted cash deposit rate

[5] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

[6] *See Initiation Notice,* 89 FR 43810.

[7] *See* Memoranda, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Cambodia, Malaysia, and Thailand: Preliminary Scope Decision Memorandum,'' dated concurrently with this notice and ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from Vietnam,'' dated concurrently with this notice (collectively, Preliminary Scope Decision Memoranda).

[8] *See, e.g., Thermal Paper from Spain: Final Determination of Sales at Less Than Fair Value,* 86 FR 54162, 54163 (September 30, 2021).

[9] *See* Petitioner's Letter, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam, Petitions for the Imposition of Antidumping and Countervailing Duties'' dated April 24, 2024 (Petition).

[10] *See Initiation Notice,* 89 FR 43812.

may be found in the ''Preliminary Determination'' section above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting estimated antidumping duty cash deposits unadjusted for countervailed export subsidies at the time that the provisional CVD measures expire. These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of preliminary determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily applied AFA to the individually examined companies in this investigation, in accordance with section 776 of the Act, and the applied AFA rate is based solely on the Petition, there are no calculations to disclose.

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address or do not satisfy the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination if the ministerial error allegation is included with issues raised in the case briefs or other written comments.

Verification

Because both mandatory respondents in this investigation withdrew their participation and did not act to the best of their ability to provide information requested by Commerce, and Commerce preliminarily determines the mandatory respondents have been uncooperative, Commerce will not conduct verification.

Public Comment

All interested parties will have the opportunity to submit scope case and rebuttal briefs, to allow interested parties to comment on our preliminary scope decision at that time. For all scope case and rebuttal briefs, parties must file identical documents simultaneously on the records of the ongoing LTFV and CVD investigations of solar cells from Cambodia, Malaysia, the Socialist Republic of Vietnam, and Thailand. No new factual information or business proprietary information may be included in either scope case or rebuttal briefs.

Case briefs or other written comments regarding non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the date of publication of the preliminary determination. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[11] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[12]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their briefs that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[13] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[14]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On November 14, 2024, pursuant to 19 CFR 351.210(e), Hounen and Solar Long requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[15] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporter(s) account(s) for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of

[11] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[12] *See* 19 CFR 351.309(c)(2) and (d)(2).

[13] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[14] *See APO and Service Final Rule.*

[15] *See* Hounen and Solar Long's Letter, ''Request to Postpone Final Determination,'' dated November 14, 2024.

its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: November 27, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by these investigations is crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels and building integrated materials.

These investigations cover crystalline silicon photovoltaic cells of thickness equal to or greater than 20 micrometers, having a p/n junction formed by any means, whether or not the cell has undergone other processing, including, but not limited to, cleaning, etching, coating, and/or addition of materials (including, but not limited to, metallization and conductor patterns) to collect and forward the electricity that is generated by the cell.

Merchandise under consideration may be described at the time of importation as parts for final finished products that are assembled after importation, including, but not limited to, modules, laminates, panels, building-integrated modules, building-integrated panels, or other finished goods kits. Such parts that otherwise meet the definition of merchandise under consideration are included in the scope of the investigations.

Excluded from the scope of the investigations are thin film photovoltaic products produced from amorphous silicon (a-Si), cadmium telluride (CdTe), or copper indium gallium selenide (CIGS). Also excluded from the scope of the investigations are crystalline silicon photovoltaic cells, not exceeding 10,000 mm^2 in surface area, that are permanently integrated into a consumer good whose function is other than power generation and that consumes the electricity generated by the integrated crystalline silicon photovoltaic cell. Where more than one cell is permanently integrated into a consumer good, the surface area for purposes of this exclusion shall be the total combined surface area of all cells that are integrated into the consumer good.

Additionally, excluded from the scope of the investigations are panels with surface area from 3,450 mm^2 to 33,782 mm^2 with one black wire and one red wire (each of type 22 AWG or 24 AWG not more than 206 mm in length when measured from panel extrusion), and not exceeding 2.9 volts, 1.1 amps, and 3.19 watts. For the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Also excluded from the scope of the investigations are:

1. Off grid CSPV panels in rigid form with a glass cover, with the following characteristics: (A) a total power output of 100 watts or less per panel; (B) a maximum surface area of 8,000 cm^2 per panel; (C) do not include a built-in inverter; (D) must include a permanently connected wire that terminates in either an 8 mm male barrel connector, or a two-port rectangular connector with two pins in square housings of different colors; (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features, and foam for transport); and

2. Off grid CSPV panels without a glass cover, with the following characteristics: (A) a total power output of 100 watts or less per panel; (B) a maximum surface area of 8,000 cm^2 per panel; (C) do not include a built-in inverter; (D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and (E) each panel is (1) permanently integrated into a consumer good; (2) encased in a laminated material without stitching, or (3) has all of the following characteristics: (i) the panel is encased in sewn fabric with visible stitching, (ii) includes a mesh zippered storage pocket, and (iii) includes a permanently attached wire that terminates in a female USB–A connector.

In addition, the following CSPV panels are excluded from the scope of the investigations: off-grid CSPV panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water: (A) a total power output of no more than 80 watts per panel; (B) a surface area of less than 5,000 square centimeters (cm^2) per panel; (C) do not include a built-in inverter; (D) do not have a frame around the edges of the panel; (E) include a clear glass back panel; and (F) must include a permanently connected wire that terminates in a twoport rectangular connector.

Additionally excluded from the scope of these investigations are off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (1) a total power output of 200 watts or less per panel; (2) a maximum surface area of 16,000 cm^2 per panel; (3) no built-in inverter; (4) an integrated handle or a handle attached to the package for ease of carry; (5) one or more integrated kickstands for easy installation or angle adjustment; and (6) a wire of not less than 3 meters either permanently connected or attached to the package that terminates in an 8 mm diameter male barrel connector.

Also excluded from the scope of these investigations are off-grid crystalline silicon photovoltaic panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water: (A) a total power output of no more than 180 watts per panel at 155 degrees Celsius; (B) a surface area of less than 16,000 square centimeters (cm^2) per panel; (C) include a keep-out area of approximately 1,200 cm^2 around the edges of the panel that does not contain solar cells; (D) do not include a built-in inverter; (E) do not have a frame around the edges of the panel; (F) include a clear glass back panel; (G) must include a permanently connected wire that terminates in a two-port rounded rectangular, sealed connector; (H) include a thermistor installed into the permanently connected wire before the twoport connector; and (I) include exposed positive and negative terminals at opposite ends of the panel, not enclosed in a junction box.

Further excluded from the scope of the investigations are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 10,500 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure, (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 16,000 cm^2 per panel, (C) no built-in inverter, (D) an integrated handle or a handle attached to the package for ease of carry, (E) one or more integrated kickstands for easy installation or angle adjustment, and (F) a wire either permanently connected or attached to the package terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure.

Also excluded from the scope of the investigations are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 10,500 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure, (E) must include visible parallel grid collector metallic wire lines every 1–4

millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Small off-grid panels with glass cover, with the following characteristics: (A) surface area from 3,450 mm^2 to 33,782 mm^2, (B) with one black wire and one red wire (each of type 22AWG or 28 AWG not more than 350 mm in length when measured from panel extrusion), (C) not exceeding 10 volts, (D) not exceeding 1.1 amps, (E) not exceeding 6 watts, and (F) for the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Additionally excluded from the scope of the investigations are:

1. Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 175 watts or less per panel, (B) a maximum surface area of 9,000 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure; (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

2. Off grid CSPV panels without a glass cover, with the following characteristics, (A) a total power output of 220 watts or less per panel, (B) a maximum surface area of 16,000 cm^2 per panel, (C) do not include a built-in inverter, (D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (E) each panel is encased in a laminated material without stitching.

Also excluded from the scope of these investigations are off-grid CSPV panels in rigid form, with or without a glass cover, permanently attached to an aluminum extrusion that is an integral component of an automation device that controls natural light, whether or not assembled into a fully completed automation device that controls natural light, with the following characteristics:

1. a total power output of 20 watts or less per panel;

2. a maximum surface area of 1,000 cm^2 per panel;

3. does not include a built-in inverter for powering third party devices.

Modules, laminates, and panels produced in a third-country from cells produced in a subject country are covered by the investigations; however, modules, laminates, and panels produced in a subject country from cells produced in a third-country are not covered by the investigations.

Also excluded from the scope of these investigations are all products covered by the scope of the antidumping and countervailing duty orders on *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 77 FR 73018 (December 7, 2012); *and Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Countervailing Duty Order,* 77 FR 73017 (December 7, 2012).

Merchandise covered by the investigations is currently classified in the Harmonized Tariff System of the United States (HTSUS) under subheadings 8541.42.0010 and 8541.43.0010. Imports of the subject merchandise may enter under HTSUS subheadings 8501.71.0000, 8501.72.1000, 8501.72.2000, 8501.72.3000, 8501.72.9000, 8501.80.1000, 8501.80.2000, 8501.80.3000, 8501.80.9000, 8507.20.8010, 8507.20.8031, 8507.20.8041, 8507.20.8061, and 8507.20.8091. These HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of the investigations is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–28402 Filed 12–3–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE350]

Taking of Threatened or Endangered Marine Mammals Incidental to Commercial Fishing Operations; Issuance of a Permit

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: NMFS is issuing a permit to authorize the incidental, but not intentional, take of specific Endangered Species Act (ESA)-listed marine mammal species or stocks under the Marine Mammal Protection Act (MMPA), in the Washington (WA)/Oregon (OR)/California (CA) sablefish pot fishery.

DATES: This permit is effective for a 3-year period beginning December 4, 2024.

ADDRESSES: The materials supporting the permit are available on the internet at *https://www.regulations.gov/docket/NOAA-NMFS-2024-0087.* Other supporting information is available on the internet including: recovery plans for the ESA-listed marine mammal species, *https://www.fisheries.noaa.gov/national/endangered-species-conservation/recovery-species-under-endangered-species-act;* 2024 MMPA List of Fisheries (LOF), *https://www.fisheries.noaa.gov/national/marine-mammal-protection/list-fisheries-summary-tables;* the most recent Marine Mammal Stock Assessment Reports (SAR) by region, *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region,* and stock, *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-species-stock;* and Take Reduction Teams (TRT) and Plans, *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-take-reduction-plans-and-teams.*

FOR FURTHER INFORMATION CONTACT: Dan Lawson, West Coast Region, (206) 526–4740, *Dan.Lawson@noaa.gov,* or Jaclyn Taylor, NMFS Office of Protected Resources, (301) 427–8402, *Jaclyn.Taylor@noaa.gov.*

SUPPLEMENTARY INFORMATION: The MMPA requires NMFS to authorize the incidental take of ESA-listed marine mammals in commercial fisheries provided it can make the following determinations: (1) the incidental mortality and serious injury (M/SI) from commercial fisheries will have a negligible impact on the affected species or stocks; (2) a recovery plan for all affected species or stocks of threatened or endangered marine mammals has been developed or is being developed pursuant to the ESA; and (3) where required under MMPA section 118, a take reduction plan (TRP) has been developed or is being developed, a monitoring program is established, and vessels participating in the fishery are registered. We have determined that the Category II WA/OR/CA sablefish pot fishery meets these three requirements and are issuing a permit to the fishery to authorize the incidental take of ESA-listed marine mammal species or stocks (Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whale) under the MMPA for a period of 3 years.

Background

The MMPA LOF classifies each commercial fishery as a Category I, II, or III fishery based on the level of mortality and injury of marine mammals

occurring incidental to each fishery as defined in 50 CFR 229.2. Section 118(c)(2) of the MMPA requires fishing vessels that operate in Category I and II fisheries to register with NMFS and are subsequently authorized to incidentally take marine mammals during commercial fishing operations. However, that authorization is limited to those marine mammals that are not listed as threatened or endangered under the ESA. Section 118(a)(2) of the MMPA, 16 U.S.C. 1387(a)(2), also requires an additional authorization at section 101(a)(5) of the MMPA, 16 U.S.C. 1371, for incidental taking of ESA-listed marine mammals. Section 101(a)(5)(E) of the MMPA, 16 U.S.C. 1371, states that NMFS, as delegated by the Secretary of Commerce, for a period of up to 3 consecutive years shall allow the incidental, but not intentional, taking of marine mammal species or stocks designated as depleted because of their listing as an endangered species or threatened species under the ESA, 16 U.S.C. 1531 *et seq.,* by persons using vessels of the United States, while engaging in commercial fishing operations, if NMFS makes certain determinations. NMFS must determine, after notice and opportunity for public comment, that: (1) incidental M/SI from commercial fisheries will have a negligible impact on the affected species or stock; (2) a recovery plan has been developed or is being developed for such species or stock pursuant to the ESA; and (3) where required under section 118 of the MMPA, a monitoring program has been established, vessels engaged in such fisheries are registered in accordance with section 118 of the MMPA, and a TRP has been developed or is being developed for such species or stock.

The LOF includes a list of marine mammal species or stocks incidentally killed or injured in each commercial fishery. We evaluated ESA-listed stocks or species included on the final 2024 MMPA LOF (89 FR 12257, February 16, 2024) as killed or seriously injured following NMFS' Procedural Directive 02–238 ''Process for Distinguishing Serious from Non-Serious Injury of Marine Mammals.'' Based on this evaluation, we proposed to issue a permit under MMPA section 101(a)(5)(E) to vessels registered in the Category II WA/OR/CA sablefish pot fishery, as classified on the final 2024 MMPA LOF, to incidentally kill or seriously injure individuals from the Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whale (89 FR 73377, September 10, 2024).

NMFS regularly evaluates commercial fisheries for purposes of making a negligible impact determination (NID) and issuing section 101(a)(5)(E) authorizations with the annual LOF as new information becomes available. More information about the fishery is available in the 2024 MMPA LOF (89 FR 12257, February 16, 2024) and on the internet at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/list-fisheries-summary-tables.*

We reviewed the best available scientific information to determine if the WA/OR/CA sablefish pot fishery met the three requirements of MMPA section 101(a)(5)(E) for issuing a permit. This information is included in the 2024 MMPA LOF (89 FR 12257, February 16, 2024), the SARs for these species (available at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports*), recovery plans for these species (available at: *https://www.fisheries.noaa.gov/national/endangered-species-conservation/recovery-species-under-endangered-species-act*), and other relevant information, as detailed further in the documents describing the determinations supporting the permit (available at: *https://www.regulations.gov/docket/NOAA-NMFS-2024-0087*).

Basis for Determining Negligible Impact

Prior to issuing a MMPA 101(a)(5)(E) permit to take ESA-listed marine mammals incidental to commercial fishing, NMFS must determine if the M/SI incidental to commercial fisheries will have a negligible impact on the affected marine mammal species or stocks. NMFS satisfies this requirement by making a NID. Although the MMPA does not define ''negligible impact,'' NMFS has issued regulations providing a qualitative definition of ''negligible impact,'' defined in 50 CFR 216.103, as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Criteria for Determining Negligible Impact

NMFS uses a quantitative approach for determining negligible impact detailed in NMFS Procedural Directive 02–204–02 (directive), ''Criteria for Determining Negligible Impact under MMPA section 101(a)(5)(E),'' which became effective on June 17, 2020 (NMFS 2020). The procedural directive is available online at: *https://www.fisheries.noaa.gov/national/laws-and-policies/protected-resources-policy-directives.* The directive describes NMFS' process for determining whether incidental M/SI from commercial fisheries will have a negligible impact on ESA-listed marine mammal species/stocks (the first requirement necessary for issuing a MMPA section 101(a)(5)(E) permit as noted above).

The directive first describes the derivation of two Negligible Impact Thresholds (NIT), which represent levels of removal from a marine mammal species or stock. The first, Total NIT (NIT_t), represents the total amount of human-caused M/SI that NMFS considers negligible for a given stock. The second, lower threshold, Single NIT (NIT_s) represents the level of M/SI from a single commercial fishery that NMFS considers negligible for a stock. NIT_s was developed in recognition that some stocks may experience non-negligible levels of total human-caused M/SI but one or more individual fisheries may contribute a very small portion of that M/SI, and the effect of an individual fishery may be considered negligible.

The directive describes a detailed process for using these NIT values to conduct a NID analysis for each fishery classified as a Category I or II fishery on the MMPA LOF. The NID process uses a two-tiered analysis. The Tier 1 analysis first compares the total human-caused M/SI for a particular stock to NIT_t. If NIT_t is not exceeded, then all commercial fisheries that kill or seriously injure the stock are determined to have a negligible impact on the particular stock. If NIT_t is exceeded, then the Tier 2 analysis compares each individual fishery's M/SI for a particular stock to NIT_s. If NIT_s is not exceeded, then the commercial fishery is determined to have a negligible impact on that particular stock. For transboundary, migratory stocks, because of the uncertainty regarding the M/SI that occurs outside of U.S. waters, we assume that total M/SI exceeds NIT_t and proceed directly to the Tier 2 NIT_s analysis. If a commercial fishery has a negligible impact across all ESA-listed stocks, then the first of three findings necessary for issuing a MMPA 101(a)(5)(E) permit to the commercial fishery has been met (*i.e.,* a NID). If a commercial fishery has a non-negligible impact on any ESA-listed stock, then NMFS cannot issue a MMPA 101(a)(5)(E) permit for the fishery to incidentally take ESA-listed marine mammals.

These NID criteria rely on the best available scientific information,

including estimates of a stock's minimum population size and human-caused M/SI levels, as published in the most recent SARs and other supporting documents, as appropriate. Using these inputs, the quantitative negligible impact thresholds allow for straightforward calculations that lead to clear negligible or non-negligible impact determinations for each commercial fishery analyzed. In rare cases, robust data may be unavailable for a straightforward calculation, and the directive provides instructions for completing alternative calculations or assessments where appropriate.

Negligible Impact Determination

NMFS evaluated the impact of the WA/OR/CA sablefish pot fishery following the directive and based on the best available scientific information and made a NID. The NID analysis is presented in the accompanying MMPA 101(a)(5)(E) evaluation document that provides summaries of the information used to evaluate each ESA-listed stock documented on the 2024 MMPA LOF as killed or injured incidental to the fishery (available at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/list-fisheries-summary-tables*). The MMPA 101(a)(5)(E) evaluation document is available at: *https://www.regulations.gov/docket/NOAA-NMFS-2024-0087.*

The Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whale are transboundary stocks. As noted above, because of the uncertainty regarding M/SI that occurs outside of U.S. waters for transboundary stocks, we assumed that total M/SI exceeds NIT_t for the above transboundary stocks and proceeded directly to the Tier 2 NIT_s analysis.

The most recent SARs for the Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whale include fishery-related M/SI not assigned to a specific commercial fishery (information provided in NID analyzes summaries where applicable below). This unattributed fishery-related M/SI could be from any number of commercial, recreational, or tribal fisheries, including the WA/OR/CA sablefish pot fishery. Because data are not currently available to assign the unattributed fishery-related M/SI to a specific commercial fishery, we did not include unattributed mortality in the calculations for NID Tier 2 analyses (described below). NMFS is actively monitoring the WA/OR/CA sablefish pot fishery through a fishery observer program. If additional fishery-related M/SI is documented through the observer program that indicates additional M/SI of the Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whale, then NMFS will re-evaluate the NID and the permit.

Based on the criteria outlined in the directive, the most recent SARs, and the best available scientific information, NMFS has determined that the M/SI of Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whale incidental to the WA/OR/CA sablefish pot fishery will have a negligible impact on these stocks. Accordingly, this MMPA 101(a)(5)(E) requirement is satisfied for WA/OR/CA sablefish pot fishery (see MMPA 101(a)(5)(E) determination document is available at: *https://www.regulations.gov/docket/NOAA-NMFS-2024-0087*). Summaries of the NID analyses are provided below.

The Category II WA/OR/CA sablefish pot fishery has documented incidental M/SI of the Central America/Southern Mexico-CA/OR/WA stock of humpback whale. The 2022 SAR includes a mean annual total commercial fishery-related M/SI (8.1) for the Central America/Southern Mexico-CA/OR/WA stock of humpback whale (Carretta *et al.* 2023). This comprises M/SI from all commercial fisheries, including the WA/OR/CA sablefish pot fishery, as well as fishery-related M/SI for the stock not assigned to a specific commercial fishery. The SAR also includes unattributed fishery-related M/SI (4.582) for the stock, which is not assigned to a specific commercial fishery.

The estimated M/SI of humpback whales (Central America/Southern Mexico-CA/OR/WA stock) in the WA/OR/CA sablefish pot fishery is 0.66 (Carretta *et al.* 2023). Since this M/SI (0.66) is less than NIT_s (0.68), NMFS determined that the WA/OR/CA sablefish pot fishery has a negligible impact on the Central America/Southern Mexico-CA/OR/WA stock of humpback whale (see accompanying MMPA 101(a)(5)(E) evaluation document).

The Category II WA/OR/CA sablefish pot fishery has documented incidental M/SI of the Mainland Mexico-CA/OR/WA stock of humpback whale. The 2022 SAR includes a mean annual total commercial fishery-related M/SI (11.4) for the Mainland Mexico-CA/OR/WA stock of humpback whale (Carretta *et al.* 2023). This comprises M/SI from all commercial fisheries, including the WA/OR/CA sablefish pot fishery, as well as fishery-related M/SI for the stock not assigned to a specific commercial fishery. The SAR also includes unattributed fishery-related M/SI (6.431) for the stock, which is not assigned to a specific commercial fishery.

The estimated M/SI of humpback whales (Mainland Mexico-CA/OR/WA stock) in the WA/OR/CA sablefish pot fishery is 0.902 (Carretta *et al.* 2023). Since this M/SI (0.902) is less than NIT_s (1.70), NMFS determined that the WA/OR/CA sablefish pot fishery has a negligible impact on the Mainland Mexico-CA/OR/WA stock of humpback whale (see accompanying MMPA 101(a)(5)(E) evaluation document).

Recovery Plans

A recovery plan for the globally ESA-listed humpback whale species was developed in 1991. In 2016, NMFS revised the listing status of the humpback whale under the ESA. The globally listed endangered species was divided into 14 distinct population segments (DPSs), the species-level listing was removed, and NMFS listed four DPSs as endangered and one DPS as threatened (81 FR 62260, September 8, 2016). In June 2022, NMFS published a recovery outline for the Central America, Mexico, and Western North Pacific DPSs of humpback whales (*https://www.fisheries.noaa.gov/resource/document/recovery-outline-central-america-mexico-and-western-north-pacific-distinct*). The recovery outline serves as an interim guidance document and, with the existing species-wide recovery plan, directs recovery efforts, including recovery planning, for the Central America (Central America/Southern Mexico-CA/OR/WA stock) and Mexico (Mainland Mexico-CA/OR/WA stock) DPSs of humpback whales. Once finalized, the new recovery plan will replace the species-wide recovery plan that was published in 1991.

Accordingly, the requirement that a recovery plan has been developed pursuant to the ESA is satisfied.

Take Reduction Plan

The MMPA section 118 requires the development and implementation of a TRP for each strategic stock that interacts with a Category I or II fishery. Subject to available funding, the Secretary shall give highest priority to the development of TRPs for species or stocks whose M/SI exceeds potential biological removal level, have a small population size, and which are declining most rapidly. The stocks considered for this permit are designated as strategic stocks under the MMPA because the stocks or a component of the stocks are listed as threatened species or endangered

species under the ESA (MMPA section 3(19)(C)). A TRP for the WA/OR/CA sablefish pot fishery and the affected marine mammal species or stocks (Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whale) is under development.

On September 29, 2023, NMFS published a notice (*Scoping for a Marine Mammal Take Reduction Team to Address Incidental Mortality and Serious Injury of Humpback Whale Stocks in the Pacific,* 88 FR 67254) expressing NMFS' intent to establish a TRT to develop a TRP to address the incidental mortality and serious injury of the Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whales in the WA/OR/CA sablefish pot fishery and seeking input on whether other Category I or II fisheries that incidentally kill or seriously injure these stocks of humpback whales should be addressed by the Team. For more information, please see *https://www.fisheries.noaa.gov/west-coast/marine-mammal-protection/west-coast-take-reduction-team.*

Accordingly, the requirement under MMPA section 118 to have TRPs in place or in development is satisfied (see determinations supporting the permit available on the internet at *https://www.regulations.gov/docket/NOAA-NMFS-2024-0087*).

Monitoring Program

Under MMPA section 118(d), NMFS is to establish a program for monitoring incidental M/SI of marine mammals from commercial fishing operations. The WA/OR/CA sablefish pot fishery is monitored by a NMFS fishery observer program. Accordingly, the requirement under MMPA section 118 to have a monitoring program in place is satisfied.

Vessel Registration

MMPA section 118(c) requires that vessels participating in Category I and II fisheries register to obtain an authorization to take marine mammals incidental to fishing activities. NMFS has integrated the MMPA registration process, implemented through the Marine Mammal Authorization Program, with existing state and Federal fishery license, registration, or permit systems for Category I and II fisheries on the LOF. Therefore, the requirement for vessel registration is satisfied.

Conclusions for Permit

Based on the above evaluation for the WA/OR/CA sablefish pot fishery as it relates to the three requirements of MMPA section 101(a)(5)(E), we are issuing an MMPA 101(a)(5)(E) permit to the WA/OR/CA sablefish pot fishery to authorize the incidental take of ESA-listed species or stocks during commercial fishing operations. If, during the 3-year authorization, there is a significant change in the information or conditions used to support any of these determinations, NMFS will re-evaluate whether to amend or modify the authorization, after notice and opportunity for public comment.

ESA Section 7 and National Environmental Policy Act (NEPA) Requirements

ESA section 7(a)(2) requires Federal agencies to ensure that actions they authorize, fund, or carry out are not likely to jeopardize the continued existence of any species listed under the ESA, or destroy or adversely modify designated critical habitat of any ESA-listed species. The effects of the WA/OR/CA sablefish pot commercial fishery on ESA-listed marine mammals were analyzed in the appropriate ESA section 7 Biological Opinions on the commercial fishery (see *https://www.fisheries.noaa.gov/s3/2024-11/BiOp-PCGF-BiOp-Final-MM-22NOV2024.pdf*), and incidental take was exempted for those ESA-listed marine mammals for the WA/OR/CA sablefish pot fishery in accordance with the Biological Opinions' incidental take statement. Under section 7 of the ESA, Biological Opinions quantify the effects of the proposed action on ESA-listed species and their critical habitat and, where appropriate, exempt take of ESA-listed species that is reasonably certain to occur, as specified in the incidental take statement.

Under MMPA section 101(a)(5)(E), NMFS analyzes previously documented M/SI incidental to commercial fisheries through the NID process, and when the necessary findings can be made, issues a MMPA section 101(a)(5)(E) permit that allows for an unspecified amount of incidental taking of specific ESA-listed marine mammal stocks while engaging in commercial fishing operations. Thus, the applicable standards and resulting analyses under the MMPA and ESA differ, and as such, do not always align.

NEPA requires Federal agencies to evaluate the impacts of alternatives for their actions on the human environment. Because the permit would not modify any fishery operation and the effects of the fishery operations have been evaluated in accordance with NEPA, no additional NEPA analysis beyond that conducted for the associated Fishery Management Plans and their implementing regulations is required for the permit. Issuing the permit has no additional impact on the human environment or effects on threatened or endangered species beyond those analyzed in these documents.

Comments and Responses

On September 10, 2024, NMFS published a notice and request for comments in the **Federal Register** for the proposed issuance of a permit under MMPA section 101(a)(5)(E) (89 FR 73377). The public comment period closed on October 10, 2024. NMFS received one comment letter in response to the request for comment on the proposed issuance of a permit to the WA/OR/CA sablefish pot commercial fishery and its underlying preliminary determinations. NMFS received a joint letter from Center for Biological Diversity, American Cetacean Society Oregon Chapter, Defenders of Wildlife, Earthjustice, Endangered Habitats League, Natural Resources Defense Council, Ocean Defenders Alliance, and Whale and Dolphin Conservation (CBD *et al.*) opposing issuance of the permit. NMFS' also received a joint letter from Defenders of Wildlife, Conservation Law Foundation, and Whale and Dolphin Conservation (Defenders of Wildlife *et al.*) that commented on NMFS' determination that the Category II Atlantic mixed species trap/pot fishery does not require a 101(a)(5)(E) permit. Based on Defenders of Wildlife *et al.'s* comment letter, NMFS is further evaluating the need for a 101(a)(5)(E) permit for the Atlantic mixed species trap/pot fishery and is not moving forward with the determination at this time. Only responses to significant comments pertaining to the proposed permit and preliminary determinations under MMPA section 101(a)(5)(E) for the WA/OR/CA sablefish pot commercial fishery are addressed below.

Comment 1: CBD *et al.* asserts that not including unattributed M/SI of the Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whales of humpback whales in the Tier 2 analyses can lead to erroneous NIDs. They recommend NMFS use the best available science to apportion unattributed fishery-related M/SI and consider using a correction factor to account for unattributed M/SI.

Response: As noted above, the most recent SARs (2022) for the Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whale include fishery-related M/SI not assigned to a specific commercial fishery. This unattributed fishery-related M/SI could

be from any number of commercial, recreational, or tribal fisheries, including the WA/OR/CA sablefish pot fishery. Because data are not currently available to assign the unattributed fishery-related M/SI to a specific commercial fishery, we did not include unattributed mortality in the calculations for NID Tier 2 analyses. NMFS is actively monitoring the WA/OR/CA sablefish pot fishery through a fishery observer program. If data and/or analyses become available to assign the unattributed fishery-related M/SI to specific commercial fisheries, NMFS will re-evaluate the NID and the permit for the WA/OR/CA sablefish pot fishery. In addition, if additional fishery-related M/SI is documented through the observer program that indicates additional M/SI of the Central America/Southern Mexico-CA/OR/WA or Mainland Mexico-CA/OR/WA stocks of humpback whale, then NMFS will re-evaluate the NID and the permit.

Comment 2: CBD *et al.* reiterates comments on the draft 2022 SAR that the maximum net productivity rate (R_{max}) neither reflects the best available scientific information nor the guidance set forth in the Guidelines for Assessing Marine Mammal Stocks (GAMMS). CBD *et al.* recommends NMFS adopt either a stock-specific R_{max}, similar to Curtis *et al.* (2022) or use the default value of 4 percent provided by the GAMMS.

Response: The SAR generally represents the best available scientific information on the stock. We incorporate by reference NMFS' response to Comment 17 in the final 2022 SAR **Federal Register** notice (88 FR 54592, August 11, 2023). Curtis *et al.* estimated the observed growth rate of the stock. CBD *et al.* conflates the observed growth rate of a population and R_{max}, which is the maximum theoretical or estimated growth rate that would be expected if the stock were at a small population size. R_{max} is the only relevant growth rate for calculations of PBR and the NID thresholds.

Comment 3: CBD *et al.* recommends NMFS use its discretion and deviate from NID made for the Central America/Southern Mexico-CA/OR/WA stock of humpback whales. They note that NMFS' Procedural Directive 02–204–02 acknowledges there may be circumstances when NMFS may deviate from the NID if M/SI is slightly below or slightly above the negligible impact threshold(s). Since NIT_s for the Central America/Southern Mexico-CA/OR/WA stock of humpback whale is only slightly higher than (0.02) than incidental M/SI in the WA/OR/CA sablefish pot fishery, NMFS should use its discretion and not make a NID.

Response: NMFS Procedural Directive 02–204–02, *Criteria for Determining Negligible Impact under MMPA section 101(a)(5)(E)* states, ''There may be circumstances, such as when the M/SI estimate is slightly below or slightly above the NIT threshold(s), where [NMFS] may deviate from the determination that would be dictated by strictly adhering to the NIT thresholds. Such deviations may be due to the consideration of additional factors affecting the likelihood or impact of the incidental M/SI such as data uncertainty and reliability, information on the population trend, and expected trends in commercial fisheries impacts including implemented or concurrently implemented management measures aimed at reducing M/SI below the threshold.'' NMFS considered this guidance in making the preliminary NID for the Central America/Southern Mexico-CA/OR/WA stock of humpback whales. NMFS is not aware of any specific bias in regards to the uncertainty and/or unreliability with the data on the population trend and expected trends in commercial fisheries impacts that would suggest the WA/OR/CA sablefish pot fishery would have a non-negligible impact on the Central America/Southern Mexico-CA/OR/WA stock of humpback whales. Therefore, NMFS is not deviating from the direct quantitative comparison of incidental M/SI to the NIT threshold in this case.

Thus, based on the criteria outlined in the Procedural Directive, the most recent SARs, and the best available scientific information, NMFS has determined that the M/SI of Central America/Southern Mexico-CA/OR/WA stock of humpback whale incidental to the WA/OR/CA sablefish pot fishery will have a negligible impact on this stock. If, during the 3-year authorization, there is a significant change in the information or conditions used to support the NID, NMFS will re-evaluate whether to amend or modify the authorization, after notice and opportunity for public comment.

Comment 4: CBD *et al.* claims NMFS has not developed a recovery plan for the ESA-listed humpback whale DPSs and should not rely on the recovery plan developed in 1991 for the global listing of humpback whales.

Response: As noted, a recovery plan for the humpback whale species (global listing) was developed in 1991. In June 2022, NMFS published a recovery outline for the Central America, Mexico, and Western North Pacific DPSs of humpback whales (*https://www.fisheries.noaa.gov/resource/document/recovery-outline-central-america-mexico-and-western-north-pacific-distinct*). This recovery outline serves as an interim guidance document and, along with the existing species-wide recovery plan, directs recovery efforts, including recovery planning, for the Central America (Central America/Southern Mexico-CA/OR/WA stock) and Mexico (Mainland Mexico-CA/OR/WA stock) DPSs of humpback whales. Once finalized, the new recovery plan will replace the species-wide recovery plan that was published in 1991.

Comment 5: CBD *et al.* expressed concern that the proposed permit did not include conditions or limitations to avoid incidental M/SI of humpback whales or other ESA-listed marine mammals. They note that MMPA section 101(a)(5)(E)(iv) allows the Secretary to suspend for a time certain or revoke a permit if it is determined that the conditions or limitations set forth in such permit are not being complied with. They continue that without conditions in the proposed permit, NMFS cannot use the authority granted under MMPA section 101(a)(5)(E)(iv). CBD *et al.* further recommends several permit conditions to include in the final permit.

Response: NMFS disagrees. The MMPA requires NMFS to authorize the incidental take of ESA-listed marine mammals during commercial fishing operations provided it can make the following determinations: (1) the incidental M/SI from commercial fisheries will have a negligible impact on the affected species or stocks; (2) a recovery plan for all affected species or stocks of threatened or endangered marine mammals has been developed or is being developed pursuant to the ESA; and (3) where required under MMPA section 118, a TRP has been developed or is being developed, a monitoring program is established, and vessels participating in the fishery are registered. MMPA section 101(a)(5)(E)(ii) states if the Secretary determines these requirements are met, the Secretary *shall* issue an appropriate permit under section 101(a)(5)(E). Section 101(a)(5)(E) does not require the Secretary, as delegated to NMFS, to prescribe permit conditions to ''avoid'' M/SI. Moreover, as discussed in the Take Reduction Plan section of this notice, NMFS is in the process of developing a TRP to address the incidental M/SI of the Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whales in the WA/OR/CA sablefish pot fishery. Once convened, the Take Reduction Team will recommend various mitigation measures to reduce M/SI of the Central America/Southern Mexico-CA/OR/WA and

Mainland Mexico-CA/OR/WA stocks of humpback whales in the WA/OR/CA sablefish pot fishery pursuant to the goals of MMPA section 118(f)(2). The Take Reduction Team's recommended measures will be used to develop a TRP, which will include regulatory or voluntary measures to reduce incidental M/SI in the fishery.

References

Carretta, J.W., E.M. Oleson, K.A. Forney, M.M. Muto, D.W. Weller, A.R. Lang, J. Baker, B. Hanson, A.J. Orr, J. Barlow, J.E. Moore, and R.L. Brownell. 2023. U.S. Pacific Marine Mammal Stock Assessments: 2022. U.S. Department of Commerce. NOAA Technical Memorandum NMFS–SWFSC–684. 409 p.

Curtis, K.A., J. Calambokidis, K. Audley, M.G. Castaneda, J. De Weerdt, A.J. García Chávez, F. Garita, P. Martínez-Loustalot, J. D. Palacios-Alfaro, B. Pérez, E. Quintana-Rizzo, R. Ramírez Barragan, N. Ransome, K. Rasmussen, J. Urbán R., F. Villegas Zurita, K. Flynn, T. Cheeseman, J. Barlow, D. Steel and J. Moore. 2022. Abundance of Humpback Whales (*Megaptera novaeangliae*) Wintering in Central America and Southern Mexico from a One-Dimensional Spatial Capture-Recapture Model. U.S. Department of Commerce. NOAA Technical Memorandum NMFS–SWFSC–661. 35 p. *https://doi.org/10.25923/9cq1-rx80*.

National Marine Fisheries Service (NMFS). 2020. National Marine Fisheries Service Procedure 02–204–02: Criteria for Determining Negligible Impact under MMPA Section 101(a)(5)(E). 20 p. Available online: *https://www.fisheries.noaa.gov/national/laws-and-policies/protected-resources-policy-directives.*

Dated: November 26, 2024.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024–28380 Filed 12–3–24; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER FINANCIAL PROTECTION BUREAU

[Docket No. CFPB–2024–0056]

Agency Information Collection Activities: Comment Request

AGENCY: Consumer Financial Protection Bureau.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (CFPB) requests the Office of Management and Budget's (OMB's) approval of an information collection titled ''Survey Screening Questions.''

DATES: Written comments are encouraged and must be received on or before January 3, 2025 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Anthony May, Paperwork Reduction Act Officer, at (202) 435–7278, or email: *CFPB_PRA@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.* Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Survey Screening Questions.

OMB Control Number: 3170–00XX.

Type of Review: New information collection.

Affected Public: Individuals.

Estimated Number of Respondents: 50,000.

Estimated Total Annual Burden Hours: 12,500.

Abstract: The CFPB conducts a variety of research efforts to ascertain financial issues the American public may be experiencing. The CFPB developed a list of potential screener questions formulated to allow their research efforts to focus on the appropriate consumers for each study and strengthen our ability to address financial needs and concerns of the public and to improve the CFPB's delivery of services and programs. Usage of the included questions will ensure CFPB's future survey efforts target applicable respondents, reduce administrative burden on the CFPB, and grant greater flexibility in conducting research on emergent financial issues.

Request for Comments: The CFPB published a 60-day **Federal Register** notice on October 2, 2024 (89 FR 80231) under Docket Number: CFPB–2024–0050. The CFPB is publishing this notice and soliciting comments on: (a) Whether the collection of information is necessary for the proper performance of the functions of the CFPB, including whether the information will have practical utility; (b) The accuracy of the CFPB's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be reviewed by OMB as part of its review of this request. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2024–28375 Filed 12–3–24; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2315–178]

Dominion Energy South Carolina, Inc.; Notice of Intent To Prepare an Environmental Assessment

On May 23, 2024, as supplemented on September 9, 2024, Dominion Energy South Carolina, Inc. (DESC) filed an application for a non-capacity amendment of the license for the Neal Shoals Hydroelectric Project No. 2315. The project is located on the Broad River in South Carolina and occupies Federal lands administered by the Sumter National Forest.

The licensee proposes to replace the four existing turbines in the powerhouse with eight submersible turbine-generator units to be installed at the existing draft tube openings and construct a new substation and underground duct bank at the project. The licensee proposes to decouple the existing generators, which would no longer be needed, and decommission and abandon them in place. The licensee expects the project's generating capacity to increase from 4.4 MW to 5.6

MW and hydraulic capacity to decrease from 3,500 cfs to 3,160 cfs.

On September 30, 2024, the Commission issued a public notice for the proposed amendment. On October 30, 2024, the South Caronia Department of Natural Resources filed comments on the proposal. DESC filed a response to comments on November 8, 2024.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the project.[1] Commission staff plans to issue an EA by July 18, 2025. Revisions to the schedule may be made as appropriate. The EA will be issued for a 30-day comment period. All comments filed on the EA will be reviewed by staff and considered in the Commission's final decision on the proceeding.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members, and others to access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Any questions regarding this notice may be directed to Elizabeth Moats at 202–502–6632 or *Elizabeth.OsierMoats@ferc.gov.*

Dated: November 27, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–28407 Filed 12–3–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG25–46–000.

Applicants: Bocanova Power LLC.

Description: Bocanova Power LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 11/27/24.

Accession Number: 20241127–5213.

Comment Date: 5 p.m. ET 12/18/24.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL25–22–000.

Applicants: Advanced Energy United, American Clean Power Association, Solar Energy Industries Association, American Clean Power Association Solar Energy Industries Association Advanced Energy United v. PJM Interconnection, L.L.C.

Description: Complaint of American Clean Power Association, Solar Energy Industries Association, and Advanced Energy United v. PJM Interconnection, L.L.C.

Filed Date: 11/26/24.

Accession Number: 20241126–5340.

Comment Date: 5 p.m. ET 12/16/24.

Docket Numbers: EL25–23–000.

Applicants: Rio Grande Electric Cooperative, Inc.

Description: Petition for Declaratory Order of Rio Grande Electric Cooperative, Inc.

Filed Date: 11/26/24.

Accession Number: 20241126–5341.

Comment Date: 5 p.m. ET 12/17/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER24–2034–001.

Applicants: GridLiance Heartland LLC.

Description: Compliance filing: Gridliance Heartland Further Order 2023 Compliance Filing to be effective 9/1/2024.

Filed Date: 11/27/24.

Accession Number: 20241127–5158.

Comment Date: 5 p.m. ET 12/18/24.

Docket Numbers: ER25–313–001; ER25–314–001; ER25–315–001.

Applicants: South River OnSite Generation, LLC, Martinsville OnSite Generation, LLC, Clyde Onsite Generation, LLC.

Description: Supplement to 10/31/2024, Clyde Onsite Generation, LLC submits tariff filing Notice of Change in Status and Tariff Revisions.

Filed Date: 11/22/24.

Accession Number: 20241122–5290.

Comment Date: 5 p.m. ET 12/13/24.

Docket Numbers: ER25–346–001.

Applicants: Public Service Company of Colorado.

Description: Tariff Amendment: 2024–11–27 Att O–SPS Formula Rates—Order 898—Errata Filing to be effective 1/1/2025.

Filed Date: 11/27/24.

Accession Number: 20241127–5151.

Comment Date: 5 p.m. ET 12/18/24.

Docket Numbers: ER25–580–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: WDT SA 17: November 2024 WAPA Service Agreement Biannual Filing to be effective 2/1/2025.

Filed Date: 11/27/24.

Accession Number: 20241127–5001.

Comment Date: 5 p.m. ET 12/18/24.

Docket Numbers: ER25–581–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: TO SA 59: November 2024 WAPA Interconnection Agreement Biannual Filing to be effective 2/1/2025.

Filed Date: 11/27/24.

Accession Number: 20241127–5002.

Comment Date: 5 p.m. ET 12/18/24.

Docket Numbers: ER25–582–000.

Applicants: NextEra Energy Transmission Southwest, LLC.

Description: § 205(d) Rate Filing: NextEra Energy Transmission Southwest, LLC Depreciation Rate Revisions to be effective 2/1/2025.

Filed Date: 11/27/24.

Accession Number: 20241127–5067.

Comment Date: 5 p.m. ET 12/18/24.

Docket Numbers: ER25–583–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Ministerial Clean-up Filing of Tariff, Definitions R—S to be effective 12/3/2019.

Filed Date: 11/27/24.

Accession Number: 20241127–5093.

Comment Date: 5 p.m. ET 12/18/24.

Docket Numbers: ER25–584–000.

Applicants: Constellation Mystic Power, LLC.

Description: Compliance filing: Compliance Filing of Tariff Records to Implement ROE Settlement to be effective 6/1/2022.

Filed Date: 11/27/24.

Accession Number: 20241127–5136.

Comment Date: 5 p.m. ET 12/18/24.

Docket Numbers: ER25–586–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amended ISA, SA No. 2637; AF1–177 to be effective 1/27/2025.

Filed Date: 11/27/24.

Accession Number: 20241127–5144.

Comment Date: 5 p.m. ET 12/18/24.

Docket Numbers: ER25–588–000.

Applicants: Essential Power Newington, LLC.

Description: § 205(d) Rate Filing: IROL–CIP Rate Schedule to be effective 1/27/2025.

Filed Date: 11/27/24.

Accession Number: 20241127–5166.

Comment Date: 5 p.m. ET 12/18/24.

Docket Numbers: ER25–589–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

[1] In accordance with the Council on Environmental Quality's regulations, the unique identification number for documents relating to this environmental review is EAXX–019–20–000–1732197559. 40 CFR 1501.5(c)(4) (2024).

Description: § 205(d) Rate Filing: Amendment to Rate Schedule FERC No. 57 to be effective 1/27/2025.

Filed Date: 11/27/24.

Accession Number: 20241127–5187.

Comment Date: 5 p.m. ET 12/18/24.

Docket Numbers: ER25–590–000.

Applicants: Pome BESS LLC.

Description: § 205(d) Rate Filing: POME BESS Section 205 Filing to be effective 12/31/9998.

Filed Date: 11/27/24.

Accession Number: 20241127–5240.

Comment Date: 5 p.m. ET 12/18/24.

Docket Numbers: ER25–591–000.

Applicants: Duke Energy Carolinas, LLC.

Description: § 205(d) Rate Filing: DEC–CEPCI RS No. 665 Reimbursement Agmt to be effective 2/1/2025.

Filed Date: 11/27/24.

Accession Number: 20241127–5245.

Comment Date: 5 p.m. ET 12/18/24.

Docket Numbers: ER25–592–000.

Applicants: Wisconsin Power and Light Company.

Description: Initial rate filing: WPL Rate Schedule for Blackstart Resource Services to be effective 1/27/2025.

Filed Date: 11/27/24.

Accession Number: 20241127–5255.

Comment Date: 5 p.m. ET 12/18/24.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *https://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: November 27, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–28412 Filed 12–3–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP22–21–000; CP22–21–001; CP22–22–000; CP22–22–001]

Venture Global CP2 LNG, LLC, Venture Global CP Express, LLC; Notice of Schedule for the Preparation of a Supplemental Environmental Impact Statement for the CP2 LNG Project and CP Express Pipeline Project

On June 27, 2024, the Federal Energy Regulatory Commission (Commission or FERC) issued an *Order Granting Authorizations Under Sections 3 and 7 of the Natural Gas Act* (Authorization Order) for Venture Global CP2 LNG, LLC's CP2 LNG Project and Venture Global CP Express, LLC's CP Express Pipeline Project.[1] On July 29, 2024, a coalition of petitioners (Petitioners) filed a timely request for rehearing and motion for stay of the Authorization Order. On November 27, 2024, the Commission issued an *Order Addressing Arguments Raised on Rehearing And Setting Aside Prior Order, In Part* (Rehearing Order).[2] The Rehearing Order set aside the Authorization Order, in part, regarding the Commission's analysis of the cumulative air quality impacts specific to the projects' nitrogen dioxide (NO_2) and particles with an aerodynamic diameter of less than or equal to 2.5 microns ($PM_{2.5}$) emissions, for the purpose of conducting additional environmental review in light of an opinion issued by the U.S. Court of Appeals for the District of Columbia Circuit.[3] The Rehearing Order further stated that these issues and other air quality issues raised on rehearing by Petitioners will be addressed in a future order to be issued upon completion of an environmental review, as described below.

[1] *Venture Global CP2 LNG, LLC,* 187 FERC ¶ 61,199 (2024).

[2] *Venture Global CP2 LNG, LLC,* 189 FERC ¶ 61,148 (2024).

[3] *See Healthy Gulf* v. *FERC,* 107 F.4th 1033 (D.C. Cir. 2024).

Schedule for Environmental Review

This notice identifies the planned schedule for the completion of a supplemental environmental impact statement (SEIS) for the projects to address the issues related to the Commission's analysis of the cumulative air quality impacts specific to the projects' NO_2 and $PM_{2.5}$ emissions, as raised by Petitioners.[4]

This planned schedule is based on issuance of the draft SEIS in February 2025, opening a 45-day comment period.

Issuance of Notice of Availability of the final SEIS—May 9, 2025

This notice identifies the Commission's anticipated schedule for issuance of the final order for the projects, which serves as the Commission's record of decision. We currently anticipate issuing a final order for the projects no later than:

Issuance of Final Order—July 24, 2025

If a schedule change becomes necessary, additional notice will be provided.

Projects Description

The CP2 LNG Project includes a liquefaction plant with 20 million metric tons per annum (MTPA) of nameplate liquefaction capacity and a peak achievable capacity of 28 MTPA under optimal operating conditions consisting of eighteen liquefaction blocks, four aboveground full containment LNG storage tanks, and two marine LNG loading docks.

The CP Express Pipeline Project involves an approximately 85.4-mile-long mainline pipeline from Jasper County, Texas, to the LNG Project in Cameron Parish, Louisiana, an approximately 6.0-mile-long lateral pipeline in Calcasieu Parish, Louisiana, and associated aboveground facilities in Louisiana and Texas. The pipeline project is designed to transport feed gas to the CP2 LNG Project and will allow CP Express to provide up to 4,400,000 dekatherms per day of firm transportation service.

Background

On December 2, 2021, Venture Global CP2 LNG, LLC filed a request, in Docket No. CP22–21–000, under section 3 of the Natural Gas Act (NGA) and Part 153 of the Commission's regulations for authorization to site, construct, and operate the CP2 LNG Project, a new

[4] In accordance with the Council on Environmental Quality's regulations, the unique identification number for documents relating to this environmental review is SEIS–019–20–000–1732105621. 40 CFR 1501.5(c)(4) (2024).

liquefied natural gas (LNG) export terminal in Cameron Parish, Louisiana.

In the same application, Venture Global CP Express, LLC filed a request, in Docket No. CP22–22–000, under NGA section 7(c) and Parts 157 and 284 of the Commission's regulations, for a certificate of public convenience and necessity to construct and operate the CP Express Pipeline Project, a new interstate natural gas pipeline system to connect the CP2 LNG Project to the existing natural gas pipeline grid in east Texas and southwest Louisiana.

The Commission issued a *Notice of Availability of the Draft Environmental Impact Statement* on January 19, 2023. On July 28, 2023, the final EIS was issued. As noted above, on June 27, 2024, the Commission issued an Authorization Order for the projects, agreeing with the conclusions presented in the final EIS.

Additional Information

In order to receive notification of the issuance of the SEIS and to keep track of formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This service provides automatic notification of filings made to subscribed dockets, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Additional information about the projects is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (*www.ferc.gov*). Using the ''eLibrary'' link, select ''General Search'' from the eLibrary menu, enter the selected date range and ''Docket Number'' excluding the last three digits (*i.e.,* CP22–21 and CP22–22), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–28409 Filed 12–3–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2392–041]

Ampersand Gilman Hydro, LP; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2392–041.

c. *Date filed:* March 29, 2022.

d. *Applicant:* Ampersand Gilman Hydro, LP.

e. *Name of Project:* Gilman Hydroelectric Project.

f. *Location:* The project is located on the Connecticut River and straddles the Village of Gilman, within the Town of Lunenburg, Essex County, Vermont, and the Town of Dalton, Coos County, New Hampshire. The project does not occupy any Federal or Tribal lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mr. Sayad Moudachirou, Licensing Manager, 717 Atlantic Avenue, Suite 1A, Boston, MA 02111; phone: (617) 933–7206 or email: *sayad@ampersandenergy.com.*

i. *FERC Contact:* Ousmane Sidibe, (202) 502–6245 or *ousmane.sidibe@ferc.gov.*

j. *Deadline for filing comments, recommendations, terms and conditions, and prescriptions:* 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file comments, recommendations, terms and conditions, and prescriptions using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Gilman Hydroelectric Project (P–2392–041).

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted and is ready for environmental analysis at this time.

l. The Gilman Hydroelectric Project consists of: (1) a 324.5-foot-wide concrete dam with a crest elevation of 826.8 feet above mean sea level (msl) spanning the river's width with a 5-foot-high, 108-foot-long rubber bladder and a 6.5-foot-high, 109-foot-long rubber bladder surmounted on two overflow spillways measuring 112.9 feet and 113 feet in width and an 18-foot-high, 27-foot-wide hydraulically operated crestgate; (2) a downstream fish passage system; (3) a 130-acre impoundment at a normal maximum surface elevation of 833.3 feet msl; (4) a steel- and timber-framed powerhouse with an integral water intake draft tube containing four generating turbine units with a total installed capacity of 4.95 megawatts located at the Vermont side of the dam; (5) a 242-foot-long, 23.75-foot-wide trash rack with approximately 2-inch spacing; (6) a 200-foot-long transmission line connecting the 34.5 kilovolt-ampere transformer to National Grid's switchyard; and (7) appurtenant facilities.

Ampersand Gilman Hydro, LP proposes to continue to operate the project in a run-of-river mode with no storage or flood control capacity. In accordance with Condition A of the Vermont Department of Environmental Conservation's water quality

certification issued for the project, the project adheres to the following downstream minimum flow release requirements: (1) from June 1 through October 15, when river flows are less than 1,000 cubic feet per second (cfs), pass a minimum flow of 210 cfs over the crestgate; (2) provide a minimum flow of 757 cfs during operational issues or refilling of the impoundment; and (3) for faster impoundment refill based on consultation with the U.S. Fish and Wildlife Service and other agencies, a minimum flow of no less than 300 cfs to protect the dwarf wedge mussel until normal operations are restored. The project can operate in most of the extreme conditions of the Connecticut River and generate electricity from flows of 130 cfs up to high flood conditions of 35,000 cfs. The estimated average annual generation of the project from 2008 to 2018 is 25,000 megawatt-hours.

m. A copy of the application is available for review via the internet through the Commission's Home Page (*https://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll free, (886) 208–3676 or TTY (202) 502–8659.

All filings must (1) bear in all capital letters the title ''COMMENTS,'' ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members, and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. A license applicant must file no later than 60 days following the date of issuance of this notice: (1) a copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

o. Procedural schedule: The application will be processed according to the following schedule. Revisions to the schedule will be made as appropriate.

Deadline for Filing Comments, Recommendations, and Agency Terms and Conditions/Prescriptions ...	January 26, 2025.
Licensee's Reply to REA Comments	March 12, 2025.

Dated: November 27, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–28406 Filed 12–3–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Docket No. CP24–529–000]

Tennessee Gas Pipeline Company, L.L.C.; Notice of Schedule for the Preparation of an Environmental Assessment for the 507G Line Abandonment Project

On September 30, 2024, Tennessee Gas Pipeline Company, L.L.C. filed an application in Docket No. CP24–529–000 requesting an Authorization pursuant to Section 7(b) of the Natural Gas Act to abandon certain natural gas pipeline facilities. The proposed project is known as the 507G Line Abandonment Project (Project) and would consist of abandonment in-place and by removal of a portion of the 507G–100 Line and the 507G–500 Line.

On October 11, 2024, the Federal Energy Regulatory Commission (Commission or FERC) issued its *Notice of Application and Establishing Intervention Deadline* (Notice of Application) for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's environmental document for the Project.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the Project and the planned schedule for the completion of the environmental review.[1] The EA will be issued for a 30-day comment period.

[1] In accordance with the Council on Environmental Quality's regulations, the unique identification number for documents relating to this environmental review is EAXX–019–20–000–1731681706. 40 CFR 1501.5(c)(4) (2024).

Schedule for Environmental Review

Issuance of EA—April 25, 2025
90-day Federal Authorization Decision Deadline [2]—July 24, 2025

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

The Project would consist of abandonment in-place of approximately 59.6 miles and abandonment by removal at 56 locations, totaling 15.8 miles, of the 16-inch-diameter 507G–100 Line and disconnection and removal of appurtenant facilities at 44 locations. In addition, the Project would involve abandonment in-place of about 7.9 miles and abandonment by removal of

[2] The Commission's deadline applies to the decisions of other Federal agencies, and State agencies acting under federally delegated authority, that are responsible for Federal authorizations, permits, and other approvals necessary for proposed projects under the Natural Gas Act. Per 18 CFR 157.22(a), the Commission's deadline for other agency's decisions applies unless a schedule is otherwise established by Federal law.

about 1.1 miles of the 12-inch-diameter 507G–500 supply lateral pipeline and disconnection and removal of appurtenant facilities at 7 locations. Under Section 2.55(a) of the Commission's regulations, Tennessee intends to relocate an existing pigging facility.[3]

Background

On November 7, 2024, the Commission issued a *Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed 507G Line Abandonment Project* (Notice of Scoping). The Notice of Scoping was sent to affected landowners; Federal, State, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. The Commission received comments from the West St. Mary Port Harbor and Terminal District; Josephine Heinen Wetlands, LLC; and Don Caffery, representing M.A. Patout & Son Limited, L.L.C., Sterling Sugars, L.L.C., D.T. Caffery, L.L.C., and several property owners in their individual capacity, indicating a preference that pipeline segments on their property be abandoned by removal rather than in-place. In addition, the Commission received comments from Louisiana Department of Wildlife and Fisheries regarding burial depth and potential for exposures in navigable waterways, and the Louisiana Ecological Services Office providing instructions for their online screening tool for listed species. All substantive comments will be addressed in the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This service provides automatic notification of filings made to subscribed dockets, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (*www.ferc.gov*). Using the ''eLibrary'' link, select ''General Search'' from the eLibrary menu, enter the selected date range and ''Docket Number'' excluding the last three digits (*i.e.,* CP24–529), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: November 27, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–28408 Filed 12–3–24; 8:45 am]

BILLING CODE 6717–01–P

[3] A ''pig'' is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 7883–020]

Powerhouse Systems, LLC; Notice Soliciting Scoping Comments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* P–7883–020.

c. *Date Filed:* October 2, 2023.

d. *Applicant:* Powerhouse Systems, LLC (Powerhouse Systems).

e. *Names of Project:* Weston Dam Project.

f. *Location:* On the Upper Ammonoosuc River in Coos County, New Hampshire.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Antonio Zarrella, Relevate Power, LLC, 230 Park Avenue, Suite 307, New York, New York 10169; Phone at (315) 247–0253 or email at *tz@relevatepower.com;* or Rory Cohan, Relevate Power, LLC, 230 Park Avenue, Suite 307, New York, New York 10169; Phone at (845) 532–6894 or email at *rc@relevatepower.com.*

i. *FERC Contact:* Eric Fitzpatrick at (202) 502–8584; or email at *eric.fitzpatrick@ferc.gov.*

j. *Deadline for filing scoping comments:* December 27, 2024.

The Commission strongly encourages electronic filing. Please file scoping comments using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. All filings must clearly identify the following on the first page: Weston Dam Project No. 7883–020.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. The application is not ready for environmental analysis at this time.

l. *The existing Weston Dam Project consists of the following:* (1) a 220-foot-long, 15.5-foot-high concrete-covered stone and timber crib dam (Weston Dam) that consists of the following sections: (a) a 120-foot-long concrete cap spillway topped with 4.5-foot-high wooden flashboards with a crest elevation of 867.7 feet National Geodetic Vertical Datum of 1929 (NGVD 29) at the top of the flashboards; (b) a 60-foot-long right abutment section on the northwest side of the spillway with two slide gates; and (c) a 40-foot-long left abutment section on the southeast side of the spillway with a 20-foot-long, 15-foot-wide gatehouse and two slide gates.; (2) an impoundment with a surface area of 30 acres and a storage capacity of 115 acre-feet at an elevation of 867.7 feet NGVD 29; (3) a 10.83-foot-wide, 20-foot-high intake structure that includes a trashrack with 2-inch clear bar spacing; (4) a 36.5-foot-long, 36-foot-

wide powerhouse with two Kaplan turbine-generator units; (5) two 0.48 kilovolt (kV) generator leads; (6) three 0.48/34.5-kV transformers; and (7) a 34.5-kV, 300-foot-long transmission line. The Weston Dam Project has a total installed capacity of 540 kilowatts (kW). There are no project recreation facilities.

Pursuant to Article 20 of the current license Powerhouse Systems operates in an instantaneous run-of-river mode such that discharge from the project approximates the instantaneous sum of inflow to the project impoundment. The project has an average annual generation of 2,357 megawatt-hours.

Powerhouse Systems is not proposing any changes to project facilities or operation.

m. A copy of the application can be viewed on the Commission's website at *https://www.ferc.gov* using the ''eLibrary'' link. Enter the project's docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support.

You may also register at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov.*

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n. *Scoping Process*

Pursuant to the National Environmental Policy Act (NEPA), Commission staff intends to prepare either an environmental assessment (EA) or an environmental impact statement (EIS) (collectively referred to as the ''NEPA document'') that describes and evaluates the probable effects, including an assessment of the site-specific, if any, of the proposed action and alternatives. The Commission's scoping process will help determine the required level of analysis and satisfy the NEPA scoping requirements, irrespective of whether the Commission issues an EA or an EIS.

At this time, we do not anticipate holding on-site scoping meetings. Instead, we are soliciting written comments and suggestions on the preliminary list of issues and alternatives to be addressed in the NEPA document, as described in scoping document 1 (SD1), issued November 27, 2024.

Copies of the SD1 outlining the proposed project and subject areas to be addressed in the NEPA document were distributed to the parties on the Commission's mailing list and the applicant's distribution list. Copies of SD1 may be viewed on the web at *https://www.ferc.gov* using the ''eLibrary'' link (see item m above).

Dated: November 27, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–28405 Filed 12–3–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP25–220–000.
Applicants: UGI Mt. Bethel Pipeline Company, LLC.
Description: Annual Report of Operational Purchases and Sales of UGI Mt. Bethel Pipeline, LLC.
Filed Date: 11/26/24.
Accession Number: 20241126–5223.
Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–221–000.
Applicants: UGI Sunbury, LLC.
Description: Annual Report of Operational Purchases and Sales of UGI Sunbury, LLC.
Filed Date: 11/26/24.
Accession Number: 20241126–5224.
Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–222–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreements Update (Sempra Dec 2024) to be effective 12/1/2024.
Filed Date: 11/26/24.
Accession Number: 20241126–5246.
Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–223–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (Conoco Dec 2024) to be effective 12/1/2024.
Filed Date: 11/26/24.
Accession Number: 20241126–5250.
Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–224–000.
Applicants: Total Peaking Services, L.L.C.
Description: Tariff Amendment: Notice of Cancellation to be effective 12/1/2024.
Filed Date: 11/26/24.
Accession Number: 20241126–5278.
Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–225–000.
Applicants: Colorado Interstate Gas Company, L.L.C.
Description: § 4(d) Rate Filing: CIG Qrtly LUF True-up Nov 2024 to be effective 1/1/2025.
Filed Date: 11/26/24.
Accession Number: 20241126–5326.
Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–226–000.
Applicants: Gulf Shore Energy Partners, LP.
Description: § 4(d) Rate Filing: Gulf Shore Energy Partners LP Limited Section 4 Filing to be effective 12/1/2024.
Filed Date: 11/26/24.
Accession Number: 20241126–5327.
Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–227–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 11.27.24 Negotiated Rates—Emera Energy Services, Inc. R–2715–103 to be effective 12/1/2024.
Filed Date: 11/27/24.
Accession Number: 20241127–5032.
Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–228–000.
Applicants: Gas Transmission Northwest LLC.
Description: Compliance filing: Annual Fuel Charge Adjustment 2024 Report to be effective N/A.
Filed Date: 11/27/24.
Accession Number: 20241127–5052.
Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–229–000.
Applicants: Northern Natural Gas Company.
Description: § 4(d) Rate Filing: 20241127 Negotiated Rates Filing to be effective 12/1/2024.
Filed Date: 11/27/24.
Accession Number: 20241127–5068.
Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–230–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Annual Fuel and L&U Filing 2025 to be effective 1/1/2025.
Filed Date: 11/27/24.
Accession Number: 20241127–5072.

Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–231–000.

Applicants: Carlsbad Gateway, LLC.

Description: § 4(d) Rate Filing: Carlsbad Gateway Non-Conforming NRA and Tariff Housekeeping to be effective 1/1/2025.

Filed Date: 11/27/24.

Accession Number: 20241127–5078.

Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–232–000.

Applicants: Chandeleur Pipe Line, LLC.

Description: Compliance filing: Chandeleur Annual FLLA Filing to be effective 1/1/2025.

Filed Date: 11/27/24.

Accession Number: 20241127–5084.

Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–233–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 11.27.24 Negotiated Rates—Mercuria Energy America, LLC R–7540–02 to be effective 12/1/2024.

Filed Date: 11/27/24.

Accession Number: 20241127–5103.

Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–234–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 11.27.24 Negotiated Rates—Vitol Inc. R–7495–22 to be effective 12/1/2024.

Filed Date: 11/27/24.

Accession Number: 20241127–5108.

Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–235–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 11.27.24 Negotiated Rates—Vitol Inc. R–7495–23 to be effective 12/1/2024.

Filed Date: 11/27/24.

Accession Number: 20241127–5123.

Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: RP25–236–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 11.27.24 Negotiated Rates—Twin Eagle Resource Management, LLC R–7300–31 to be effective 11/1/2024.

Filed Date: 11/27/24.

Accession Number: 20241127–5135.

Comment Date: 5 p.m. ET 12/9/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *https://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: November 27, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–28411 Filed 12–3–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP19–502–000 and CP19–502–001]

Commonwealth LNG, LLC; Notice of Schedule for the Preparation of a Supplemental Environmental Impact Statement for the Commonwealth LNG Project

On November 17, 2022, the Federal Energy Regulatory Commission (Commission or FERC) issued its *Order Granting Authorization Under Section 3 of the Natural Gas Act* (Order) for Commonwealth LNG, LLC's Commonwealth LNG Project (Project).[1] On July 16, 2024, the U.S. Court of Appeals for the District of Columbia Circuit issued an opinion finding, as relevant here, that FERC failed to properly assess the cumulative effects of the Project's nitrogen dioxide (NO_2) emissions, and remanded the Order to FERC for further proceedings.[2]

Schedule for Environmental Review

This notice identifies the planned schedule for completion of a supplemental environmental impact statement (SEIS) for the Project to address the issues related to the Commission's analysis of NO_2.[3]

This planned schedule is based on an issuance of the draft SEIS in February 2025, opening a 45-day comment period.

Issuance of Notice of Availability of the final SEIS May 16, 2025

This notice identifies the Commission's anticipated schedule for issuance of the final order for the Project, which serves as the Commission's record of decision. We currently anticipate issuing a final order for the Project no later than:

Issuance of Final Order July 24, 2025

If a schedule change becomes necessary, additional notice will be provided.

Project Description

The Project consists of two main components: (1) construction and operation of the LNG export terminal, which includes six liquefied natural gas (LNG) plant facilities to liquefy natural gas, six tanks to store the LNG, an LNG carrier loading/berthing facility (marine facility), and other appurtenant facilities; and (2) construction and operation of approximately 3.0 miles of 42-inch-diameter pipeline and one new meter station to deliver natural gas to the terminal. The Project would produce 8.4 million metric tonnes per annum of LNG for export on an average of 156 LNG carriers per year.

Background

On August 20, 2019, as amended July 8, 2021, Commonwealth LNG, LLC filed an application in Docket No. CP19–502–000 requesting authorization pursuant to section 3 of the Natural Gas Act (NGA) and Part 153 of the Commission's regulations to construct and operate a natural gas liquefaction and export facility, including an NGA section 3 natural gas pipeline, in Cameron Parish, Louisiana.

The Commission issued a *Notice of Availability of the Draft Environmental Impact Statement* on March 31, 2022. On September 9, 2022, the final EIS was issued. As noted above, on November 17, 2022, the Commission issued an order granting authorization for the

[1] *Commonwealth LNG, LLC,* 181 FERC ¶ 61,143 (2022), *order on reh'g,* 183 FERC ¶ 61,173 (2023).

[2] *Healthy Gulf* v. *FERC,* 107 F.4th 1033 (D.C. Cir. 2024).

[3] In accordance with the Council on Environmental Quality's regulations, the unique identification number for documents relating to this environmental review is SEIS–019–20–000–1732105648. 40 CFR 1501.5(c)(4) (2024).

Project and agreeing with the conclusions presented in the final EIS.

Additional Information

In order to receive notification of the issuance of the SEIS and to keep track of formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This service provides automatic notification of filings made to subscribed dockets, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (*www.ferc.gov*). Using the ''eLibrary'' link, select ''General Search'' from the eLibrary menu, enter the selected date range and ''Docket Number'' excluding the last three digits (*i.e.,* CP19–502), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

Dated: November 27, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–28410 Filed 12–3–24; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–12411–01–OW]

National Drinking Water Advisory Council; Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of a public meeting.

SUMMARY: The U.S. Environmental Protection Agency's Office of Ground Water and Drinking Water is announcing a meeting of the National Drinking Water Advisory Council (NDWAC or Council) as authorized under the *Safe Drinking Water Act.* The purpose of the meeting is for the EPA to consult with the NDWAC as required by the *Safe Drinking Water Act* on a proposed National Primary Drinking Water Regulation for perchlorate. Additional details will be provided in the meeting agenda, which will be posted on the EPA's NDWAC website prior to the meeting. See the **SUPPLEMENTARY INFORMATION** section of this announcement for more information.

DATES: The meeting will be held on January 9, 2025, from 11:30 a.m. to 4:15 p.m., Eastern time.

ADDRESSES: This will be a virtual meeting. There will be no in-person gathering for this meeting. For more information about attending, providing oral statements, and accessibility for the meeting, as well as sending written comments, see the **SUPPLEMENTARY INFORMATION** section of this announcement.

FOR FURTHER INFORMATION CONTACT: Tracey Ward, NDWAC Designated Federal Officer, Office of Ground Water and Drinking Water (Mail Code 4601), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 564–3796; email address: *ward.tracey@epa.gov.*

SUPPLEMENTARY INFORMATION:

Attending the Meeting: The meeting will be open to the general public. The meeting agenda and information on how to register for and attend the meeting online will be provided on EPA's website at: *https://www.epa.gov/ndwac* prior to the meeting.

Oral Statements: The EPA will allocate one hour for the public to present oral comments during the meeting. Oral statements will be limited to three minutes per person during the public comment period. It is preferred that only one person present a statement on behalf of a group or organization. Persons interested in presenting an oral statement should send an email to Tracey Ward at *ward.tracey@epa.gov* by noon, eastern time, on January 2, 2025.

Written Statements: Any person who wishes to file a written statement can do so before or after the Council meeting. Send written statements by email to *ward.tracey@epa.gov* or see the **FOR FURTHER INFORMATION CONTACT** section if sending statements by mail. Written statements received by noon, Eastern time, on January 2, 2025, will be distributed to all members of the Council prior to the meeting. Statements received after that time will become part of the permanent file for the meeting and will be forwarded to the Council members after conclusion of the meeting. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the NDWAC website. Copyrighted material will not be posted without the explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, or to request accommodations for a disability, please contact Tracey Ward by email at *ward.tracey@epa.gov,* or by phone at (202) 564–3796, preferably at least 10 days prior to the meeting to allow as much time as possible to process your request.

National Drinking Water Advisory Council: The NDWAC was created by Congress on December 16, 1974, as part of the *Safe Drinking Water Act* of 1974, Public Law 93–523, 42 U.S.C. 300j–5, and is operated in accordance with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. 10. The NDWAC was established to advise, consult with, and make recommendations to the EPA Administrator on matters relating to activities, functions, policies, and regulations under the *Safe Drinking Water Act.* General information concerning the NDWAC is available at: *https://www.epa.gov/ndwac.*

Jennifer L. McLain,

Director, Office of Ground Water and Drinking Water.

[FR Doc. 2024–28360 Filed 12–3–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX; FR ID 265489]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection.

Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before January 3, 2025.

ADDRESSES: Comments should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the web page *https://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–XXXX.

Title: Application to Participate in a 5G Fund Auction, FCC Form 184.

Form Number: FCC Form 184.

Type of Review: New collection.

Respondents: Business or other for-profit entities, not-for-profit institutions, and State, local or Tribal governments.

Number of Respondents and Responses: 300 respondents and 300 responses.

Estimated Time per Response: 7 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is 47 U.S.C. 154, 254 and 303(r).

Total Annual Burden: 2,100 hours.

Total Annual Cost: No cost.

Needs and Uses: The Commission will use the information collected under this information collection to determine whether applicants are qualified to participate in a 5G Fund auction.

In its November 2011 USF/ICC Transformation Order, the Commission took numerous steps to comprehensively reform and modernize the universal service program to ensure that robust, affordable fixed and mobile voice and broadband service are available to those in rural, insular, and high cost areas of the country. Connect America Fund et al., Order and Further Notice of Proposed Rulemaking, FCC 11–161 (USF/ICC Transformation Order). Among other things, the Commission (1) established a two-phased Mobility Fund to award universal service support for mobile services in a cost-effective manner to no more than one provider per area in areas where a private-sector business case was lacking, (2) directed that universal service support under the Mobility Fund be awarded by competitive bidding, (3) adopted the rules and framework for Mobility Fund Phase I, and (4) sought comment on the rules and proposed framework for Mobility Fund Phase II. In its February 2017 Mobility Fund Phase II Report and Order, the Commission adopted the rules and framework for Mobility Fund Phase II to provide ongoing universal service support over a ten-year term to areas of the country unlikely to receive 4G LTE service absent subsidies, along with the framework for a challenge process to resolve disputes about areas that were found to be presumptively ineligible for support. Connect America Fund; Universal Service Reform—Mobility Fund II, Report and Order and Further Notice of Proposed Rulemaking, FCC 17–11. However, in its October 2020 5G Fund Report and Order, the Commission established the 5G Fund as a replacement for Mobility Fund Phase II, and adopted the framework and rules for the 5G Fund to award universal service support in two phases through separate reverse auctions to ensure the deployment of high-speed, 5G mobile service in areas unlikely to see such service absent subsidies. Establishing a 5G Fund for Rural America, Report and Order, FCC 20–150 (5G Fund Report and Order). In the 5G Fund Report and Order, the Commission, among other things, adopted a two-stage application process for 5G Fund auctions consisting of pre-auction requirements for applicants seeking to participate in a 5G Fund auction and post-auction requirements for winning bidders applying for 5G Fund support. The Commission decided that applicants seeking to participate in a 5G Fund auction would be required to provide both the information required by section 1.21001(b) of the Commission's existing Part 1, Subpart AA universal service competitive bidding rules, 47 CFR 1.21001(b), and the additional application disclosures and certifications specific to the 5G Fund required by § 54.1014(a) of the Commission's rules, 47 CFR 54.1014(a). In its recent 5G Fund Second Report and Order (FCC 24–89), the Commission adopted an additional requirement that each applicant seeking to participate in the 5G Fund Phase I auction certify in its application that it has read the public notice adopting procedures for the auction and that it has familiarized itself both with the auction procedures and with the requirements, terms, and conditions associated with the receipt of 5G Fund support.

Under this new information collection, the Commission will collect the information, disclosures, and certifications required by §§ 1.21001(b) and 54.1014(a) of the Commission's rules from each applicant seeking to participate in a 5G Fund auction, and will use the information, disclosures, and certifications to determine whether an applicant is legally, technically, and financially qualified to participate in a 5G Fund auction. To aid in collecting this information, the Commission has created FCC Form 184, which will be used to provide the information, disclosures, and certifications required by §§ 1.21001(b) and 54.1014(a). Commission staff will review the information, disclosures, and certifications collected on FCC Form 184 as part of the pre-auction process, prior to the start of the auction, and determine whether each applicant satisfies the Commission's requirements to participate in an auction for 5G Fund support. Without the information collected on FCC Form 184, the Commission will not be able to determine if an applicant is legally qualified to participate in a 5G Fund auction and has complied with the various applicable regulatory and statutory auction requirements for such participation. This approach provides an appropriate screen to ensure serious participation without being unduly burdensome.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–28385 Filed 12–3–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0856; FR ID 265502]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written PRA comments should be submitted on or before February 3, 2025. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION: The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

OMB Control Number: 3060–0856.

Title: Universal Service—Schools and Libraries Universal Service Support Program Reimbursement Forms.

Form Numbers: FCC Forms 472, 473, and 474.

Type of Review: Revision of a currently approved collection.

Respondents: Businesses or other for-profit institutions, Not-for-profit institutions, and State, Local or Tribal government.

Number of Respondents and Responses: 27,953 respondents; 133,214 responses.

Estimated Time per Response: Form 472—1.5 hours; Form 473—2 hours; Form 474—1.5 hours, and 0.5 hours for recordkeeping requirements.

Frequency of Response: On occasion and annual reporting requirements, recordkeeping and third-party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. The Commission's statutory authority to collect this information is contained in sections 1, 4(i), 4(j), 201–205, 214, 254, 312(d), 312(f), 403 and 503(b) of the Communications Act of 1934, as amended. 5 U.S.C. 553(b)(3), 601–612; 15 U.S.C. 1, 632; 44 U.S.C. 3506(c)(4); 47 U.S.C. 1, 4(i), 4(j), 201–205, 214, 254, 312(d), 312(f), 403, 503(b).

Total Annual Burden: 195,615 hours.

Total Annual Cost: No cost.

Needs and Uses: The Commission will submit this information collection to the Office of Management and Budget (OMB), which is a revision of a currently approved collection, to obtain a full three-year clearance from OMB. The requirements contained herein are necessary to implement the Congressional mandate for universal service. It provides the Commission and USAC with the necessary information to administer the E-Rate program, determine the amount of support entities seeking funding are eligible to receive, to determine if entities are complying with the Commission's rules, and to prevent waste, fraud, and abuse. The information will also allow the Commission to evaluate the extent to which the E-Rate program is meeting the statutory objectives specified in section 254 of the 1996 Act, the Commission's performance goals established in the *2014 First and Second E-Rate Orders,* and to evaluate the need and feasibility for any future revisions to program rules.

FCC Forms 472, 473, and 474 were revised. On July 29, 2024 the Commission released a Report and Order and Further Notice of Proposed Rulemaking (WC Docket No. 21–31, FCC 24–76) (*Report and Order*); finding that the off-premises use of wireless internet services and the Wi-Fi hotspot devices needed to deliver the services; serves an educational purpose and are eligible for E-Rate support. The *Report and Order,* 89 FR 67303, August 20, 2024, adds certifications to the FCC Form 473 for participating service providers on the hotspots non-usage notice and termination requirement, prohibition against charging the balance for terminated services, and certifying that the cost of Wi-Fi hotspots do not exceed commercial value. The *Report and Order* also adds a certification to FCC Forms 472 and 474 to certify that there is no duplicative funding and funding is not being requested for eligible equipment and services that have been funded by other sources. The hourly burden will increase by 50,865 hours for FCC Forms 472, 473, and 474. The public burden for the collection contained herein will increase to 195,615 burden hours.

FCC Form 472 ''*Billed Entity Applicant Reimbursement Form.*'' Billed

entities may pay the full amount for eligible services directly to the service providers and then, once services have been received, seek reimbursement from USAC to cover the amounts of the discounts for which they have qualified. The FCC Form 472 is used by the billed entity to request such reimbursement from USAC. USAC disburses payments directly to the billed entity to cover services that have been properly invoiced. The information on FCC Form 472 enables this direct reimbursement process. This information includes the amount paid for approved services delivered on or after the actual services start date, as reported on the FCC Form 486 (approved under OMB Control No. 3060–0853).

FCC Form 473 ''Service Provider Annual Certification Form.'' The FCC Form 473 must be filed by service providers to attest that the invoices submitted under the E-Rate program comply with the FCC's rules. The service provider must annually submit an FCC Form 473 for each service provider identification number (SPIN).

FCC Form 474 ''Service Provider Invoice (SPI) FCC Form 474.'' As an alternative to paying in full for eligible services, the billed entity can pay only the amounts for eligible services that have been discounted already by the service provider. Under this alternative, once services have been received, service providers seek payment from USAC to cover the amounts of the discounts for which the billed entity qualifies. Service providers use the FCC Form 474 to request direct payment for invoices submitted for services that comply with the rules of the E-Rate program. The information on the FCC Form 474 must be received by USAC before a participating service provider can receive payment for the discounted portion of its bill for eligible services to eligible entities. Subsequent to receipt and review of the FCC Form 474, USAC will authorize payment based on the invoices.

All of the requirements contained in this information collection are necessary to implement the Congressional mandate for the E-Rate program and reimbursement process.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–28383 Filed 12–3–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1228; FR ID 265194]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.'' The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before January 3, 2025.

ADDRESSES: Comments should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the web page *https://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–1228.

Title: Connect America Fund—High Cost Portal Filing.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions.

Number of Respondents and Responses: 2,015 unique respondents; 4,590 responses.

Estimated Time per Response: 8 hours–60 hours.

Frequency of Response: On occasion, quarterly reporting requirements, annual reporting requirements, and recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151–154, 155, 201–206, 214, 218–220, 251, 252, 254,

256, 303(r), 332, 403, 405, 410, and 1302.

Total Annual Burden: 86,263 hours.

Total Annual Cost: No Cost.

Needs and Uses: Through several orders, the Federal Communications Commission (the Commission) has recently changed or modified reporting obligations for high-cost support. Pursuant to the following orders, this collection includes location reporting and related certification requirements of high-cost support recipients: *Connect America Fund et al.,* Report and Order, Order and Order on Reconsideration, and Further Notice of Proposed Rulemaking, 31 FCC Rcd 3087 (2016) (*2016 Rate-of-Return Order*); *Connect America Fund et al.,* Report and Order and Further Notice of Proposed Rulemaking, 31 FCC Rcd 5949 (2016) (*Phase II Auction Order*); *Connect America Fund et al.,* Order, 31 FCC Rcd 12086 (2016) (*ACS Phase II Order*); Connect America Fund et al., Report and Order and Notice of Proposed Rulemaking, 29 FCC Rcd 876 (2014) (*Rural Broadband Experiments Order*); *Connect America Fund et al.,* Report and Order, 29 FCC Rcd 15644 (2014) (*Price Cap Order*); *Technology Transitions et al.,* Order *et al.,* 29 FCC Rcd 1433 (2014) (*Tech Transitions Order*); *Connect America Fund et al.,* Report and Order and Further Notice of Proposed Rulemaking, 31 FCC Rcd 10139 (2016) (*Alaska Plan Order*); *Connect America Fund et al.,* Order, 32 FCC Rcd 968 (2017) (*New York Auction Order*); *Connect America Fund et al.,* Report and Order, Further Notice of Proposed Rulemaking, and Order on Reconsideration, 33 FCC Rcd 11–893 (2018) (*2018 Rate-of-Return Order*); *The Uniendo a Puerto Rico and the Connect USVI Fund et al.,* Report and Order and Order on Reconsideration, 34 FCC Rcd 9109 (2019) (*PR–USVI Stage 2 Order*); *Rural Digital Opportunity Fund et al.,* Report and Order, 35 FCC Rcd 686 (2020) (*2020 Rural Digital Opportunity Fund Order*); *Enhanced A–CAM Report and Order,* FCC 23–60; *Connect America Fund et al.,* WC Docket No. 10–90 et al. WT Docket No. 10–208, Notice of Proposed Rulemaking and Report and Order, FCC 23–87 (Oct. 20, 2023) (*Administrative Order*).

This information collection addresses the requirement that certain carriers with high-cost reporting obligations file information about the locations to which they have deployed broadband service meeting applicable public interest requirements (location information). The HUBB, a web-based portal, is used to accept this information. The Commission and the Universal Service Administrative Company (USAC) will use this information to monitor the deployment progress of reporting carriers, to verify the reporting carriers' claims of service at the reported locations, and to conform broadband deployment data between the HUBB and BDC. Such activities help the Commission ensure that support is being used as intended. In addition, because data filed in the HUBB is publicly accessible, the reporting helps ensure public accountability and transparency.

This information collection further addresses the Commission's efforts to develop and establish a uniform national dataset of locations where broadband could be deployed and upon which new coverage data could be overlaid using a single methodology to harmonize fixed broadband reporting nationwide with granular location data as part of the BDC and required by the Broadband Deployment Accuracy and Technology Availability Act, Public Law 116–130, 134 Stat. 228 (2020) (Broadband DATA Act). In furtherance of its obligations, the Commission established the Broadband Serviceable Location Fabric (Fabric), which consists of a single, nationwide fabric that will contain geocoded information for all locations where a broadband connection can be installed in the United States and territories (Broadband Serviceable Location or BSL). Each BSL contained in the Fabric is provided a unique identification number. The HUBB portal will be updated in order to have support recipients include the unique Fabric identification number when reporting or revising high-cost broadband deployment location data. Including the BSL Fabric Identification Number in HUBB reporting will improve the accuracy and reliability of the broadband data used to monitor progress and ensure accountability with Commission programs. All BSL Fabric Identification Numbers are associated with the latitude, longitude, address, and number of units at the location. Accordingly, reporting the BSL Fabric Identification Number associated with a location encompasses the latitude, longitude, address, and number of units at the location.

This information collection addresses the location reporting and related certification requirements of high-cost support recipients electing to receive support through the Enhanced A–CAM program, *see generally Enhanced A–CAM Order,* and other programs. On October 30, 2023, the Wireline Competition Bureau (WCB) authorized 368 rate-or-return carriers to receive Enhanced A–CAM support in various states. Of this number, 100 electing carriers had been receiving cost-based CAF BLS support in 118 unique study areas, and 216 electing carriers had been receiving model-based support (A–CAM). The interim and final deployment milestones required for the Enhanced A–CAM program will supersede the existing interim and final deployment milestones for the carriers participating in eligible programs. However, Enhanced A–CAM carriers were required to still report in the HUBB their deployments for calendar year 2023 prior to the start of the support term for Enhanced A–CAM program (January 1, 2024) to ensure carriers continue in good faith to deploy broadband pursuant to existing commitments.

Carriers receiving high-cost support to serve locations are subject to specific public interest obligations related to speed, usage, latency, and price as well as certain deployment milestones. Specifically, the Commission imposed defined deployment obligations and associated HUBB reporting requirements (annual location reporting and build-out certifications) for all fixed support recipients as well as annual reporting and certification requirements for Uniendo a Puerto Rico Fund and Connect USVI Fund Stage 2 mobile support recipients.

We therefore propose to revise this information collection. Finally, we propose to modify the burdens associated with existing and new reporting requirements to account for additional carriers that will be subject to these requirements.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–28386 Filed 12–3–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0466; FR ID 265496]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this

opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written comments should be submitted on or before February 3, 2025. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

As part of its continuing effort to reduce paperwork burdens, and as required by the PRA of 1995 (44 U.S.C. 3501–3520), the FCC invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control Number: 3060–0466.

Title: Sections 74.783, 73.1201 and 74.1283, Station Identification.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not for-profit institutions; State, Local or Tribal Government.

Number of Respondents and Responses: 28,246 respondents; 28,246 responses.

Estimated Time per Response: 0.166–1 hour.

Frequency of Response: On occasion reporting requirement; Recordkeeping requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or maintain benefits. The statutory authority for this collection of information is contained in 47 U.S.C. 151, 152, 154(i), 303, 307 and 308.

Total Annual Burden: 26,735 hours.

Total Annual Costs: None.

Needs and Uses: The information collection requirements for this collection are as following: 47 CFR 73.1201(a) requires television broadcast licensees to make broadcast station identification announcements at the beginning and ending of each time of operation, and hourly, as close to the hour as feasible, at a natural break in program offerings. Television and Class A television broadcast stations may make these announcements visually or aurally.

47 CFR 74.783(b) requires licensees of television translators whose station identification is made by the television station whose signals are being rebroadcast by the translator, must secure agreement with this television station licensee to keep in its file, and available to FCC personnel, the translator's call letters and location, giving the name, address and telephone number of the licensee or his service representative to be contacted in the event of malfunction of the translator. It shall be the responsibility of the translator licensee to furnish current information to the television station licensee for this purpose.

47 CFR 73.1201(b)(1) requires that the official station identification consist of the station's call letters immediately followed by the community or communities specified in its license as the station's location. The name of the licensee, the station's frequency, the station's channel number, as stated on the station's license, and/or the station's network affiliation may be inserted between the call letters and station location. Digital Television (DTV) stations, or DAB Stations, choosing to include the station's channel number in the station identification must use the station's major channel number and may distinguish multicast program streams. For example, a DTV station with major channel number 26 may use 26.1 to identify a High Definition Television (HDTV) program service and 26.2 to identify a Standard Definition Television (SDTV) program service. A radio station operating in DAB hybrid mode or extended hybrid mode shall identify its digital signal, including any free multicast audio programming streams, in a manner that appropriately alerts its audience to the fact that it is listening to a digital audio broadcast. No other insertion between the station's call letters and the community or communities specified in its license is permissible. A station may include in its official station identification the name of any additional community or communities, but the community to which the station is licensed must be named first.

Regulations at 47 CFR 74.791(c) permit low power TV permittees or licensees to request to be assigned four-letter call signs in lieu of the five-character alpha-numeric call signs.

Regulations at 47 CFR 74.1283(c)(1) require a FM translator station licensee whose identification is made by the primary station must arrange for the primary station licensee to furnish the translator's call letters and location (name, address, and telephone number of the licensee or service representative) to the FCC. The licensee must keep this information in the primary station's files.

On April 17, 2023, the Commission released a Report and Order, Amendment of parts 73 and 74 of the Commission's Rules to Establish Rules for Digital Low Power Television and Television Translator Stations, FCC 23–25. With the advent of digital television operation, there were a number of duplicative rules for both analog and digital television operations. Sections 74.783(e) and 74.791(c) are such rules. Section 74.783(e) referred to analog operations whereas 74.791(c) referred to digital operations. Since all television operations are now required to be digital and the rule sections are duplicative, the analog referenced rule, 74.783(e) has been deleted and replaced with Section 74.791(c), *See* FCC 23–25 for the actions described herein.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–28387 Filed 12–3–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0853; FR ID 265528]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written PRA comments should be submitted on or before February 3, 2025. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION: The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

OMB Control Number: 3060–0853.

Title: Certification by Administrative Authority to Billed Entity Compliance with the Children's internet Protection Act Form, FCC Form 479; Receipt of Service Confirmation and Certification of Compliance with the Children's internet Protection Act Form, FCC Form 486; and Funding Commitment and Adjustment Request Form, FCC Form 500.

Form Numbers: FCC Forms 479, 486 and 500.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents and Responses: 84,010 respondents, 94,203 responses.

Estimated Time per Response: 1 hour for FCC Form 479, 1 hour for FCC Form 486, 1 hour for FCC Form 500, 0.75 hours for maintaining and updating the Internet Safety Policy, and 0.50 hours for recordkeeping requirements.

Frequency of Response: On occasion and annual reporting requirements and recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154(i), 155, 201, 205, 214, 219, 220, 254, 303(r), 403, and 1302.

Total Annual Burden: 78,319 hours.

Total Annual Cost: No cost.

Needs and Uses: The Commission will submit this information collection to the Office of Management and Budget (OMB), which is a revision of a currently approved collection, to obtain a full three-year clearance from OMB. The requirements contained herein are necessary to implement the Congressional mandate for universal service. It provides the Commission and USAC with the necessary information to administer the E-Rate program, determine the amount of support entities seeking funding are eligible to receive, to determine if entities are complying with the Commission's rules, and to prevent waste, fraud, and abuse. The information will also allow the Commission to evaluate the extent to which the E-Rate program is meeting the statutory objectives specified in section 254 of the 1996 Act, the Commission's performance goals established in the *2014 First and Second E-Rate Orders,* and to evaluate the need and feasibility for any future revisions to program rules.

FCC Form 486 was revised. On July 29, 2024 the Commission released a Report and Order and Further Notice of Proposed Rulemaking (WC Docket No. 21–31, FCC 24–76) (*Report and Order*); finding that the off-premises use of wireless internet services and the Wi-Fi hotspot devices needed to deliver the services; serves an educational purpose and are eligible for E-Rate support. The *Report and Order,* 89 FR 67303, August 20, 2024, adds certifications to the FCC Form 486. Applicants that receive support for Wi-Fi hotspots and service for off-premises use uses the FCC Form 486 to certify that they have updated and publicly posted their ''acceptable use policy (AUP)'' consistent with the requirements in 47 CFR 54.516(f); the Wi-Fi hotspots and/or services the school, library, or consortium purchased using E-Rate support for off-premises use have been activated and made available to students, school staff, and/or library patrons; public notice of their availability has been provided; and the authorized person is not requesting reimbursement for Wi-Fi hotspots and/or services that have not been made available for distribution.

The hourly burden will increase by 10,044 hours for FCC Forms 479, 486, and 500. The public burden for the collection contained herein will increase to 78,319 burden hours.

FCC Form 486 ''Receipt of Service Confirmation and Certification of Compliance with the Children's Internet Protection Act.'' After the Administrator reviews the funding request and commits to fund the eligible equipment and/or services requested, applicants use the FCC Form 486 to notify USAC of their service start dates for their funding requests. Universal service support will not be paid on an approved funding commitment prior to receipt of the FCC Form 486.

Billed entities also use the FCC Form 486 to certify compliance with the Children's internet Protection Act (CIPA), *see* 47 U.S.C. 254 (h)–(l), or qualification for a CIPA exemption when they seek discounts for category one services (*i.e.,* internet access) and category two services (*i.e.,* internal connections, managed internal broadband services, or basic maintenance of internal connections). When the billed entities are members of a larger consortia, they individually certify CIPA compliance by submitting the FCC Form 479 ''Certification by Administrative Authority to Billed Entity of Compliance with Children's internet Protection Act'' to the consortium leader. The consortium leader can then file the FCC Form 486 certifying CIPA compliance on behalf of

the consortia. CIPA requires schools and libraries that have computers with internet access to certify that they have in place certain internet safety policies and technology protection measures to be eligible to receive program services under section 254(h) of the Act. *See also* 47 CFR 54.520. The FCC Form 486 is also a necessary prerequisite for invoicing and payment.

FCC Form 500 ''Funding Commitment Adjustment Request.'' The FCC Form 500 is used by E-Rate participants to make adjustments to previously filed forms, such as changing the contract expiration date noted on the FCC Form 471, changing the funding year service start date listed on the FCC Form 486, cancelling or reducing the amount of a funding request, and extending the service delivery deadline for non-recurring services.

All of the requirements contained in this information collection are necessary to implement the Congressional mandate for the E-Rate program and reimbursement process.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–28384 Filed 12–3–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreement to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. A copy of the agreement is available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 201436.

Title: MSC/Zim Cooperative Working Agreement.

Parties: Mediterranean Shipping Company S.A. and Zim Integrated Shipping Services Ltd.

Filing Party: Wayne Rohde; Cozen O'Connor; 2001 M Street NW, Suite 500; Washington, DC 20036.

Synopsis: The Agreement authorizes the Parties to operate jointly a string of vessels between Asia and the U.S. Atlantic and Gulf Coasts and to exchange space on five (5) other services operated individually by one Party or the other. The geographic scope of the Agreement is the trade between ports on the U.S. Atlantic and Gulf Coasts on the one hand and ports in Singapore, Thailand, China, Vietnam, South Korea, Panama, Colombia, Mexico, Jamaica and the Bahamas on the other hand. The Agreement would replace FMC Agreement No. 201263 when that agreement is terminated following the end of the Maersk/MSC Vessel Sharing Agreement (2M Alliance) in early 2025.

Proposed Effective Date: January 9, 2025.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/86581.

Dated: November 29, 2024.

Alanna Beck,

Federal Register Alternate Liaison Officer.

[FR Doc. 2024–28381 Filed 12–3–24; 8:45 am]

BILLING CODE 6730–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Privacy Act of 1974; System of Records

AGENCY: Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS) is establishing a new system of records to be maintained by the Office of Refugee Resettlement (ORR) within HHS' Administration for Children and Families (ACF), System No. 09–80–0323, ORR Unaccompanied Children Bureau (UCB) Child Abuse or Neglect Investigation Records and Central Registry.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this system of records is effective December 4, 2024 to a 30-day period in which to comment on the routine uses, described below. Please submit any comments by January 3, 2025.

ADDRESSES: The public should address written comments on the system of records notice to Hanan Abu Lebdeh, Senior Agency Officer for Privacy, by mail at Administration for Children and Families, Mary E. Switzer Building, 330 C Street SW, Washington, DC 20201, or by email at *hanan.abulebdeh@acf.hhs.gov*.

FOR FURTHER INFORMATION CONTACT: General questions about the system of records may be submitted to Edward Nazarko, Technical Lead for UC Technology, Administration for Children and Families, by mail or email at 330 C Street SW, Washington, DC 20201, or *edward.nazarko@acf.hhs.gov*, or by telephone at (202) 839–0615.

SUPPLEMENTARY INFORMATION:

I. Background on ORR Responsibilities, Affecting New SORN 09–80–0323

Within ORR, the Unaccompanied Children Bureau (UCB) administers ORR's responsibilities for the placement, care, and services provided to unaccompanied children who are in Federal custody by reason of their immigration status. Such responsibilities are carried out pursuant to ORR's statutory and delegated authorities under section 462 of the Homeland Security Act of 2002 (HSA), 6 U.S.C. 279, section 235 of the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA), 8 U.S.C. 1232, and regulations at 45 CFR parts 410 and 411. Systems of records maintained by ORR are ''mixed,'' in that they contain, or could contain, records pertaining to both (1) individuals who are covered by the Privacy Act and (2) individuals who are not covered by the Privacy Act. SORN 09–80–0323 includes a statement to this effect in the ''Categories of Individuals'' section.

The Privacy Act applies only to individuals who are U.S. citizens or non-U.S. citizens lawfully admitted for permanent residence in the United States. As a matter of discretion, ORR treats information maintained in its mixed systems of records as being subject to the protections of the Privacy Act, regardless of whether the information relates to individuals covered by the Privacy Act. This policy implements a 1975 Office of Management and Budget (OMB) recommendation to apply, as a matter of discretion, the administrative provisions of the Privacy Act to records about individuals who aren't covered by the Privacy Act when the records are maintained in mixed systems of records (referred to as the non-U.S. persons policy). *See OMB Privacy Act Implementation: Guidelines and*

Responsibilities, 40 FR 28948, 28951 (July 9, 1975).

The Privacy Act defines a ''routine use'' with respect to the disclosure of a record to mean ''the use of such record for a purpose which is compatible with the purpose for which it was collected.'' 5 U.S.C. 552a(a)(7). Because ORR is not an immigration enforcement agency—but rather is responsible for placing unaccompanied children with vetted and approved sponsors, providing care and services to unaccompanied children who are in Federal custody by reason of their immigration status, and identifying and assessing the suitability of a potential sponsor for each child—it is incompatible with ORR's program purposes to share information in a system of records, particularly confidential mental health or behavioral information in children's case files, for immigration enforcement purposes. *See* H.R. Rep No. 116–450, at 185 (2020) (directing ORR to ''refrain from sharing any information with immigration courts for master calendar hearings, where the court is not making any decisions about the child's custody,'' and to ''develop policies and protocols to ensure the confidentiality of counseling and mental health services provided to unaccompanied children, and of all related documentation, including case notes and records of therapists and other clinicians, and to incorporate these policies into the ORR policy guide . . .''); *see also id.* at 230 (noting the inclusion in that year's appropriations a provision ''prohibiting the use of funds to share information provided by unaccompanied children during mental health or therapeutic services with the Department of Homeland Security or the Department of Justice for the purposes of immigration enforcement.'').[1] Accordingly, SORN 09–80–0323 mentions at the start of the ''Routine Uses'' section that disclosures for immigration enforcement purposes will not be made under routine uses, but would be made only with the subject individual's prior, written consent.

ORR may share relevant information in system of records 09–80–0323 for other law enforcement purposes, such as anti-trafficking investigations, child welfare investigations, or other investigations that seek to ensure that children are ''protected from traffickers and other persons seeking to victimize or otherwise engage such children in criminal, harmful, or exploitative activity.'' 8 U.S.C. 1232(c)(1). Accordingly, SORN 09–80–0323 includes routine uses authorizing disclosures for such law enforcement purposes.

II. Purpose for Establishing New System of Records 09–80–0323, ORR Unaccompanied Children Bureau (UCB) Child Abuse or Neglect Investigation Records and Central Registry

The purpose for establishing new system of records 09–80–0323 is to cover any Privacy Act records ORR maintains related to reports and investigations of child abuse and neglect allegations at ORR care provider facilities located in States that will not investigate such reports, as well as at ORR Emergency or Influx Facilities. Such records are also used to maintain a Central Registry of ORR care provider facility staff, contractors or sub-grantees, volunteers, or other individuals who have access to children in ORR care through contracts or grants with ORR, who are determined by ORR, pursuant to ORR regulations and policies, to have a sustained allegation of child abuse or neglect of a child while the child was in ORR custody. The Central Registry is used to vet prospective candidates to ensure individuals on the registry are not permitted to work on ORR grants or contracts or have access to unaccompanied children. Relevant records consist of personnel history, investigation records, administrative review findings, case file records of unaccompanied children, and personally identifiable information of individuals listed in the Central Registry.

III. The Privacy Act

The Privacy Act (5 U.S.C. 552a) governs the means by which the U.S. Government collects, maintains, and uses information about individuals in a system of records. A ''system of records'' is a group of any records under the control of a federal agency from which information about an individual is retrieved by the individual's name or other personal identifier. The Privacy Act requires each agency to publish in the **Federal Register** a system of records notice (SORN) identifying and describing each system of records the agency maintains, including the purposes for which the agency uses information about individuals in the system, the routine uses for which the agency discloses such information outside the agency, and how individual record subjects can exercise their rights under the Privacy Act (*e.g.,* to determine if the system of records contains information about them).

As required by the Privacy Act at 5 U.S.C. 552a(r), HHS has sent a report of this new system of records to the Committee on Homeland Security and Governmental Affairs of the Senate, the Committee on Oversight and Accountability of the House of Representatives, and the OMB Office of Information and Regulatory Affairs.

Robin Dunn Marcos,

Deputy Assistant Secretary for Humanitarian Services, Director, Office of Refugee Resettlement.

SYSTEM NAME AND NUMBER:

ORR Unaccompanied Children Bureau (UCB) Child Abuse or Neglect Investigation Records and Central Registry, 09–80–0323.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

The address of the component responsible for the system of records is the Bureau of Operations of the Office of Refugee Resettlement, Administration for Children and Families (ACF), Department of Health and Human Services (HHS), Mary E. Switzer Building, 330 C Street SW, Washington, DC 20201.

SYSTEM MANAGER(S):

Principal Deputy Director, Office of Refugee Resettlement, Administration for Children and Families, Mary E. Switzer Building, 330 C Street SW, Washington, DC 20201, *UCPolicy-RegulatoryAffairs@acf.hhs.gov*, (202) 401–9246.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

6 U.S.C. 279 and 8 U.S.C. 1232; *see also* 45 CFR parts 410, 411, and 412.

PURPOSE(S) OF THE SYSTEM:

Records are used within HHS/ACF/ORR to investigate reports of child abuse and neglect arising at ORR care provider facilities located in States that do not investigate such reports, as well as at ORR Emergency or Influx Facilities (EIFs). Records are also used to maintain a Central Registry of ORR care provider facility staff, contractors or sub-grantees, volunteers, or other individuals who have access to children in ORR care through contracts or grants with ORR,

[1] *See also,* the Consolidated Appropriations Act, 2024, Public Law 118–364, division H, section 216 (incorporating by reference section 216 of division D of the Consolidated Appropriations Act, 2020, Pub. L. 116–93, prohibiting the Department of Homeland Security from using funds provided by the Act or any other Act, except in certain circumstances, ''to place in detention, remove, refer for a decision whether to initiate removal proceedings, or initiate removal proceedings against a sponsor, potential sponsor, or member of a household of a sponsor or potential sponsor of an unaccompanied alien child (as defined in section 462(g) of the Homeland Security Act of 2002 (6 U.S.C. 279(g)) based on information shared by the Secretary of Health and Human Services).''

and who are determined by ORR, pursuant to ORR regulations and policies, to have a sustained allegation of child abuse or neglect of a child while the child was in ORR custody.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records are about the following categories of individuals:

- Unaccompanied children (UC), which include:
  - unaccompanied children currently and formerly in ORR's care and custody;
  - children of unaccompanied children who are housed together with their unaccompanied child parents who are in ORR custody;
  - unaccompanied children who later receive an adjustment of status or become U.S. citizens; and
  - children referred to ORR as likely to be an unaccompanied child.
- Alleged perpetrators of abuse or neglect against unaccompanied children at certain facilities specified under ORR regulations, *i.e.,* ORR care provider facility staff, contractors or sub-grantees, volunteers, and other individuals with access to unaccompanied children in ORR custody through contracts or grants with ORR,[2] who are alleged to have committed abuse or neglect against an unaccompanied child while the child was in ORR custody, and with respect to whom ORR conducts or may conduct investigations to determine whether abuse or neglect occurred.
- Records about alleged perpetrators may also include information about additional individuals otherwise associated with an allegation, intake report, or investigation.

Unaccompanied children (UC) are children who have no lawful immigration status in the United States; have not attained 18 years of age; and with respect to whom (i) there is no parent or legal guardian in the United States; or (ii) no parent or legal guardian in the United States is available to provide care and physical custody. *See* 6 U.S.C. 279(g)(2).

The Privacy Act applies only to U.S. citizens and non-U.S. citizens lawfully admitted for permanent residence in the United States. As a matter of discretion, ORR will treat information that it maintains in its mixed systems of records (*i.e.,* those that contain records about both individuals who are—and individuals who aren't—covered by the Privacy Act) as being subject to the provisions of the Privacy Act, regardless of whether the information relates to individuals covered by the Privacy Act. This implements a 1975 Office of Management and Budget (OMB) recommendation to apply, as a matter of policy, the administrative provisions of the Privacy Act to records about individuals who aren't covered by the Privacy Act when the records are maintained in mixed systems of records (referred to as the non-U.S. persons policy).

CATEGORIES OF RECORDS IN THE SYSTEM:

The records are child abuse and neglect investigation records, consisting of these categories of records and contents:

1. *Personal history information about individuals alleged to have perpetrated abuse or neglect against unaccompanied children.* Such records may include, as applicable, the alleged perpetrator's name; date of birth; Social Security Number (SSN); Alien Registration Number; contact information; identity of any care provider facilities, contractors, or grantees where the individual was employed or volunteered; length of employment or volunteer service; background checks; ORR investigative findings and determinations, including the evidence and documentation supporting them; and records of any subsequent administrative reviews.

2. *Division of Child Protection Investigations investigative records.* These records include reports providing a description of child abuse or neglect alleged to have been perpetrated against an unaccompanied child by an individual identified above, including narrative information and identifying information about the child, the alleged perpetrator, and witnesses; supporting documents and evidence related to investigative findings; and information on the alleged perpetrator's role in the alleged child abuse or neglect incident(s).

3. *HHS Departmental Appeals Board administrative review findings.* These records include administrative review findings of allegations of child abuse and neglect and supporting documents and evidence pertaining to the administrative review findings.

4. *HHS Assistant Secretary for the Administration for Children and Families administrative review findings.* These records include administrative review findings of allegations of child abuse and neglect and supporting documents and evidence pertaining to the administrative review findings.

5. *Case file records of unaccompanied children (UC).* These records contain information about the unaccompanied child alleged to have been abused or neglected, which may include the child's biographical information such as name, Alien Registration Number, Fingerprint Identification Number (FIN), and date and place of birth, as well as information regarding the allegations of child abuse and neglect.

6. *Sustained perpetrator records.* These records contain the names and other identifying information, (*e.g.,* date of birth, SSN, and address), of individuals determined by ORR, pursuant to ORR regulations and policies, to have a sustained allegation of child abuse or neglect of a child while the child was in ORR custody, and details regarding the sustained allegations.

RECORD SOURCE CATEGORIES:

Information in the records is obtained directly from the record subjects; family members of unaccompanied children; care provider staff, contractors, and volunteers, home study providers, and post-release program providers; the ORR National Call Center; child advocates; attorneys serving unaccompanied children; Division of Child Protection Investigation reports; HHS Departmental Appeals Board decision findings; HHS Assistant Secretary for the Administration for Children and Families administrative review findings; ORR staff; hospitals and health care providers; third parties; other federal agencies; and state and local governments, agencies, and instrumentalities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to the disclosures authorized directly in the Privacy Act at 5 U.S.C. 552a(b), these routine uses, which are published pursuant to 5 U.S.C. 552a(b)(3) and (e)(4)(D) and (11), specify circumstances under which ORR may disclose information from this system of records without the prior written consent of the record subject. A routine use is defined in the Privacy Act at 5 U.S.C. 552a(a)(7) as a disclosure of a record for a use that is compatible with the purpose for which the record was collected; accordingly, these routine uses authorize disclosures for purposes that are compatible with the purpose for which the information was collected.

Each proposed disclosure of information under these routine uses (and any proposed disclosure in response to a law enforcement request that complies with 5 U.S.C. 552a(b)(7)) will be evaluated to ensure that the disclosure is legally permissible and

[2] *E.g.,* individuals who are affiliated with legal service providers, child advocates, or other grantees or contractors engaged by ORR or the relevant care provider facility with respect to the care of unaccompanied children in ORR custody.

consistent with ORR's responsibilities under the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008, 8 U.S.C. 1232 and the Homeland Security Act, 6 U.S.C. 279. ORR is not an immigration enforcement agency and does not maintain records for immigration enforcement purposes. Accordingly, in no case shall a disclosure under a routine use (or a disclosure in response to a law enforcement request that complies with 5 U.S.C. 552a(b)(7)) include sharing information from this system of records with other federal agencies or entities (*e.g.,* the Department of Homeland Security, the Department of Justice) for immigration enforcement purposes (such as, determining whether an individual should be removed from the United States, for immigration detention or bond determinations, or probing the truth or falsity of an individual's request for asylum or other immigration relief). Any disclosure for immigration enforcement purposes would be made only with the prior, written consent of the subject individual(s).

1. *Disclosure Necessary to Conducting Investigations of Child Abuse or Neglect.* Information may be disclosed to the extent necessary to investigate reports of child abuse or neglect alleged to have occurred in ORR care provider facilities located in States that do not investigate such reports, as well as at ORR Emergency or Influx Facilities (EIFs). Recipients of disclosures under this routine use may include Federal, state, and local law enforcement agencies; schools; medical providers; experts asked to do forensic or other analyses; state and local child welfare entities; state licensing entities; child advocacy centers; witnesses; the respondent(s); and organizations with which the respondent was previously employed.

2. *Disclosure to Alleged Perpetrator and Their Attorney.* Information regarding the allegation of abuse or neglect, the initiation of an investigation by ORR, and the disposition determined by HHS/ACF/ORR regarding the allegation of abuse and neglect; information regarding an appeal by an individual determined by HHS/ACF/ORR to have perpetrated child abuse or neglect of an unaccompanied child in ORR custody; and information regarding further administrative review of such determination may be disclosed to the alleged perpetrator and their attorney. If the alleged perpetrator appeals or requests further administrative review of determinations of child abuse and neglect, ORR may disclose information contained in supporting documents and evidence pertaining to the disposition of the allegation, as well as the final decisions on appeal and on further administrative review.

3. *Disclosure to Alleged Victim, Their Attorney and Child Advocate, the Alleged Victim's Parent(s), or Legal Guardian(s), Sponsors, and Care Provider Facility.* Information regarding the allegation of abuse or neglect, the initiation of an investigation by ORR, and the disposition determined by HHS/ACF/ORR regarding the report of abuse and neglect, may be disclosed to the alleged victim and to the alleged victim's attorney and child advocate, parent(s) or legal guardian(s), sponsor (as appropriate), and care provider facility. In addition, notice that an alleged perpetrator of abuse or neglect has appealed a disposition substantiating the allegation, and that such appeal will be conducted by an Administrative Law Judge (ALJ), may be disclosed to the alleged victim and the alleged victim's parent(s) or legal guardian(s) (as appropriate). A copy of the ALJ's decision may be provided to the alleged victim and to the alleged victim's attorney and child advocate (as applicable) and parent(s) or legal guardian(s) (as appropriate). If an alleged perpetrator of child abuse or neglect requests further administrative review by the Assistant Secretary of ACF of a finding against them, notice of such request as well as a copy of the final decision of the Assistant Secretary may be provided to the alleged victim and to the alleged victim's attorney and child advocate (as applicable) and parent(s) or legal guardian(s) or sponsor (as appropriate).

4. *Disclosure to ORR Care Providers, Home Study Providers, and Post-Release Services Providers.* Personally identifiable information of individuals listed in the Central Registry may be disclosed to ORR care provider facilities, home study providers, and post-release service providers to inform their employment and hiring decisions about a candidate seeking employment or volunteer work with that grantee or contractor that may involve direct contact with unaccompanied children.

5. *Disclosure to State and Local Licensing, Child Welfare Investigative Agencies, and Federal Investigative Entities.* Names and other identifying information of individuals listed in the Central Registry may be shared with state and local licensing, child welfare, and law enforcement entities, as well as with federal investigative entities, including law enforcement entities, in accordance with applicable reporting laws and policies, as well as for coordinating with other investigations that may occur concurrently with ORR's investigation.

6. *Disclosure to the National Archives and Records Administration (NARA).* Information may be disclosed to the National Archives and Records Administration in its records management inspections.

7. *Disclosure to Congressional Office.* Information may be disclosed to a congressional office from the record of an individual in response to a written inquiry from the congressional office made at the written request of the individual.

8. *Disclosure to Department of Justice, or in Proceedings.* Information may be disclosed to the Department of Justice, or in a proceeding before a court, adjudicative body, or other administrative body before which HHS is authorized to appear, when any of the following is a party to the proceedings or has an interest in such proceedings, and the use of such records by the Department of Justice or HHS is deemed by HHS to be relevant and necessary to the proceedings:

- HHS, or any component thereof;
- any employee of HHS in his or her official capacity;
- any employee of HHS in his or her individual capacity where the Department of Justice or HHS has agreed to represent the employee; or
- the United States, and the use of such records by the Department of Justice or HHS is arguably relevant to the proceedings.

9. *Disclosure in the Event of a Security Breach Experienced by HHS.* Information may be disclosed to appropriate agencies, entities, and persons when (1) HHS suspects or has confirmed that there has been a breach of the system of records; (2) HHS has determined, as a result of the suspected or confirmed breach, there is a risk of harm to individuals, the agency (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HHS' efforts to respond to the suspected or confirmed breach, or to prevent, minimize, or remedy such harm.

10. *Disclosure to Assist Another Agency Experiencing a Breach.* Information may be disclosed to another federal agency or federal entity, when HHS determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach, or (2) preventing, minimizing, or remedying

the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Paper records are stored in file folders. Electronic records are stored in a database on a computer network.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Personal identifiers used for retrieval include the subject individual's name, date of birth, SSN, and Alien Registration Number (if applicable).

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The records have not yet been scheduled with the National Archives and Records Administration (NARA). Until they have been scheduled with NARA and have met the applicable retention period, the records must be retained indefinitely.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Information in this system is safeguarded in accordance with applicable laws, rules, and policies. Access to the records is restricted to authorized personnel who are advised of the confidentiality of the records and the civil and criminal penalties for misuse. All record keepers are required to maintain appropriate administrative, technical, and physical safeguards to protect the records from unauthorized access. Administrative safeguards include training individuals who have access to the records how to handle them appropriately, incident response plans, mandatory security and privacy awareness training, limiting access to individuals who need to know the information, and reviewing security controls on an ongoing basis. Technical safeguards include the use of antivirus software, vulnerability patching, multi-factor authentication when required, or username and password, and storing electronic records in encrypted form, to limit system access to authorized users. Physical safeguards include storing hard copy records and computer terminals used to access electronic records in physically locked locations when not in use. Safeguards conform to the HHS Information Security Program, *https://www.hhs.gov/ocio/securityprivacy/index.html.*

RECORD ACCESS PROCEDURES:

Upon completion of an exemption rulemaking, this system of records will be exempt from access by subject individuals to the extent permitted by 5 U.S.C. 552a(k)(2). However, consideration will be given to any access request addressed to the System Manager, listed above. Individuals may request access to a record about them in this system of records by submitting a written access request to the System Manager. The request must include, as applicable, the individual's name, Alien Registration Number, date and place of birth, telephone number and/or email address, current address, and signature. In addition, to further verify the individual's identity, the individual must provide either a notarization of the request or a written certification that the requester is the individual who the requester claims to be and understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act, subject to a fine of up to $5,000. An individual may also request an accounting of disclosures that have been made of any records about that individual. Verification of identity is also required for a parent or legal guardian who makes a request on behalf of a minor (in addition to verifying the minor's identity).

CONTESTING RECORD PROCEDURES:

Upon completion of an exemption rulemaking, this system of records will be exempt from amendment to the extent permitted by 5 U.S.C. 552a(k)(2). However, consideration will be given to any amendment request addressed to the System Manager, listed above. Individuals seeking to amend a record about them in this system of records must submit a written request for amendment to the System Manager. The request must provide the same information described under ''Record Access Procedures,'' including identity verification information; and must specify the information that is contested, the corrective action sought, and the reason(s) for requesting the correction, and include supporting information. The right to contest records is limited to information that is factually inaccurate, incomplete, irrelevant, or untimely (obsolete). Records of an administrative proceeding that results in a final agency determination that an individual perpetrated child abuse or neglect of a child while the child was in ORR custody will not be subject to amendment, if the records establish that the individual exhausted administrative amendment remedies in that proceeding (*i.e.,* wasn't merely offered the opportunity for amendment) as required for the individual to pursue judicial remedies.

NOTIFICATION PROCEDURES:

Upon completion of an exemption rulemaking, this system of records will be exempt from notification to the extent permitted by 5 U.S.C. 552a(k)(2). However, consideration will be given to any notification request addressed to the System Manager, listed above. Individuals seeking to determine whether this system of records contains information about them must submit a written notification request to the System Manager. The request must include the same information described under ''Record Access Procedures,'' including identity verification information.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Upon completion of an exemption rulemaking, law enforcement investigatory material in this system of records will be exempt from certain requirements of the Privacy Act as follows:

- Based on 5 U.S.C. 552a(k)(2), all investigatory material compiled for law enforcement purposes will be exempt from the requirements in subsections (c)(3), (d)(1) through (4), (e)(1), (e)(4)(G) through (I), and (f) of the Privacy Act; provided, however, if maintenance of the records causes a subject individual to be denied a federal right, privilege, or benefit to or for which the individual would otherwise be entitled or eligible, the exemption will be limited to material that would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence.

HISTORY:

None.

[FR Doc. 2024–28382 Filed 12–3–24; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Child Care; Statement of Organization, Functions, and Delegations of Authority

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice; establishment of the Regional Operations Division within the Office of Child Care.

SUMMARY: The Administration for Children and Families (ACF) has made

minor adjustments to the organization of the Office of Child Care (OCC) by adding a new Regional Operations Division. Impacted staff are being moved from the Office of the Director to this new division.

FOR FURTHER INFORMATION CONTACT: Anne-Marie Twohie, Deputy Director, Office of Child Care, 330 C Street SW, Washington, DC 20201, (240) 935–1159.

SUPPLEMENTARY INFORMATION: This notice amends Part K of the Statement of Organization Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF): Chapter KV, Office of Child Care (OCC) as last amended 88 FR 32227–32230, May 19, 2023.

I. Delete Chapter KV, Office of Child Care, in Its Entirety and Replace With the Following

KV.00 Mission. The Office of Child Care (OCC) has primary responsibility for the overall direction, policy, implementation, budget planning and development, and oversight of child care program operations authorized under the Child Care and Development Block Grant (CCDBG) and section 418 of the Social Security Act. OCC supports state, tribal, and territorial grantees' efforts to provide child care subsidies to families with low incomes, improve the quality of child care for all children, support a high-quality and well-compensated workforce, and support a strong child care system able to meet the needs of children and families. OCC provides leadership and coordination for child care issues within ACF, HHS, and with relevant federal, state, local, and tribal governmental and non-governmental organizations.

KV.10 Organization. OCC is headed by a Director who reports to the Deputy Assistant Secretary for Early Childhood Development (ECD). OCC is organized as follows:

Office of the Director (KVA)
Training and Technical Assistance Division (KVA1)
Program Operations Division (KVA2)
Oversight and Accountability Division (KVA3)
Policy, Data, and Planning Division (KVA4)
Regional Operations Division (KVAD)
Child Care Regional Offices (KVADI–X)

KV.20 Functions.

A. *Office of the Director (KVA):* The Office of the Director (OD) is responsible for leading the Program Office to ensure OCC fulfills its statutory responsibilities and programmatic objectives. The OD is responsible for the overall management, oversight, and policy and budget development specific to child care programs and for the supervision of the OCC Division Directors. The OD is also responsible for strategic planning and setting operational goals, planning initiatives to support strong implementation of the Child Care and Development Fund (CCDF) and other initiatives that support a child care sector that meets the developmental needs of children and supports families and child care providers. The OD also responds to inquiries from the public and governmental and non-governmental leaders.

The Deputy Director and Associate Deputy Director report to the Director and manage the day-to-day operations of OCC; share supervision and management responsibilities for the OCC Division Directors and other OD staff; coordinate with and provide direction to the ECD Budget and Administrative Operations divisions to manage the budget and administrative needs of OCC; assist the Director in carrying out the duties of the OD; and perform the duties of the Director when absent.

B. *Training and Technical Assistance Division (KVA1):* The Training and Technical Assistance Division is responsible for overseeing the training and technical assistance system including coordination and oversight of technical assistance grants, cooperative agreements, and contracts. The division also oversees publications to support CCDF lead agencies and OCC priorities and coordinates with the other divisions in OCC on content related to program implementation, monitoring, policy, interagency agreements, and websites.

C. *Program Operations Division (KVA2):* The Program Operations Division is responsible for supporting the development, management, and oversight of CCDF plans, plan amendments, and waiver requests to support compliance with federal law and regulation. The division works in partnership with regional program staff to facilitate responses to issues and questions on program implementation, policy, and other issues. The division is also responsible for analyzing information related to grantee program implementation.

D. *Oversight and Accountability Division (KVA3):* The Oversight and Accountability Division is responsible for monitoring grantees for compliance in the implementation of CCDF plans, and for programmatic and fiscal compliance with federal law, policies, and regulations. The division manages the program integrity and accountability oversight program, including audits, improper payments, error rates, and corrective actions. The division responds to inquiries from the Office of Inspector General and Government Accountability Office.

E. *Policy, Data, and Planning Division (KVA4):* The Policy, Data, and Planning Division is responsible for overseeing development and issuance of policies, regulations, and other policy guidance. The division is responsible for legislative issues and budget formulation in coordination with ECD and consistent with ACF early childhood priorities. The division oversees activities for implementation of major policy, legislative, regulatory and budget new initiatives and prepares materials in response to Congressional inquiries. The division also oversees collection of state, territory, and tribal grantee data and reports and reviews and analyzes grantee data and performance measures.

F. *Regional Operations Division (KVA5):* The Regional Operations Division is responsible for providing oversight, direction, and guidance to the 10 OCC Regional Offices and integrates regional work in central office planning.

G. *Child Care Regional Offices (KVADI–X):* Each of the 10 OCC Regional Offices is headed by an OCC Regional Program Manager (RPM) who reports to the Director of Regional Operations within the Regional Operations Division. OCC Regional Offices are responsible for ongoing oversight and monitoring, and technical assistance and working to resolve issues to bring all Lead Agencies in their region in full compliance with federal law, regulations, and policy. The RPM is responsible for liaising within each Region to OCC central office and maintaining relationships with state, territory, tribal, and local officials.

II. Continuation of Policy

Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

III. Delegation of Authority

All delegations and re-delegations of authority made to officials and employees of affected organizational components will continue in them, or their successors, pending further re-delegations, provided they are consistent with this reorganization.

IV. Funds, Personnel, and Equipment

Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

Meg Sullivan,

Principal Deputy Assistant Secretary for the Administration for Children and Families, performing the delegable duties of the Assistant Secretary for Children and Families.

[FR Doc. 2024–28368 Filed 12–3–24; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number(s): 93.645]

Notice of Allotment Percentages to States for Child Welfare Services State Grants.

AGENCY: Administration on Children, Youth and Families—Children's Bureau (ACYF–CB), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of biennial publication of allotment percentages for States under the IV–B subpart 1, Stephanie Tubbs Jones Child Welfare Services Grant Program.

SUMMARY: The Department is publishing the allotment percentage for each State under the Title IV–B Subpart 1, Stephanie Tubbs Jones Child Welfare Services Grant Program. The allotment percentages are one of the factors used in the computation of the Federal grants awarded under the Program.

DATES: The allotment percentages will be effective for Federal Fiscal Years 2026 and 2027.

FOR FURTHER INFORMATION CONTACT: Sona Cook, Grants Management Officer, Family Protection & Resilience Portfolio, Office of Grants Management, Office of Administration, Administration for Children and Families, 330 C Street SW, Washington, DC 20201. Telephone (214) 767–2973, Email: *sona.cook@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: As required by section 423(c) of the Social Security Act (42 U.S.C. 623(c)), the Department is publishing the allotment percentage for each State under the Title IV–B Subpart 1, Stephanie Tubbs Jones Child Welfare Services Grant Program. The allotment percentage for each State is determined on the basis of paragraphs (b) and (c) of section 423 of the Social Security Act. These figures are available on the ACF internet homepage at *http://www.acf.hhs.gov/programs/cb/.* The allotment percentage for each State is as follows:

ALLOTMENT **

State	Percentage
Alabama	61.01
Alaska *	34.07
Arizona	56.72
Arkansas	53.55
California [1]	30.00
Colorado	51.41
Connecticut	43.82
Delaware	62.90
District of Columbia [1]	30.00
Florida	68.02
Georgia	55.69
Hawaii *	45.23
Idaho	54.70
Illinois	39.67
Indiana	57.23
Iowa	48.57
Kansas	48.66
Kentucky	57.37
Louisiana	46.97
Maine	45.15
Maryland	41.98
Massachusetts	39.62
Michigan	66.22
Minnesota	40.39
Mississippi	65.78
Missouri	37.96
Montana	47.96
Nebraska	45.58
Nevada	53.08
New Hampshire	39.99
New Jersey	48.14
New Mexico	66.28
New York [1]	30.00
North Carolina	62.31
North Dakota	41.15
Ohio	57.65
Oklahoma	51.17
Oregon	43.87
Pennsylvania	49.01
Rhode Island	50.82
South Carolina	57.67
South Dakota	36.59
Tennessee	57.23
Texas	47.07
Utah	51.66
Vermont	47.75
Virginia	44.99
Washington	45.32
West Virginia	67.04
Wisconsin	38.25
Wyoming	38.79
America Samoa	70.00
Guam	70.00
Puerto Rico	70.00
N. Mariana Islands	70.00
Virgin Islands	70.00

* State Percentage = 50 percent of year average divided by the National United States 3-year average.

** "State Percentage minus 100 percent yields the IV–BI allotment percentage.

* Estimates prior to 1950 are not available for Alaska and Hawaii.

[1] Allotment Percentage has been adjusted in accordance with Section 423(b)(1).

Statutory Authority: Section 423(c) of the Social Security Act (42 U.S.C. 623(c)).

Anthony Petruccelli,

Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.

[FR Doc. 2024–28398 Filed 11–29–24; 4:15 pm]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Planning, Research, and Evaluation Statement of Organization, Functions, and Delegations of Authority

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: The Administration for Children and Families (ACF) has reorganized the Office of Planning, Research, and Evaluation (OPRE). This reorganization creates a new Office of Research and Evaluation (ORE) and an Office of the Chief Data Officer (OCDO). This notice provides the Statement of Organizations, Functions, and Delegations of Authority for the new office of officer.

FOR FURTHER INFORMATION CONTACT: Lauren Supplee, Deputy Assistant Secretary for Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF), as follows: Chapter KM, Office of Planning, Research, and Evaluation (OPRE), as last amended 87 FR 67693–67696 (November 2022).

I. Under Chapter KM, Office of Planning, Research, and Evaluation,

delete in its entirety and replace with the following:

KM.00 Mission

OPRE is the principal advisor to the Assistant Secretary for Children and Families on improving the effectiveness and efficiency of programs designed to make measurable improvements in the economic and social well-being of children and families. OPRE provides guidance, analysis, technical assistance, and oversight to ACF programs and across programs in the agency on strategic planning aimed at measurable results; performance measurement and management; research and evaluation methodologies; demonstration testing and model development; statistical policy and program analysis; synthesis and dissemination of research, evaluation, and demonstration findings; data science; data governance; data use, re-use, and integration; data ethics; data sharing, privacy, and confidentiality; data talent; interoperability; and application of emerging technologies to improve the effectiveness of programs and service delivery.

KM.10 Organization

OPRE is headed by a Deputy Assistant Secretary, who reports to the Assistant Secretary for Children and Families. The Office is organized as follows:

Office of the Deputy Assistant Secretary (KMA)
Office of Research and Evaluation (KMF)
Division of Economic Independence (KMB)
Division of Child and Family Development (KMC)
Division of Family Strengthening (KMD)
Office of the Chief Data Officer (KMG)
Division of Data Governance (KMH)
Division of Data Capacity (KMI)
Division of Data Privacy (KMJ)

KM.20 Functions

A. The Office of the Deputy Assistant Secretary provides day-to-day direction and executive leadership to OPRE in administering its responsibilities. It serves as principal advisor to the Assistant Secretary for Children and Families on all matters and directs and coordinates all activities pertaining to improving the effectiveness and efficiency of ACF programs. It represents the Assistant Secretary for Children and Families at various planning, research, evaluation, data, and improvement forums and carries out special Departmental and Administration initiatives.

The Office of the Deputy Assistant Secretary manages the formulation and execution of budgets for OPRE programs; manages correspondence; coordinates the provision of OPRE staff development and training; provides support for OPRE's personnel administration, including staffing, employee and labor relations, and employee recognition; manages OPRE space, facilities, and supplies; and oversees travel, time and attendance, and other administrative functions for OPRE. The Deputy Assistant Secretary for Planning, Research, and Evaluation currently serves as ACF's Chief Evaluation Officer and Scientific Integrity Officer and provides support for and oversight of the ACF Evaluation Policy and ACF's implementation of the Foundations for Evidence-Based Policymaking Act of 2018. The Deputy Assistant Secretary for Planning, Research and Evaluation provides day-to-day executive leadership and direction to the Office of Research and Evaluation and the Office of the Chief Data Officer.

F. The Office of Research and Evaluation (ORE) is directed by ACF's Chief Evaluation Officer, who serves as the principal advisor to the Deputy Assistant Secretary for Planning, Research and Evaluation on all matters related to ACF's evaluation and learning agenda activities. The ORE provides coordination and leadership in implementing Titles I and III of the Foundations for Evidence-Based Policymaking Act of 2018 and oversees and manages the research and evaluation programs under sections 403, 413, 418, 429, 510, 511, 513, 1110, and 2008 of the Social Security Act and section 640 and 649 of the Head Start Act, as well as other research, evaluation, and evidence-building activities authorized by Congress and related to ACF programs and the populations they serve. These activities include priority setting and analysis; developing learning agendas; managing and coordinating major cross-cutting, leading-edge studies and special initiatives; improving ACF capacity to support the development and use of evaluation; and collaborating with federal partners, states, communities, foundations, professional organizations, and others to promote the safety, well-being, and development of children, families, and communities.

The ORE provides strategic direction, focus, and support to the research and evaluation activities that occur within OPRE's three research and evaluation divisions: Division of Economic Independence, Division of Child and Family Development, and Division of Family Strengthening. It serves as principal advisor to the Assistant Secretary for Children and Families on all matters pertaining to improving the effectiveness and efficiency of ACF programs; strategic planning; research, evaluation, statistical, and analysis methods; program and policy evaluation; research and demonstrations; state and local innovations and progress; and synthesis and dissemination of research and evaluation findings.

B. The Division of Economic Independence, in cooperation with ACF income support programs and others, works with federal counterparts, states, community agencies, and the private sector to understand and overcome barriers to economic independence; promote parental responsibility; and assist in improving the effectiveness of programs that further economic independence. The Division provides guidance, analysis, technical assistance, and oversight in ACF on strategic planning and performance measurement for economic independence; statistical, policy, and program analysis; surveys, research, and evaluation methodologies; demonstration testing and model development; synthesis and dissemination of research and evaluation findings; and application of emerging technologies to programs that promote employment, parental responsibility, and economic independence. The Division develops learning agendas and policy-relevant research priorities; conducts, manages, and coordinates major cross-program, leading-edge research, demonstrations, and evaluation studies; manages and conducts statistical, policy, and program analyses on trends in employment, child support payments, and other income supports; and works in partnership with states, communities, and the private sector to promote employment, parental responsibility, and family economic independence. Division staff also provides consultation, coordination, direction, and support for research and evaluation activities related to employment, parental responsibility, and family economic independence across ACF programs.

C. The Division of Child and Family Development, in cooperation with ACF programs and others, works with federal counterparts, states, community agencies, and the private sector to improve the effectiveness and efficiency of programs, and foster safety and sound growth and development of children and their families. The Division provides guidance, analysis, technical assistance, and oversight in ACF on strategic planning and performance measurement for child and family development; statistical, policy, and

program analysis; surveys, research, and evaluation methodologies; demonstration testing and model development; synthesis and dissemination of research and evaluation findings; and application of emerging technologies to improve the effectiveness of programs and service delivery. The Division conducts, manages, and coordinates major cross-programs, leading-edge research, demonstration and evaluation studies; develops learning agendas and policy-relevant research priorities; and manages and conducts statistical, policy, and program analyses related to children and families. Division staff also provides consultation, coordination, direction, and support for research and evaluation activities related to children and families across ACF programs.

D. The Division of Family Strengthening, in cooperation with ACF programs and others, works with federal counterparts, states, community agencies, and the private sector to improve the effectiveness and efficiency of programs; foster the safety, positive growth and development of children, youth, parents, and vulnerable populations; and strengthen families. The Division provides guidance, analysis, technical assistance, and oversight in ACF on parent, child, youth, and family development and dynamics; child safety; statistical, policy, and program analysis; surveys, research, and evaluation methodologies; demonstration testing and model development; synthesis and dissemination of research and evaluation findings; and application of emerging technologies to improve the effectiveness of programs and service delivery. The Division conducts, manages, and coordinates major cross-program, leading-edge research, demonstration, and evaluation studies; develops learning agendas and policy-relevant research priorities; and manages and conducts statistical, policy, and program analyses related to strengthening families. Division staff also provides consultation, coordination, direction, and support for research and evaluation activities related to strengthening families across ACF programs.

G. The Office of the Chief Data Officer (OCDO) is directed by the Chief Data Officer (CDO). The responsibilities of the CDO are to oversee data governance and facilitate the use of data to create evidence to support decision-making. OCDO supports ACF programs in responsibly managing and using data to improve the effectiveness, equity, and efficiency of human services programs; provides coordination, oversight, and leadership in ACF's implementation of the Government Performance and Results Act Modernization Act, the Paperwork Reduction Act, the Information Quality Act, and the Title II of the Foundations for Evidence-Based Policymaking Act of 2018; and provides expert advice on matters related to data use and reuse, privacy and confidentiality, and the sharing of information. The office coordinates mandated Office of Management and Budget (OMB) information collection approvals and plans and includes ACF's Information Collection Clearance Officer. OCDO works with ACF programs and, in cooperation with ACF programs and others, works with federal counterparts, states, community agencies, and the private sector to improve the effectiveness, efficiency, and equity of programs through improved management and use of data.

The OCDO provides strategic direction, focus, and support to the data activities that occur within OPRE's three data divisions: Division of Data Governance, Division of Data Capacity, and Division of Data Privacy. The OCDO serves as principal advisor to the Deputy Assistant Secretary for Planning, Research, and Evaluation on all matters pertaining to performance measurement and management; supporting ACF programs in responsibly managing and using data to improve the effectiveness, equity, and efficiency of human services programs; data governance; data management, collection, analysis, and use; data sharing, privacy, and confidentiality; data talent; interoperability; and application of emerging technologies to improve the effectiveness of programs and service delivery.

H. The Division of Data Governance provides coordination, consultation, direction, oversight, and technical assistance to ACF on data governance activities, policy, and operational issues. This includes work related to data standards setting, including interoperability and ACF-wide Paperwork Reduction Act policy, coordination, and support; open data initiative work, including ACF data asset cataloging and management; implementation and oversight of the Information Quality Act within ACF; advising on existing and emerging data governance policy issues, such as artificial intelligence; and coordination and support of the ACF Data Governance Council. The Division develops policy-relevant priorities for data collection and analysis and conducts demonstrations and develops tools, policies, and procedures that support the increased accessibility and reuse of administrative and survey data for statistical purposes.

I. The Division of Data Capacity supports ACF leadership and ACF offices by providing ''surge support'' and leadership on high-priority campaigns to analyze and use data, including the associated capacity improvements necessary to maintain those activities going forward. Division staff provide guidance, analysis, technical assistance, and oversight on strategic planning and performance measurement and management; statistical policy and program analysis; continuous improvement; surveys, data collection, and analysis methodologies; application of data analyses to program operations and decision-making; and data skill development. Support includes both quantitative and qualitative data efforts. The Division conducts, manages, and coordinates major cross-program, leading-edge research, demonstration, and evaluation activities related to responsible data management and use, and provides consultation, coordination, direction, and support for ACF research and evaluation activities related to responsible data management and use.

J. The Division of Data Privacy provides guidance, technical assistance, and oversight on data ethics, data sharing, data privacy, and data confidentiality. This includes provision of policy analysis to ACF programs on improving program coordination, enhancing information sharing and collaboration, and identifying statutory, regulatory, or policy limitations. Division staff interpret and analyze statutes, bills, reports, and policies relating to data sharing and privacy to determine their effect on ACF and its programs; design, schedule, and execute major projects and studies to analyze interrelated issues of legality, policymaking, and operational need; coordinate and collaborate with the Office of the Chief Technology Officer to evaluate data sharing for potential privacy risks and recommend solutions, coordinate responsibility to ensure implementation of information privacy protections and adherence to federal laws, and support in ACF incident identification, notification, and response activities; develop, oversee, and implement privacy policies, procedures, and compliance across the full range of ACF activities; and advise ACF on data privacy, data confidentiality, and data sharing throughout the full life cycle of information from design, collection, maintenance, disclosure, and archiving or disposition.

IV. Continuation of Policy. Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization, are continued in full force and effect.

V. Delegation of Authority. All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

VI. Funds, Personnel, and Equipment. Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

Xavier Becerra,

Secretary, Health and Human Services.

[FR Doc. 2024–28428 Filed 12–3–24; 8:45 am]

BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2628]

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance entitled ''Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions.'' This guidance demonstrates FDA's commitment to developing innovative approaches to the regulation of artificial intelligence (AI)-enabled devices. More specifically, this guidance provides recommendations on the information to include in a Predetermined Change Control Plan (PCCP) in a marketing submission for a device that includes one or more AI-enabled device software functions (AI–DSFs). This guidance recommends that a PCCP describe the planned AI–DSF modifications, the associated methodology to develop, validate, and implement those modifications, and an assessment of the impact of those modifications. FDA reviews the PCCP as part of a marketing submission for a device to ensure the continued safety and effectiveness of the device without necessitating additional marketing submissions for implementing each modification described in the PCCP.

DATES: The announcement of the guidance is published in the **Federal Register** on December 4, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–2628 for ''Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Marketing

Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Sonja Fulmer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5530, Silver Spring, MD 20993–0002, 240–402–5979; James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Tala Fakhouri, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6330, Silver Spring, MD 20993–0002, 301–837–7407; or Stephanie Shapley, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5118, Silver Spring, MD 20993–0002, 301–796–4836.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has a longstanding commitment to develop and apply innovative approaches to the regulation of medical device software and other digital health technologies to ensure their safety and effectiveness. As technology continues to advance all facets of healthcare, medical software incorporating AI, including the subset of AI known as machine learning (ML), has become an important part of many medical devices. In April 2019, FDA published the ''Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)—Discussion Paper and Request for Feedback.'' [1] The 2019 discussion paper received a substantial amount of feedback from a wide array of interested parties that contributed to the development of the draft of this guidance.

On December 29, 2022, section 3308 of the Food and Drug Omnibus Reform Act of 2022, Title III of Division FF of the Consolidated Appropriations Act, 2023 (FDORA) (Pub. L. 117–328), added section 515C ''Predetermined Change Control Plans for Devices'' to the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 360e–4). Section 515C of the FD&C Act has provisions regarding PCCPs for devices requiring premarket approval (PMA) or premarket notification (510(k)). While under the FD&C Act FDA may approve or clear a PCCP for a variety of devices, this guidance provides recommendations specifically for PCCPs for AI–DSFs.

A notice of availability of the draft guidance, under the title ''Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions,'' appeared in the **Federal Register** of April 3, 2023 (88 FR 19648). FDA considered comments received and revised the guidance as appropriate in response to the comments, including the title. In this final guidance, FDA provides additional clarification throughout, including related to the scope of the guidance, information related to the PCCP to include in labeling and publicly available decision summaries, implementation of a modification to a device consistent with an authorized PCCP, and postmarket surveillance recommendations. We revised the definitions of the terms ''artificial intelligence'' and ''machine learning'' to align with definitions in Executive Order 14110 of October 30, 2023.[2] In response to comments received, we also clarified other terminology used in the guidance, including clarifications for training, tuning, and test data.

This final guidance represents the Agency's next step in working to develop innovative approaches tailored to AI-enabled devices. These recommendations are based on the statutory authorities provided in the FD&C Act, including the provisions added by FDORA, as well as feedback obtained through our various interactions with interested parties and through public comment on the draft of this guidance. The recommendations in this guidance are intended to provide a forward-thinking approach to promote the development of safe and effective AI-enabled devices.

This guidance provides recommendations on the information to include in a PCCP in a marketing submission for a device that includes one or more AI–DSFs. The guidance recommends that a PCCP describe the planned AI–DSF modifications, the associated methodology to develop, validate, and implement those modifications, and an assessment of the impact of those modifications. FDA reviews the PCCP as part of a marketing submission for a device to ensure the continued safety and effectiveness of the device without necessitating additional marketing submissions for implementing each modification described in the PCCP.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.* Persons unable to download an electronic copy of ''Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00020049 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of

[1] Available at *https://www.fda.gov/media/122535/download?attachment,* and also at FDA's website on ''Artificial Intelligence and Machine Learning in Software as a Medical Device,'' available at *https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device.*

[2] E.O. 14110 of October 30, 2023, Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence, available at *https://www.federalregister.gov/d/2023-24283.*

information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
860, subpart D	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
822	Postmarket Surveillance of Medical Devices	0910–0449
50, 56	Protection of Human Subjects and Institutional Review Boards.	0910–0130
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Dated: November 25, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–28361 Filed 12–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1334]

Notifying the Food and Drug Administration of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Notifying FDA of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula.'' Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), a manufacturer of a critical food (which includes infant formula) must notify FDA of a permanent discontinuance or an interruption of the manufacture of a critical food that is likely to lead to a meaningful disruption in the supply of the food in the United States. The draft guidance, when finalized, is intended to help the infant formula industry comply with this notification requirement as it pertains to infant formula.

DATES: Submit either electronic or written comments on the draft guidance by February 18, 2025 to ensure that we consider your comment on this draft guidance before we begin work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by February 3, 2025.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–1334 for ''Notifying FDA of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly

available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this draft guidance to the Office of Nutrition and Food Labeling, Human Foods Program (HF–305), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Barbara Little, Office of Policy, Regulations, and Information; Human Foods Program; Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–8808.

With regard to the proposed collection of information: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Notifying FDA of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the notification requirement in section 424 of the FD&C Act (21 U.S.C. 350m) as it pertains to infant formula. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

Section 424(a)(1) of the FD&C Act requires that a manufacturer of a critical food notify FDA of a permanent discontinuance in the manufacture or an interruption of the manufacture of such food that is likely to lead to a meaningful disruption in the supply of such food in the United States, and the reasons for such discontinuance or interruption, as soon as practicable, but not later than 5 business days after such discontinuance or such interruption. Section 201(ss) of the FD&C Act (21 U.S.C. 321(ss)) defines a ''critical food'' as a food that is (1) an infant formula or (2) a medical food as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). The draft guidance discusses notification under section 424(a)(1) of the FD&C Act as it pertains to infant formula. The guidance is informed by FDA's recent experience involving manufacturer interruptions of these products and our work to improve the resiliency of the infant formula market. Although this guidance is specific to infant formula, manufacturers of other types of critical foods are still required to comply with section 424 of the FD&C Act.

The draft guidance provides FDA's interpretation of key terms used in section 424(a) of the FD&C Act; discusses what section 424(a) of the FD&C Act requires the notification to include, as well as information that FDA recommends the notification include; and provides recommendations on how manufacturers should notify FDA of a permanent discontinuance or interruption.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. FDA invites comment, in particular, on the accuracy of its estimate regarding the number of notifications a manufacturer may be expected to submit per year.

Infant Formula Requirements

OMB Control Number 0910–0256—Revision

Section 424(a)(1) of the FD&C Act requires a manufacturer of a critical food to notify FDA of a permanent discontinuance or an interruption of the manufacture of a critical food that is likely to lead to a meaningful disruption in the supply of the food in the United States. Section 201(ss) of the FD&C Act defines a ''critical food'' as a food that is (1) an infant formula or (2) a medical food as defined in section 5(b)(3) of the Orphan Drug Act. A manufacturer of a critical food is required to notify FDA of a permanent discontinuance in the manufacture or an interruption of the manufacture of such food that is likely to lead to a meaningful disruption in the supply of such food in the United States, and the reasons for such discontinuance or interruption, as soon as practicable, but not later than 5 business days after such discontinuance or such interruption. To help facilitate the process, FDA accepts notifications via email (*CriticalFoodShortage@fda.hhs.gov*).

The draft guidance entitled ''Notifying FDA of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula,'' when finalized, will provide FDA's interpretation regarding the circumstances under which infant formula manufacturers should notify FDA. The draft guidance provides recommendations for notifications to

include certain information and how respondents should notify FDA of a permanent discontinuance or interruption of supply of infant formula.

Section 424(b) of the FD&C Act requires a manufacturer of a critical food to develop, maintain, and implement a redundancy risk management plan that identifies and evaluates risks to the supply of the food for each establishment in which a critical food is manufactured. A risk management plan may identify and evaluate risks to the supply of more than one critical food manufactured at the same establishment. A risk management plan may also identify mechanisms by which the manufacturer would mitigate the impacts of a supply disruption through alternative production sites, alternative suppliers, stockpiling of inventory, or other means. Records of a risk management plan are subject to FDA inspection and copying.

Description of Respondents: Respondents to this information collection are manufacturers of critical foods.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; section 424(a)(1) of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification of a permanent discontinuance or an interruption of the manufacture of a critical food	8	1	8	2	16

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimates in table 1 are based on our experience with similar notification programs. We estimate that each year 5 manufacturers of infant formula will submit notifications in compliance with section 424(a)(1) of the FD&C Act and following recommendations found in the draft guidance. We also estimate that each year 3 manufacturers of medical foods will submit notifications in compliance with section 424(a)(1) of the FD&C Act, for a total of 8 manufacturers of a critical food. We estimate that each manufacturer will submit 1 notification for 8 total annual notifications (8 manufacturers × 1 notification). Each submission will take an estimated 2 hours to complete for an annual reporting burden of 16 hours (8 notifications × 2 hours).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; section 424(b) of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Risk management plan	11	1	11	60	660

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimates in table 2 are based on our experience with similar risk management programs. We estimate that each year 11 manufacturers of critical foods will create and maintain a risk management plan in compliance with section 424(b) of the FD&C Act. We estimate that each risk management plan will take an estimated 60 hours to create and maintain for an annual recordkeeping burden of 660 hours (11 records × 60 hours).

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/guidance-documents-regulatory-information-topic-food-and-dietary-supplements*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov.*

Dated: November 26, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–28230 Filed 12–2–24; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1993–D–0285]

Evaluating Target Animal Safety and Effectiveness of Antibacterial New Animal Drugs for Bovine Mastitis; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft revised guidance for industry (GFI) #49 entitled ''Evaluating Target Animal Safety and Effectiveness of Antibacterial New Animal Drugs for Bovine Mastitis.'' This draft guidance provides recommendations and considerations for bovine mastitis drug products with antibacterial activity that are administered by intramammary infusion.

DATES: Submit either electronic or written comments on the draft guidance by February 3, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted,

such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–1993–D–0285 for ''Evaluating Target Animal Safety and Effectiveness of Antibacterial New Animal Drugs for Bovine Mastitis.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Paulette Salmon, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6556, *pauline.salmon@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft revised GFI #49 entitled ''Evaluating Target Animal Safety and Effectiveness of Antibacterial New Animal Drugs for Bovine Mastitis.'' This draft guidance replaces final GFI #49, issued in April 1996 entitled ''Target Animal Safety And Drug Effectiveness Studies for Anti-Microbial Bovine Mastitis Products (Lactating and Non-Lactating Cow Products).'' This draft guidance provides recommendations and considerations for bovine mastitis drug products with antibacterial activity that are administered by intramammary infusion. However, this guidance may also be applicable to mastitis products administered by other routes or to products using other technologies (including those with non-antibacterial mechanisms of action).

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Evaluating Target Animal Safety and Effectiveness of Antibacterial New Animal Drugs for Bovine Mastitis.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 514 have been approved under OMB control number 0910–0032; 21 CFR 511.1 have been approved under OMB control number 0910–0117.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: November 25, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–28362 Filed 12–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Neurodevelopment, Oxidative Stress, and Synaptic Plasticity Fellowship Study Section.

Date: December 20, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Robert C. Elliott, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5190, MSC 7846, Bethesda, MD 20892, 301–435–3009, *elliotro@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 29, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–28391 Filed 12–3–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 24–17]

Notice of Finding That Aluminum Extrusions and Profile Products and Derivatives Produced or Manufactured Wholly or in Part by Kingtom Aluminio S.R.L. With the Use of Convict, Forced or Indentured Labor Are Being, or Are Likely To Be, Imported Into the United States

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice of forced labor finding.

SUMMARY: This document notifies the public that U.S. Customs and Border Protection (CBP), with the approval of the Secretary of Homeland Security, has determined that aluminum extrusions and profile products and derivatives produced or manufactured wholly or in part by Kingtom Aluminio S.R.L. with the use of convict, forced or indentured labor, are being, or are likely to be, imported into the United States.

DATES: This Finding applies to any merchandise described in Section II of this Notice that is imported on or after December 4, 2024. It also applies to any merchandise described in Section II of this Notice that has already been imported and has not been released from CBP custody before December 4, 2024.

FOR FURTHER INFORMATION CONTACT: Brian M. Hoxie, Director, Forced Labor Division, Trade Remedy Law Enforcement Directorate, Office of Trade, (202) 841–3081 or *forcedlabor@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to section 307 of the Tariff Act of 1930, as amended (19 U.S.C. 1307), ''[a]ll goods, wares, articles, and merchandise mined, produced or manufactured wholly or in part in any foreign country by convict labor or/and forced labor or/and indentured labor under penal sanctions shall not be entitled to entry at any of the ports of the United States, and the importation thereof is hereby prohibited.'' Under this section, ''forced labor'' includes ''all work or service which is exacted from any person under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily'' and includes forced or indentured child labor.

U.S. Customs and Border Protection (CBP) regulations promulgated under the authority of 19 U.S.C. 1307 are found at sections 12.42 through 12.45 of title 19 of the Code of Federal Regulations (CFR) (19 CFR 12.42–12.45). Among other things, these regulations allow any person outside of CBP to communicate a belief that a certain ''class of merchandise . . . is being, or is likely to be, imported into the United States [in violation of 19 U.S.C. 1307].'' 19 CFR 12.42(a), (b). Upon receiving such information, the Commissioner of CBP will initiate an investigation if warranted by the circumstances. 19 CFR 12.42(d). CBP also has the authority to self-initiate an investigation. 19 CFR 12.42(a).

If the Commissioner of CBP finds that the information available ''reasonably but not conclusively'' demonstrates that such merchandise within the purview of 19 U.S.C. 1307 is being, or is likely to be, imported into the United States, the Commissioner of CBP will order port directors to seize and withhold the merchandise pending further instructions. 19 CFR 12.42(e). After issuance of such a withhold release order, the covered merchandise will be detained by CBP for an admissibility determination and will be excluded unless the importer demonstrates that the merchandise was not made using labor in violation of 19 U.S.C. 1307. 19 CFR 12.43–12.44. The importer may also export the merchandise. 19 CFR 12.44(a).

These regulations also set forth the procedure for the Commissioner of CBP to issue a Finding when he determines that the merchandise is subject to the provisions of 19 U.S.C. 1307. Pursuant to 19 CFR 12.42(f), if the Commissioner of CBP finds that merchandise within the purview of 19 U.S.C. 1307 is being, or is likely to be, imported into the United States, the Commissioner will, with the approval of the Secretary of Homeland Security, publish a Finding to that effect in the Customs Bulletin and in the **Federal Register**.[1] Under the authority of 19 CFR 12.44(b), CBP may seize and forfeit imported merchandise covered by a Finding.

Through its investigation, CBP has determined that there is sufficient information to support a Finding that Kingtom Aluminio S.R.L. is using convict, forced, or indentured labor in a factory in the Dominican Republic to produce or manufacture in whole or in part aluminum extrusions and profile products and derivatives, and that such products are being, or are likely to be, imported into the United States.

II. Finding

A. General

Pursuant to 19 U.S.C. 1307 and 19 CFR 12.42(f), it is hereby determined that certain articles described in section II.B. of this Notice, that are produced or manufactured in whole or in part with the use of convict, forced, or indentured labor by Kingtom Aluminio S.R.L., are being, or are likely to be, imported into the United States. Based upon this determination, the port director may seize the covered merchandise for violation of 19 U.S.C. 1307 and commence forfeiture proceedings pursuant to 19 CFR part 162, subpart E, unless the importer establishes by satisfactory evidence that the merchandise was not produced or manufactured in any part with the use of prohibited labor specified in this Finding. 19 CFR 12.42(g).

[1] Although the regulation states that the Secretary of the Treasury must approve the issuance of a Finding, the Secretary of the Treasury delegated this authority to the Secretary of Homeland Security in Treasury Order No. 100–16, 68 FR 28322 (May 23, 2003). Under Delegation Order 7010.3, Section II.A.3, the Secretary of Homeland Security delegated the authority to issue a Finding to the Commissioner of CBP, with the approval of the Secretary of Homeland Security. The Commissioner of CBP, in turn, delegated the authority to make a Finding regarding prohibited goods under 19 U.S.C. 1307 to the Executive Assistant Commissioner, Office of Trade.

B. Articles and Entities Covered by This Finding

This Finding covers aluminum extrusions and profile products and derivatives produced or manufactured wholly or in part with aluminum and articles thereof classified under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7604.21.0010, 7604.29.1010, 7604.29.3060, 7604.29.5050, 7604.29.5090, 7608.20.0090, 7610.90.0080 and any other relevant subheadings under Chapter 76, which are produced or manufactured wholly or in part by Kingtom Aluminio S.R.L. The Secretary of Homeland Security has reviewed and approved this Finding.

Rose M. Brophy,

Acting Executive Assistant Commissioner, Office of Trade.

[FR Doc. 2024–27686 Filed 12–3–24; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_AK_FRN_MO4500183286; AA–10495]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: The Bureau of Land Management (BLM) hereby provides constructive notice that it will issue an appealable decision approving conveyance of the surface and subsurface estates in certain lands to Sealaska Corporation, an Alaska Native regional corporation, pursuant to the Alaska Native Claims Settlement Act of 1971 (ANCSA), as amended.

DATES: Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the time limits set out in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: You may obtain a copy of the decision from the Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, AK 99513–7504.

FOR FURTHER INFORMATION CONTACT: Dina L. Torres, BLM Alaska State Office, 907–271–5699, or *dtorres@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point of contact in the United States.

SUPPLEMENTARY INFORMATION: As required by 43 CFR 2650.7(d), notice is hereby given that the BLM will issue an appealable decision to Sealaska Corporation. The decision approves conveyance of the surface and subsurface estates in certain lands pursuant to ANCSA (43 U.S.C. 1601, *et seq.*), as amended. The lands are located on Baranof Island, Alaska, within T. 57 S., R. 64 E., Copper River Meridian, Alaska, and aggregate 10.54 acres.

The decision addresses public access easements, if any, to be reserved to the United States pursuant to sec. 17(b) of ANCSA (43 U.S.C. 1616(b)), in the lands described above.

The BLM will also publish notice of the decision once a week for four consecutive weeks in the ''Juneau Empire'' newspaper.

Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the following time limits:

1. Unknown parties, parties unable to be located after reasonable efforts have been expended to locate, parties who fail or refuse to sign their return receipt, and parties who receive a copy of the decision by regular mail which is not certified, return receipt requested, shall have until January 3, 2025 to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4 shall be deemed to have waived their rights. Notices of appeal transmitted by facsimile will not be accepted as timely filed.

Dina L. Torres,

Management and Program Analyst, Division of Lands and Cadastral.

[FR Doc. 2024–28373 Filed 12–3–24; 8:45 am]

BILLING CODE 4331–10–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–608 and 731–TA–1420 (Review)]

Steel Racks From China; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping and countervailing duty orders on steel racks from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: November 4, 2024.

FOR FURTHER INFORMATION CONTACT: Peter Stebbins (202) 205–2039, Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On November 4, 2024, the Commission determined that the domestic interested party group response to its notice of institution (89 FR 62779, August 1, 2024) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.[1] Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Act (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report.—A staff report containing information concerning the subject matter of the reviews has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for these reviews on January 28, 2025. A public version will be issued

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

thereafter, pursuant to § 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in § 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the reviews may file written comments with the Secretary on what determination the Commission should reach in the reviews. Comments are due on or before 5:15 p.m. on February 5, 2025, and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by February 5, 2025. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined that these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Act; this notice is published pursuant to § 207.62 of the Commission's rules.

By order of the Commission.

[2] The Commission has found the response submitted on behalf of the Coalition for Fair Rack Imports, an association of U.S. producers of steel racks, to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

Issued: November 29, 2024.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2024–28413 Filed 12–3–24; 8:45 am]

BILLING CODE 7020–02–P

NATIONAL SCIENCE FOUNDATION

Astronomy and Astrophysics Advisory Committee; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Astronomy and Astrophysics Advisory Committee (13883) (Hybrid).

Date and Time: January 30–January 31, 2025; 9:30 a.m.–4:30 p.m.

Place: National Science Foundation, 2415 Eisenhower Avenue, Room 2210/2220, Alexandria, VA 22314 (In-Person and Virtual).

This is a hybrid meeting. Members and the public may attend virtually via Zoom or in person.

Attendance information for the meeting will be forthcoming on the website: *https://www.nsf.gov/mps/ast/aaac.jsp.*

The link for registration for Zoom is: *https://nsf.zoomgov.com/webinar/register/WN_ihbu7M8uTȲG1GQjf0F6YHw.*

Type of Meeting: Open.

Contact Person: Dr. Daniel Fabrycky, Program Director, Division of Astronomical Sciences, Suite W 9176, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: 703–292–8490.

Purpose of Meeting: To hear presentations of current programming by representatives from NSF, NASA, DOE and other agencies relevant to astronomy and astrophysics; to discuss current and potential areas of cooperation between the agencies; to formulate recommendations for continued and new areas of cooperation and mechanisms for achieving them.

Agenda: To provide updates on Agency activities and to discuss the Committees draft annual report due 15 March 2025.

Dated: November 29, 2024.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2024–28400 Filed 12–3–24; 8:45 am]

BILLING CODE 7555–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Request To Release Airport Property at the Laredo International Airport (LRD), Laredo, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of request to release airport property.

SUMMARY: The FAA proposes to rule and invite public comment on the release of land at the Laredo International Airport under the provisions of the Federal Property and Administrative Services Act of 1949, and the Surplus Property Act of 1944.

DATES: Comments must be received on or before January 3, 2025.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Mr. Rodney Clark, Manager, Federal Aviation Administration, Southwest Region, Airports Division, Texas Airports Development Office, ASW–650, Fort Worth, Texas 76177.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Gilberto Sanchez, Airport Director, at the following address: 5210 Bob Bullock Loop, Laredo, TX 78041.

FOR FURTHER INFORMATION CONTACT: Mr. Sean Newton, Program Manager, Federal Aviation Administration, Texas Airports Development Office, ASW–650, 10101 Hillwood Parkway, Fort Worth, Texas 76177. Telephone: (817) 222–5560. Email: *Sean.A.Newton@FAA.gov.* Fax: (817) 222–5989.

SUPPLEMENTARY INFORMATION: The Laredo International Airport is under the provisions of the Federal Property and Administrative Services Act of 1949, and the Surplus Property Act of 1944.

The following is a brief overview of the request:

The City of Laredo requests the release of 7.498 acres of airport land located at approximately 5210 Bob Bullock Loop, Laredo, TX 78041. The land was acquired by Indenture of the Federal Property and Administrative Services Act of 1949, and the Surplus Property Act of 1944. The property to be released will be sold to Texas Department of Transportation for US Highway 59 right-of-way improvements. The proceeds of the sale will benefit civil aviation through airport improvements.

Any person may inspect the request in person at the FAA office listed above

under **FOR FURTHER INFORMATION CONTACT.**

In addition, any person may, upon request, inspect the application, notice and other documents relevant to the application in person at the City of Laredo Legal Department, telephone number (956) 791–7318.

Issued in Fort Worth, Texas, on November 14, 2024.

Ignacio Flores,

Director, Office of Airports Southwest Region.

[FR Doc. 2024–28301 Filed 12–3–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Request To Release Airport Property at the Roswell Air Center, Roswell, New Mexico

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of request to release airport property.

SUMMARY: The FAA proposes to rule and invite public comment on the release of land at the Roswell Air Center under the provisions of the Federal Property and Administrative Services Act of 1949, and the Surplus Property Act of 1944.

DATES: Comments must be received on or before January 3, 2025.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Mr. Justin Barker, Manager, Federal Aviation Administration, Southwest Region, Airports Division, Louisiana/New Mexico Airports Development Office, ASW–640, Fort Worth, Texas 76177.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Bobbi Thompson, Airport Director, at the following address: 1 Jerry Smith Circle, Roswell, New Mexico 88203.

FOR FURTHER INFORMATION CONTACT: Ms. Sarah Young, Program Manager, Federal Aviation Administration, Louisiana/New Mexico Airports Development Office, ASW–640, 10101 Hillwood Parkway, Fort Worth, Texas 76177. Telephone: (817) 222–5146. Email: *Sarah.J.Young@FAA.gov.* Fax: (817) 222–5989.

SUPPLEMENTARY INFORMATION: The Roswell Air Center under the provisions of the Federal Property and Administrative Services Act of 1949, and the Surplus Property Act of 1944. The following is a brief overview of the request:

The City of Roswell requests the release of 45.23 acres of land located at approximately 42 West Earl Cummings Loop, Roswell, New Mexico, 88203. The land was acquired by Indenture of the Federal Property and Administrative Services Act of 1949, and the Surplus Property Act of 1944. The property to be released will be sold to ARK Prefab LLC for expansion of their manufacturing business. The proceeds of the sale will benefit civil aviation through airport improvements.

Any person may inspect the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT.**

In addition, any person may, upon request, inspect the application, notice and other documents relevant to the application in person at the City of Roswell Legal Department, telephone number (575) 637–6200.

Issued in Fort Worth, Texas, on November 25, 2024.

Ignacio Flores,

Director, Office of Airports Southwest Region.

[FR Doc. 2024–28300 Filed 12–3–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of limitation on claims for judicial review of actions by the California Department of Transportation (Caltrans).

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans that are final. The actions relate to a proposed highway project, State Route-47 on the Vincent Thomas Bridge in the County of Los Angeles, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before May 5, 2025. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: Jason Roach, Senior Environmental Scientist, Caltrans, 100 South Main Street, Los Angeles, California, Hours: 8:00–4:30, Phone: (213) 310–2653, Email: *jason.roach@dot.ca.gov.*

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that the Caltrans has taken final agency actions subject to 23 U.S.C. 139(l)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: The Vincent Thomas Bridge (VTB) Deck Replacement Project on State Route 47 in Los Angeles County proposes to replace the entire bridge deck, guardrail barriers, and seismic sensors on the bridge to preserve the structural integrity of the VTB deck and to enhance the bridge's overall safety. The transportation project's construction is anticipated to last approximately 16 months. The VTB has been in service for 60 years. Although the bridge is structurally sound, the bridge deck is rapidly deteriorating due to concrete fatigue caused by heavy truck traffic and environmental deterioration due to age and the marine environment. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Environmental Assessment/Finding of No Significant Impact (EA/FONSI) for the project, approved on September 27, 2024 and in other documents in the project records. The EA/FONSI and other project records are available by contacting Caltrans at the address provided above. The Caltrans EA/FONSI can be viewed and downloaded from the project website at *https://www.virtualeventroom.com/caltrans/vtb/.*

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. National Environmental Policy Act of 1969
2. Clean Air Act, 42 U.S.C. 7401–7671
3. Endangered Species Act of 1973 (ESA), 16 U.S.C. 1531–1544
4. National Historic Preservation Act of 1966 (NHPA)
5. Clean Water Act, 33 U.S.C. 1251–1387 (sections 319, 401, and 404)

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on

Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Antonio Johnson,

Director of Planning, Environmental and Right of Way, Federal Highway Administration, California Division.

[FR Doc. 2024–28369 Filed 12–3–24; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2022–0233]

Crash Preventability Determination Program

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), U.S. Department of Transportation (DOT).

ACTION: Notice; response to public comments.

SUMMARY: FMCSA announces changes to its Crash Preventability Determination Program (CPDP). Under the CPDP carriers and drivers may submit requests for data review (RDR) to FMCSA to determine the preventability of commercial motor vehicle (CMV) crashes. FMCSA proposed these changes in its **Federal Register** notice, ''Crash Preventability Determination Program,'' published at *https://www.regulations.gov/docket/FMCSA-2022-0233* on April 13, 2023. This notice finalizes the proposed changes, responds to comments received, and outlines next steps for implementation.

FOR FURTHER INFORMATION CONTACT: Mr. Catterson Oh, Compliance Division, Office of Enforcement and Compliance, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 366–6160, *Catterson.Oh@dot.gov.*

If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION: FMCSA organizes this notice as follows:

I. Background

FMCSA currently accepts RDRs in its DataQs system to evaluate the preventability of 16 specific crash types as set forth in a notice published in the **Federal Register** on May 6, 2020 (85 FR 27017). On April 13, 2023, FMCSA proposed changes to existing and new crash types in CPDP and announced a 60-day preview and comment period for stakeholders (88 FR 22518). The comment period ended on June 12, 2023.

II. Summary of Public Comments and Response

FMCSA received 60 unique comments in response to the April 2023, notice; one comment was received outside the notice comment period. Of these, 53 submissions contained comments specifically on the changes proposed in that notice. The commenters included motor carriers, drivers/owner-operators, industry associations, and safety consultants. The following entities submitted relevant comments: AIST Safety Consultants, American Trucking Associations (ATA), Big M, Cessna Transport, David W. Blankenship LLC, Fuel Delivery Services Inc., Heyl Truck Lines, Independent Carrier Safety Association, J.B. Hunt Transport, Inc., Knight-Swift Transportation, Lytx, National Motor Freight Traffic Association, Inc. (NFMTA), National Tank Truck Carriers (NTTC), National Waste and Recycling Association, Owner-Operator Independent Drivers Association (OOIDA), Ray Walker Trucking, Sanborn, Brandon, Duvall & Bobbitt Cp., L.P.A., Siskiyou Transportation, Inc., The Forward Group, Inc., TMC Transportation, Trailiner Corp, Veolia North America, Werner Enterprisers, Inc., a consortium of associations Air & Expedited Motor Carriers Association, Airforwarders Association, Alliance for Safe, Efficient and Competitive Truck Transportation, Auto Haulers Association of America, American Home Furnishings Alliance, Apex Capital Corp, National Association of Small Trucking Companies, Sompo International, Specialized Furniture Carriers, The Expedite Association of North American, Transportation & Logistics Council, Transportation Loss Prevention and Security Association, and individuals who did not identify their organizations. Many stakeholders provided comments on multiple proposed changes and topics. Comments outside the scope of the April 2023 notice are not discussed in this notice.

Comments in response to the April 2023, notice largely supported the proposed changes. The relevant topics generating the most responses were: (1) proposal for new crash types, particularly the inclusion of requests that have video evidence of the crash; (2) changing the eligibility standard for wrong direction crashes; and (3) the turnaround time for a preventability determination on an eligible crash. In addition, many commenters suggested additional crash types to include as eligible for the program. Two commenters (Josh Curry and Charles E. Guitard) stated their opposition to expanding the program. Josh Curry noted that the ''cost to benefits ratio can't justify it,'' and Charles E. Guitard would like the Agency to address existing issues, such as the lack of truck parking. The following sections provide a summary of the comments received and the Agency's responses.

III. List of Eligible Crash Types

A. Changes to Existing Crash Types

While many commenters favored expanding the eligibility of the program, few specifically addressed the changes to existing crash types that would allow more crashes to be eligible. Five commenters (Werner, NFMTA, NTTC, Steve Davis, Siskiyou Transportation, Inc., and OOIDA) specifically expressed support for the proposed modifications.

AIST Safety Consulting supported FMCSA's proposal to remove the phrase ''The Commercial Motor Vehicle (CMV) was struck because'' to address unfair disqualification of CMVs that were the striking vehicle but could not have avoided the collision.'' They also supported the acceptance of multi-vehicle crashes as eligible under the existing crash types.

The Independent Carrier Safety Association and ATA supported the change to the crash type originally worded ''When the CMV was struck by a driver who admitted to falling asleep or admitted to distracted driving'' to remove the admission requirement.

Barry Poole of Griffith, Indiana, recommended that FMCSA, ''Please strike the term committing or attempting to commit suicide and replace with died by or attempting to die by.''

FMCSA Response

FMCSA will modify the list of existing crash types as proposed in the April 13, 2023, notice. These changes will encompass more scenarios, such as where the CMV was not the striking vehicle and multi-vehicle crashes.

B. New Crash Types

Many commenters welcomed the addition of new eligible crash types to the program. The notice proposed adding the following types:

1. CMV was struck on the side by a motorist operating in the same direction.
2. CMV was struck because another motorist was entering the roadway from a private driveway or parking lot.
3. CMV was struck because another motorist lost control of their vehicle. The Police Accident Report (PAR) must specifically mention loss of control either in the citation, contributing factors, and/or PAR narrative.
4. Any other type of crash involving a CMV where a video demonstrates the sequence of events of the crash.

Twenty-six commenters supported the inclusion of the four new crash types. The crash type ''Any other crash involving a CMV where a video demonstrates the sequence of events of the crash,'' generated the most comments, with fourteen commenters (The Forward Group, Inc., Jeff Loggins, Trailiner Corp, AIST Safety Consultants, J.B. Hunt, NWRA, NTTC, Independent Carrier Safety Association, ATA, Werner Enterprises, Inc., David Search, and three anonymous posters) specifically addressing this change.

Three commenters (Jeff Loggins, Trailiner Corp, and an anonymous commenter) offered remarks on the challenges of uploading videos to the DataQs system. These commenters requested that the DataQs system be updated to allow upload of more file types and larger file sizes.

ATA, J.B. Hunt Transport, Inc., and an anonymous commenter expressed concerns with the Agency's handling of video files. ATA's comments noted ''ATA urges FMCSA to further clarify that any video evidence should be reviewed, not just an onboard video recorder (*i.e.,* surveillance footage, cell phone video, etc.). Furthermore, FMCSA should clarify the expectation for demonstrating the sequence of events of the crash . . . FMCSA should not expect, nor require, video evidence in the hours and days leading up to the crash. Additionally, FMCSA should take steps to ensure data privacy when submitting video evidence and ensure that any video submissions are permanently deleted after a determination has been made.'' J.B. Hunt Transport, Inc., believes that video submissions should be treated as confidential business information and exempt from public disclosure. An anonymous commenter inquired about the policies surrounding video submissions, stating ''What will be done with the videos that are submitted? . . . Just think it should also be disclosed if we will be submitting our private footage.''

In addition to the four proposed crash types, many commenters also requested the program expand to include other crash types. The crash types suggested by commenters are listed below.

1. Crashes at non-controlled intersections, when video evidence is provided
2. Crashes where the other vehicle tries to outrun the truck
3. Crashes with an abandoned vehicle left in the roadway
4. Crashes where the other vehicle makes an improper lane change or a sideswipe crash
5. Crashes where the other driver is not legally licensed to drive
6. Weather related crashes (2 comments)
7. Crashes where the other driver took unsafe actions (2 comments)
8. Crashes where the other vehicle is operated at excessive speed
9. Crashes where the other vehicle has an extreme lane incursion
10. Crashes where the other motorist causes the crash
11. Crashes where other vehicle pulls out of parking lot
12. Crashes where other vehicle ''Failed to Maintain Lane''
13. Crashes where other vehicle fails to ''yield right of way''
14. Crashes instigated by a road rage incident
15. Crashes if the Crash avoidance systems were not recording or detecting any harsh or hard handling prior to the crash or improper handling of the CMV prior to or at the time of the crash

FMCSA Response

FMCSA reviewed the list of proposed crash types and found that many were already incorporated in the new and modified crash types proposed in the April 2023, notice. FMCSA does not plan to include additional crash types beyond those proposed in the April 13, 2023, notice at this time. The eligible crash types listed are less complex crash events that do not require extensive expertise to review. Crash scenarios not specifically listed as eligible may be accepted to the program if a video showing the sequence of the crash is submitted with the request.

Regarding suggestions to increase file size and type limitations in DataQs to accommodate video file submissions, FMCSA notes that in September 2023, the file size limitation in DataQs was increased to 25 MB, and the system accepts most commonly used file formats. In response to comments by ATA, J.B. Hunt and an anonymous commenter on video privacy and security, FMCSA notes that all files uploaded to DataQs are encrypted. Information submitted to the CPDP is not used for enforcement purposes. FMCSA also notes that documents uploaded to RDRs continue to be accessible in DataQs after a determination is made, and the RDR may be reopened if additional information is provided to the Agency. Federal records management regulations require the Agency to keep files submitted to the DataQs system for a mandated timeframe.

The video footage submitted with the CPDP request is expected to include the full sequence of the crash, but submitters should not include video files of hours or days preceding the crash. As a result, the final list of eligible crash types is as follows:

1. CMV was struck in the rear by a motorist
2. CMV was struck on the side at the rear by a motorist
3. CMV was struck while legally stopped at a traffic control device or parked, including while the vehicle was unattended
4. CMV was struck because another motorist was driving in the wrong direction
5. CMV was struck because another motorist was making a U-turn or illegal turn
6. CMV was struck because another motorist did not stop or slow in traffic
7. CMV was struck because another motorist failed to stop at a traffic control device
8. CMV was struck because another individual was under the influence (or related violation, such as operating while intoxicated), according to the legal standard of the jurisdiction where the crash occurred
9. CMV was struck because another motorist experienced a medical issue which contributed to the crash
10. CMV was struck because another motorist fell asleep
11. CMV was struck because another motorist was distracted (*e.g.,* cellphone, GPS, passengers, other)
12. CMV was struck by cargo or equipment from another vehicle, or debris (*e.g.,* fallen rock, fallen trees, unidentifiable items in the road)
13. CMV crash was a result of an infrastructure failure
14. CMV struck an animal
15. CMV crash involving a suicide death or suicide attempt

16. CMV was struck on the side by a motorist operating in the same direction as CMV
17. CMV was struck because another motorist was entering the roadway from a private driveway or parking lot
18. CMV was struck because another motorist lost control of the vehicle
19. CMV was involved in a crash with a non-motorist
20. CMV was involved in a crash type that seldom occurs and does not meet another eligible crash type (*e.g.,* being struck by an airplane, skydiver, or a deceased driver in another vehicle)
21. Any other type of crash, not listed above, where a CMV was involved and a video demonstrates the sequence of events of the crash

IV. Reminders on CPDP Process and System Impacts

A. Process

Two commenters (OOIDA and Bryan Henry) want FMCSA to proactively review crashes for preventability and remove the requirement for the motor carrier or driver to submit a request. OOIDA stated that ''Given the CPDP data over the last five years, the burden should now fall on the agency, rather than the submitter, to overturn qualifying crashes . . . We believe transferring the burden to the agency to determine crash preventability will help keep safe, experienced motor carriers in business and will also reduce the current backlog of CPDP submissions.''

Additionally, two other commenters (Sanborn, Brandon, Duvall & Bobbitt Co., L.P.A. and Henry Seaton) believe that the CPDP lacks due process. Sanborn, Brandon, Duvall & Bobbitt Co., L.P.A. commented ''We advocate for the CPDP to restore procedural and substantive due process to the CPDP by providing a hearing, a right to appeal, the right to subpoena evidence and witnesses, and by withholding the CSA score effects of crashes until the due process results in a finding the crash was preventable.''

Eleven commenters (Jeff Wood, Stephen Hobbs, AIST Safety Consulting, Knight-Swift Transportation, Ray Walker Trucking, TMC Transportation, Sanborn, Brandon, Duvall & Bobbitt Co., L.P.A., J.B. Hunt Transport, Inc., National Tank Truck Carriers, ATA, and OOIDA) addressed the review time associated with receiving a determination from the CPDP. All eleven comments on this topic noted that the review time is too long. J.B. Hunt Transport, Inc., asked FMCSA to ensure adequate staffing for the expanded program.

The April 2023 notice maintained that for crashes resulting in a fatality, proper DOT post-accident drug and alcohol testing results or the required explanation of why the tests were not completed or not completed within the timeframes specified in § 382.303(d)(1) and (d)(2), must be submitted. Knight-Swift Transportation commented on this requirement and would like more consideration for circumstances where privacy laws prevent the motor carrier from getting an update on the severity of injuries from the crash. They request that an ''Undecided'' determination be rendered only if the carrier does not provide a reason for not performing the test.

FMCSA Response

The CPDP process will remain initiated by a request from the motor carrier, driver, or authorized representatives. The burden is on the submitter to provide compelling evidence that the crash is eligible and not preventable. Submitters are encouraged to submit other documents to support their request including videos, pictures, and court documents. The crash data fields that are submitted to FMCSA in the Motor Carrier Management Information System (MCMIS) are a subset of the information that is available on the PAR. FMCSA does not have direct access to PARs or other supporting documentation about a crash; and a preventability determination requires more information than is available in MCMIS.

Regarding the due process comments, the CPDP is a voluntary program that supports the SMS. FMCSA does not believe that using recorded crashes for safety assessment and enforcement workload prioritization purposes constitutes deprivation of a property interest for which due process is required. This program does not amend any prior legislative rules, nor does it provide a basis for any new enforcement actions. And it does not require a notice and comment rulemaking under the Administrative Procedure Act (49 U.S.C. 551, 553). This program does not alter FMCSA's safety fitness standard under 49 U.S.C. 31144 and 49 CFR part 385. As expressly stated on the SMS website, FMCSA uses SMS data to prioritize motor carriers for further monitoring, and data ''is not intended to imply any federal safety rating of the carrier pursuant to 49 U.S.C. 31144.'' This program does not impact preventability determinations made through FMCSA safety investigations conducted under 49 CFR part 385, nor the preventability standard contained therein. Preventability will be determined according to the following standard: ''If a driver, who exercises normal judgment and foresight could have foreseen the possibility of the accident that in fact occurred and avoided it by taking steps within his/her control which would not have risked causing another kind of mishap, the accident was preventable.''

The crash preventability determinations made under this program thus will not affect any carrier's safety rating or ability to operate. FMCSA will not issue penalties or sanctions on the basis of these determinations, and the determinations do not establish any obligations or impose legal requirements on any motor carrier. These determinations also will not change how the Agency will make enforcement decisions.

FMCSA emphasizes that these determinations do not establish legal liability, fault, or negligence by any party. Fault is generally determined in the course of civil or criminal proceedings and results in the assignment of legal liability for the consequences of a crash. By contrast, a preventability determination is not a proceeding to assign legal liability for a crash. Under 49 U.S.C. 504(f), FMCSA's preventability determinations may not be admitted into evidence or used in a civil action for damages and are not reliable for that purpose (85 FR 27017, 27018).

If a submitter receives a determination that the crash was Preventable or Undecided, or if the RDR is closed for failure to submit additional requested documents, the RDR may be re-opened once. Additionally, submitters have an option to create a new RDR if additional documents or evidence is provided. FMCSA will reconsider the request if the submitter provides additional documentation to support the request.

Regarding Knight-Swift Transportation's request for leniency on the program requirement for proper DOT post-accident drug and alcohol testing results or the required explanation of why the tests were not completed or not completed within the timeframes specified in § 382.303(d)(1) and (d)(2), the Agency will not change this requirement for fatal crashes. This program requirement aligns with carriers' responsibilities for post-accident drug and alcohol testing outlined in the Federal Motor Carrier Safety Regulations.

FMCSA continues to provide clarification and individual reminders to submitters participating in the program, as questions have arisen. To assist the public in better understanding the CPDP process and system impacts,

FMCSA is providing the following reminders.

Preventability Standard

The Agency emphasizes that these changes to the CPDP do not affect the legal standard for or procedures governing FMCSA's safety fitness determinations under 49 U.S.C. 31144 and 49 CFR part 385, subpart A. The Agency's standard for making a preventability determination for purposes of assigning a safety fitness rating remains unchanged and is set forth in 49 CFR part 385, Appendix B, section II.B(e). The burden for a CPDP not preventable determination continues to be on the submitter to show by compelling evidence that the crash was not preventable. FMCSA will continue to display the current disclaimer on the SMS website and will continue to include language in its determination notifications to submitters explaining that a crash preventability determination does not assign fault or legal liability for the crash.

Process

FMCSA will continue to make a determination of ''Preventable'' if there is evidence that the driver or carrier could have prevented the crash or was prohibited from operating the CMV at the time of the crash. This includes, but is not limited to, out-of-service violations, license violations, and driver prohibitions in the Agency's Drug and Alcohol Clearinghouse.

FMCSA will continue to rely on the MCMIS crash report to confirm that the driver was properly licensed at the time of the crash. If this information is missing from the MCMIS report or MCMIS indicates the wrong license class for the vehicle being operated, the Commercial Driver's License Information System (CDLIS) report will be used to verify the driver's license. Additionally, the CDLIS report is used to confirm the driver was not operating with an open license withdrawal or while suspended due to a drug or alcohol violation. The crash will be deemed ''Preventable'' if documentation shows that the driver was not qualified at the time of the crash.

If CDLIS is used to verify the license and the driver has renewed the license or medical certificate since the date of the crash, evidence of licensing or medical certification on the date of the crash will continue to be requested from the submitter. Failure to provide any requested information within 14 calendar days will continue to preclude a ''Not Preventable'' determination and result in an ''Undecided'' determination.

As a reminder, for crashes resulting in a fatality, proper DOT post-accident drug and alcohol testing results, or the required explanation of why the tests were not conducted or not completed within the timeframes specified in § 382.303(d)(1) and (d)(2), must be submitted. The tests must be conducted in accordance with the requirements of 49 CFR part 40, which requires the use of a urine specimen for drug testing and either breath or saliva testing for alcohol. An exception for post-accident alcohol testing conducted under the authority of Federal, State, or local officials permits the use of a blood test. Additionally, post-accident drug testing under the authority of Federal, State, or local officials requires the use of a urine specimen for drug testing. The crash will be deemed ''Preventable'' if the drug or alcohol test results are positive or the driver refuses to submit to a test. More information about proper drug and alcohol testing procedures can be found at *https://www.fmcsa.dot.gov/regulations/drug-alcohol-testing-program.*

Failure to provide requested documents within 14 calendar days may preclude a ''Not Preventable'' determination and may result in an ''Undecided'' determination.

B. Document Requirements

Three commenters (Siskiyou Transportation, Inc., ATA, and Werner Enterprises, Inc.) responded to FMCSA's continued requirement for submitters to provide the complete PAR to participate in the program. Siskiyou Transportation, Inc. and ATA want FMCSA to accept requests that do not include a PAR but have other crash information reports. Werner Enterprises, Inc. would like the PAR requirement rescinded for requests where there is sufficient video footage of the event. Both ATA and Werner Enterprises, Inc. commented on the difficulty and delay that is associated with obtaining PARs.

FMCSA Response

FMCSA will continue to require a PAR issued from a law enforcement agency as a condition of eligibility for the program. This official documentation is needed to corroborate other information provided with the RDR to ensure the correct carrier, driver, and crash event is being reviewed for preventability. Additionally, the Agency found during the 2-year Crash Preventability Demonstration Program that the PAR is best single source of crash information and that the majority of PARs submitted contained sufficient detail to complete a preventability review (84 FR 38087).

C. Impacts to SMS and PSP

FMCSA did not propose changes to the use, display, and notations of determinations from the CPDP on SMS and PSP. Six commenters (the National Motor Freight Traffic Association (NMFTA), TMC Transportation, the Owner-Operators OOIDA, Lewis Britton, Jeff Loggins, and Sanborn, Brandon, Duvall & Bobbitt Co., L.P.A.) recommended that FMCSA modify how crashes submitted to the program, and those determined ''Not Preventable,'' are handled on SMS and PSP. NMFTA and OOIDA want FMCSA to remove crashes determined ''Not Preventable'' entirely from SMS. TMC Transportation would like a 30-day grace period before a crash is posted to SMS so the carrier has an opportunity to request a preventability review of the crash. Lewis Britton, Jeff Loggins, and Sanborn, Brandon, Duvall & Bobbitt Co., L.P.A. would like FMCSA to suspend the use of crashes submitted to the CPDP in SMS calculations while the requests are under review.

FMCSA Response

FMCSA is not making changes to the way determinations from the CPDP are used, displayed, or notated on SMS and PSP at this time. FMCSA will continue to list Not Preventable crashes on the public SMS website. However, the crash will continue to appear in a separate table from all other crashes. Crashes found to be ''Not Preventable'' will not be included in the calculation of the motor carrier's Crash Indicator BASIC. Crashes found to be ''Preventable'' and ''Undecided'' will continue to be used the calculation of the Crash Indicator BASIC. Only not preventable determinations will continue to be noted on the driver's PSP record. The Agency believes that the public display of all crashes, regardless of the preventability determination, provides the most complete information regarding a motor carrier's safety performance record. The Agency is committed to the open and transparent reporting of safety performance data.

FMCSA is committed to ensuring that its methodology for prioritizing motor carriers for interventions accurately reflects carriers' safety performance. The Agency will continue to evaluate the methodology's effectiveness and propose improvements when needed.

D. Implementation of Crash Type Updates to CPDP

FMCSA stated in the April 2023, notice that it expected to have a start date for the new crash types, and the

new crash types would not be retroactive, that is, a crash that occurred before the start date of the new crash types would not become eligible for submission under the CPDP after the start date. Keith Shields, John Casey, and an anonymous commenter requested that FMCSA apply eligibility of the new crash types retroactively. Keith Shields asked that the new crash types apply to crashes that occurred 1 year to 18 months before the start date of the new crash types. The anonymous commenter would like a 12-to-24-month retroactive application for the acceptance of crashes with video evidence.

FMCSA Response

The eligibility criteria for the new and updated crash types will not be applied retroactively to ensure that crashes that occurred during the same period are analyzed with a consistent set of criteria. The Agency will accept RDRs for the new and updated crash types for crashes that occur on or after December 1, 2024. FMCSA will announce on the CPDP website at *https://www.fmcsa.dot.gov/crash-preventability-determination-program* when DataQs will be available to accept the submissions of the new and updated crash types. Crashes that occur before December 1, 2024, will be evaluated under the eligibility criteria established on May 2020 (87 FR 27017).

The Agency reworded the updated crash type to expand eligibility by including indirect types of crashes. For example, ''CMV was struck by a driver who experienced a medical issue which contributed to the crash'' has changed to ''CMV was struck because another motorist experienced a medical issue which contributed to the crash,'' which allows for scenarios where a motorist (V1) experiencing a medical issue strikes another vehicle (V2) which then strikes a CMV (V3). To be eligible for the prior definition, V1 had to directly strike V3, but the updated changes allow for an indirect strike.

The below table shows the current list and new and updated eligible crash types for crashes occurring on or after December 1, 2024:

Current list of eligible crash types	Final list of new and updated eligible crash types (for crashes occurring on or after December 1, 2024)
1. CMV was struck in the rear by a motorist	1. CMV was struck in the rear by a motorist.
2. CMV was struck on the side at the rear by a motorist	2. CMV was struck on the side at the rear by a motorist.
3. MV was struck while legally stopped at a traffic control device (*e.g.,* stop sign, red light or yield); or while parked, including while the vehicle was unattended.	3. CMV was struck while legally stopped at a traffic control device or parked, including while the vehicle was unattended.
4. CMV was struck by a motorist driving in the wrong direction	4. CMV was struck because another motorist was driving in the wrong direction.
5. CMV was struck by another motorist in a crash when a driver was operating in the wrong direction.	
6. CMV was struck by a vehicle that was making a U-turn or illegal turn	5. CMV was struck because another motorist was making a U-turn or illegal turn.
7. CMV was struck by a vehicle that did not stop or slow in traffic	6. CMV was struck because another motorist did not stop or slow in traffic.
8. CMV was struck by a vehicle that failed to stop at a traffic control device.	7. CMV was struck because another motorist failed to stop at a traffic control device.
9. CMV was struck by an individual under the influence (or related violation, such as operating while intoxicated), according to the legal standard of the jurisdiction where the crash occurred, where the individual was charged or arrested, failed a field or other test, or refused to test.	8. CMV was struck because another individual was under the influence (or related violation, such as operating while intoxicated), according to the legal standard of the jurisdiction where the crash occurred.
10. CMV was struck by another motorist in a crash where an individual was under the influence (or related violation such as operating while intoxicated), according to the legal standard of the jurisdiction where the crash occurred, where the individual was charged or arrested, failed a field or other test, or refused to test.	
11. CMV was struck by a driver who experienced a medical issue which contributed to the crash.	9. CMV was struck because another motorist experienced a medical issue which contributed to the crash.
12. CMV was struck by a driver who admitted falling asleep or admitted distracted driving (*e.g.,* cellphone, GPS, passengers, other).	10. CMV was struck because another motorist fell asleep.
	11. CMV was struck because another motorist was distracted (*e.g.,* cellphone, GPS, passengers, other).
13. CMV was struck by cargo, equipment, or debris (*e.g.,* fallen rock, fallen trees, unidentifiable items in the road); or crash was a result of an infrastructure failure.	12. CMV was struck by cargo or equipment from another vehicle, or debris (*e.g.,* fallen rock, fallen trees, unidentifiable items in the road).
	13. CMV crash was a result of an infrastructure failure.
14. CMV struck an animal	14. CMV struck an animal.
15. CMV struck an individual committing or attempting to commit suicide.	15. CMV crash involving a suicide death or suicide attempt.
	16. CMV was struck on the side by a motorist operating in the same direction as CMV.
	17. CMV was struck because another motorist was entering the roadway from a private driveway or parking lot.
	18. CMV was struck because another motorist lost control of the vehicle.
	19. CMV was involved in a crash with a non-motorist.
16. CMV was involved in a crash type that seldom occurs and does not meet another eligible crash type (*e.g.,* being struck by an airplane or skydiver or being struck by a deceased driver).	20. CMV was involved in a crash type that seldom occurs and does not meet another eligible crash type (*e.g.,* being struck by an airplane, skydiver, or a deceased driver in another vehicle).

Current list of eligible crash types	Final list of new and updated eligible crash types (for crashes occurring on or after December 1, 2024)
	21. Any other type of crash, not listed above, where a CMV was involved and a video demonstrates the sequence of events of the crash.

V. Other Comments on Changes Not Proposed

In addition to the changes proposed in the April 2023, notice, six commenters (Jeff Loggins, Steve Davis, AIST Safety Consulting, Knight-Swift Transportation, Siskiyou Transportation, Inc., and TMC Transportation) requested that FMCSA expand the eligibility requirements for the crash type ''CMV was struck because another motorist was driving in the wrong direction.'' The current eligibility guide states that the crash must have the following elements, ''The vehicle in the crash was driving in the wrong direction (*e.g.,* northbound in the southbound lanes) AND the vehicle was completely in the wrong lane (*i.e.,* not partially across the center line).'' All six commenters want FMCSA to consider crashes where the other vehicle was partially across the center line as eligible under this crash type. Steve Davis made the recommendation, ''My recommendation is that if any portion of the oncoming vehicle crosses the center line and strikes our CMV resulting in a DOT Recordable accident, then it should be deemed as non-preventable on the part of the motor carrier.'' AIST Safety Consulting would like FMCSA to, ''Broaden eligibility for Wrong Direction cases . . . Consider cases where a vehicle is partially in the opposite lane, making it impossible for a CMV to avoid a collision without swerving dangerously.'' The comments from Knight-Swift Transportation included the suggestion, ''Wrong way accidents—we would like the CPDP amended to allow for wrong way accident to allow DataQ submission when:

1. Not Fully Over the Centerline—The vehicle that struck the CMV was not completely over the center line when the crash occurred.

2. Opposing Direction Sideswipe—The vehicle that struck the CMV was not completely over the center line when it side-swiped the CMV.

Three commenters would like FMCSA to offer educational resources for carriers and drivers submitting requests to CPDP. Joshua Anderson would like additional fields when submitting an RDR to help users select the appropriate crash type. AIST Safety Consulting recommends adding a glossary to the Eligibility Guide that is available at *https://fmcsa.dot.gov/crash-preventability-determination-program.* And ATA wants enhanced resources for carriers that explain the RDR process, including minimum documentation requirements.

FMCSA Response

The current eligibility guide states that the crash must have the following elements, ''The vehicle in the crash was driving in the wrong direction (*e.g.,* northbound in the southbound lanes) AND the vehicle was completely in the wrong lane (*i.e.,* not partially across the center line).'' In response to the commenters, the Agency is staying with the current criteria for the ''wrong direction'' crash type and will NOT allow for partial crossing of the center line. As stated above, the crash types that are eligible for the CPDP are less complex crash events that do not require extensive expertise to review. However, the addition of the new crash type, where a CMV was involved and a video demonstrates the sequence of events of the crash, may allow for partial crossing of the center line types of crashes.

FMCSA will continue to update the Eligibility Guide to ensure it provides the most up-to-date criteria for each crash type. All the resources published on the *https://www.fmcsa.dot.gov/crash-preventability-determination-program* website will be updated to ensure submitters have the resources to make a complete request.

VII. Next Steps

FMCSA will post information on the CPDP website *https://fmcsa.dot.gov/crash-preventability-determination-program* notifying submitters of the date when FMCSA will accept submissions under the new and updated crash types set forth in this notice.

Vincent G. White,

Deputy Administrator.

[FR Doc. 2024–28377 Filed 12–3–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2022–0246]

Parts and Accessories Necessary for Safe Operation; Application for an Exemption From Polytech Plastic Molding, Inc., USDOT #1764512

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition; denial of exemption.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) announces its decision to deny an application from Polytech Plastic Molding, Inc. (Polytech, USDOT #1764512) for an exemption to allow it to operate commercial motor vehicles (CMVs) equipped with a module manufactured by Intellistop, Inc. (Intellistop). The Intellistop module is designed to pulse the required rear clearance, identification, and brake lamps from a lower-level lighting intensity to a higher-level lighting intensity 4 times in 2 seconds when the brakes are applied and then return the lights to a steady-burning state while the brakes remain engaged. The Agency has determined that Polytech did not demonstrate that it would likely achieve a level of safety equivalent to, or greater than, the level of safety achieved by the regulation.

FOR FURTHER INFORMATION CONTACT: Mr. David Sutula, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, MC–PSV, (202) 366–9209, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; *MCPSV@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Viewing Comments and Documents

To view comments, go to *www.regulations.gov,* insert the docket number ''FMCSA–2022–0246'' in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click ''Browse Comments.''

To view documents mentioned in this notice as being available in the docket, go to *www.regulations.gov,* insert the

docket number ''FMCSA–2022–0246'' in the keyword box, click ''Search,'' and chose the document to review.

If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from certain parts of the FMCSRs if it ''finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent the exemption.'' FMCSA must publish a notice of each exemption request in the **Federal Register** and provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analysis, and an opportunity for public comment on the request (49 U.S.C. 31315(b)(6)(A); 49 CFR 381.315(a).

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice, if granted, must also specify the effective period and explain the terms and conditions of the exemption.

III. Background

A. Current Regulatory Requirements

Section 393.25(e) of the Federal Motor Carrier Safety Regulations (FMCSRs) requires all exterior lamps (both required lamps and any additional lamps) to be steady burning, with certain exceptions not relevant here. Two other provisions of the FMCSRs—section 393.11(a) and section 393.25(c)—mandate that required lamps on CMVs meet the requirements of Federal Motor Vehicle Safety Standard (FMVSS) No. 108 in effect at the time of manufacture. FMVSS No. 108, issued by the U.S. Department of Transportation's National Highway Traffic Safety Administration (NHTSA), includes a requirement that installed brake lamps, whether original or replacement equipment, be steady burning.

B. Applicant's Request

Polytech applied for an exemption from 49 CFR 393.25(e) to allow it to operate CMVs, equipped with Intellistop's module. When the brakes are applied, the Intellistop module is designed to pulse the rear clearance, identification, and brake lamps from a lower-level lighting intensity to a higher-level lighting intensity 4 times in 2 seconds and then maintain the original equipment manufacturer's (OEM) level of illumination for those lamps until the brakes are released and reapplied. Intellistop asserts that its module is designed to ensure that if the module ever fails, the clearance, identification, and brake lamps will default to normal OEM function and illumination.

Polytech's application followed the Agency's October 7, 2022 (87 FR 61133), denial of Intellistop's application for an industry-wide exemption to allow all interstate motor carriers to operate CMVs equipped with the Intellistop module. While the Agency determined that the scope of the exemption Intellistop sought was too broad to ensure that an equivalent level of safety would be achieved, the Agency explained that individual motor carrier applications for exemption may be more closely aligned with FMCSA authorities. Exemptions more limited in scope would allow the Agency to ensure compliance with all relevant FMCSA regulations because the individual exemptee would be easily identifiable and its compliance with applicable regulations could be monitored, thus providing a level of safety equivalent to compliance with 49 CFR 393.25(e).

Polytech stated that previous research demonstrated that the use of pulsating brake-activated lamps increases the visibility of vehicles and should lead to a significant decrease in rear-end crashes. In support of its application, Polytech submitted several reports of research conducted by NHTSA on the issues of rear-end crashes, distracted driving, and braking signals.[1] [2] [3] This same body of research was also referenced in Intellistop's industry-wide exemption application. Relying on these studies, Polytech stated that the addition of brake-activated pulsating lamp(s) will not have an adverse impact on safety and would likely maintain a level of safety equivalent to or greater than the level of safety achieved without the exemption.

A copy of the application is included in the docket referenced at the beginning of this notice.

IV. Comments

FMCSA published a notice of the application in the **Federal Register** on February 1, 2023, and asked for public comment (88 FR 6809). The Agency received 16 comments from the American Trucking Associations (ATA); Intellistop, Inc.; the National Truck Equipment Association (NTEA); the Transportation Safety Equipment Institute (TSEI); and 12 other commenters. Fifteen of the commenters favored the exemption application, while TSEI expressed concerns.

TSEI reiterated comments it had previously made in support of the safety benefits of brake-activated warning lamps when used in conjunction with steady burning red brake lamps as well as its prior support of the exemption requests from Groendyke Transport, National Tank Truck Carriers (NTTC), and Grote Industries. Despite these previous expressions of support for the potential benefits of some brake warning lamp configurations, TSEI stated that it is concerned about any exemption permitting the pulsing of lamps that are currently required to be steady burning without a thorough consideration of safety data and research. TSEI stated that the aim of future rulemaking should be to ensure consistent application across all vehicles equipped with such pulsating lamps and recommended that the Agency engage in a formal rulemaking to amend Part 393 to allow for pulsating brake lamps.

ATA supported Polytech's request and stated that enhanced rear signaling (ERS) can provide functionality beyond what traditional CMV lighting and reflective devices offer, including drawing attention to CMVs stopped ahead; increasing awareness of roadside breakdowns; notification of emergency

[1] See NHTSA Study—Evaluation of Enhanced Brake Lights Using Surrogate Safety Metrics *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/811127.pdf;* As part of the General Findings the NHTSA study report concluded that ''rear lighting continues to look promising as a means of reducing the number and severity of rear-end crashes.''

[2] See also NHTSA Study—Enhanced Rear Lighting and Signaling Systems *https://tinyurl.com/y2romx76* or *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/task_3_results_0.pdf;* As part of the conclusions NHTSA found that enhanced, flashing brake lighting ''demonstrated improvements in brake response times and other related performance measures.''

[3] See also NHTSA—Traffic Safety Facts *https://tinyurl.com/yxglsdax* or *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/tsf811128.pdf;* which concluded that flashing brake lights were a promising signal for improving attention-getting during brake applications.

braking; and improving driver confidence from both vehicles. ATA also stated that, in addition to these safety benefits, ERS performance is superior to that of steady burning brake lamps in conditions of severe weather, taillight glare, and around infrastructure obstacles. Specifically, ATA noted that this ''request by Polytech presents another opportunity for the DOT to learn about the performance of ERS in real world applications.'' Further, ATA stated that ''[it] believes the exemption process is well-suited for these kinds of situations, where the DOT can monitor small, controlled deployments to learn about benefits and costs and gather important data to make sound judgments on a broader industry exemption or change in regulations.''

ATA recommended that, if granted, the Agency provide clear guidance in the terms and conditions of the exemption grant to aid the Agency in monitoring the exemption for unintended consequences and aid the Applicant in understanding expectations for potential renewal of the exemption application. ATA further commented that FMCSA should work with industry to develop research efforts that examine the performance of ERS to supplement future DOT decisions on ERS technologies. and aid the Applicant in understanding expectations for potential renewal of the exemption application. ATA further commented that FMCSA should work with industry to develop research efforts that examine the performance of ERS to supplement future DOT decisions on ERS technologies.

The NTEA supported a temporary exemption. The NTEA, however, expressed concern that some of its members who are manufacturers and alterers of motor vehicles receive requests from fleet operators to install brake-activated pulsating warning lamps on certain new vehicles they construct or modify. As manufacturers of new motor vehicles, NTEA members are required to certify these vehicles to applicable NHTSA Federal Motor Vehicle Safety Standards (FMVSS). NTEA noted that FMCSA does not have the authority to exempt CMV manufacturers from their obligation to certify FMVSS compliance. It recommended the Agency clarify in the terms and conditions carrier, manufacturer, and repair facility responsibilities and limitations and the conditions under which such modifications may be made. NTEA specifically requested that FMCSA ''make clear that [this] exemption does not currently change any NHTSA regulations applying to the certification of federal motor vehicle safety standards,'' if it grants the exemption.

Intellistop supported the Applicant's request for exemption. It commented that for over 20 years, multiple States have allowed pulsing or flashing of brake lamps. Intellistop also asserted many State driver training schools recommend tapping brakes to warn other motorists when a CMV is slowing or stopping. Intellistop stated that it is unlikely that other motorists would confuse the use of their module with the recommendation to tap brakes when a CMV is slowing or stopping, as ''[s]eeing brake lights flash is a commonly communicated method to alert other drivers that a vehicle is slowing down or stopping.''

Twelve additional comments were submitted in support of granting the exemption. These commenters believe that any technology that has been shown to reduce rear-end crashes should be allowed and cited various benefits of brake activated pulsating lamps, including (1) enhanced awareness that the vehicle is making a stop, especially at railroad crossings, and (2) increased visibility in severe weather conditions. Several commenters noted that 37 States currently allow brake lamps to flash. In addition, three commenters noted that the guidelines developed by the American Driver and Traffic Safety Education Association advise driving instructors to teach new drivers to pulse brake lamps when stopping to improve visibility.

V. FMCSA Equivalent Level of Safety Analysis

Polytech petitioned FMCSA to grant an exemption from 49 CFR 393.25(e)—requiring certain exterior lamps to be steady burning—to allow it to operate CMVs equipped with Intellistop's module. FMCSA has determined that in order for Polytech to operate vehicles in compliance with the FMCSRs, an exemption from 49 CFR 393.25(e) must be accompanied by limited exemptions from 49 CFR 393.11(a) and 393.25(c), both of which mandate that required lamps on CMVs operated in interstate commerce must, ''at a minimum, meet the applicable requirements of 49 CFR 571.108 (FMVSS No. 108) in effect at the time of manufacture of the vehicle.'' FMCSA grants exemptions only when it determines ''such exemption[s] would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent the exemption[s].''

Rear-end crashes generally account for approximately 30 percent of all crashes. They often result from a failure to respond (or delays in responding) to a stopped or decelerating lead vehicle. Data on crashes that occurred between 2010 and 2016 show that large trucks are consistently three times more likely than other vehicles to be struck in the rear in two-vehicle fatal crashes.[4] [5] FMCSA is deeply interested in the development and deployment of technologies that can reduce the frequency, severity, and risk of rear-end crashes.

Both FMCSA and NHTSA have examined alternative rear-signaling systems to reduce the incidence of rear-end crashes. While research efforts concluded that improvements in the incidence of rear-end crashes could be realized through certain rear-lighting systems that flash,[6] the FMCSRs do not currently permit the use of pulsating, brake-activated lamps on the rear of CMVs. FMCSA believes that the two agencies' previous research programs demonstrate that rear-signaling systems may be able to ''improve attention getting'' to reduce the frequency and severity of rear-end crashes. Any possible benefit must be balanced against a possible risk of increased driver distraction and confusion. In balancing these interests, the Agency was compelled to deny the Intellistop application for exemption because the industry-wide scope of the request was too broad for the Agency to effectively monitor for the potential risk of driver distraction or confusion.

The Agency acknowledges the limitations of the research studies completed to date and the overall data deficiencies in this area. Nonetheless, as noted in its Intellistop decision, the Agency recognizes that existing data do suggest a potential safety value in the use of alternative rear-signaling systems, generally. Specifically, FMCSA considered NHTSA's research concerning the development and evaluation of rear-signaling applications designed to reduce the frequency and severity of rear-end crashes via enhancements to rear-brake lighting. The study examined enhancements for (1) redirecting drivers' visual attention

[4] U.S. Department of Transportation, National Highway Traffic Safety Administration (2012), Traffic Safety Facts—2010 Data; Large Trucks, Report No. DOT HS 811 628, Washington, DC (June 2012), *available at: https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/811628.*

[5] U.S. Department of Transportation, National Highway Traffic Safety Administration (2018), Traffic Safety Facts—2016 Data; Large Trucks, Report No. DOT HS 812 497, Washington, DC (May 2018), *available at: https://crashstats.nhtsa.dot.gov/Api/Public/Publication/812497.*

[6] Expanded Research and Development of an Enhanced Rear Signaling System for Commercial Motor Vehicles: Final Report, William A. Schaudt *et al.* (Apr. 2014) (Report No. FMCSA–RRT–13–009).

to the forward roadway (for cases involving a distracted driver) and (2) increasing the saliency or meaningfulness of the brake signal (for inattentive drivers).[7] The research considered the attention-getting capability and discomfort glare of a set of candidate rear brake lighting configurations using driver judgments and eye-drawing metrics. The results of this research served to narrow the set of candidate lighting configurations to those that would most likely be carried forward for additional on-road study. Based on subjective participant responses, this research indicates some form of flashing or variation in brake light brightness may be more than two times more attention-getting than the baseline, steady-burning brake lights for distracted drivers.[8]

While some of the data collected in the study may not be statistically significant, the study results nonetheless indicate that additional efforts to get drivers' attention when they are approaching the rear of a CMV that is stopping may be helpful to reduce driver distraction and, ultimately, rear-end crashes. This was among several reasons why researchers concluded that the promising nature of enhanced brake lighting systems warranted additional work and research. FMCSA believes the acquisition of relevant data through real-world monitoring is of critical importance as the Agency continues to seek new and innovative options for reducing crashes. This is particularly true given the data limitations noted in previous studies.

Despite finding a potential safety value in the use of alternative rear-signaling technology, in the Intellistop decision the Agency determined that the data presently available did not justify an exemption to allow all interstate motor carriers to alter the performance of an FMVSS-required lighting device (*i.e.,* stop lamps) on any CMV. In contrast, however, Polytech's application requests an exemption from the steady-burning brake lamp requirement for CMV operations for only a single interstate motor carrier. As FMCSA noted in its denial of Intellistop's industry-wide exemption application, individual motor carrier exemption requests more closely align with FMCSA and NHTSA authorities to ensure compliance with all other applicable regulations and with the safety performance of the smaller population of affected motor carriers. With an individual motor carrier exemption, the Agency can also more easily monitor compliance with terms and conditions intended to ensure operations conducted under the exemption do in fact provide an equivalent level of safety. Polytech's application demonstrates why this is particularly true, since the vehicles operated by Polytech under the exemption would be easily identifiable, and compliance with NHTSA's ''make inoperative'' prohibition and other related regulations could be readily checked.

The Agency's decision to deny this exemption is based on the unavailablity of carrier and safety data. Polytech was issued a notice for ''Failure to complete biennial update'' on April 8, 2015, which deactivated its USDOT number. Any subsequent operations in interstate commerce were illegal. FMCSA is unable to ascertain how many CMVs operated by Polytech would have an Intellistop module installed, nor does the Agency have any safety data to compare the performance of Polytech against industry averages.

Additionally, the Polytech website states that it maintains a small fleet of delivery vehicles to service a delivery area within the US and Canada. FMCSA notes that these deliveries must be occurring with delivery vehicles owned by Polytech that are not registered under a USDOT carrier number. Thus, Polytech is either using delivery vehicles that are not subject to the FMCSRs because they do not meet the definition of a CMV or is operating in violation of the FMCSRs. In the former case, FMCSA does not have jurisdiction to grant an exemption. In the latter case, nine years of illegal operations strongly suggests that Polytech is unlikely to comply with the terms and conditions of an exemption.

VI. Exemption Decision

a. Denial of Exemption

FMCSA has evaluated Polytech's exemption application and the comments received. For the reasons given above, the Agency is denying Polytech's application for a temporary exemption.

Vincent G. White,

Deputy Administrator.

[FR Doc. 2024–28376 Filed 12–3–24; 8:45 am]

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[7] See NHTSA Study—Evaluation of Enhanced Brake Lights Using Surrogate Safety Metrics *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/811127.pdf.*

[8] Ibid. While data demonstrated that brighter flashing lights were the most attention-getting combination for distracted drivers in this study, flashing lights with no increase in brightness were still more effective at capturing a distracted driver's attention than the baseline steady-burning brake lamps. Both look-up (eye drawing) data and interview data supported the hypothesis that simultaneous flashing of all rear lighting combined with increased brightness would be effective in redirecting the driver's eyes to the lead vehicle when the driver is looking away with tasks that involve visual load.

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 512

Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 512

[CMS–5535–F]

RIN 0938–AU51

Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule describes a new mandatory alternative payment model, the Increasing Organ Transplant Access Model (IOTA Model), that will test whether performance-based upside risk payments or downside risk payments paid to or owed by participating kidney transplant hospitals increase access to kidney transplants for patients with end-stage renal disease (ESRD) while preserving or enhancing the quality of care and reducing Medicare expenditures. This final rule also adopts standard provisions that will apply to the Radiation Oncology Model, the End-Stage Renal Disease (ESRD) Treatment Choices Model, and mandatory Innovation Center models, including the IOTA Model, whose first performance period begins on or after January 1, 2025. The finalized standard provisions relate to beneficiary protections; cooperation in model evaluation and monitoring; audits and records retention; rights in data and intellectual property; monitoring and compliance; remedial action; model termination by CMS; limitations on review; miscellaneous provisions on bankruptcy and other notifications; and the reconsideration review process.

DATES: These regulations are effective January 3, 2025.

FOR FURTHER INFORMATION CONTACT:

Thomas Duvall (410) 786–8887, for questions related to the Increasing Organ Transplant Access Model.

Lina Gebremariam, (410) 786–8893, for questions related to the Increasing Organ Transplant Access Model.

Christina McCormick (410) 786–4012, for questions related to the Increasing Organ Transplant Access Model.

CMMItransplant@cms.hhs.gov for questions related to the Increasing Organ Transplant Access Model.

CMMI-StandardProvisions@cms.hhs.gov for questions related to the Standard Provisions for Innovation Center Models.

SUPPLEMENTARY INFORMATION:

Current Procedural Terminology (CPT) Copyright Notice

I. Executive Summary

A. Purpose

Section 1115A of the Social Security Act (the Act) gives the Secretary of the Department of Health and Human Services the authority to test innovative payment and service delivery models to reduce program expenditures in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of care furnished to individuals covered by such programs. Specifically, section 1115A(b)(2)(a) of the Act states that ''the Secretary shall select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title.'' [1] This final rule describes a new mandatory Medicare payment model to be tested under section 1115A of the Act—the Increasing Organ Transplant Access Model (IOTA Model)—which will begin on July 1, 2025, and end on June 30, 2031. In this final rule, we address payment policies, participation requirements, and other provisions to test the IOTA Model. We will test whether performance-based incentives (including both upside and downside risk payments) for participating kidney transplant hospitals can increase the number of functioning kidney transplants (including both living donor and deceased donor transplants) furnished to end stage renal disease (ESRD) patients, encourage investments in care processes and patterns with respect to patients who need kidney transplants, encourage investments in value-based care and improvement activities, and promote greater accountability by participating kidney transplant hospitals by tying payments to the value of the care provided. The IOTA Model is also intended to advance health equity by improving equitable access to the transplantation ecosystem for all patients, such as rural and underserved populations, through design features such as voluntary health equity plans to address health outcome disparities.

This final rule also includes standard provisions that will apply to the RO Model, the ETC model, and all mandatory Innovation Center models whose first performance periods begin on or after January 1, 2025. The standard provisions address beneficiary protections; cooperation in model evaluation and monitoring; audits and record retention; rights in data and intellectual property; monitoring and compliance; remedial action; model termination by CMS; limitations on review; miscellaneous provisions on bankruptcy and other notifications; and the reconsideration review process.

As we stated in the notice of proposed rulemaking, the IOTA Model will test ways to reduce Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries. We are finalizing several, but not all, of the provisions discussed in the proposed rule, and we intend to address certain other provisions discussed in the proposed rule in future rulemaking. We also note that some of the public comments were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed in this final rule. We have summarized the public comments that are within the scope of the proposed rule and have included our responses to those public comments. However, we note that in this final rule we are not addressing most comments received with respect to the provisions of the proposed rule that we are not finalizing at this time. Rather, we will address them at a later time, in a subsequent rulemaking document, as appropriate. We are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further action, it shall be severable from other parts of this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar

[1] U.S. Congress. (1940) United States Code: Social Security Act, 42 U.S.C. 1315a(b)(2)(a).

circumstances. Through this rule, we adopt provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear.

B. Summary of the Provisions

1. Standard Provisions for Innovation Center Models

The standard provisions for Innovation Center models will be applicable to the RO Model, the ETC Model, and all mandatory Innovation Center models whose first performance periods begin on or after January 1, 2025.

We are codifying these standard provisions to increase transparency, efficiency, and clarity in the operation and governance of mandatory Innovation Center models, and to avoid the need to restate the provisions in each model's governing documentation. The standard provisions include terms that have been repeatedly memorialized, with minimal variation, in existing models' governing documentation. The standard provisions are not intended to encompass all of the terms and conditions that will apply to each mandatory Innovation Center model, as each model includes unique design features and implementation plans that may require additional, more tailored provisions, including with respect to payment methodology, care delivery and quality measurement, that will continue to be included in each model's governing documentation. We note that while we are not finalizing our proposal to apply the standard provisions to voluntary Innovation Center models, we expect to utilize the provisions in voluntary models and will incorporate them by reference into the models' governing documentation as appropriate based on the model's design. Model-specific provisions applicable to the IOTA Model are described in section III of this final rule.

2. Model Overview—Proposed Increasing Organ Transplant Access Model

a. Proposed IOTA Model Overview

End-Stage Renal Disease (ESRD) is a medical condition in which a person's kidneys cease functioning on a permanent basis, leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life.[2] The best treatment for most patients with kidney failure is kidney transplantation. Nearly 808,000 people in the United States are living with ESRD, with about 69 percent on dialysis and 31 percent with a kidney transplant.[3] Relative to dialysis, a kidney transplant can improve survival, reduce avoidable health care utilization and hospital acquired conditions, improve quality of life, and lower Medicare expenditures.[4] [5] However, despite these benefits of kidney transplantation, evidence shows low rates of ESRD patients placed on kidney transplant hospitals' waitlists, a decline in living donors over the past 20 years, and underutilization of available donor kidneys, coupled with increasing rates of donor kidney discards, and wide variation in kidney offer acceptance rates and donor kidney discards by region and across kidney transplant hospitals.[6] [7] Further, there are substantial disparities in both deceased and living donor transplantation rates among structurally disadvantaged populations. Strengthening and improving the performance of the organ transplantation system is a priority for the Department of Health and Human Services (HHS).[8] Consistent with this priority, and through joint efforts with HHS' Health Resources and Services Administration (HRSA), the IOTA Model will aim to reduce Medicare expenditures and improve quality performance and equity in kidney transplantation by creating performance-based incentive payments for participating kidney transplant hospitals tied to kidney transplant] access and quality of care for ESRD patients on the hospitals' waitlists.

The IOTA Model will be a mandatory model that will begin on July 1, 2025, and end on June 30, 2031, resulting in a 6-year model performance period comprised of 6 individual performance years (''PYs''). The IOTA Model will test whether performance-based incentives paid to, or owed by, participating kidney transplant hospitals can increase access to kidney transplants for patients with ESRD, while preserving or enhancing quality of care and reducing Medicare expenditures. CMS will select kidney transplant hospitals to participate in the IOTA Model through the methodology proposed in section III.C.3.d of this final rule. As this will be a mandatory model, the selected kidney transplant hospitals will be required to participate. CMS will measure and assess the participating kidney transplant hospitals' performance during each PY across three performance domains: achievement, efficiency, and quality.

The achievement domain will assess each participating kidney transplant hospital on the overall number of kidney transplants performed during a PY, relative to a participant-specific target. The efficiency domain will assess the kidney organ offer acceptance rate ratios of each participating kidney transplant hospital relative to a national ranking or the participating kidney transplant hospital's past organ offer acceptance rate ratio. The quality domain will assess the quality of care provided by the participating kidney transplant hospitals via a composite graft survival ratio. Each participating kidney transplant hospital's performance score across these three domains will determine its final performance score and corresponding amount for the upside risk payment that CMS would pay to the participating kidney transplant hospital, or the downside risk payment that would be owed by the participating kidney transplant hospital to CMS. The upside risk payment will be a lump sum payment paid by CMS after the end of a PY to a participating kidney transplant hospital with a final performance score of 60 or greater. Conversely, beginning in PY 2, the downside risk payment will be a lump sum payment paid to CMS by any participating kidney transplant hospital with a final performance score of 40 or lower. There is no downside risk payment for PY 1 of the model.

[2] End-Stage Renal Disease (ESRD) | CMS. (n.d.). *https://www.cms.gov/medicare/coordination-benefits-recovery/overview/end-stage-renal-disease-esrd.*

[3] United States Renal Data System. 2022 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2022.

[4] Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S., & Gill, J. (2011). Systematic Review: Kidney Transplantation Compared With Dialysis in Clinically Relevant Outcomes. *American Journal of Transplantation, 11*(10), 2093–2109. *https://doi.org/10.1111/j.1600-6143.2011.03686.x.*

[5] Cheng, X.S., Han, J., Braggs-Gresham, J.L., Held, P.J., Busque, S., Roberts, J.P., Tan, J.C., Scandling, J.D., Chertow, G.M., & Dor, A. (2022). Trends in Cost Attributable to Kidney Transplantation Evaluation and Waitlist Management in the United States, 2012–2017. *JAMA network open, 5*(3), e221847. *https://doi:10.1001/jamanetworkopen.2022.1847.*

[6] Al Ammary, F., Bowring, M.G., Massie, A.B., Yu, S., Waldram, M.M., Garonzik-Wang, J., Thomas, A.G., Holscher, C.M., Qadi, M.A., Henderson, M.L., Wiseman, A.C., Gralla, J., Brennan, D.C., Segev, D.L., & Muzaale, A.D. (2019). The changing landscape of live kidney donation in the United States from 2005 to 2017. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 19*(9), 2614–2621. *https://doi.org/10.1111/ajt.15368.*

[7] Mohan, S., Yu, M., King, K.L., & Husain, S.A. (2023). Increasing Discards as an Unintended Consequence of Recent Changes in United States Kidney Allocation Policy. *Kidney International Reports, 8*(5), 1109–1111.

[8] *https://doi.org/10.1016/j.ekir.2023.02.1081.*

b. Model Scope

Participation in the IOTA Model will be mandatory for approximately 50 percent of all eligible kidney transplant hospitals in the United States. We anticipate that a total of approximately 90 kidney transplant hospitals will be selected to participate in the IOTA Model. Additionally, we note that we intend to publicly post information regarding the selection process and how it resulted in the list of DSAs and kidney transplant hospitals selected to participate in the model. As discussed in section III.C.3.b. of this final rule, we believe that mandatory participation is necessary to minimize the potential for selection bias and to ensure a representative sample size nationally, thereby guaranteeing that there will be adequate data to evaluate the model test.

Eligible kidney transplant hospitals will be those that: (1) performed at least eleven kidney transplants for patients 18 years of age or older annually regardless of payer type during the three-year period ending 12 months before the model's start date; and (2) are non-pediatric transplant facilities that furnished more than 50 percent of the hospital's annual kidney transplants to patients 18 years of age or older during that same period. CMS will select the kidney transplant hospitals that will be required to participate in the IOTA Model from the group of eligible kidney transplant hospitals using a stratified random sampling of donation service areas (''DSAs'') to ensure that there is a fair selection process and representative group of participating kidney transplant hospitals. For the purposes of this final rule, a DSA has the same meaning given to that term at 42 CFR 486.302.

c. Performance Assessment

CMS will assess each participating kidney transplant hospital's performance across three performance domains during each PY of the model, with a maximum possible final performance score of 100 points. The three performance domains will include: (1) an achievement domain worth up to 60 points, (2) an efficiency domain worth up to 20 points, and (3) a quality domain worth up to 20 points.

The achievement domain will assess the number of kidney transplants performed by each IOTA participant for attributed patients, with performance on this domain worth up to 60 points. The final performance score will be heavily weighted on the achievement domain to align with the IOTA Model's goal to increase access to kidney transplants to improve the quality of care and reduce Medicare expenditures. The IOTA Model theorizes that improvement activities, including those aimed at reducing unnecessary deceased donor discards and increasing living donors, may help increase access to kidney transplants.

CMS will set a target number of kidney transplants for each IOTA participant for each PY to measure the IOTA participant's performance in the achievement domain), as described in section III.C.5.c of the final rule. Each IOTA participant's transplant target for a given PY will be based on the IOTA participant's historical volume of deceased and living donor transplants furnished to attributed patients in the relevant baseline years, adjusted by the national trend rate in the number of kidney transplants performed. Section III.C.5.c. of this final rule describes the variation in the number of kidney transplants performed across kidney transplant hospitals, which would make it challenging to set transplant targets on a regional or national basis. The IOTA Model will therefore set a transplant target that is specific to each IOTA participant to address this concern, while still accounting for the national trend rate in the number of kidney transplants performed. It is expected that IOTA participants' transplant targets may change from PY to PY due to this calculation methodology.

The efficiency domain will assess the kidney organ offer acceptance rate ratio for each IOTA participant. The kidney organ offer acceptance rate ratio measures the number of kidneys an IOTA participant accepts for transplant over the expected value, based on variables such as kidney quality. CMS will assess the kidney organ offer acceptance rate ratio relative to either the kidney organ offer acceptance rate ratio across all kidney transplant hospitals or the IOTA participant's own past kidney organ offer acceptance rate ratio, with CMS using whichever method results in the IOTA participant receiving the most points, with performance on the efficiency domain being worth up to 20 points.

Finally, the quality domain will assess IOTA participants' performance on a composite graft survival ratio measuring post-transplant outcomes—relative to the composite graft survival ratio across all kidney transplant hospitals, with performance on this domain being worth up to 20 points.

Each IOTA participant's final performance score will be the sum of the points earned for each domain: achievement, efficiency, and quality. The final performance score in a PY will determine whether the IOTA participant will be eligible to receive an upside risk payment from CMS, fall into the neutral zone where no upside or downside risk payment would apply, or owe a downside risk payment to CMS for the PY as described in section III.C.6 of this final rule.

d. Performance-Based Upside Risk Payment and Downside Risk Payment Formula

Each IOTA participant's final performance score will determine whether: (1) CMS will pay an upside risk payment to the IOTA participant; (2) the IOTA participant will fall into a neutral zone where no performance-based incentive payment will be paid to or owed by the IOTA participant; or (3) the IOTA participant will owe a downside risk payment to CMS. For a final performance score of 60 and above, CMS will apply the formula for the upside risk payment, which will be equal to the IOTA participant's final performance score minus 60, then divided by 40, then multiplied by $15,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to attributed patients with Medicare Fee-for-Service (FFS) as their primary or secondary payer during the PY. Final performance scores below 60 in PY 1 and final performance scores of 41 to 59 (inclusive) in PYs 2–6 will fall in the neutral zone where there will be no payment owed to the IOTA participant or CMS.

We will phase-in the downside risk payment beginning in PY2. We explain in section III.C.5.b of this final rule that new entrants to value-based payment models may need a ramp-up period before they are able to accept downside risk. Thus, the IOTA Model utilizes an upside risk-only approach for PY 1 as an incentive in each of the three performance domains. This will give IOTA participants time to consider, invest in, and implement value-based care and quality improvement initiatives before downside risk payments begin. Beginning in PY 2, for a final performance score of 40 and below, CMS will apply the formula for the downside risk payment, which will be equal to 40 minus the IOTA participant's final performance score, then divided by 40, then multiplied by $2,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to attributed patients with Medicare FFS as their primary or secondary payer during the PY.

CMS will pay the upside risk payment in a lump sum to the IOTA participant after the PY. The IOTA participant will pay the downside risk payment to CMS in a lump sum after the PY.

e. Data Sharing

CMS will collect certain quality, clinical, and administrative data from IOTA participants for model monitoring and evaluation activities under the authority in 42 CFR 403.1110(b). We will also share certain data with IOTA participants upon request as described in section III.C.3.a. of this final rule and as permitted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and other applicable law. We will offer each IOTA participant the opportunity to request certain beneficiary-identifiable data for their attributed Medicare beneficiaries for treatment, case management, care coordination, quality improvement activities, and population-based activities relating to improving health or reducing health care costs, as permitted by 45 CFR 164.506(c). The data uses and sharing will be allowed only to the extent permitted by the HIPAA Privacy Rule and other applicable law and CMS policies. We will also share certain aggregate, de-identified data with IOTA participants.

f. Other Requirements

There are several other model requirements for selected transplant hospitals, including transparency requirements and public reporting requirements. IOTA participants may also submit a voluntary health equity plan during the model, as described in section III.C.8. of this rule.

(1) Transparency Requirements

Patients are often unsure whether they qualify for a kidney transplant at a given kidney transplant hospital. IOTA participants will be required to publish, on a public facing website, the criteria they use when determining whether or not to add a patient to the kidney transplant waitlist.

(2) Health Equity Requirements

An IOTA participant may submit a health equity plan (''HEP'') to CMS. The submission of HEPs will be voluntary for IOTA participants for the duration of the model. The HEP will identify health disparities within the IOTA participant's population of attributed patients and outline a course of action to address them.

g. Medicare Payment Waivers and Additional Flexibilities

We believe it is necessary to waive certain requirements of title XVIII of the Act solely for purposes of carrying out the testing of the IOTA Model under section 1115A of the Act. We will issue these waivers using our waiver authority under section 1115A(d)(1) of the Act, which states that the Secretary may waive such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for purposes of carrying out this section with respect to testing models described in section 1115A(b) of the Act. Each of the waivers is discussed in detail in section III.C.11.i. of this final rule.

h. Overlaps With Other Innovation Center Models and CMS Programs

We expect that there could be situations where a Medicare beneficiary attributed to an IOTA participant is also assigned, aligned, or attributed to another Innovation Center model or CMS program. Overlap could also occur among providers and suppliers at the individual or organization level, such as where an IOTA participant or one of their providers participates in multiple Innovation Center models. We believe that the IOTA Model will be compatible with existing models and programs that provide opportunities to improve care and reduce spending. The IOTA Model will not be replacing any covered services or changing the payments that participating hospitals receive through the inpatient prospective payment system (IPPS) or outpatient prospective payment system (OPPS). Rather, the IOTA Model implements performance-based payments separate from what participants will be paid by CMS for furnishing kidney transplants to Medicare beneficiaries. Additionally, we will work to resolve any potential overlaps between the IOTA Model and other Innovation Center models or CMS programs that could result in duplicative payments for services, or duplicative counting of savings or other reductions in expenditures. Therefore, we are allowing overlaps between the IOTA Model and other Innovation Center models and CMS programs.

i. Monitoring

We will closely monitor the implementation and outcomes of the IOTA Model throughout its duration consistent with the monitoring requirements in the Standard Provisions for Innovation Center models in section II of this final rule and the requirements in section III.C.13. of this final rule. The purpose of this monitoring will be to ensure that the IOTA Model is implemented safely and appropriately, that the quality and experience of care for beneficiaries is not harmed, and that adequate patient and program integrity safeguards are in place.

j. Beneficiary Protections

As mentioned in section III.C.10. of this final rule, CMS will not allow beneficiaries or patients to opt out of attribution to an IOTA participant; however, the IOTA Model will not restrict a beneficiary's freedom to choose another kidney transplant hospital or any other provider or supplier for healthcare services, and IOTA participants will be subject to the Standard Provisions for Innovation Center Models outlined in section II of this final rule protecting Medicare beneficiary freedom of choice and access to medically necessary services. We also require that IOTA participants notify Medicare beneficiaries of the IOTA participant's participation in the IOTA Model by, at a minimum, prominently displaying informational materials in offices or facilities where beneficiaries receive care.

C. Summary of Costs and Benefits

The IOTA Model aims to incentivize transplant hospitals to overcome system-level barriers to kidney transplantation. The chronic shortfall in kidney transplants results in poorer outcomes for patients and increases the burden on Medicare in terms of payments for dialysis and dialysis-based enrollment in the program. Based on quantitative and qualitative analyses, there is reasonable evidence that the savings to Medicare resulting from an incremental growth in transplantation as a result of the IOTA Model will potentially exceed the payments projected under the model's incentive structure.

II. Standard Provisions for Innovation Center Models

A. Introduction

Section 1115A of the Act authorizes the Center for Medicare and Medicaid Innovation (the ''Innovation Center'') to ''test innovative payment and service delivery models to reduce program expenditures under the applicable titles [Medicare, Medicaid, and CHIP] while preserving or enhancing the quality of care furnished to individuals under such titles . . . In selecting such models, the Secretary shall give preference to models that also improve the coordination, quality, and efficiency of health care services . . .'' We have designed and tested both voluntary Innovation Center models—governed by participation agreements, cooperative agreements, and model-specific addenda to existing contracts with CMS—and mandatory Innovation Center models that are governed by regulations. Each voluntary and

mandatory model features its own specific payment methodology, quality metrics, and certain other applicable policies, but each model also features numerous provisions of a similar or identical nature, including provisions regarding cooperation in model evaluation; monitoring and compliance; and beneficiary protections.

On September 29, 2020, we published in the **Federal Register** a final rule titled ''Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures'' (85 FR 61114) (hereinafter the ''Specialty Care Models final rule''), in which we adopted General Provisions Related to Innovation Center models at 42 CFR part 512 subpart A that apply to the End-Stage Renal Disease Treatment Choices (ETC) Model and the Radiation Oncology (RO) Model.[9] The Specialty Care Models final rule codified general provisions regarding beneficiary protections, cooperation in model evaluation and monitoring, audits and record retention, rights in data and intellectual property, monitoring and compliance, remedial action, model termination by CMS, limitations on review, and bankruptcy and other notifications. These general provisions were adopted only for the ETC and RO Models (and, in practice, applied only to the ETC Model). However, in the notice of proposed rulemaking, we explained that we now believe the general provisions should apply to Innovation Center models more broadly. As we noted, the Innovation Center models share numerous similar provisions, and we explained that we believed codifying the general provisions in regulation to expand their applicability across models, except where otherwise explicitly specified in a model's governing documentation, would promote transparency, efficiency, clarity, and ensure consistency across models to the extent appropriate, while avoiding the need to restate the provisions in each model's governing documentation.

We also proposed a new provision pertaining to the reconsideration review process that would apply to Innovation Center models that waive the appeals processes provided under section 1869 of the Act.

B. General Provisions Codified in the Code of Federal Regulations That Would Apply to Innovation Center Models

Each Innovation Center model features many unique aspects that must be memorialized in its governing documentation, but each model also includes certain provisions that are common to most or all models. We explained that we believe codifying these common provisions would facilitate their uniform application across models (except where the governing documentation for a particular model dictates otherwise) and promote program efficiency and consistency that would benefit CMS' program administration and model participants.

As such, we proposed to expand the applicability of the 42 CFR part 512 subpart A ''General Provisions Related to Innovation Center Models'' to all Innovation Center models whose first performance periods begin on or after January 1, 2025, unless otherwise specified in the models' governing documentation, and also to any Innovation Center models whose first performance periods begin prior to January 1, 2025 if incorporated by reference into the models' governing documentation. To accomplish this, we proposed that the provisions codified at 42 CFR part 512 subpart A for the ETC and RO Models, including those with respect to definitions, beneficiary protections, cooperation in model evaluation and monitoring, audits and record retention, rights in data and intellectual property, monitoring and compliance, remedial action, Innovation Center model termination by CMS, and limitations on review, would be designated as the newly defined ''standard provisions for Innovation Center models'' and would apply to all Innovation Center models as described previously. We proposed specific revisions that would be necessary to expand the scope of several of the current general provisions, but otherwise proposed that the general provisions (which would be referred to as the ''standard provisions for Innovation Center models'') would not change. In particular, we proposed that the substance of the following provisions would not change, except that they would apply to all Innovation Center Models as opposed to just the ETC and RO Models: § 512.120 Beneficiary protections; § 512.130 Cooperation in model evaluation and monitoring; § 512.135 Audits and record retention; § 512.140 Rights in data and intellectual property: § 512.150 Monitoring and compliance; § 512.160 Remedial action; § 512.165 Innovation center model termination by CMS; § 512.170 Limitations on review; and § 512.180 Miscellaneous provisions on bankruptcy and other notifications.

C. Revisions to the Titles, Basis and Scope Provision, and Effective Date

We proposed to amend the title of part 512 to read ''Standard Provisions for Innovation Center Models and Specific Provisions for the Radiation Oncology Model and the End Stage Renal Disease Model'' so that it more

[9] In the autumn of 2020, due to the Secretary of Health and Human Services' Determination that a Public Health Emergency Exists for the Coronavirus disease 2019 (COVID–19) (*https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx*), CMS revised the RO Model's performance period to begin on July 1, 2021, and to end on December 31, 2025, in the CY 2021 Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs final rule with comment period (85 FR 85866). Section 133 of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116–260) (hereinafter referred to as ''CAA, 2021''), enacted on December 27, 2020, included a provision that prohibited implementation of the RO Model before January 1, 2022. This congressional action superseded the July 1, 2021, start date that we had established in the CY 2021 OPPS/ASC IFC. To align the RO Model regulations with the requirements of the CAA, 2021, we proposed to modify the definition of ''model performance period'' in 42 CFR 512.205 to provide for a 5-year model performance period starting on January 1, 2022, unless the RO Model was prohibited by law from starting on January 1, 2022, in which case the model performance period would begin on the earliest date permitted by law that is January 1, April 1, or July 1. We also proposed other modifications both related and unrelated to the timing of the RO Model in the proposed rule that appeared in the August 4, 2021, **Federal Register** titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals'' (86 FR 42018). These provisions were finalized in a final rule with comment period titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model'' that appeared in the November 16, 2021 **Federal Register** (86 FR 63458) (hereinafter referred to as the ''CY 2022 OPPS/ASC FC'').

On December 10, 2021, the Protecting Medicare and American Farmers from Sequester Cuts Act (Pub. L. 117–71) was enacted, which included a provision that prohibits implementation of the RO Model prior to January 1, 2023. The CY 2022 OPPS/ASC final rule with comment period specified that if the RO Model was prohibited by law from beginning on January 1, 2022, the model performance period would begin on the earliest date permitted by law that is January 1, April 1, or July 1. As a result, under the current definition for model performance period at § 512.205, the RO Model would have started on January 1, 2023, because that date is the earliest date permitted by law. However, given the multiple delays to date, and because both CMS and RO participants must invest operational resources in preparation for implementation of the RO Model, we have considered how best to proceed under these circumstances. In a final rule titled ''Radiation Oncology (RO) Model,'' which appeared in the **Federal Register** on August 29, 2022 (87 FR 52698), we delayed the start date of the RO Model to a date to be determined through future rulemaking, and modified the definition of the model performance period at § 512.205 to provide that the start and end dates of the model performance period for the RO Model would be established in future rulemaking. We have not undertaken rulemaking to determine the start date for the RO Model and, thus, the model is not active at this time.

closely aligns with the other changes we proposed and to ensure that the title indicates that part 512 includes both standard provisions for Innovation Center models and specific provisions for the RO and ETC Models. We also proposed to amend the title of subpart A to read ''Standard Provisions for Innovation Center Models'' to use the term we proposed to define the provisions codified at 42 CFR part 512 subpart A.

Additionally, we proposed to amend § 512.100(a) and (b) so that the standard provisions would take effect on January 1, 2025, and would apply to each Innovation Center model where that model's first performance period begins on or after January 1, 2025, unless the model's governing documentation indicates otherwise, as well as any Innovation Center model that begins testing its first performance period prior to January 1, 2025, if the model's governing documentation incorporates the provisions by reference in whole or in part. We proposed to determine on a case-by-case basis, based on each model's unique features and design, whether the standard provisions would apply to a particular model, or whether we would specify alternate terms in the model's governing documentation.

We noted in the proposed rule that these standard provisions are necessary for the testing of the IOTA Model. As such, as an alternative to the previous proposal, we proposed making these standard provisions for Innovation Center models applicable to, and effective for, the IOTA Model beginning on January 1, 2025, absent extending the standard provisions to all Innovation Center models. Under such an alternative, the general provisions in the Specialty Care Models final rule would also still be applicable to the ETC Model and the RO Model.

We specified in the proposed rule that these proposed standard provisions would not, except as specifically noted in section II of the proposed rule, affect the applicability of other provisions affecting providers and suppliers under Medicare fee-for-service (FFS). We invited public comment on these proposed changes.

Comment: We received a comment that emphasized that the proposed standard provisions should not affect the applicability of other provisions affecting providers and suppliers under Medicare fee-for-service. The commenter believed that standardization of provisions across models would decrease administrative burden for providers and simplify understanding of complex models.

Response: We thank the commenter for their comment. We agree. We are finalizing the proposed regulation text at § 512.100(b)(3) to provide that, except as specifically noted in subpart A of Part 512, the standard provisions will not affect the applicability of other provisions affecting providers and suppliers under Medicare fee-for-service, including provisions regarding payment, coverage, and program integrity. We agree with the commenter that the standardization of provisions across models will decrease administrative burden and simplify understanding of our Innovation Center models.

After consideration of the public comment we received, we are finalizing the proposed revisions to the titles for 42 CFR part 512 and for subpart A as described later in this section. Further, we are finalizing the proposed revisions to the basis and scope provision at 42 CFR 512.100 with modification to apply the standard provisions to mandatory Innovation Center models that begin their performance periods on or after January 1, 2025, rather than to both mandatory and voluntary Innovation Center models. After further consideration, we do not believe it is necessary to adopt the standard provisions for voluntary models because we can include those provisions, or other provisions, if necessary, in the models' governing documentation. We also are not including in the final regulation text the reference to applying the standard provisions ''unless otherwise specified in the Innovation Center model's governing documentation'' at proposed § 512.100(b)(ii) because we are able to include the standard provisions, or other provisions as appropriate, in voluntary Innovation Center model participation agreements. We anticipate utilizing the standard provisions in most voluntary Innovation Center model participation agreements and will reference them or incorporate them by reference as appropriate.

We also are not codifying the proposed regulation text at § 512.100(b)(i), which provided that the standard provisions would apply to each Innovation Center model that began its first performance period before January 1, 2025, if incorporated by reference, in whole or in part, into the Innovation Center model's governing documentation. If we believe it is appropriate to apply the standard provisions, in whole or in part, to an Innovation Center model for which the first performance period began before January 1, 2025, we will amend the model's governing documentation as appropriate, including through notice and comment rulemaking if necessary. We are finalizing that the standard provisions will apply to the RO and ETC Models as well as all other mandatory Innovation Center models, including the IOTA model.

We are finalizing revised titles for 42 CFR part 512 and subpart A that refer to ''Standard Provisions for *Mandatory* Innovation Center Models.'' We are revising § 512.100(a)—''Basis''—to provide that the standard provisions apply to ''certain'' Innovation Center models. At § 512.100(b)—''Scope''—we are adding language to provide that the standard provisions apply to the RO Model, the ETC Model, and to Innovation Center Models ''for which participation by Model participants is mandatory.''

D. Provisions Revising Certain Definitions

We proposed to amend the definition of ''Innovation Center model'' at 42 CFR 512.110 by replacing the specific references to the RO and ETC Models with a definition consistent with section 1115A of the Act and intended to encompass all Innovation Center models. We proposed to amend the definition for ''Innovation Center model'' to read as follows: ''an innovative payment and service delivery model tested under the authority of section 1115A(b) of the Act, including a model expansion under section 1115A(c) of the Act.''

We proposed to add a new definition of the term ''governing documentation'' at § 512.110 to mean, ''the applicable Federal regulations, and the model-specific participation agreement, cooperative agreement, and any addendum to an existing contract with CMS, that collectively specify the terms of the Innovation Center model.'' We proposed to add a new definition, ''standard provisions for Innovation Center models,'' at § 512.110 to mean the provisions codified in 42 CFR part 512 subpart A. We proposed to add a new definition, ''performance period,'' at § 512.110 to mean, ''the period of time during which an Innovation Center model is tested and model participants are held accountable for cost and quality of care; the performance period for each Innovation Center model is specified in the governing documentation.''

Further, we proposed to amend the definitions of ''Innovation Center model activities,'' ''model beneficiary,'' and ''model participant'' to pertain to all ''Innovation Center models,'' as we proposed to define that term, instead of just the models previously implemented under part 512. As such, we proposed

to define ''Innovation Center model activities'' to mean ''any activities affecting the care of model beneficiaries related to the test of the Innovation Center model.'' We proposed to define ''model beneficiary'' to mean ''a beneficiary attributed to a model participant or otherwise included in an Innovation Center model.'' We proposed to define ''model participant'' to mean ''an individual or entity that is identified as a participant in the Innovation Center model.''

We invited public comment on these proposed changes to the definitions of ''Innovation Center model,'' ''Innovation Center model activities,'' ''model beneficiary,'' and ''model participant'' and the proposed definitions of ''governing documentation,'' ''standard provisions for Innovation Center models,'' and ''performance period.''

Comment: We received a comment that was supportive of our proposed definitions.

Response: We appreciate the commenter's support of our proposed definitions.

After consideration of the public comment we received, we are finalizing the proposed revisions to the definitions at § 512.110 without modification.

E. Proposed Reconsideration Review Process

We proposed to add a new § 512.190 to part 512 subpart A to codify a reconsideration review process, based on processes implemented under current Innovation Center models. The process would enable model participants to contest determinations made by CMS in certain Innovation Center models, where model participants would not otherwise have a means to dispute determinations made by CMS. We proposed at § 512.190(a)(1) that such a reconsideration process would apply only to Innovation Center models that waive section 1869 of the Act, which governs determinations and appeals in Medicare, or where section 1869 would not apply because model participants are not Medicare-enrolled. We proposed at § 512.190(a)(2) that only model participants may utilize the dispute resolution process, unless the governing documentation for the Innovation Center model states otherwise. Such limitations with respect to such models are, we believe, appropriate, because with respect to such models, model participants do not have another means to dispute determinations made by CMS. We proposed to codify a reconsideration review process in regulation in order to have a transparent and consistent method of reconsideration for model participants participating in models that do not utilize the standard reconsideration process outlined in section 1869 of the Act.

This proposed reconsideration review process would be utilized where a model-specific determination has been made and the affected model participant disagrees with, and wishes to challenge, that determination. Each Innovation Center model features a unique payment and service delivery model, and, as such, requires its own model-specific determination process. Each Innovation Center model's governing documentation details the model-specific determinations made by CMS, which may include, but are not limited to, model-specific payments, beneficiary attribution, and determinations regarding remedial actions. Each Innovation Center model's governing documentation also includes specific details about when a determination is final and may be disputed through the model's reconsideration review processes.

We proposed at § 512.190(b) that model participants may request reconsideration of a determination made by CMS in accordance with an Innovation Center model's governing documentation only if such reconsideration is not precluded by section 1115A(d)(2) of the Act, part 512 subpart A, or the model's governing documentation. A model participant may challenge, by requesting review by a CMS reconsideration official, those final determinations made by CMS that are not precluded from administrative or judicial review. We proposed at § 512.190(b)(i) that the CMS reconsideration official would be someone who is authorized to receive such requests and was not involved in the initial determination issued by CMS or, if applicable, the timely error notice review process. We proposed at § 512.190(b)(ii) that the reconsideration review request would be required to include a copy of CMS's initial determination and contain a detailed written explanation of the basis for the dispute, including supporting documentation. We proposed at § 512.190(b)(iii) that the request for reconsideration would have to be made within 30 days of the date of CMS' initial determination for which reconsideration is being requested via email to an address as specified by CMS in the governing documentation. At § 512.190(b)(2), we proposed that requests that do not meet the requirements of paragraph (b)(1) would be denied.

We proposed at § 512.190(b)(3) that the reconsideration official would send a written acknowledgement to CMS and to the model participant requesting reconsideration within 10 business days of receiving the reconsideration request. The acknowledgement would set forth the review procedures and a schedule that would permit each party an opportunity to submit position papers and documentation in support of its position for consideration by the reconsideration official.

We proposed to codify at § 512.190(b)(4) that, to access the reconsideration process for a determination concerning a model-specific payment where the Innovation Center model's governing documentation specifies an initial timely error notice process, the model participant must first satisfy those requirements before submitting a reconsideration request under this process. Should a model participant fail to timely submit an error notice with respect to a particular model-specific payment, we proposed that the reconsideration review process would not be available to the model participant with regard to that model-specific payment.

We proposed to codify standards for reconsideration at § 512.190(c). First, during the course of the reconsideration, we proposed that both CMS and the party requesting the reconsideration must continue to fulfill all responsibilities and obligations under the governing documentation during the course of any dispute arising under the governing documentation. Second, the reconsideration would consist of a review of documentation timely submitted to the reconsideration official and in accordance with the standards specified by the reconsideration official in the acknowledgement at § 512.190(b)(3). Finally, we proposed that the model participant would bear the burden of proof to demonstrate with clear and convincing evidence to the reconsideration official that the determination made by CMS was inconsistent with the terms of the governing documentation.

We proposed to codify at § 512.190(d) that the reconsideration determination would be an on-the-record review. By this, we mean a review that would be conducted by a CMS reconsideration official who is a designee of CMS who is authorized to receive such requests under proposed § 512.190(b)(1)(i), of the position papers and supporting documentation that are timely submitted and in accordance with the schedule specified under proposed § 512.190(b)(3)(ii) and that meet the standards of submission under proposed § 512.190(b)(1) as well as any

documents and data timely submitted to CMS by the model participant in the required format before CMS made the initial determination that is the subject of the reconsideration request. We proposed at § 512.190(d)(2) that the reconsideration official would issue to the parties a written reconsideration determination. Absent unusual circumstances, in which the reconsideration official would reserve the right to an extension upon written notice to the model participant, the reconsideration determination would be issued within 60 days of CMS's receipt of the timely filed position papers and supporting documentation in accordance with the schedule specified under proposed § 512.190(b)(3)(ii). Under proposed § 512.190(d)(3), the determination made by the CMS reconsideration official would be final and binding 30 days after its issuance, unless the model participant or CMS were to timely request review of the reconsideration determination by the CMS Administrator in accordance with §§ 512.190(e)(1) and (2).

We proposed to codify at § 512.190(e) a process for the CMS Administrator to review reconsideration determinations made under § 512.190(d). We proposed that either the model participant or CMS may request that the CMS Administrator review the reconsideration determination. The request to the CMS Administrator would have to be made via email, within 30 days of the reconsideration determination, to an email address specified by CMS. The request would have to include a copy of the reconsideration determination, as well as a detailed written explanation of why the model participant or CMS disagrees with the reconsideration determination. The CMS Administrator would promptly send the parties a written acknowledgement of receipt of the request for review. The CMS Administrator would send the parties notice of whether the request for review was granted or denied. If the request for review is granted, the notice would include the review procedures and a schedule that would permit each party to submit a brief in support of the party's positions for consideration by the CMS Administrator. If the request for review is denied, the reconsideration determination would be final and binding as of the date of denial of the request for review by the CMS Administrator. If the request for review by the CMS Administrator is granted, the record for review would consist solely of timely submitted briefs and evidence contained in the record of the proceedings before the reconsideration official and evidence as set forth in the documents and data described in proposed § 512.190(d)(1)(ii); the CMS Administrator would not consider evidence other than information set forth in the documents and data described in proposed § 512.190(d)(1)(ii). The CMS Administrator would review the record and issue to the parties a written determination that would be final and binding as of the date the written determination is sent.

We invited public comment on the proposed reconsideration review process for Innovation Center models.

We received no comments on this proposal and are finalizing this provision as proposed with a few technical changes for clarity.

III. Increasing Organ Transplant Access (IOTA) Model

A. Introduction

In this final rule, we finalize the IOTA Model, a new mandatory Medicare alternative payment model that will be tested under the authority of the Innovation Center at section 1115A(b) of the Act, that will begin on July 1, 2025, and end on June 30, 2031. The IOTA Model will test whether using performance-based incentive payments in the form of upside risk payments and downside risk payments to and from transplant hospitals selected to participate in the model increases the number of kidney transplants furnished to patients with ESRD, thereby reducing Medicare expenditures while preserving or enhancing quality of care.

The goal of the performance-based payments is to increase the number of kidney transplants furnished to ESRD patients placed on a kidney transplant hospital's waitlist; encourage investments in value-based care and quality improvement activities, particularly those that promote an equitable kidney transplant process prior to, during, and post transplantation for all patients; encourage better use of the current supply of deceased donor organs and greater provider and community collaborations to address the medical and non-medical needs of patients; and increased awareness, education, and support for living donations. The IOTA Model payment structure will also promote IOTA participant accountability by linking performance-based payments to quality. We theorize that increasing the number of kidney transplants furnished to ESRD patients on the participating hospitals' waitlists will reduce Medicare expenditures by reducing dialysis expenditures and avoidable health care service utilization and will improve the quality of life for patients with ESRD.

As discussed in section III.B of this final rule, studies show that kidney transplant hospitals are underutilizing donor kidneys and have become more conservative in accepting organs for transplantation, with notable variation by region and across transplant hospitals.[10] The IOTA Model aims to address these access and equity problems through financial incentives that reward IOTA participants that improve their kidney organ offer acceptance rate ratios over time and hold them financially accountable for not doing so. The IOTA Model's payment structure includes upside and downside performance-based incentive payments (''upside risk payment'' or ''downside risk payment'') for kidney transplant hospitals selected to participate in the IOTA Model (''IOTA participant'') that are tied to performance on achievement, efficiency, and quality domains.

The achievement domain will assess the number of kidney transplants performed relative to a participant-specific target, with performance on this domain being worth up to 60 points. The efficiency domain will assess kidney organ offer acceptance rate ratios relative to a national rate for all kidney transplant hospitals, including those not selected to participate in the model, to 20 points. or to the IOTA participant's own past kidney organ offer acceptance rate ratio, with performance on this domain being worth up to 20 points. The quality domain will assess performance based on post-transplant outcomes, with performance on this domain being worth up to 20 points. The achievement domain will be weighted more heavily than the other two domains because increasing the number of transplants is a key goal of the model and will be a primary factor in determining the amount of the performance-based payment.

The final performance score for each IOTA participant will be the sum of the points earned across the achievement domain, efficiency domain, and quality domain. The final performance score will determine whether an upside risk payment or downside risk payment would be owed and the amount of such payment. Specifically:

[10] Mohan, S., Chiles, M.C., Patzer, R.E., Pastan, S.O., Husain, S.A., Carpenter, D.J., Dube, G.K., Crew, R.J., Ratner, L.E., & Cohen, D.J. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney International, 94*(1), 187–198. *https://doi.org/10.1016/j.kint.2018.02.016.*

• For PY 1, if an IOTA participant has a final performance score between 60 and 100 points, it would qualify for the upside risk payment in accordance with the proposed calculation methodology described in section III.C.6.c.(2)(a) of this final rule (final performance score minus 60, then divided by 40, then multiplied by $15,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to beneficiaries with Medicare FFS as a primary or secondary payer during the PY).

• For PY 1, if an IOTA participant has a final performance score below 60, it would fall into a neutral zone where no upside risk payment and no downside risk payment would apply.

• For PY 2 and each subsequent PY (PYs 2–6), if an IOTA participant achieves a final performance score of 41 to 59 points, it would fall into a neutral zone where no upside risk payment and no downside risk payment would apply.

• For PY 2 and each subsequent PY, if an IOTA participant achieves a final performance score of 40 points or below, it would be subject to the downside risk payment in accordance with the calculation methodology described in section III.C.6.c.(2)(b) of this final rule (40 minus final performance score, then divided by 40, then multiplied by $2,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to beneficiaries with Medicare FFS as a primary or secondary payer during the PY).

We recognize the complexity of the transplant ecosystem, which requires coordination between transplant hospitals, other health care providers, organ procurement organizations (OPOs), patients, potential donors, and their families. The IOTA Model does not prescribe or require specific processes or policy approaches that each selected IOTA participant must implement for purposes of the model test.

We believe the IOTA Model will complement other efforts in relation to the transplant ecosystem to enhance health and safety outcomes, increase transparency, increase the number of transplants, and reduce disparities. We also believe that the payment methodology will act in concert with efforts that are currently under development by HRSA to increase the numbers of both deceased and living donor organ transplants.

This model falls within a larger framework of activities initiated by the Federal Government during the past several years and planned for the upcoming year to enhance the donation, procurement, and transplantation of solid organs. This Federal collaborative, called the Organ Transplantation Affinity Group (OTAG), is a coordinated group working together to strengthen accountability, equity, and performance in organ donation, procurement, and transplantation.[11]

B. Background

A review of the literature on kidney transplantation shows that the increasing numbers of kidney transplants is unable to keep pace with the increasing need for organs and is discussed in section III.B.3.d of this final rule.[12] While more people die waiting for a kidney transplant, the short- and long-term outcomes of patients who undergo kidney transplantation have improved, despite both recipients and donors increasing in age and adverse health conditions.[13] Recent studies show that transplant hospitals have become more conservative in accepting organs for transplantation when offered for specific patients, avoiding the use of less-than-ideal organs on account of perceived risk.[14] Wide variation among geographic regions and transplant hospitals in rates of kidney transplantation, along with access and equity issues, raises the need to hold kidney transplant hospitals accountable for performance.[15] The IOTA Model includes a two-sided performance-based payment structure that rewards IOTA participants for high performance in the achievement, efficiency, and quality domains, and imposes financial accountability on IOTA participants that perform poorly on those domains. We proposed the IOTA Model as a complement to wider efforts aimed at transplant ecosystem performance and equity improvements as discussed in section III.B of the proposed rule. Ultimately, we seek a set of interventions that focus on ESRD patients in need of a kidney transplant. In section III.B of the proposed rule, we summarized the transplant ecosystem and HHS oversight within CMS and HRSA related to kidney transplantation, highlight related initiatives and priorities nationally, and outlined our rationale for the proposed IOTA Model informed by literature, data, and studies.

1. The Transplant Ecosystem

Kidney transplantation occurs within an overall organ donation and transplantation system (also known and referred to as the transplant ecosystem) that comprises a vast network of institutions dedicated to ensuring that patients are evaluated and, if appropriate, placed onto the organ transplant waitlist, and that those on the organ transplant waitlist receive lifesaving organ transplants. Transplantation of livers, hearts, lungs, and other organs is also well established within the U.S. health care system. The transplant ecosystem includes the Organ Procurement and Transplantation Network (OPTN); Organ Procurement Organizations (OPOs); transplant hospitals and providers; histocompatibility laboratories that provide blood, tissue, and antibody testing for the organ matching process; and patients, including ESRD patients in need of a transplant, their families, and caregivers.[16] For kidney transplantation, it also includes ESRD facilities, commonly known as dialysis facilities.

The National Organ Transplant Act of 1984, referred to herein as NOTA, established the OPTN, with HHS oversight, to manage and operate the national organ transplantation system (42 U.S.C. 274). The OPTN is a network that coordinates the nation's organ procurement, distribution, and transplantation systems.

Organ Procurement Organizations (OPOs) are non-profit organizations operating under contract with the Federal Government that are charged, under section 371(b) of the Public

[11] Moody-Williams, J.D., & Nair, S. (2023, September 15). Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance | CMS. *BLOG. https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

[12] Penn Medicine News. (2020, December 16). *Too Many Donor Kidneys Are Discarded in U.S. Before Transplantation—Penn Medicine.* (2020, December 16). *www.pennmedicine.org. https://www.pennmedicine.org/news/news-releases/2020/december/too-many-donor-kidneys-are-discarded-in-us-before-transplantation www.pennmedicine.org.*

[13] Hariharan, S., Israni, A.K., & Danovitch, G. (2021). Long-Term Survival after Kidney Transplantation. *New England Journal of Medicine, 385*(8), 729–743. *https://doi.org/10.1056/nejmra2014530.*

[14] Stewart, D.E., Garcia, V.C., Rosendale, J.D., Klassen, D.K., & Carrico, B.J. (2017). Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States. *Transplantation, 101*(3), 575–587. *https://doi.org/10.1097/tp.0000000000001539.*

[15] Mohan, S., Chiles, M.C., Patzer, R.E., Pastan, S.O., Husain, S.A., Carpenter, D.J., Dube, G.K., Crew, R.J., Ratner, L.E., & Cohen, D.J. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney International, 94*(1), 187–198. *https://doi.org/10.1016/j.kint.2018.02.016.*

[16] Moody-Williams, J.D., & Nair, S. (2023, September 15). Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance | CMS. *BLOG. https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

Health Service Act (PHS Act, 42 U.S.C. 273(b)) with activities including, but not limited to, identifying potential organ donors, providing for the acquisition and preservation of donated organs, the equitable allocation of donated organs, and the transportation of donated organs to transplant hospitals. Section 371(b) of the Public Health Services Act requires that an OPO must have a defined service area, a concept that is defined at 42 CFR part 486 subpart G as the Donation Service Area (DSA). Section 1138(b) of the Act states that the Secretary may not designate more than one OPO to serve each DSA. There are currently 56 OPOs that serve the United States and Puerto Rico.

Section 1138(b) of the Act lays out the requirements that an OPO must meet for organ acquisition costs to be payable under Title XVIII and Title XIX. Separately, CMS sets out the components of allowable Medicare organ acquisition costs at 42 CFR 413.402(b). Allowable organ acquisition costs are those costs incurred in the acquisition of organs intended for transplant, and include, but are not limited to: costs associated with special care services, the surgeon's fee for excising the deceased donor organ from the donor patient (limited to $1,250 for kidneys), operating room and other inpatient ancillary services provided to the living or deceased donor, organ preservation and perfusion costs, and donor and beneficiary evaluation. OPOs and transplant hospitals may incur organ acquisition costs and include these and some additional administrative and general costs on the Medicare cost report.

The CMS conditions for coverage for OPOs at 42 CFR 486.322 require an OPO to have written agreements with 95 percent of the Medicare and Medicaid certified hospitals and critical access hospitals in its DSA that have a ventilator and an operating room and have not been granted a waiver to work with another OPO. These hospitals, known as donor hospitals, are required by the CMS conditions of participation for hospitals at 42 CFR 482.45 to have an agreement with an OPO under which the donor hospital must notify the OPO of patients who are expected to die imminently and of patients who have died in the hospital. (Under the hospital conditions of participation, such an agreement is required of all hospitals that participate in Medicare.) Also, under the hospital conditions of participation, donor hospitals are responsible for informing donor patient families of the option to donate organs, tissues, and eyes, or to decline to donate; and to work collaboratively with the OPO to educate hospital staff on donation, improve its identification of potential donors, and work with the OPO to manage the potential donor patient while testing and placement of the potential donor organ occurs.

At 42 CFR 482.70, CMS defines a transplant hospital as ''a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients,'' and a transplant program as ''an organ-specific transplant program within a transplant hospital,'' as so defined. In accordance with 42 CFR 482.98(b), a transplant program must have a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation. The transplant surgeon is responsible for providing surgical services related to transplantation, and the transplant physician is responsible for providing and coordinating transplantation care.

In accordance with CMS' Conditions for Coverage (CfC) for ESRD Facilities at 42 CFR part 494, ESRD facilities are charged with delivering safe and adequate dialysis to ESRD patients, and, among other requirements, informing patients of their treatment modalities, including dialysis and kidney transplantation. The CfCs require ESRD facilities to conduct a patient assessment that includes evaluation of suitability for referral for transplantation, based on criteria developed by the prospective transplantation center and its surgeon(s). General nephrologists refer patients for evaluation for kidney transplants.[17] Candidates for kidney transplant undergo a rigorous evaluation by a transplant program prior to placement on a waitlist, involving evaluation by a multidisciplinary team for conditions pertaining to the potential success of the transplant, the possibility of recurrence, and surgical issues including frailty, obesity, diabetes and other causes of ESRD, infections, malignancies, cardiac disease, pulmonary disease, peripheral arterial disease, neurologic disease, hematologic conditions, and gastrointestinal and liver disease and an immunological assessment; a psychosocial assessment; assessment of adherence behaviors; and tobacco counseling.[18]

Once placed on the waitlist, potential recipients must maintain active status to be eligible to receive a deceased donor transplant.[19] An individual may receive a status of 'inactive' if they are missing lab results, contact information, or any of the other requirements that would be necessary for them to receive an organ transplant if offered. An individual may only receive an organ offer if they have a status of 'active.' [20] Each transplant hospital has its own waitlist, and patients can attempt to be placed on multiple waitlists; OPTN maintains a national transplant waiting list that encompasses the waitlists for all kidney transplant hospitals.[21] [22] Individuals already on dialysis continue to receive regular dialysis treatments while waiting for an organ to become available. After surgery, a transplant nephrologist manages the possible outcomes of organ rejection and infection, and other medical complications.[23]

2. HHS Oversight and Priorities

HRSA, which oversees the OPTN, and CMS play a vital role in protecting the health and safety of Americans as they engage with the U.S. health care system.[24] The OPTN operates a complex network of computerized interactions whereby specific deceased donor organs get matched to individual patients on the national transplant waiting list. The Scientific Registry of Transplant Recipients (SRTR), operated under

[17] Virmani, S., & Asch, W.S. (2020). The Role of the General Nephrologist in Evaluating Patients for Kidney Transplantation: Core Curriculum 2020. *American Journal of Kidney Diseases, 76,* 567–579. *https://doi.org/10.1053/j.ajkd.2020.01.001.*

[18] Chadban, S.J., Ahn, C., Axelrod, D.A., Foster, B.J., Kasiske, B.L., Kher, V., Kumar, D., Oberbauer, R., Pascual, J., Pilmore, H.L., Rodrigue, J.R., Segev, D.L., Sheerin, N.S., Tinckam, K.J., Wong, G., & Knoll, G.A. (2020). KDIGO Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation. *Transplantation, 104*(4S1), S11. *https://doi.org/10.1097/TP.0000000000003136.*

[19] National kidney Foundation. (2017, February 10). *The Kidney Transplant Waitlist—What You Need to Know.* National Kidney Foundation. *https://www.kidney.org/atoz/content/transplant-waitlist.*

[20] *The kidney transplant waitlist.* (n.d.). Transplant Living. *https://transplantliving.org/kidney/the-kidney-transplant-waitlist/.*

[21] National kidney Foundation. (2019, June 12). *Understanding the transplant waitlist.* National Kidney Foundation. *https://www.kidney.org/content/understanding-transplant-waitlist.*

[22] National kidney Foundation. (2016, August 4). *Multiple Listing for Kidney Transplant.* National Kidney Foundation. *https://www.kidney.org/atoz/content/multiple-listing.*

[23] *Transplant Nephrology Fellowship.* (n.d.). *www.hopkinsmedicine.org.* Retrieved May 30, 2023, from *https://www.hopkinsmedicine.org/nephrology/education/transplant-fellowship.*

[24] On March 22, 2023, HRSA announced an initiative that included several actions to strengthen accountability and transparency in the OPTN. These actions include modernization of the OPTN information technology system.

contract with HRSA, is responsible for providing statistical and analytic support to the OPTN. Section 373 of the PHS Act requires the operation of the SRTR to support ongoing evaluation of the scientific and clinical status of solid organ transplantation.[25]

CMS oversees and evaluates OPO performance. OPOs must meet performance measures and participate in, and abide by certain rules of, the OPTN.[26] The PHS Act requires the Secretary to establish outcome and process performance measures to recertify OPOs (Part H section 371; 42 U.S.C. 273). CMS has promulgated the OPO CfCs at 42 CFR part 486 subpart G.

Additionally, OPTN policies specify that OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold would be reviewed by the OPTN Membership Professional Standards Committee (MPSC).[27] CMS also conducts oversight of transplant programs, located within transplant hospitals, which must abide by both the hospital and the transplant program conditions of participation (CoPs). CMS contracts with quality improvement entities such as the ESRD Networks and Quality Improvement Organizations to provide technical support to providers and patients seeking improvements in the transplant ecosystem.

Medicare covers certain transplant-related services when provided at a Medicare-approved facility. Medicare Part A covers the costs associated with a Medicare kidney transplant procedure received in a Medicare-certified hospital and any additional inpatient hospital care needed following the procedure, and kidney acquisition costs including kidney registry fees, surgeons' fees for excising a kidney for transplant, and laboratory tests associated with the evaluation of a Medicare transplant candidate. The evaluation or preparation of a living kidney donor, the living donor's donation of the kidney, and postoperative recovery services directly related to the living donor's kidney donation are covered under Medicare. In addition, deductible and coinsurance requirements do not apply to living donors for services furnished to an individual in connection with the donation of a kidney for transplant surgery for a Medicare beneficiary. Medicare Part B coverage includes the surgeon's fees for performing the kidney transplant procedure and perioperative care. Medicare Part B also covers physician services for the living kidney donor without regard to whether the service would otherwise be covered by Medicare. Part A and Part B share responsibility for covering blood, including packed red blood cells, blood components and the cost of processing and receiving blood.

Medicare Part B covers immunosuppressive drugs following an organ transplant for which payment is made under Title XVIII. Immunosuppressive drugs following an organ transplant are covered by Part D when an individual did not have Part A at the time of the transplant. Beneficiaries who have Medicare due to ESRD alone lose Medicare coverage 36 months following a successful kidney transplant. Section 402(a) of the Consolidated Appropriations Act (CAA) of 2021 added section 1836(b) of the Act to provide coverage for immunosuppressive drugs beginning January 1, 2023, for eligible individuals whose eligibility for Medicare based on ESRD ends by reason of section 226A(b)(2) of the Act for those three-years post kidney transplant. Under section 1833 of the Act, the amounts paid by Medicare for immunosuppressive drugs are equal to 80 percent of the applicable payment amount; beneficiaries are thus subject to a 20 percent coinsurance for immunosuppressive drugs covered by both Part B and the Medicare Part B Immunosuppressive Drug Benefit (Part B–ID).

3. Federal Government Initiatives To Enhance Organ Transplantation

a. CMS Regulatory Initiatives To Enhance Organ Transplantation

On September 30, 2019, we published the final rule, ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51732). The rulemaking, in part, aimed to address the concern that too many organs are being discarded that could be transplanted successfully, including hearts, lungs, livers, and kidneys. This rule implemented changes to the transplant program regulations, eliminating requirements for re-approval of transplant programs pertaining to data submission, clinical experience, and outcomes. We believed that the removal of these requirements aligned with our goal of increasing access to kidney transplants by increasing the utilization of organs from deceased donors and reducing the organ discard rate (84 FR 51732). We sought improved organ procurement, greater organ utilization, and reduction of burden for transplant hospitals, while still maintaining the importance of safety in the transplant process.

On December 2, 2020, we issued a final rule titled, ''Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations'' (85 FR 77898), which revised the OPO CfCs by replacing the previous outcome measures with new transparent, reliable, and objective outcome measures. In modifying the metrics used for assessing OPO performance, we sought to promote greater utilization of organs that might not otherwise be recovered or used due to perceived organ quality.[28]

While these regulatory changes went into effect with the goal of improving the performance of transplant hospitals and OPOs and to promote the procuring of organs and delivering them to prospective transplant recipients, we acknowledged the need for improvements in health, safety, and outcomes across the transplant ecosystem, including in transplant programs, OPOs, and ESRD facilities.[29] [30] In particular, we recognize that further action must be taken to address health disparities and lower rates of transplantation for underserved populations observed across transplant hospitals.

We published a request for information in the **Federal Register** on

[25] *Mission, Vision, and Values.* (n.d.). *www.srtr.org. https://www.srtr.org/about-srtr/mission-vision-and-values/.*

[26] U.S. Congress. (1934) United States Code: Social Security Act, 42 U.S.C. 301–Suppl. 4 1934.

[27] Bylaws–OPTN. (n.d.). Optn.*transplant.hrsa.gov.* Retrieved September 13, 2024, from *https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.*

[28] The Organ Procurement Organizations Annual Public Aggregated Performance Report for 2023 is available at *https://www.cms.gov/files/document/opo-annual-public-performance-report-2023.pdf.*

[29] One study—Doby, B. One study—Doby, B. One study—Doby, B. One study showed that deceased donor organ donation increased during 2019, during the period of public debate about regulating OPO performance. *See* Doby, B.L., Ross-Driscoll, K., Shuck, M., Wadsworth, M., Durand, C.M., & Lynch, R.J. (2021). Public discourse and policy change: Absence of harm from increased oversight and transparency in OPO Performance. *American Journal of Transplantation, 21*(8), 2646–2652. *https://doi.org/10.1111/ajt.16527.*

[30] In addition, CMS finalized a policy in the final rule for FY 2023 for the Medicare Physician Fee Schedule that Medicare Part A and Part B payment can be made for dental or oral examinations, including necessary treatment, performed as part of a necessary workup prior to organ transplant surgery. In the final rule, CMS describes certain dental services as inextricably linked and integral to the clinical success of organ transplantation. (87 FR 69671–69675).

December 3, 2021, titled ''Request for Information: Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Facilities'' (86 FR 68594) (hereafter known as the ''Transplant Ecosystem RFI''). This RFI solicited public comments on potential changes to the requirements that transplant programs, OPOs, and ESRD facilities must meet to participate in the Medicare and Medicaid programs. Specifically, we solicited public comments on ways to:

- Continue to improve systems of care for all patients in need of a transplant;
- Increase the number of organs available for transplant for all solid organ types;
- Encourage the use of dialysis in alternate settings or modalities over in-center hemodialysis where clinically appropriate and advantageous;
- Ensure that the CMS and HHS policies appropriately incentivize the creation and use of future new treatments and technologies; and
- Harmonize requirements across government agencies to facilitate these objectives and improve quality across the organ donation and transplantation ecosystem.

We also solicited information related to opportunities, inefficiencies, and inequities in the transplant ecosystem and what can be done to ensure all segments of our healthcare systems are invested and accountable in ensuring improvements to organ donation and transplantation rates (86 FR 68596). The Transplant Ecosystem RFI focused on questions in the areas of transplantation, kidney health and ESRD facilities, and OPOs. For transplant programs, specific topics included transplant program CoPs, patient rights, and equity in organ transplantation and organ donation (86 FR 68596). For kidney health and ESRD facilities, topics included maintaining and improving health of patients, ways to identify those at risk of developing chronic kidney disease (CKD), improving detection rates of CKD, and ways to close the CKD detection, education, and care health equity gap (86 FR 68599). Other topics included home dialysis, dialysis in alternative settings such as nursing homes and mobile dialysis, and alternate models of care (86 FR 68600). For OPOs, specific topics included assessment and recertification, organ transport and tracking, the donor referral process, organ recovery centers, organ discards, donation after cardiac death, tissue banks, organs for research, and vascular composite organs. (86 FR 68601 through 68606).

The Transplant Ecosystem RFI followed three executive orders addressing health equity that were issued by President Biden on January 20 and January 21, 2021—

- Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (E.O. 13985, 86 FR 7009, January 20, 2021);
- Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation (E.O. 13988, 86 FR 7023, January 25, 2021); and
- Executive Order on Ensuring an Equitable Pandemic Response and Recovery (E.O. 13995, 86 FR 7193, January 26, 2021).

The RFI was among several issued by CMS in 2021 to request public comment on ways to advance health equity and reduce disparities in our policies and programs.

CMS's regulatory initiatives since 2018 pertaining to organ donation and transplantation have included final rules modifying CoPs and CfCs for transplant programs (84 FR 51732) and OPOs (85 FR 77898), respectively, and our recent RFI on transplant program CoPs, OPO CfCs, and the ESRD facility CfCs (86 FR 68594). These regulations and RFIs have sought to foster greater health and safety for patients, greater transparency for all patients, increases in organ donation and transplantation, and reduced disparities in organ donation and transplantation. Through these regulations, we are working to attain these goals by designing and implementing policies that improve health for all people affected by the transplant ecosystem.

b. CMS Innovation Center Payment Models

The Innovation Center is currently pursuing complementary alternative payment model tests—the ESRD Treatment Choices (ETC) Model and the Kidney Care Choices (KCC) Model—aimed at enhancing kidney transplantation and improving health-related outcomes for patients with late-stage CKD and ESRD, thereby reducing costs to the Medicare program. The impetus for the ETC and KCC Models originated with evaluation findings for the earlier Comprehensive ESRD Care (CEC) Model, which ran from October 2015 through March 2021, that showed large dialysis organizations achieving positive clinical and financial outcomes relating to services to Medicare beneficiaries receiving dialysis, though the CEC Model did not achieve net savings to Medicare.[31] The CEC Model focused on patients being treated in ESRD facilities, with no explicit incentives to encourage increases in kidney transplantation.

The ETC and KCC Models have engaged a broader range of health care providers beyond ESRD facilities, including nephrology professionals and transplant providers, and address transplantation. Each model includes direct financial incentives for increasing the number of kidney transplants.

The ETC Model, which began January 1, 2021, and which is scheduled to end on June 30, 2027, is a mandatory model that tests whether greater use of home dialysis and kidney transplantation for Medicare beneficiaries with ESRD reduces Medicare expenditures while preserving or enhancing the quality of care furnished to those beneficiaries. We established requirements for the ETC Model in the Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures final rule (85 FR 61114 through 61381). These requirements are codified at 42 CFR subpart C. The ETC Model tests the effects of certain Medicare payment adjustments to participating ESRD facilities and Managing Clinicians (clinicians who manage ESRD beneficiaries and bill the Monthly Capitation Payment (MCP)).

The payment adjustments are designed to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance quality of care. Under the ETC Model, CMS makes upward adjustments to certain payments under the ESRD Prospective Payment System (PPS) to certain dialysis facilities on home dialysis claims, and upward adjustments to the MCP paid to certain Managing Clinicians on home dialysis-related claims (85 FR 61117). In addition, CMS makes upward and downward adjustments to PPS payments to participating ESRD facilities and to the MCP paid to participating Managing Clinicians based on the Participant's home dialysis rate and transplant waitlisting and living

[31] The results of the CMS-sponsored evaluation of the CEC Model are available at *https://innovation.cms.gov/innovation-models/comprehensive-esrd-care.* The 5-year model test reduced Medicare expenses by $217 million, or 1.3 percent relative to the pre-CEC period. These results do not account for shared savings payments to the model participants. There was a 3 percent decrease in the number of hospitalizations and a 0.4 percent increase in the number of outpatient dialysis sessions for Medicare beneficiaries in CEC compared to non-CEC beneficiaries. In addition, the CEC Model improved key quality outcomes.

donor transplant rate (85 FR 61117). The ETC Model's objectives, as described in the final rule, include supporting paired donations and donor chains, and reducing the likelihood that potentially viable organs are discarded (85 FR 61128). The ETC Model was updated by the final rule dated November 8, 2021, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' and the final rule dated November 7, 2022, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' (87 FR 67136). We finalized further modifications to the ETC Model related to the availability of administrative review of an ETC Participant's targeted review request in the final rule issued on November 6, 2023, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' (88 FR 76345). As of the second model evaluation report covering the first two years of the model, the model has not shown statistically significant results as home dialysis grew similarly across ETC areas and the comparison group and no statistically significant differences in waitlisting and living donor transplant rates. As noted earlier, CMS will continue to evaluate the effectiveness of the ETC Model.

CMS is also operating the ETC Learning Collaborative, which is focused on increasing the availability of deceased donor organs for transplantation.[32] The ETC Learning Collaborative regularly convenes ETC Participants, transplant hospitals, OPOs, and large donor hospitals, with the goal of using learning and quality improvement techniques to systematically spread the best practices of the highest performing organizations. CMS is employing quality improvement approaches to improve performance by collecting and analyzing data to identify the highest performers, and to help others to test, adapt and spread the best practices of these high performers throughout the entire national organ recovery system (85 FR 61346).

The KCC Model, which began its performance period on January 1, 2022, and is scheduled to end on December 31, 2026, is a voluntary model that also builds upon the CEC Model structure to encourage health care providers to better manage the care for Medicare beneficiaries with CKD stages 4 and 5 and ESRD, delay the onset of dialysis, and incentivize kidney transplantation. Various entities are participating in the KCC Model, including nephrologists and nephrology practices, dialysis facilities, and other health care providers. The participating entities receive a bonus payment for each aligned beneficiary who receives a kidney transplant, so long as the transplant remains successful over a certain time period. CMS plans to continue to evaluate the effectiveness of the ETC and KCC Models in achieving clinical goals, improving quality of care, and reducing Medicare costs.[33]

The IOTA Model will complement the ETC and KCC Models and expand kidney model participation to hospitals, which are a key player in the transplant ecosystem, to test whether two-sided risk payments based on performance increase access to kidney transplants for ESRD patients placed on the waitlists of participating transplant hospitals.

c. HRSA Initiatives Involving Kidney Transplants

NOTA established the OPTN almost 40 years ago to coordinate and operate the nation's organ procurement, allocation, and transplantation system. There are about 400 member organizations that comprise the OPTN. Section 372(b)(2)(A) of the PHS Act charges the OPTN with establishing a national list of individuals who need organs and a national computer system to match organs with individuals on the waitlist. HRSA has also undertaken efforts in alignment with CMS efforts and Federal Government initiatives to improve accountability in OPTN functions. On March 22, 2023, HRSA launched the OPTN Modernization Initiative to strengthen accountability, equity, and performance in the organ donation and transplantation system through a focus on five key areas: technology, data transparency, governance, operations, and quality improvement and innovation.[34] The OPTN Modernization Initiative was further supported by the Securing the U.S. Organ Procurement and Transplantation Network Act (Pub. L. 118–14), which included several key provisions proposed in the President's Fiscal Year 2024 Budget and was signed into law on September 22, 2023.[35] The new law expressly authorizes HHS to make multiple awards to different entities, which could enable the OPTN to benefit from best-in-class vendors and provide a more efficient system that strengthens oversight and improves patient safety.

Effective July 14, 2022, revisions to OPTN policies were made related to the Transplant Program Performance to establish new criteria for identification of transplant programs that enter MPSC performance review based on the following criteria:[36]

- The transplant program's 90-day post-transplant graft survival hazard ratio is greater than 1.75 during the 2.5-year time period; or
- The transplant program's 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival hazard ratio is greater than 1.75 during a 2.5-year period.

Transplant programs that meet either of the criteria, as reported by the SRTR, must participate in the OPTN Membership and Professional Standards Committee (MPSC) performance review, which may require the member to take appropriate actions to determine if the transplant program has demonstrated sustainable improvement, including, but not limited to—

- Providing information about the program structure, procedures, protocols and quality;
- Review processes;
- Adopting and implementing a plan for improvement;
- Participating in an informal discussion with MPSC members; and
- Participating in a peer visit.

The MPSC would continue to review the transplant program under the performance review until the MPSC determines that the transplant program has made sufficient and sustainable improvements to avoid risk to public

[32] Centers for Medicare & Medicaid Services. *https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model.*

[33] The evaluation report for the first two years (2021, 2022) of the ETC Model is available at *https://www.cms.gov/priorities/innovation/innovation-models/esrd-treatment-choices-model* and the evaluation report for the first year (2022) of the KCC Model is available at *https://www.cms.gov/priorities/innovation/innovation-models/kidney-care-choices-kcc-model.*

[34] *HRSA Announces Organ Procurement and Transplantation Network Modernization Initiative | HRSA.* (n.d.). *www.hrsa.gov.* Retrieved August 20, 2023, from *https://www.hrsa.gov/optn-modernization/march-2023.*

[35] The White House. (2023, September 22). *Bill Signed: H.R. 2544.* The White House. *https://www.whitehouse.gov/briefing-room/legislation/2023/09/22/bill-signed-h-r-2544/.*

[36] OPTN. (n.d.). *Bylaws.* Retrieved September 15, 2024 from *https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.*

health or patient safety. If the MPSC's review determines that a risk to patient health or public safety exists, the MPSC may request that a member inactivate or withdraw a designated transplant program, or a specific component of the program, to mitigate the risk. Transplant programs that do not participate in the MPSC performance review process or fail to act to improve their performance are subject to the policies described in Appendix L of OPTN policies, Reviews and Actions, including the declaration of ''Member Not in Good Standing.'' While being designated ''Member Not in Good Standing'' does not necessarily lead to the closure or removal of that program from receiving reimbursement from Federal health insurance programs, the Secretary can, based on a recommendation from the OPTN Board of Directors, revoke OPTN membership, close an OPTN member, or remove the ability of the member to receive Federal funding from Medicare or Medicaid. Additionally, numerous private payers align with the MPSC metrics and SRTR star rating system that evaluate transplant hospitals on post-transplant performance to create their Center of Excellence (COE) programs. Therefore, MPSC reviews and performance on the MPSC monitoring measures are a powerful regulatory incentive for transplant programs.

In the final rule, dated September 22, 2020, titled ''Removing Financial Disincentives to Living Organ Donation'' (85 FR 59438), HRSA expanded the scope of qualified reimbursable expenses incurred by living donors under the Living Organ Donation Reimbursement Program to include lost wages and dependent care (childcare and elder care) expenses to further the goal of reducing financial barriers to living organ donation. The program previously only allowed for reimbursement of travel, lodging, meals, and incidental expenses. In the final notice, dated September 22, 2020, titled, ''Reimbursement of Travel and Subsistence Expenses Toward Living Organ Donation Program Eligibility Guidelines,'' HRSA increased the income eligibility threshold under the Living Organ Donation Reimbursement Program from 300 percent to 350 percent of the Federal Poverty Guidelines (85 FR 59531).

3. Rationale for the Proposed IOTA Model

a. Alignment With Federal Government Initiatives and Priorities

For decades, patients and health care providers have confronted an imbalance in the number of transplant candidates and the supply of acceptable donor organs, including kidneys and other organs. Observed variation in access to organ transplantation by geography, race/ethnicity, disability status, and socioeconomic status, as well as the overall performance of the organ transplantation ecosystem, raised the need to make performance improvements and address disparities.[37] Strengthening and improving the performance of the organ transplantation ecosystem is a priority for HHS. To that end, OTAG was established in 2021 by CMS and HRSA and has expanded interagency coordination and collaboration to ''drive improvements in donations, clinical outcomes, system improvement, quality measurement, transparency, and regulatory oversight.'' [38] Collectively, CMS and HRSA seek to—

- Reduce variation of pre-transplant and referral practices; [39]
- Increase availability and use of donated organs;
- Increase accountability for organ procurement and matching;
- Promote equitable access to transplants; and
- Empower patients, families, and caregivers to actively engage in the transplant journey.

As discussed in section III.C. of the proposed rule, we believe the IOTA Model has the potential to substantially increase the number of kidney transplants in a way that enhances fairness for all affected individuals, regardless of socioeconomic status or other factors that limit access to care and negatively affect health outcomes, thereby improving quality of care, reducing costs to Medicare, and prolonging lives. The IOTA Model is complementary to the ETC and KCC Models, and to other CMS and HRSA initiatives, with the collective goal of achieving improvements in processes among transplant hospitals that would spur an increase in both deceased donor and living donor kidney transplantation and reduce population health disparities. The IOTA Model is targeted to kidney transplant programs, but it will test specific modifications for Medicare payment and other programmatic measures that could establish a framework for interventions for transplantation that could potentially be applied to the other solid organ types in the future.

In the following sections of this final rule, we review scientific literature that outlines specific ways to enhance kidney transplantation. Our analysis is focused on kidney transplantation, but we also present findings pertaining to the transplantation of other organs, especially livers. We aim to show how the types of interventions that we proposed might also apply for any future efforts to increase transplant numbers for other organ types, and to continue to pursue the goal of greater equity. We also describe recent efforts from CMS and HRSA to enhance organ transplantation that complement to the IOTA Model's use of upside risk payments and downside risk payments as a policy lever to increase the number of kidney transplants and achieve a fairer distribution. of kidney transplants.

b. End Stage Renal Disease Impact

According to the United States Renal Data System (USRDS), in 2021 about 808,536 people in the United States were living with ESRD, almost double the number in 2001.[40] Prevalence of ESRD varied by Health Service Area (HSA) and ESRD Network.[41] Stratified by age and race/ethnicity, ESRD was consistently more prevalent among older people (65 and older) and in Black people.[42] Diabetes and hypertension are most often the primary cause of ESRD.[43] According to the National Kidney Foundation, these diseases disproportionately affect minority populations, increasing the risk of kidney disease.[44] Year-over-year, incidence of ESRD continues to increase, as the number of patients newly registered increased from 97,856 in 2001 to 134,837 in 2019 and 135,972 in 2021.[45] Studies show that people

[37] Moody-Williams, J.D., & Nair, S. (2023, December 13). Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance | CMS. *BLOG. https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

[38] Moody-Williams, J.D., & Nair, S. (2023, December 13). Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance | CMS. *BLOG. https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

[39] Pre-transplant/referral practices are inclusive of the referring physician's assessment criteria, patient education, and feedback to the referring physician from the transplant assessment.

[40] United States Renal Data System. 2023. End Stage Renal Disease: Chapter 1. Figure 1.5.

[41] United States Renal Data System. 2023. End Stage Renal Disease: Chapter 1. Figure 1.7.

[42] United States Renal Data System. 2023. End Stage Renal Disease: Chapter 1. Figure 1.8.

[43] United States Renal Data System. 2023. End Stage Renal Disease. Chapter 1. Table 1.3.

[44] National Kidney Foundation. (2016, January 7). *Race, Ethnicity and Kidney Disease.* National Kidney Foundation. *https://www.kidney.org/atoz/content/minorities-KD.*

[45] United States Renal Data System. 2023. End Stage Renal Disease. Chapter 1. Figure 1.1.

with kidney transplants live longer than those who remain on dialysis.[46] [47] Despite these positive outcomes, the percentage of prevalent ESRD patients with a functioning kidney transplant remained relatively stable over the past decade, increasing only slightly from 29.7 percent in 2011 to 30.51 percent in 2021.[48] In 2021, 72,864 patients with ESRD were on the kidney transplant waitlist, of which 27,413 were listed during that year.[49] The IOTA Model will partially focus on the ESRD patients who are on the kidney transplant waitlists of the kidney transplant hospitals that would be required to participate in this Model. ESRD patients represent a small portion of the U.S. population, but the disease burden to the patient and to CMS is great in terms of health outcomes, survival, quality of life, and cost. The ESRD population accounted for 6.1% of total Medicare expenditures in 2020.[50]

Due to wide variability across eligible kidney transplant hospitals, we are unable to estimate the IOTA Model's attributed patient population until the IOTA participants are randomly selected.

c. Benefits of Kidney Transplantation

ESRD, when a person's kidney function has declined to the point of requiring regular dialysis or a transplant for survival, as the person's kidneys are no longer able to perform life-sustaining functions, is the final stage of CKD. ESRD is a uniquely burdensome condition, with uncertain survival and poor quality of life for patients. The higher mortality and substantially greater expenditures and hospitalization rates for ESRD beneficiaries compared to the overall Medicare population suggest the need to explore policy interventions to enhance patients' survival and life experience, as well as to reduce the impact to Medicare. The IOTA Model aims to improve patient outcomes by incentivizing increased access to kidney transplantation across IOTA participants. Access to this lifesaving treatment may delay or avert dialysis, reduce costs to the Medicare program and to patients, and enhance survival and quality of life.

A kidney transplant involves surgically transplanting a kidney from a living or deceased donor to a kidney transplant recipient. The replacement organ is known as a graft. Most kidneys are transplanted alone, as kidneys transplanted along with other organs are very rare.[51] Fewer than 1,000 patients each year receive a simultaneous kidney-pancreas transplant, which is generally conducted for patients who have kidney failure related to type 1 diabetes mellitus.[52] The kidney in such a simultaneous transplant may come from a living or deceased donor, but other organs mostly come from a deceased donor.

About three-quarters of kidney transplants in the U.S. are deceased donor kidney transplants.[53] For deceased donor transplantation, a patient needs to contact a transplant hospital and arrange for an evaluation to assess the feasibility of surgery. The patient's name would then be added to a list of individuals who can receive organ offers. This is known as the kidney transplant hospital's kidney transplant waitlist. Living donation occurs when a living person donates an organ to a family member, friend, or other individual. People unknown to one another sometimes take part in paired exchanges, which allow the switching of recipients based on blood type and other biological factors. The number of deceased donor kidney donations has increased over the past decade, while living donor kidney donation has remained relatively constant, declining in 2020 with the COVID–19 pandemic.[54]

Kidney transplantation is considered the optimal treatment option for most ESRD patients. Although not a cure for kidney disease, a transplant can help a person live longer and improve quality of life. On average, patients experience 14 to 16 years of function from a kidney from a living kidney donor, while few people survive more than a decade on dialysis.[55] According to one source, the majority of deceased donor kidneys are expected to function for about 9 years, with high quality organs lasting longer.[56] A systematic review of studies worldwide finds significantly lower mortality and risk of cardiovascular events associated with kidney transplantation compared with dialysis.[57] Additionally, this review finds that patients who receive transplants experience a better quality of life than treatment with dialysis.[58] The average dialysis patient is admitted to the hospital nearly twice a year, often as a result of infection, and more than 35 percent of dialysis patients who are discharged are re-hospitalized within 30 days of being discharged.[59] Among transplant recipients, there are lower rates of hospitalizations, emergency department visits, and readmissions compared to those still on dialysis.[60] In general, from the standpoint of long-term survival and quality of life, a living donor kidney transplant is considered the best among all kidney transplant options for most people with CKD.[61] [62]

A cost advantage also arises with kidney transplantation. Per-person per-

[46] Strohmaier, S., Wallisch, C., Kammer, M., Geroldinger, A., Heinze, G., Oberbauer, R., & Haller, M.C. (2022). Survival Benefit of First Single-Organ Deceased Donor Kidney Transplantation Compared With Long-term Dialysis Across Ages in Transplant-Eligible Patients With Kidney Failure. *JAMA Network Open, 5*(10), e2234971. *https://doi.org/10.1001/jamanetworkopen.2022.34971*.

[47] Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S., & Gill, J. (2011). Systematic Review: Kidney Transplantation Compared With Dialysis in Clinically Relevant Outcomes. *American Journal of Transplantation, 11*(10), 2093–2109. *https://doi.org/10.1111/j.1600-6143.2011.03686.x*.

[48] United States Renal Data System. 2023. End Stage Renal Disease: Chapter 7. Figure 7.16.

[49] United States Renal Data System. 2023. End Stage Renal Disease: Chapter 7. Figures 7.1 and 7.2.

[50] United States Renal Data System. 2022. End Stage Renal Disease: Chapter 9.

[51] According to OPTN data, in 2022, there were 389 kidney-heart transplants in the U.S. 789 kidney-liver transplants, 22 kidney-lung transplants, and 3 kidney-intestine transplants. See *https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/*.

[52] Health Resources and Services Administration. (2020). Scientific Registry for Transplant Recipients. *OPTN/SRTR 2020 Annual Data Report: Pancreas. https://srtr.transplant.hrsa.gov/annual_reports/2020/Pancreas.aspx*.

[53] United States Renal Data System. 2022. USRDS Annual Data Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 7: Transplantation. Figure 7.10b.

[54] United States Renal Data System. 2022. USRDS Annual Data Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 7: Transplantation. Figure 7.10b.

[55] *Get the Facts on Kidney Transplantation Before You Start Dialysis—Penn Medicine.* (2019, July 24). *www.pennmedicine.org. https://www.pennmedicine.org/updates/blogs/transplant-update/2019/july/kidney-transplant-facts-before-dialysis*.

[56] Organ Procurement and Transplantation Network. Kidney Donor Profile Index (KDPI) Guide for Clinicians. *https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/kidney-donor-profile-index-kdpi-guide-for-clinicians/#:~:https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/kidney-donor-profile-index-kdpi-guide-for-clinicians/*.

[57] Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S., & Gill, J. (2011). Systematic Review: Kidney Transplantation Compared With Dialysis in Clinically Relevant Outcomes. *American Journal of Transplantation, 11*(10), 2093–2109. *https://doi.org/10.1111/j.1600-6143.2011.03686.x*.

[58] Ibid.

[59] United States Renal Data System. 2022. USRDS Annual Data Report. 2022. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 5: Hospitalization. Figures 5.1a, 5.9.

[60] United States Renal Data System. 2021. USRDS Annual Data Report. Volume 2. End-Stage Renal Disease (ESRD) in the United States. Chapter 5: Hospitalization, Figures 5.1a, 5.6a, 5.8.

[61] Nemati, E., Einollahi, B., Lesan Pezeshki, M., Porfarziani, V., & Fattahi, M.R. (2014). Does Kidney Transplantation With Deceased or Living Donor Affect Graft Survival? *Nephro-Urology Monthly, 6*(4). *https://doi.org/10.5812/numonthly.12182*.

[62] United States Renal Data System. 2022. USRDS Annual Data Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 7: Hospitalization. Figure 7.20.b.

year Medicare FFS spending for beneficiaries with ESRD with a transplant is less than half that for either hemodialysis or peritoneal dialysis.[63] While the benefits to patient survival and quality of life from living donor kidney transplantation are more pronounced, a recent literature review shows that deceased donor kidney transplantation generally produced better outcomes at a lower cost compared to dialysis, although old age and a high comorbidity load among kidney transplant patients may mitigate this advantage.[64] An earlier study, based on a single hospital, showed rates of hospitalization, a substantial factor in health care costs, to be lower among kidney transplant patients than for those on dialysis.[65]

Despite these positive outcomes associated with kidney transplantation, in 2020, only about 30 percent of prevalent ESRD patients (those with existing ESRD diagnoses) in the U.S. had a functioning kidney transplant, or graft.[66] In 2016, only 2.8 percent of incident ESRD patients (patients newly diagnosed with ESRD) received a preemptive kidney transplant, allowing them to avoid dialysis.[67] These rates are substantially below those of other developed nations. The U.S. was ranked 17th out of 42 reporting countries in kidney transplants per 1,000 dialysis patients in 2020, with 42 transplants per 1,000 dialysis patients in 2020.[68] We seek to test policy approaches aimed at increasing the number of kidney transplants over current levels given these relatively low numbers and the overall benefit to patients from transplantation, as well as the potential savings to Medicare.

d. Kidney Transplant Rates and Unmet Needs

Annually, more than one hundred thousand individuals in the U.S. begin treatment for ESRD.[69] Despite transplantation being widely regarded as the optimal treatment for people with ESRD, as well as being more cost-effective in the long term compared to dialysis, only a minority of people with ESRD (13 percent) are added to the waitlist, and even fewer receive a transplant. To be added to the kidney transplant waitlist, a patient must complete an evaluation at a transplant hospital, and the patient must be found to be a good candidate for a transplant. Nearly 5,000 patients on the national kidney transplant waiting list die each year.[70] [71] [72] These trends have persisted for several decades despite increases in the number of kidney transplants from deceased donors and living donors.

From 1996 to 2019, the number of kidneys made available for transplantation from deceased donors grew steadily, in part because of organs that became available as a result of the opioid epidemic.[73] [74] In 2018 and 2019, the total number of kidney transplants rose steadily as compared to previous years.[75] In 2019, almost one third of patients received a transplant within one year of being placed on the waitlist (32.9 percent), and the rate reached 51.8 percent within 5 years of being placed on the waitlist.[76] The number of kidney transplants increased by 10.2 percent from 2018 to 2019, but fell by 2.7 percent from 2019 to 2020, from 24,511 to 23,853. The reduction was precipitated by a 23.6 percent decline in living donor transplants on account of the COVID–19 pandemic.[77] The overall number of patients with a functioning graft continued its upward trend, reaching 245,846 in 2020, an increase of 2.7 percent from 2019.[78] Nonetheless, these gains in kidney transplantation in the U.S. have fallen far short of the prevailing need among individuals with ESRD or facing the prospect of kidney failure. The number of individuals with ESRD added to the waitlist for a kidney transplant reached a high of 28,533 in 2019, but dropped slightly to 25,136 in 2020, while rising to 27,413 in 2021.[79] At the end of 2021, 72,864 individuals were on the waitlist for a kidney transplant.[80]

The increase in deceased donor kidney transplantation was accompanied by a gradual but steady decline in the number of living donor transplants as compared to patients undergoing dialysis. The total number of living donor transplants per year has risen moderately over the past two decades, from 5,048 in 2000 to 5,241 in 2020, and 5,971 in 2021.[81] [82] With the overall dialysis population growing, the rate of living donor transplants per 100 patient-years on dialysis declined from 1.4 to 0.8 transplants from 2010 to 2020.[83] A report states the proportion of patients undergoing living donor kidney donation to have decreased from 37 percent in 2010 to 29 percent in 2019.[84] A study in 2013 of OPTN data found that the decline in living donation

[63] United States Renal Data System. 2022. USRDS Annual Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 9: Healthcare Expenditures for Persons with ESRD. Figure 9.11.

[64] Fu, R., Sekercioglu, N., Berta, W., & Coyte, P.C. (2020). Cost-effectiveness of Deceased-donor Renal Transplant Versus Dialysis to Treat End-stage Renal Disease. *Transplantation Direct, 6*(2), e522. *https://doi.org/10.1097/txd.0000000000000974.*

[65] Khan, S., Tighiouart, H., Kalra, A., Raman, G., Rohrer, R.J., & Pereira, B.J.G. (2003). Resource utilization among kidney transplant recipients. *Kidney International, 64*(2), 657–664. *https://doi.org/10.1046/j.1523-1755.2003.00102.x.*

[66] United States Renal Data System. *2022 Annual Data Report. Volume 2. End Stage Renal Disease Chapter 7 Transplantation Figure 7.16.*

[67] United States Renal Data System. *2018. Annual Data Report. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. Figure 1.2.* Retrieved from *https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/usrds/prior-data-reports/2018.*

[68] United States Renal Data System. 2022. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 11.17b.

[69] United States Renal Data System. 2022. USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD; 2022.Volume 2: End-stage Renal Disease (ESRD) in the United States, Chapter 1: Incidence, Prevalence, Patient Characteristics.

[70] Scientific Registry of Transplant Recipients. Program Specific Reports. *www.srtr.org.* Retrieved June 15, 2023, from *https://www.srtr.org/reports/program-specific-reports/.*

[71] Penn Medicine News. (2020, December 16). *Too Many Donor Kidneys Are Discarded in U.S. Before Transplantation—Penn Medicine. www.pennmedicine.org. https://www.pennmedicine.org/news/news-releases/2020/december/too-many-donor-kidneys-are-discarded-in-us-before-transplantation.*

[72] United States Renal Data System. 2022 Annual Data Report. Volume 2. End Stage Renal Disease Chapter 7 Transplantation Figure 7.4.

[73] Hariharan, S., Israni, A.K., & Danovitch, G. (2021). Long-Term Survival after Kidney Transplantation. New England Journal of Medicine, 385(8), 729–743. *https://doi.org/10.1056/nejmra2014530.*

[74] Durand, C.M., Bowring, M.G., Thomas, A.G., Kucirka, L.M., Massie, A.B., Cameron, A., Desai, N.M., Sulkowski, M., & Segev, D.L. (2018). The Drug Overdose Epidemic and Deceased-Donor Transplantation in the United States: A National Registry Study. *Annals of Internal Medicine, 168*(10), 702–711. *https://doi.org/10.7326/M17-2451.*

[75] United States Renal Data System. 2021. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.11.

[76] United States Renal Data System. 2021. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.7.

[77] United States Renal Data System. 2022. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.10b.

[78] United States Renal Data System. 2022. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.16.

[79] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.1.

[80] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.2.

[81] United States Renal Data System. 2012. Annual Data Report. Atlas ESRD. Table 7.1.

[82] United States Renal Data System. 2023. Annual Data report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.10a.

[83] United States Renal Data System. 2022. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.10a.

[84] Charnow, J.A. (2021, June 8). *Living Donor Kidney Transplants Declined in the Last Decade.* Renal and Urology News. *https://www.renalandurologynews.com/news/living-donor-kidney-transplantation-decreased-after-2010-united-states-trends/.*

appeared most prominent among men, Black/African Americans, and younger and lower income adults, potentially leading to longer waiting times for transplantation, greater dialysis exposure, higher death rates on the waitlist, lower graft and patient survival for recipients, and higher overall healthcare costs for the care of patients with ESRD.[85]

e. Disparities

Kidney transplantation research in the U.S. reveals disparities across a number of different axes including geography, race and ethnicity, disability, socioeconomic status, neighborhood factors, and availability of health insurance.[86] [87] [88] [89] [90] A 2020 study showed substantial disparities in kidney transplant rates among transplant programs at a national level, as well as both among and within donation service areas (DSAs).[91] [92] This study examined data from a registry that included all U.S. adult kidney transplant candidates added to the waitlist in 2011 and 2015, comprising 32,745 and 34,728 individuals, respectively.[93] Among transplant programs nationwide, in 2015, the study found that the probability of a deceased donor transplant within three years for the average patient to be up to 16 times greater in some transplant hospitals as compared to others.[94] Substantial differences in probability of deceased donor transplantation were found even within DSAs, where all transplant programs utilize the same OPO and local organ supply. For the 2015 cohort, there was a median 2.3-fold difference between the highest and lowest hospital in each DSA in the 43 of 58 DSAs with more than one transplant hospital. The largest absolute difference in probability of transplant occurred in a DSA with seven transplant programs, with a patient on the waitlist at the transplant program with the highest probability of transplant being 9.8 times more likely to receive a transplant than a patient at the transplant program with the lowest probability of receiving a transplant.[95] Factors such as local organ supply, the characteristics of individuals on the waitlist of a given transplant program, the size of the waitlist, and the transplant program's volume of transplants may account for the differences observed nationally across DSAs. However, the variation among transplant programs across DSAs is significantly associated with organ offer acceptance patterns at individual transplant hospitals.[96] This underscores the need to address geographic disparities and for more transparency on how transplant programs make decisions on organ offers for their waitlist patients.

Living donor kidney donation also varies widely among transplant hospitals. A 2018 report using OPTN data from 2015 showed that while most transplant hospitals perform few living donor kidney transplants, certain transplant hospitals have substantially higher rates for their waitlist patients than the median rate. Differences among transplant hospitals were correlated with geographic region and the number of deceased donor kidney transplantations performed.[97] This underscores the need for initiatives and processes among transplant hospitals to encourage living donations to reduce geographic disparities.

Disparities in kidney transplantation rates for various populations in the U.S. have long been documented. Literature over the past two decades has focused on Non-Hispanic Black patients, who experience lower rates of deceased and living donor kidney transplantation as compared to Non-Hispanic White patients, while being four times more likely to have kidney failure. Black/African Americans and Hispanics/Latinos with kidney failure experience lower rates of kidney transplantation compared with White patients.[98] Additionally, Black/African Americans and Hispanics/Latinos, along with Asians, American Indian/Alaskan Natives, and other minorities, are at a higher risk of illnesses that may eventually lead to kidney failure, such as diabetes and high blood pressure.[99]

The literature over several decades has also addressed the effect of differences in age, gender, socioeconomic status (SES), and cultural aspects.[100] Recent studies have emphasized poverty and income differentials in analyzing the interplay of these and other factors among populations referred for kidney transplantation at several large transplant hospitals.[101] [102] [103] [104] This

[85] Rodrigue, J.R., Schold, J.D., & Mandelbrot, D.A. (2013). The Decline in Living Kidney Donation in the United States. *Transplantation Journal, 96*(9), 767–773. *https://doi.org/10.1097/tp.0b013e318298fa61*.

[86] King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. Journal of the *American Society of Nephrology, 31*(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335*.

[87] Melanson T., Basu M., Plantiga L., Pastan S., Mohan S., Patzer R. (2017). Variation in Living Donor Kidney Transplantation among U.S. Transplant Centers. *American Journal of Transplantation, 17* (suppl 3).

[88] United States Renal Data System. 2022. Annual Data Report. Supplements: COVID–19, Racial and Ethnic Disparities Figures 14.14 and 14.15.

[89] Wesselman, H., Ford, C.G., Leyva, Y., Li, X., Chang, C.-C.H., Dew, M.A., Kendall, K., Croswell, E., Pleis, J.R., Ng, Y.H., Unruh, M.L., Shapiro, R., & Myaskovsky, L. (2021). Social Determinants of Health and Race Disparities in Kidney Transplant. *Clinical Journal of the American Society of Nephrology, 16*(2), 262–274. *https://doi.org/10.2215/cjn.04860420*.

[90] Ng, Y.-H., Pankratz, V.S., Leyva, Y., Ford, C.G., Pleis, J.R., Kendall, K., Croswell, E., Dew, M.A., Shapiro, R., Switzer, G.E., Unruh, M.L., & Myaskovsky, L. (2019). Does Racial Disparity in Kidney Transplant Wait-listing Persist After Accounting for Social Determinants of Health? *Transplantation,* 1. *https://doi.org/10.1097/tp.0000000000003002*.

[91] With the enactment of NOTA, CMS designated DSAs; generally, each DSA includes an OPO within its geographic area. Until March 2021, when OPTN implemented the current policy for allocation of deceased donor kidneys, the priority for organs acquired by an OPO was based, among other factors, on an individual's residence within the DSA extending around the OPO.

[92] King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. Journal of the *American Society of Nephrology, 31*(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335*.

[93] King et al. 2020. 2900.

[94] King et al. 2020. 2903.

[95] King et al., 2020. 2903.

[96] King et al. 2020. 2903–2904.

[97] Melanson T., Basu M., Plantiga L., Pastan S., Mohan S., Patzer R. (2017). Variation in Living Donor Kidney Transplantation among U.S. Transplant Centers. *American Journal of Transplantation, 17* (suppl 3).

[98] United States Renal Data System. 2022. Annual Data Report. Supplements: COVID–19, Racial and Ethnic Disparities Figures 14.14 and 14.15.

[99] National Kidney Foundation. (2016, January 7). Race, Ethnicity, & Kidney Disease. National Kidney Foundation. *https://www.kidney.org/atoz/content/minorities-KD*.

[100] Patzer, R.E., & Pastan, S.O. (2020). Policies to promote timely referral for kidney transplantation. *Seminars in Dialysis, 33*(1), 58–67. *https://doi.org/10.1111/sdi.12860*.

[101] Patzer, R. Perryman, J. Schrager, J. Pastan, S. Amaral, S. Gazmararian, J. Klein, M. Kutner, N. McClellan, W. 2012. Patzer, R.E., Perryman, J.P., Schrager, J.D., Pastan, S., Amaral, S., Gazmararian, J.A., Klein, M., Kutner, N., & McClellan, W.M. (2012). The Role of Race and Poverty on Steps to Kidney Transplantation in the Southeastern United States. *American Journal of Transplantation, 12*(2), 358–368. *https://doi.org/10.1111/j.1600-6143.2011.03927.x*.

[102] Wesselman, H., Ford, C.G., Leyva, Y., Li, X., Chang, C.-C.H., Dew, M.A., Kendall, K., Croswell, E., Pleis, J.R., Ng, Y.H., Unruh, M.L., Shapiro, R., & Myaskovsky, L. (2021). Social Determinants of Health and Race Disparities in Kidney Transplant. *Clinical Journal of the American Society of Nephrology, 16*(2), 262–274. *https://doi.org/10.2215/cjn.04860420*.

[103] Ng, Y.-H., Pankratz, V.S., Leyva, Y., Ford, C.G., Pleis, J.R., Kendall, K., Croswell, E., Dew, M.A., Shapiro, R., Switzer, G.E., Unruh, M.L., & Myaskovsky, L. (2019). Does Racial Disparity in Kidney Transplant Wait-listing Persist After Accounting for Social Determinants of Health? *Transplantation,* 1. *https://doi.org/10.1097/tp.0000000000003002*.

[104] Schold, J.D., Gregg, J.A., Harman, J.S., Hall, A.G., Patton, P.R., & Meier-Kriesche, H.-U. (2011). Barriers to Evaluation and Wait Listing for Kidney

research extends in time prior to the Kidney Allocation System (KAS) of 2014, which aimed to lessen the impact of racial differences on access to kidney transplantation.

Research findings support the proposition that a broad interpretation of social determinants of health (SDOH) may substantially explain racial disparities in both deceased and living donor kidney transplantation.[105] Recently, a comprehensive survey of the literature on disparities in transplantation for kidneys and other organs found that socioeconomic factors may substantially explain disproportionately lower transplant rates and longer wait times.[106] As described in recent literature, a person's SDOH may contribute to inequities in their prospects for waitlist registration and receipt of transplantation.[107] [108] [109] SDOH is defined more broadly than socioeconomic status, to include those conditions in the places where people live, learn, work, and play that affect a wide range of health and quality of life risks and outcomes.[110] More specifically, SDOH include variations in employment, neighborhood factors, education, social support systems, and healthcare coverage that impact health outcomes.

A salient group of recent analyses focused on a cohort of patients initially referred for evaluation for a kidney transplant at a large urban transplant hospital between 2010 and 2012. These studies showed lower waitlist registration and transplant rates for Black/African Americans, regardless of SDOH.[111] [112] One of the studies reports that racial difference showed a weaker association with the rate of waitlist registration after the introduction of the KAS. Another of these studies, focusing on transplant rates as the outcome, showed that even after accounting for social determinants of health, Black patients had a lower likelihood of kidney transplant and living-donor transplant, but not deceased-donor transplant. Black race, older age, lower income, public insurance, more comorbidities, being transplanted before changes to the KAS, greater religiosity, less social support, less transplant knowledge, and fewer learning activities were each associated with a lower probability of any kidney transplant.[113] Similarly, an earlier study of a population at a single transplant hospital found that income and insurance attenuated the association between racial difference and placement on the waitlist for a kidney transplant.[114] The findings in these studies of the enduring influence of cultural, socioeconomic and demographic factors apart from racial difference underscore the need to consider initiatives and improvement activities aimed at addressing SDOH for ESRD patients to remove barriers to access to kidney transplantations.

Living donor transplantation has demonstrated the enduring influence of racial disparities, but also the importance of SES and neighborhood factors. The cohort of patients identified previously, initially referred for evaluation at a large urban hospital between 2010 and 2012, showed that for living donor transplantation, Black/African American race and lower income held a stronger association with a lower probability of living donor transplant than with deceased donor donation.[115] These results accord with findings nationwide that White patients are more likely to receive a living donor transplant, followed by Asian and Hispanic/Latino patients. Black/African American patients have had lower rates of living donor transplants than other racial or ethnic groups.[116] Explanations for these differences have included disparate rates of diabetes, obesity, and hypertension observed among minority populations that may contraindicate living donation by a relative; cultural differences in willingness to donate or ask for a living donation; concerns about costs among potential donors; and lack of knowledge about living donor transplantation on the part of patients, their families, and health care providers.[117] [118]

Research over several decades confirms the relation between health care access and SES factors and disparities in living donor kidney transplantation receipt for Black/African American and Hispanic/Latino patients, and, additionally, that these disparities have increased over time.[119] [120] [121] [122] According to one study, between 1995 and 2014, disparities in the receipt of living donor kidney transplantation grew more for Black/African Americans and Hispanics/Latinos: (1) living in poorer (versus wealthier) neighborhoods; (2) without (versus with) a college degree; and (3) with Medicare (versus private insurance).[123] The study suggests that delays in the receipt of kidney care may contribute to reported racial and ethnic differences in the quality and timing of discussions among patients, families, and clinicians about living donor kidney transplantation as a treatment option.[124]

One study also established associations between rates of living donor kidney transplantation for Black/African Americans and transplant hospital characteristics. While recognizing the potential effect of clinical factors, the study found that hospitals with high overall rates of living donor kidney transplantation

Transplantation. *Clinical Journal of the American Society of Nephrology, 6*(7), 1760–1767. *https://doi.org/10.2215/cjn.08620910.*

[105] Reed, R.D., & Locke, J.E. (2020). Social Determinants of Health: Going Beyond the Basics to Explore Racial Disparities in Kidney Transplantation. *Transplantation, 104,* 1324–1325.(7), 1324–1325.–1325. *https://doi.org/10.1097/TP.0000000000003003.*

[106] National Academies of Sciences, Engineering, and Medicine. (2022). *Realizing the Promise of Equity in the Organ Transplantation System* (K.W. Kizer, R.A. English, & M. Hackmann, Eds.; pp. 88–93). National Academies Press. *https://doi.org/10.17226/26364.*

[107] Centers for Disease Control and Prevention. *Social Determinants of Health at CDC.* Retrieved June 13, 2023, from *https://www.cdc.gov/about/priorities/social-determinants-of-health-at-cdc.html?CDC_AAref_Val=https://www.cdc.gov/about/sdoh/index.html.*

[108] Wesselman et al, 2021.

[109] Ng et al, 2020.

[110] Centers for Disease Control and Prevention. *Social Determinants of Health at CDC.* Retrieved June 13, 2023, from *https://www.cdc.gov/about/priorities/social-determinants-of-health-at-cdc.html?CDC_AAref_Val=https://www.cdc.gov/about/sdoh/index.html.*

[111] Ng Y et al. 2020. 1453.

[112] Wesselman et al, 2021. 271.

[113] Wesselman et al. 2021. 262.

[114] Schold et al, 2021.

[115] Wesselman et al, 2021. 270.

[116] United States Renal Data System. 2022. Annual Data Report. End Stage Renal Disease Chapter 7 Transplantation Figure 7.10a.

[117] Purnell, T.S., Hall, Y.N., & Boulware, L.E. (2012). Understanding and Overcoming Barriers to Living Kidney Donation Among Racial and Ethnic Minorities in the United States. *Advances in Chronic Kidney Disease, 19*(4), 244–251. *https://doi.org/10.1053/j.ackd.2012.01.008.*

[118] Rodrigue, J.R., Kazley, A.S., Mandelbrot, D.A., Hays, R., LaPointe Rudow, D., & Baliga, P. (2015). Living Donor Kidney Transplantation: Overcoming Disparities in Live Kidney Donation in the US—Recommendations from a Consensus Conference. *Clinical Journal of the American Society of Nephrology, 10*(9), 1687–1695. *https://doi.org/10.2215/cjn.00700115.*

[119] Purnell, T.S., Luo, X., Cooper, L.A., Massie, A.B., Kucirka, L.M., Henderson, M.L., Gordon, E.J., Crews, D.C., Boulware, L.E., & Segev, D.L. (2018). Association of Race and Ethnicity With Live Donor Kidney Transplantation in the United States From 1995 to 2014. *JAMA, 319*(1), 49. *https://doi.org/10.1001/jama.2017.19152.*

[120] Hall, E.C., James, N.T., Garonzik Wang, J.M., Berger, J.C., Montgomery, R.A., Dagher, N.N., Desai, N.M., & Segev, D.L. (2012). Center-Level Factors and Racial Disparities in Living Donor Kidney Transplantation. *American Journal of Kidney Diseases, 59*(6), 849–857. *https://doi.org/10.1053/j.ajkd.2011.12.021.*

[121] Gore, J.L., Danovitch, G.M., Litwin, M.S., Pham, P–T.T., & Singer, J.S. (2009). Disparities in the Utilization of Live Donor Renal Transplantation. *American Journal of Transplantation, 9*(5), 1124–1133. *https://doi.org/10.1111/j.1600-6143.2009.02620.x.*

[122] Rodrigue et al. 2015.

[123] Purnell et al. 2015. 58.

[124] Purnell et al. 2015. 59.

showed significantly decreased racial disparities. The authors suggest that such high rates reveal commitment to living donor kidney transplantation, possibly shown in better education programs, more formalized procedures to reduce failure to complete transplant evaluations, increased use of medically complex and unrelated donors, and more success in reducing financial barriers to living donor kidney donation.[125] The study also notes that hospitals with higher percentages of Black/African American candidates experience greater racial disparities. The authors surmise that such a high percentage might indicate an urban setting exhibiting greater differences in access to health care between Black/African Americans and other populations.[126]

Studies have also shown discrimination on the basis of disability with regard to organ transplantation, particularly for individuals with intellectual and developmental disabilities, who are often assumed by transplant providers to be unable to manage post-transplantation care requirements.[127] Discrimination occurs even though individuals' disabilities that are not related to the need for an organ transplant generally have little or no impact on the likelihood that the transplant would be successful.[128] The American Society of Transplant Surgeons has recommended that no patient be discriminated against or precluded from transplant listing solely due to the presence of a disability, whether physical or psychological.[129]

CMS kept these concerns in mind when developing the IOTA Model proposals. The IOTA Model uses performance-based payments that hold transplant hospitals selected as the IOTA participants financially accountable for improvements in access to both deceased and living donor kidney transplantations. To reduce disparities and promote health equity, CMS proposed that the IOTA participants would be required to develop and submit a Health Equity Plan to CMS. This model design feature is aimed at encouraging IOTA participants to reassess their processes and policies around living and deceased donor kidneys and promote investments in performance and quality improvement activities that address barriers to care, including SDOH. The sequence of steps that patients need to undertake to gain access to kidney transplantation is complex, and the challenge posed by this process for potential recipients may be compounded by racial, socioeconomic and neighborhood factors.

f. Post-Transplant Outcomes

While the need for kidney transplants has grown, the rates of patient and graft survival have increased. Between 2001 and 2020, graft survival rates at 1 and 5 years showed an increasing trend.[130] Patient survival at 1 year increased from 97.5 percent in 2001 to 99.2 percent in 2018, but then declined to 98.9 percent in 2019 and 98.4 percent in 2020; patient survival at 5 years rose from 89.8 percent in 2001 to an all-time high of 93.6 percent in 2013, dropping slightly to 93.2 percent in 2016.[131] For living donor kidney transplants, the rate of graft failure at 3 years decreased from 3.0 per 100 person years in 2010 to 2.1 per 100 person years in 2018. The rate of death at 3 years with a functioning graft also decreased from 1.2 to 1.0 per 100 person-years.[132] For deceased donor kidney transplants, the rate of graft failure at 3 years decreased from 2010 (6.3 per 100 patient years) to 2014 (4.9 per 100 patient years), but increased to 5.3 per 100 patient years in 2018. The same pattern was observed for death with a functioning graft, except that the rate in the 2018 cohort (2.8 per 100 patient years) exceeded that of the 2010 cohort (2.6 per 100 patient years).[133]

A study published in the New England Journal of Medicine in 2021 shows the advantage of transplantation using deceased donor organs over long-term dialysis, even with an increasing trend of adverse conditions among recipients and donors. Notably, patient survival improved between the 1990s and the period from 2008 to 2011, despite increases in both (a) recipients' age, body-mass index (BMI), frequency of diabetes, and length of time undergoing dialysis, as well as a higher proportion of recipients with a previous kidney transplant; and (b) donors' age and in the percentage of donations after circulatory death.[134] Early referral of patients for transplants, kidney exchange programs, better diagnostic tools to identify early acute rejection, innovative therapies for countering rejection and infection, and optimization of immunosuppressive medications may be opportunities to enhance kidney graft survival.[135]

g. Non-Acceptance and Discards in Kidney Transplantation

Studies have documented the substantial extent of deceased donor kidney non-utilization in the U.S. relative to other countries (although methods of defining these rates differ among countries), as well as a steady increase in that trend over the past two decades.[136] [137] [138] [139] [140] A study in 2018 described donor-specific factors, such as biopsy findings and donor history, along with an increasing selectivity among transplant hospitals in accepting organs for transplant and inability to locate a recipient as contributing to this increase

[125] Hall et al. 2012. 855.

[126] Hall et al. 2012. 855.

[127] *See, for example,* National Council on Disability. (2019). *Organ Transplant Discrimination Against People with Disabilities: Part of the Bioethics and Disability Series. https://www.ncd.gov/report/organ-transplant-discrimination-against-people-with-disabilities.*

[128] *Id.* at 38–40.

[129] Am. Soc'y of Transplant Surgeons, *Statement Concerning Eligibility for Solid Organ Transplant Candidacy* (Feb. 12, 2021), *https://asts.org/advocacy/position-statements.https://asts.org/advocacy/position-statements.*

[130] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Transplantation. Figures 7.19a and 7.19b.

[131] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figures 7.20a and 7.20b.

[132] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.21a.

[133] United States Renal Data System. 2023. Annual Data Report Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.21b.

[134] Hariharan, S., Israni, A.K., & Danovitch, G. (2021). Long-Term Survival after Kidney Transplantation. *New England Journal of Medicine, 385*(8), 729–743. *https://doi.org/10.1056/nejmra2014530.*

[135] Hariharan, S., Israni, A.K., & Danovitch, G. (2021). Long-Term Survival after Kidney Transplantation. *New England Journal of Medicine, 385*(8), 729–743. *https://doi.org/10.1056/nejmra2014530.*

[136] Mohan, S., Chiles, M.C., Patzer, R.E., Pastan, S.O., Husain, S.A., Carpenter, D.J., Dube, G.K., Crew, R.J., Ratner, L.E., & Cohen, D.J. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney International, 94*(1), 187–198. *https://doi.org/10.1016/j.kint.2018.02.016.*

[137] Aubert, O. Reese. P. Audry, B. Bouatou, B. Raynaud, M. Viglietti, D. Legendre, C. Glotz, D. Empana, J. Jouben, X. Lefaucheur, C. Jacquelinet, C. Loupy, A. (2019). Disparities in Acceptance of Deceased Donor Kidneys Between the United States and France and Estimated Effects of Increased US Acceptance. *JAMA Internal Medicine, 179*(10), 1365–1374. *https://doi.org/10.1001/jamainternmed.2019.2322.*

[138] Ibrahim, M., Vece, G., Mehew, J., Johnson, R., Forsythe, J., Klassen, D., Callaghan, C., & Stewart, D. (2019). An international comparison of deceased donor kidney utilization: What can the United States and the United Kingdom learn from each other? *American Journal of Transplantation, 20*(5), 1309–1322. *https://doi.org/10.1111/ajt.15719.*

[139] Stewart, D.E., Garcia, V.C., Rosendale, J.D., Klassen, D.K., & Carrico, B.J. (2017). Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States. *Transplantation, 101*(3), 575–587. *https://doi.org/10.1097/tp.0000000000001539.*

[140] Health Resources and Services Administration. OPTN. (2017). *Two year analysis shows effects of kidney transplantation system.* Optn. *transplant.hrsa.gov.* Retrieved May 30, 2023, from *https://optn.transplant.hrsa.gov/news/two-year-analysis-shows-effects-of-kidney-allocation-system/.*

in non-utilization.[141] Within the context of the COVID–19 pandemic, the non-utilization of deceased donor kidneys in 2020 rose to the highest level up to that time, 21.3 percent, despite the decline in discard of organs from hepatitis C-positive donors.[142] [143] According to one analysis, the deceased donor kidney discard rate peaked at 27 percent during the fourth quarter of 2021.[144]

Since the KAS went into effect in 2014, the OPTN has aimed to address the high rate of kidneys going unused. The new kidney allocation system was developed in response to higher than necessary discard rates of kidneys, variability in access to transplants for candidates who are harder to match due to biologic reasons, inequities resulting from the way waiting time was calculated, and a matching system that results in unrealized life years and high re-transplant rates.[145] The KAS also revised the system that matched waitlisted individuals with available organs.[146] As part of the KAS, the Kidney Donor Profile Index (KDPI) was implemented to assess the quality of kidneys procured for kidney transplants. The KDPI is based on a preliminary measurement, the Kidney Donor Risk Index (KDRI), which estimates the relative risk of post-transplant kidney graft failure based on scores for the deceased donor on a set of 10 demographic and clinic characteristics, including age, height, weight, ethnicity, history of hypertension, history of diabetes, cause of death, serum creatinine, hepatitis C virus status, and donation after circulatory death status.[147] This relative risk is determined in relation to the overall distribution of a grouping of these scores across the overall deceased donor population for the previous year. The KDPI transforms the KDRI to a zero-to-100 scale. Lower KDPI scores are associated with greater expected post-transplant longevity, while higher KDPI scores are associated with a worse expected outcome in this regard.[148]

According to these new allocation rules, the KDPI of an available organ was to be assessed, with donor kidneys with low KDPI scores being offered to patients scoring high in terms of expected longevity. New revisions to the KAS also included an individual's time on dialysis prior to waitlisting to assess waiting time used for determining priority for an available organ, and new rules that allowed for greater access for candidates with blood type B to donor kidneys with other blood types.[149]

An OPTN data analysis from 2014 to 2016, the first two years after KAS implementation, showed that despite substantial increases in both deceased kidney donor transplants and deceased kidney donation, the kidney discard rate increased to 19.9 percent in 2016.[150] The OPTN linked the discard rates to KDPI scores, with fewer than 3 percent of donor kidneys with KDPI between zero and 20 percent discarded, compared with 60 percent of donor kidneys with KDPI between 86 and 100 percent being discarded.[151]

In March 2021, OPTN finalized a newer allocation policy, which eliminated the use of DSAs and regions from kidney and pancreas donor distribution. These measures were part of a framework announced in 2019 that also applied to heart, lung, and liver donor distribution, with the goal of reducing the importance of geography in patients' access to organs, and, instead, emphasizing medical urgency.[152] [153] The new system instituted a point system with up to 2 points (equal to 2 years on the wait list) for patients listed at transplant hospitals within 250 nautical miles of the donor hospital, and the points decreasing linearly from the donor hospital to the circle perimeter. The more points an individual has, the higher their position on the waitlist and the more likely they are to receive an organ offer. If there is no candidate within the designated radius, the kidney is offered to patients listed at hospitals outside the fixed circle, based on separate proximity points that decrease linearly as the location of a patient approaches 2,500 nautical miles from the donor hospital.[154]

Interested parties within the transplant ecosystem commented that the new policy might further contribute to the increasing rate of donor organ non-acceptance. According to one review, sharing kidneys over a broader geographic region means that OPOs would need to work with transplant hospitals with which there was no prior relationship.[155] Concern was also expressed about increased transportation time and procurement costs, risk associated with air transport, and a greater number of interactions between transplant hospitals and OPOs.[156] [157] [158] One study notes that policymakers would need to assess the extent to which the new kidney allocation policy might affect organ offer acceptance patterns, organ recovery and utilization rates, and wait times both for the transplant hospital and broader

[141] Mohan, Chiles et al. (2018).

[142] Lentine, K. Smith, J. Hart, A. Miller, J. Skeans, M. Larkin, L. Robinson, A. Gauntt, K. Israni, A. Hirose, R. Snyder, J. (2022). OPTN/SRTR 2020 Annual Data Report: Kidney. American Journal of Transplantation 22(Suppl 2) 21–136.

[143] Following the introduction of certain anti-viral drugs, transplanting kidneys from donors infected with Hepatitis C has shown promising outcomes in recent studies. See Penn Medicine News ''Penn Researchers Continue to Advance Transplantation of Hepatitis C Virus-infected kidneys into HCV-Negative Recipients'' August 31, 2020 *https://www.pennmedicine.org/news/news-releases/2020/august/penn-researchers-advance-transplantation-hepatitis-c-virus-infected-kidneys-hcv-negative-recipients.*

[144] Cron, D. Husain, S. Adler, J. (2022). The new distance-based kidney allocation system: Implications for patients, transplant centers, and Organ Procurement Organizations. *Current Transplantation Reports, 9*(4), 304. *https://doi.org/10.1007/s40472-022-00384-z.*

[145] OPTN Kidney Transplantation Committee. (n.d.). *The New Kidney Allocation System (KAS) Frequently Asked Questions.* Retrieved December 6, 2023, from *https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* p. 4.

[146] OPTN. (n.d.) *The New Kidney Allocation System (KAS) Frequently Asked Questions. https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* p. 4.

[147] OPTN. (n.d.). *The New Kidney Allocation System Frequently Asked Questions. https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* pp. 8–9.

[148] OPTN. (n.d.). *The New Kidney Allocation System Frequently Asked Questions . https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* p. 4.

[149] OPTN. (n.d.). *The New Kidney Allocation System Frequently Asked Questions. https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* p. 4.

[150] OPTN. (2017, July 9). *Two Year Analysis shows effects of Kidney Allocation System.* Retrieved June 9, 2023, from *https://optn.transplant.hrsa.gov/news/two-year-analysis-shows-effects-of-kidney-allocation-system/.*

[151] OPTN. (2017, July 9). *Two Year Analysis shows effects of Kidney Allocation System.* Retrieved June 9, 2023, from *https://optn.transplant.hrsa.gov/news/two-year-analysis-shows-effects-of-kidney-allocation-system/.*

[152] Potluri, V.S., & Bloom, R.D. (2021). Effect of Policy on Geographic Inequities in Kidney Transplantation. *American Journal of Kidney Diseases, 79*(6), 897–900. *https://doi.org/10.1053/j.ajkd.2021.11.005.*

[153] Penn Medicine. (2021, November 17). Update: Change in Organ Allocation Designed to Increase Equity in US Kidney and Pancreas Transplantation. *Penn Medicine Physician Blog. https://www.pennmedicine.org/updates/blogs/penn-physician-blog/2021/november/change-in-organ-allocation-designed-to-increase-equity-in-us-kidney-and-pancreas-transplantation.*

[154] Potluri, Bloom. (2021). 897–898.

[155] Potluri, Bloom. (2021) 898.

[156] Gentry, S.E., Chow, E.K.H., Wickliffe, C.E., Massie, A.B., Leighton, T., & Segev, D.L. (2014). Impact of broader sharing on the transport time for deceased donor livers. *Liver Transplantation, 20*(10), 1237–1243. *https://doi.org/10.1002/lt.23942.*

[157] Chow, E.M., DiBrito, S.R., Luo, X., Wickliffe, C., Massie, A.B., Locke, J.E., Gentry, S.E., Garonzik-Wang, J., & Segev, D.L. (2018). Long Cold Ischemia Times in Same Hospital Deceased Donor Transplants. *Transplantation, 102*(3), 471–477. *https://doi.org/10.1097/tp.0000000000001957.*

[158] Adler, J.T., Husain, S.A., King, K.L., & Mohan, S. (2021). Greater complexity and monitoring of the new Kidney Allocation System: Implications and unintended consequences of concentric circle kidney allocation on network complexity. *American Journal of Transplantation, 21*(6), 2007–2013. *https://doi.org/10.1111/ajt.16441.*

geographic areas.[159] Another report cited unpublished SRTR data, saying that preliminary results suggest an increase in the transplant rate overall, but a trend toward higher donor kidney discard and increased cold ischemia time.[160]

A similar study assessing deceased donor kidney discards from 2000 to 2015 found that 17.3 percent of 212,305 procured deceased donor kidneys were discarded, representing a 91.5 percent increase in deceased donor kidney discards during the same time period. The increase in donor kidney discards outpaced the number of organs recovered for transplantation, adversely impacting transplantation rates and waitlist times. Kidneys with higher KDPIs and from donors with more disadvantageous characteristics were more likely to be discarded. The estimated 5-year graft survival for even the lowest quality kidneys substantially exceeds the average 5-year dialysis survival rate, making discard patterns concerning.[161] The study indicates a significant overlap in the quality of discarded and transplanted deceased donor kidneys, and substantial geographical variation in the odds of donor kidney discards, which, as seen previously, would continue to be observed in SRTR data for following years.[162] The study also found patterns that indicate factors beyond organ quality, including biopsy findings, donor history and poor organ function, and inability to locate a kidney donor recipient, may factor into deceased organ acceptance decisions. Other factors may be driving the deceased donor organ discard rates, as the study found that ''discarded organs were more likely to come from older, heavier donors who were Black, female, diabetic, hypertensive, with undesirable social behavior and higher terminal creatinine.'' [163] This finding accords with observed discard patterns from earlier studies whereby recipients of marginal kidneys, in terms of advanced donor age, hypertension, diabetes, or greater cold ischemia time, showed lower mortality and greater survival benefit for many candidates as compared to staying on the transplant wait list.[164] [165] [166]

Research at this time suggests that CMS regulatory requirements and OPTN policies may have been contributing to transplant hospitals growing more selective in choosing organs for their waitlisted patients. A study from 2017 examined OPTN registry data for deceased donors from 1987 to 2015, showing that changes in the donor pool and certain clinical practices explained about 80 percent of the increase in non-utilization of deceased donor kidneys.[167] However, according to the study, the remainder of kidney discards, not accounted for by these factors, suggests that increased risk aversion was leading transplant hospitals to be more selective about the kidneys they accept, regardless of the actual risk profile. Furthermore, increasing reliance on the part of OPTN, CMS, and private insurers on program-specific reports that assessed the performance of transplant hospitals on transplant graft and recipient survival rates might have been contributing to the overall trend of organs going unused.[168]

The finding of high rates of non-use of organs that could potentially be transplanted with positive outcomes has led to closer examination of trends among transplant hospitals in declining the possible use of organs for specific patients. Information on each organ that is recovered by an OPO is shared with the OPTN, which runs the matching system that determines which organ should be offered to which recipient. If an organ is determined to be a good match for a particular patient, then the OPTN would offer that organ to the transplant hospital at which the patient is waitlisted on the patient's behalf.[169] A transplant hospital can decline an offer without informing the candidate of the offer or the reason it was declined.[170] A study in 2019 focused on patient outcomes associated with declines in offers of organs by transplant hospitals. Using OPTN data, the study identified a cohort of 280,041 adults on the kidney transplant waitlist (out of 367,405 candidates on the waitlist from 2008 through 2015, the study period) who received one or more offers for a deceased donor kidney during that period. More than 80 percent of deceased donor kidneys were declined on behalf of one or more candidates before being accepted for transplant, and a mean of 10 candidates who previously received an offer died every day during the study period.[171] As reported by transplant hospitals, organ or donor quality concerns accounted for 92.6 percent of all declined offers, whereas 2.6 percent of offers were refused because of patient-related factors, and an even smaller number for logistical limitations or other concerns. While organ or donor quality concerns remained the primary reason for declined offers across all KDPI ranges, the study observed marked State-level variability in the interval between first offer and death or transplant and in the likelihood of dying while having remained on the wait list after receiving an offer.[172]

The methodology and findings of this study are notable since they draw a correlation between the specific patterns among transplant hospitals of organ non-acceptance and the longevity of patients on the wait list. The tendency among certain hospitals to choose to not use kidneys for specific patients is shown apart from the distinct finding of organs going unused and being discarded. The study shows the potential for a similar effect on patient survival from organ offer non-acceptance as for organ non-use. The authors of an earlier study commented that low acceptance rates of organ offers lead to inefficiency, longer ischemia time, unequal access to donated kidneys, and perhaps to higher rates of discarded organs.[173] The findings in the

[159] Adler et al., 2021. 2012.

[160] Cron, D.C., S. Ali Husain, & Adler, J.T. (2022). The New Distance-Based Kidney Allocation System: Implications for Patients, Transplant Centers, and Organ Procurement Organizations. *Current Transplantation Reports, 9*(4), 302–307. *https://doi.org/10.1007/s40472-022-00384-z.*

[161] Mohan, Chiles et al. 2018. p. 192.

[162] Mohan et al. 2018. p. 195.

[163] Mohan et al. 2018. 192.

[164] Ojo, A.O., Hanson, J.A., Herwig Ulf Meier-Kriesche, Chike Nathan Okechukwu, Wolfe, R.R., Leichtman, A.B., Agodoa, L.Y., Kaplan, B., & Port, F.K. (2001). Survival in Recipients of Marginal Cadaveric Donor Kidneys Compared with Other Recipients and Wait-Listed Transplant Candidates. *Journal of the American Society of Nephrology, 12*(3), 589–597. *https://doi.org/10.1681/asn.v123589.*

[165] Massie, A.B., Luo, X., Chow, E.K.H., Alejo, J.L., Desai, N.M., & Segev, D.L. (2014). Survival Benefit of Primary Deceased Donor Transplantation With High-KDPI Kidneys. *American Journal of Transplantation, 14*(10), 2310–2316. *https://doi.org/10.1111/ajt.12830.*

[166] Cohen, J.B., Eddinger, K.C., Locke, J.E., Forde, K.A., Reese, P.P., & Sawinski, D. (2017). Survival Benefit of Transplantation with a Deceased Diabetic Donor Kidney Compared with Remaining on the Waitlist. *Clinical Journal of the American Society of Nephrology, 12*(6), 974–982. *https://doi.org/10.2215/cjn.10280916.*

[167] Stewart et al. (2017). 575.

[168] Stewart et al. (2017). 585.

[169] National kidney Foundation. (2017, February 10). *The Kidney Transplant Waitlist—What You Need to Know.* National Kidney Foundation. *https://www.kidney.org/atoz/content/transplant-waitlist.*

[170] Husain, S.A., King, K.L., Pastan, S., Patzer, R.E., Cohen, D.J., Radhakrishnan, J., & Mohan, S. (2019). Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. *JAMA Network Open, 2*(8), e1910312. *https://doi.org/10.1001/jamanetworkopen.2019.10312.*

[171] Husain et al. 2019.

[172] Husain et al. 2019.

[173] Wolfe, R.A., Laporte, F., Rodgers, A.M., Roys, E., Fant, G., & Leichtman, A.B. (2007). Developing Organ Offer and Acceptance Measures: When

2019 study of a wide range of organ offer acceptance rates among transplant hospitals nationwide, as well as of the relation between organ offer declines and patient deaths, suggest the need for incentives for transplant hospitals to accept earlier offers for their patients, which, in turn, could reduce cold ischemia time, and, on the whole, increase patient survival.

h. Non-Acceptance and Discards in Transplantation for Other Solid Organ Types

SRTR has also tracked the non-use, or discard rate, of other solid organ types. In 2020, 9.5 percent of livers recovered were not transplanted, with livers from older donors less likely to be transplanted.[174] The discard rate for pancreases was 23.4 percent in 2020; organs from obese donors were highly likely not to be transplanted.[175] The discard rate for hearts in 2020 was one percent, having stayed similar over the previous decade.[176]

Liver transplantation shows survival benefits for individuals with chronic liver disease, but liver transplantation suffers from a severe shortage of donor organs.[177] [178] A study from 2012 shows organ offer non-acceptance patterns on the part of transplant programs affect mortality for individuals with end-stage liver disease in a similar manner as for ESRD patients. According to the study, most candidates for a liver transplant who died or were removed from the wait list had received at least one organ offer, suggesting that a substantial portion of waitlist mortality results in part from declined organ offers.[179] As the IOTA Model does for kidney transplantation, understanding and addressing why livers, and possibly other organs, are not chosen for specific patients also has the potential to lead to improved outcomes and longer lives.

i. Organ Transplant Affinity Group

On September 15, 2023, CMS published a blog post titled ''Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance.'' [180] This blog discussed the formation of OTAG, a Federal collaborative with staff from CMS and HRSA working together to strengthen accountability, equity, and performance to improve access to organ donation, procurement, and transplantation for patients, donors, families and caregivers, and providers. The IOTA Model is a part of this coordinated effort from the OTAG and relies on input from across CMS and HRSA.

C. Provisions of the Regulation

1. Implementing the IOTA Model

In this section III.C of the final rule, we discuss our policies for the IOTA Model, including model-specific definitions and the general framework for implementation of the IOTA Model. The upside risk payments owed to the IOTA participants and the downside risk payments owed to CMS are designed to increase access to kidney transplants for patients with ESRD on the IOTA participant's waitlist. As described in section I of this final rule, access to kidney transplants varies widely by region and across transplant hospitals, and disparities by demographic characteristics are pervasive, raising the need to strengthen and improve performance by kidney transplant hospitals. We theorize that the IOTA Model financial incentives will promote improvement activities across selected transplant hospitals that address access barriers, including SDOH, thereby increasing the number of transplants, quality of care, and the provision of cost-effective treatment. Selected transplant hospitals may be motivated to revisit processes and policies around deceased and living donor organ acceptance to identify opportunities for improvement. The IOTA Model payments incentivize selected transplant hospitals to engage in care delivery transformation to better coordinate and manage patient care and needs, invest in infrastructure, improve the patient, family, and caregiver experience, and engage a care delivery team that is tasked with holistic patient care.

a. Model Performance Period

In section III.C.1.a of the proposed rule, we proposed a 6-year ''model performance period.'' We proposed to define the model performance period as the 72-month period from the model start date, comprised of 6 individual PYs. The IOTA participants' performance would be measured and assessed during the model performance period for purposes of determining their performance-based payments. We proposed to define the ''performance year'' (PY) as a 12-month calendar year during the model performance period. We proposed to define the start of the model performance period as the ''model start date,'' and we proposed a model start date of January 1, 2025, meaning that PY 1 would be January 1, 2025, to December 31, 2025, and the model performance period would end on December 31, 2030. We proposed a 6-year model performance period to allow sufficient time for selected transplant hospitals to invest in care delivery transformation and realize returns on investments.

We alternatively considered a 3- or 5-year model performance period; however, we believe that a 3-year model performance period would be too short to allow adequate time for selected transplant hospitals to invest in care delivery transformations. Additionally, our analyses detailed in section V of this final rule project that considerable savings to Medicare will be achieved after the fifth PY, which is another reason why we proposed a 6-year model performance period. We also considered a 10-year model performance period similar to some more recent Innovation Center models; however, given that this is a mandatory model, we felt it was important to limit the duration of the initial test to a shorter period.

We alternatively considered proposing to begin the IOTA Model on April 1, 2025, or July 1, 2025, to allow selected transplant hospitals more time to prepare to implement the model and to better align the model performance period with that of our data sources, as detailed in section III.C.5.a of this final rule. However, we proposed a January 1, 2025, start date because we believed that there would be sufficient time for IOTA participants to prepare for the model. A proposed start date of January 1, 2025, also aligned with other CMS calendar year rules. We separately proposed that in the event the model start date is delayed from the proposed start date, the model performance period for the entire model would be 6

''Good'' Organs Are Turned Down. *American Journal of Transplantation,* 7, 1404–1411. *https://doi.org/10.1111/j.1600-6143.2007.01784.x.*

[174] OPTN/SRTR 2020 Annual Data Report. 2020. Liver. Figures LI 49, 50.

[175] OPTN/SRTR 2021 Annual Data Report. Pancreas. Figures PA 39, 43.

[176] OPTN/SRTR 2021 Annual Data Report. Heart. Figure HR 52.

[177] Merion, R.M., Schaubel, D.E., Dykstra, D.M., Freeman, R.B., Port, F.K., & Wolfe, R.A. (2005). The Survival Benefit of Liver Transplantation. *American Journal of Transplantation, 5*(2), 307–313. *https://doi.org/10.1111/j.1600-6143.2004.00703.x.*

[178] Ross, K., Patzer, R.E., Goldberg, D.S., & Lynch, R.J. (2017). Sociodemographic Determinants of Waitlist and Posttransplant Survival Among End-Stage Liver Disease Patients. *American Journal of Transplantation, 17*(11), 2879–2889. *https://doi.org/10.1111/ajt.14421.*

[179] Lai, J.C., Feng, S., & Roberts, J.P. (2012). An Examination of Liver Offers to Candidates on the Liver Transplant Wait-List. *Gastroenterology, 143*(5), 1261–1265. *https://doi.org/10.1053/j.gastro.2012.07.105.*

[180] Moody-Williams, J., Nair, S. Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance. CMS Blog, September 15, 2023. *https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

PYs, with each PY being a 12-month period that begins on the model start date. For example, if the IOTA Model were to begin on April 1, 2025, ''performance year'' would be defined as a 12-month period beginning on the model start date, meaning April 1, 2025, to March 31, 2026. As a result, the model performance period would also shift to include a 72-month period from the model start date. In this example, the model performance period would be April 1, 2025, to March 31, 2031.

We sought comment on the proposed model performance period of 6 years and the proposed model start date. We also sought comment on the alternative model performance periods that we considered of 3, 5, and 10 years. Finally, we sought comment on the alternative start dates of April 1, 2025, and July 1, 2025, and the subsequent adjustments to the model performance period if the model start date were to change.

Comment: A few commenters supported the proposed model length of six years, indicating that is an appropriate length of time to be able to evaluate a model to determine success.

Response: We thank the commenters for the support and agree a six-year model test should provide sufficient evidence to determine if the IOTA Model is achieving its goals of improving quality of care and reducing Medicare expenditures.

Comment: Several commenters expressed concern around the six-year model performance period. A few commenters felt that a post-transplant evaluation time horizon of six-years contradicts the current OPTN standard of one to three years of post-transplant follow-up. A few commenters also felt that six-years is too long of a model performance period as a shorter model performance period may allow for more immediate assessment and refinement and an adjustment period for unintended consequences. Finally, a commenter felt that the six-year model performance period should be suspended in the event that CMS changes the organ acquisition methodology as initially proposed in the Fiscal Year 2022 Hospital Inpatient Prospective Payment System notice of proposed rulemaking in order to first evaluate the unintended consequences of that proposed change.

Response: We appreciate commenters expressing concern about the six-year model performance period. We believe a six-year model performance period is necessary to allow selected kidney transplant hospitals enough time to invest in care delivery changes necessary for success under the model. CMS research also shows that savings to the Medicare trust fund occur after at least five years of a model performance period. We disagree that a six-year model performance period contradicts current OPTN metrics given that the main focus of the model is to increase the number of transplants year over year, and not to follow post-transplant outcomes after six years. We believe the composite graft survival ratio discussed in section III.C.5.e(1) of this final rule does not contradict the OPTN standard of one to three years of post-transplant follow-up, but rather expands upon existing metrics. Furthermore, models are constantly evaluated and modified even during the model performance period through subsequent rulemaking. A shorter model performance period is not required to make changes responsive to IOTA participant feedback.

We recognize that there may be other efforts occurring simultaneously with the implementation of the IOTA Model, such as the OPTN Modernization efforts and the implementation of the updated OPO Conditions for Coverage. We believe these efforts are synergistic rather than antagonistic because they broadly share the aims of increasing the number of successful transplants and improve quality outcomes for transplant recipients. Therefore, we do not believe that we need to make changes to the six-year model performance period.

Comment: Several commenters felt that the proposed January 1, 2025, model start date did not provide sufficient time for selected transplant hospitals to authorize necessary investments, understand updated organ offer patterns from the updated kidney allocation system, and understand model performance goals. A few commenters also noted that a January 1, 2025, start date would fall outside of the standard hospital institutional budgeting cycle, which would complicate implementation investments. In response, a few commenters supported the alternative model start date discussed in the proposed rule of July 1, 2025, and a few commenters suggested a January 1, 2026, model start date.

Response: We appreciate comments expressing concerns around the timing of this model. We are sensitive to commenters' concerns about the level of preparation needed to implement care redesign activities and develop stakeholder and personnel relationships and processes, especially for hospitals new to value-based care. As such, we are modifying our proposal and finalizing a model start date of July 1, 2025, to allow the selected transplant hospitals more time to prepare for model implementation, and to allow for inclusion of any necessary investments as a result of the IOTA Model in the annual hospital budget cycle. As discussed in section III.C.8 of this final rule, several requirements are voluntary in this first year to allow IOTA participants a grace period to determine how they will implement these requirements and focus on achieving success under the model.

Comment: A few commenters suggested that CMS delay the start of the model until after the request for proposal process for the OPTN is complete, as the possibility of new contractors and multiple vendors could present a risk for errors to attribution which would inhibit beneficiary notification and full implementation of the program.

Response: We thank commenters for their concern regarding the potential overlap between the IOTA Model and the OPTN request for proposal process. HRSA is in the process of conducting their solicitation as part of the OPTN Modernization Process. They released their first requests for proposals in May 2024 and are conducting a series of procurements to support OPTN operations. HRSA has committed to ensuring smooth continued operation of the transplant system and the OPTN, stating that ''while modernization work is complex, the integrity of the organ matching process is paramount and cannot be disrupted.'' [181] At this time, we do not believe that this OPTN Modernization Process would disrupt the beneficiary attribution process of the IOTA Model because attribution status is based on waitlisting, which has not been subject to any major changes during the OPTN modernization process. We will continue to monitor the operation of the model to determine if there are any unforeseen circumstances.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing without modification the proposed definition of model performance period at § 512.402. In light of the public comments, we are also finalizing an alternative model start date of July 1, 2025. As such, we are finalizing our proposed definition for model start date at § 512.402 with slight modification to specify a July 1, 2025, model start date, and finalizing our proposed definition for performance year at § 512.402 with modification to specify a 12-month period beginning on July 1 and ending

[181] *https://www.hrsa.gov/about/news/press-releases/organ-procurement-transplantation-network-modernization-initiative.*

the following June 30 of each year during the model performance period.

b. Other Proposals

We are also finalizing additional policies for the IOTA Model, including the following: (1) the method for selecting transplant hospitals for participation; (2) the schedule and methodologies for the performance-based payments, and waivers of certain Medicare payment requirements solely as necessary to test these payment methodologies under the model; (3) the performance assessment methodology for selected transplant hospitals, including the proposed methodologies for patient attribution, target setting and scoring, and calculation of performance across the achievement domain, efficiency domain, and quality domain; (4) monitoring and evaluation; and (5) overlap with other Innovation Center models and CMS programs.

We proposed that IOTA participants would be subject to the general provisions for Innovation Center models specified in 42 CFR part 512 subpart A and in 42 CFR part 403 subpart K, effective January 1, 2025. The general provisions at subpart A of part 512 are also the subject of revisions in this final rule. As described in section II.B. of this final rule, we proposed to expand the applicability of the general provisions for Innovation Center models to provide a set of standard provisions for Innovation Center models that are applicable more broadly across Innovation Center models. We believed that this approach would promote transparency, efficiency, and clarity in Innovation Center models and avoid the need to restate the provisions in each model's governing documentation. We believed that applying these provisions to the IOTA Model would also promote these purposes.

We sought comment on our proposal to apply the general provisions for Innovation Center models, or the proposed standard provisions for Innovation Center models, to the IOTA Model.

We received no comments on the proposal to make IOTA Participants subject to the general provisions for Innovation Center models, or the standard provisions for Innovation Center models if they were finalized. Therefore, we are finalizing the policy as proposed. Since we are finalizing the proposed revisions to the standard provisions described in section II of this final rule with modification, including that the standard provisions will apply only to the RO Model, the ETC Model, and mandatory Innovation Center models with performance periods that begin on or after January 1, 2025, we are also finalizing our proposal to make the standard provisions for Innovation Center models applicable to the IOTA Model.

2. Definitions

We proposed at § 512.402 to define certain terms for the IOTA Model. We describe these proposed definitions in context throughout section III of this final rule. We proposed to codify the definitions and policies of the IOTA Model at 42 CFR part 512 subpart D (proposed §§ 512.400 through 512.470). In addition, we proposed that the definitions contained in the general provision related to Innovation Center models at subpart A of part 512, and the revisions to those provisions proposed in the notice of proposed rulemaking, would also apply to the IOTA Model. We sought comment on these proposed definitions for the IOTA Model.

We received no comments on these proposals and are therefore finalizing the proposed definitions without modification at § 512.402.

3. IOTA Participants

a. Proposed Participants

We proposed to define ''IOTA participant'' as a kidney transplant hospital, as defined at § 512.402, that is required to participate in the IOTA Model pursuant to § 512.412. In addition, we noted that the definition of ''model participant'' contained in 42 CFR 512.110, as well as the proposed revisions to that definition, would include an IOTA participant.

We proposed to define ''transplant hospital'' as a hospital that furnishes organ transplants as defined in 42 CFR 121.2. We proposed this definition to align with the definition used by Medicare. We proposed to define ''kidney transplant hospital'' as a transplant hospital with a Medicare approved kidney transplant program. A transplant program, as defined at 42 CFR 482.70, is ''an organ-specific transplant program within a transplant hospital.'' Kidney transplants are the most common form of transplants, but not all transplant hospitals have a kidney transplant program. As the focus of the IOTA Model is kidney transplants, we proposed this definition of kidney transplant hospital to refer specifically to transplant hospitals that perform kidney transplants. We proposed to define ''kidney transplant'' as the procedure in which a kidney is surgically transplanted from a living or deceased donor to a transplant recipient, either alone or in conjunction with any other organ(s). As described in section III.B.3.c of this final rule, the vast majority of kidney transplants are performed alone. However, we believed that it is necessary to include in the definition of kidney transplant those kidney transplants that occur in conjunction with other organ transplants to avoid creating a disincentive for multi-organ transplants within the IOTA Model.

Kidney transplant hospitals are the focus of the IOTA Model because they are the entities that furnish kidney transplants to ESRD patients on the waiting list and ultimately decide to accept donor recipients as transplant candidates. Kidney transplant hospitals play a key role in managing transplant waitlists and patient, family, and caregiver readiness. They are also responsible for the coordination and planning of kidney transplantation with the OPO and donor facilities, staffing and preparation for kidney transplantation, and oversight of post-transplant patient care, and they are largely responsible for managing the living donation process. The IOTA Model is intended to promote improvement activities across selected kidney transplant hospitals that reduce access barriers, including SDOH, thereby increasing the number of transplants, quality of care, and cost-effective treatment. The IOTA Model aims to improve quality of care for ESRD patients on the waiting list pre-transplant, during transplant, and during post-transplant care. As described in section III.B.2.a of this final rule, kidney transplant access and acceptance rates vary nationally across kidney transplant hospitals by geography and other demographic and socioeconomic factors. The Innovation Center has implemented models targeting dialysis facilities and nephrology providers, including in the CEC, ETC, and KCC Models. CMS has also implemented changes to the OPO CfCs to strengthen performance accountability for OPOs. However, kidney transplant hospitals have not been the principal focus of any Innovation Center models to date. Expanding accountability to kidney transplant hospitals—key players in the transplantation ecosystem for ESRD patients—aligns with the larger efforts across CMS and HRSA to improve performance and address disparities in kidney transplantation.

We alternatively considered having the IOTA participants be accountable care organizations (ACOs), such as a kidney transplant ACOs, instead of individual kidney transplant hospitals. In this alternative conception, a kidney transplant ACO would form as a

separate legal entity, potentially including kidney transplant hospitals, OPOs, transplant surgeons, and other provider types. The kidney transplant ACO would assume accountability for the number of kidney transplants, equity in the distribution of transplants, and the quality of transplant services from the point of a patient being waitlisted to after a transplant recipient's condition stabilizes following transplantation. This alternative would potentially carry some advantages in the potential for improved coordination among individual providers and suppliers in the kidney transplant ACO, but we believe that it would be administratively burdensome, as it would require the formation of an ACO governing board distinct from the governing boards of individual providers. In addition, such an ACO arrangement would potentially be subject to additional Federal, State, and tribal laws with respect to grievance, licensure, solvency, and other regulations, as well as considerable overlap with other ACO-based Innovation Center models. We therefore proposed to define ''IOTA participant'' as a kidney transplant hospital, as defined at § 512.402, that is required to participate in the IOTA Model pursuant to § 512.412.

We further alternatively considered requiring OPO participation in the IOTA Model as the entity charged with identifying eligible donors and securing organs from deceased donors (89 FR 43540). However, in 2020, CMS issued a final rule that updated OPO CfC requirements to receive Medicare and Medicaid payment (85 FR 77898). This final rule focuses on holding OPOs in the transplant ecosystem accountable for improving performance, and the Innovation Center does not plan further interventions regarding OPOs at this time. Given the interactions between OPOs and transplant hospitals throughout the donation process, transplant hospitals may wish to collaborate or partner with OPOs on strategies to increase donation and other quality improvement activities.

We sought public comment on the proposal that the IOTA participants would be kidney transplant hospitals.

The following is a summary of the comments received on our proposal that the IOTA participants would be kidney transplant hospitals and our responses:

Comment: Several commenters expressed support for the proposed definition of IOTA participants.

Response: We thank the commenters for their support.

Comment: A commenter sought clarification on the definition of ''kidney transplant'' and whether safety-net kidney transplants would still be counted as kidney transplantations in the year following a liver, heart, and/or lung transplant(s).

Response: We thank the commenter for their input. As described and finalized in this section, kidney transplant means the procedure in which a kidney is surgically transplanted from a living or deceased donor to a transplant recipient, either alone or in conjunction with any other organ(s).

A September 2023 OPTN proposal established criteria for prioritizing patients who previously received either a heart or lung transplant, and now need a kidney transplant. This prioritization is referred to as a ''safety net'' for these patients.[182] As such, we clarify that safety-net kidney transplants will be counted as kidney transplantations in the year following a liver, heart, or lung transplant(s).

After careful consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing the definitions of IOTA participant and kidney transplant at § 512.402 as proposed without modification. We did not receive any comments on our proposed definitions of transplant hospital and kidney transplant hospital and are therefore finalizing these definitions as proposed without modification at § 512.402. Additionally, we note that we intend to publicly post kidney transplant hospitals selected to participate in the model and information regarding the participant selection process, as described and finalized in section III.C.3.d(1) of this final rule, and how it resulted in the list of DSAs.

b. Proposed Mandatory Participation

We proposed that all kidney transplant hospitals that meet the eligibility requirements contained in section III.C.3.c of the proposed rule, and that are selected through the participation selection process contained in section III.C.3.d of the proposed rule, would be required to participate in the IOTA Model. We believe that a mandatory model is necessary to ensure that a sufficient number of kidney transplant hospitals participate in the IOTA Model such that CMS will be able to conduct a sound evaluation of the model's effects on cost and quality of care in accordance with section 1115A(b)(4) of the Act. A mandatory model would also minimize the potential for selection bias, thereby ensuring that the model participants are a representative sample of kidney transplant hospitals. We believe a mandatory model is necessary to obtain relevant information about the effects of the model's proposed policies on Medicare savings, kidney transplant volume, kidney transplant acceptance rates, health equity, and quality of care.

In the proposed rule we stated that, nationally, kidney transplant hospitals serve diverse patient populations, operate in varied organizational and market contexts, and differ in size, staffing, and capability (89 FR 43541). There is also wide variation across kidney transplant hospitals on performance on kidney transplant access and organ offer acceptance rate ratios by geography and other demographic and socioeconomic factors. We believed that selection bias would be a challenge in a voluntary model because the IOTA Model would include financial accountability on access to kidney transplants and quality of care, as well as downside risk for kidney transplant hospitals that score poorly on the performance domains. Voluntary participation could result in certain kidney transplant hospitals choosing not to participate in the model and ultimately could inhibit the model from testing a representative sampling of kidney transplant hospitals. We explained in the proposed rule that a mandatory model would address potential selection bias concerns that would exist for a voluntary model by ensuring that our model reaches ESRD patients residing in underserved communities and including other safeguards against selection bias.

As described in section III.C.3.b of the proposed rule, we alternatively considered making participation in the IOTA Model voluntary. However, we were concerned that a voluntary model would not be evaluable, would result in insufficient numbers of kidney transplant hospital participants, and would not be representative of kidney transplant hospitals and ESRD patients nationally. These concerns reflected our expectation that the proposed payment approach would disproportionately attract kidney transplant hospitals already performing well in kidney transplant volume, organ offer

[182] James. (2024, January 31). *FAQ: New Multi-organ polices in effect.* UNOS. *https://unos.org/news/faq-safety-net-policies-for-multi-organ-transplantation/* American Organ Transplant Association. (n.d.). Establish eligibility criteria and safety net for heart-kidney and lung-kidney allocation. U.S. Department of Health and Human Services. Retrieved November 9, 2024, from *https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/establish-eligibility-criteria-and-safety-net-for-heart-kidney-and-lung-kidney-allocation/#:~:text=At%20a%20glance&text=The%20eligibility%20is%20based%20on,safety%20net%E2%80%9D%20for%20these%20patients.*

acceptance rate ratios, and quality of care pre- and post-transplantation, as they would expect to receive upside risk payments. Kidney transplant hospitals already positioned to score high in the IOTA Model's achievement, efficiency, and quality domains may be more likely to join the model than other kidney transplant hospitals, as they would expect to receive upside risk payments. This may be especially true for kidney transplant hospitals that would stand to benefit the most from a model that rewards an increase in the number of kidney transplants. We believed that selection bias in a voluntary model would also limit our ability to assess systematic differences in the IOTA Model's effects on kidney transplant disparities and may further widen disparity gaps for underserved communities that stand to lose if the model does not reach them. We therefore proposed that the IOTA Model would be mandatory for all eligible kidney transplant hospitals selected for participation in the model, as we believed this would minimize the risk of potential distortions in the model's effects on outcomes resulting from hospital self-selection.

We sought public comment on our proposal to make participation in the IOTA Model mandatory.

The following is a summary of the comments received on our proposal to make participation in the IOTA Model mandatory and our responses:

Comment: Several commenters expressed support for requiring mandatory participation in the IOTA Model. Some commenters expressed that mandatory participation would help increase access to kidney transplants and improve kidney transplant outcomes.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern with making participation in the IOTA Model mandatory. Commenters shared that mandatory participation could negatively impact patients. A commenter stated that CMS wrongly presumes that all IOTA participants have the same opportunity for success in the model, and that careful analysis is required to determine whether IOTA Model participation would improve quality of care without sacrificing financial viability. Moreover, a commenter suggested that the nature of mandatory models diverts critical resources that could be used for patient care and instead would redirect resources to administrative tasks, causing administrative burden, in order for transplant hospitals to comply with a mandatory model's unproven and experimental requirements. This commenter also noted that mandatory participation in the IOTA Model could be particularly burdensome for hospitals operating with small financial margins.

Response: We thank the commenters for their feedback. As described in section III.C.3.b of the proposed rule, we believe that a mandatory model is necessary to ensure that a sufficient number of kidney transplant hospitals participate in the IOTA Model such that CMS will be able to conduct a sound evaluation of the model's effects on cost and quality of care. A mandatory model would also minimize the potential for selection bias, thereby ensuring that the model participants are a representative sample of kidney transplant hospitals. We believe a mandatory model is necessary to obtain relevant information about the effects of the model's proposed policies on Medicare savings, kidney transplant volume, kidney transplant acceptance rates, health equity, and quality of care. Transplant hospitals may have to make upfront investments to accommodate the IOTA Model's requirements, but we believe that the low volume threshold of 11 adult kidney transplants performed during each of the baseline years, as described and finalized in section III.C.3.c of this final rule, will substantially mitigate the demands placed on smaller transplant hospitals. Additionally, we do not believe the IOTA Model will divert critical or financial resources, nor do we believe the IOTA Model will negatively impact patient care. Rather, we believe the incentives of the IOTA Model will complement other efforts in relation to the transplant ecosystem to enhance health and safety outcomes, increase transparency, increase the number of transplants, and reduce disparities. For these reasons, we are finalizing our proposal without modification.

Comment: Multiple commenters suggested that introducing a mandatory payment model on top of existing modernization initiatives would add unnecessary disruption, risk, and uncertainty to the transplant system. A commenter highlighted a specific initiative, the OPTN Modernization Initiative launched in March 2023, which focuses on five key areas: technology, data transparency and analytics, governance, operations, and quality improvement and innovation. A commenter also noted that, alternatively, a voluntary model would minimize disruption for transplant programs whose regulatory environment is already uncertain.

Response: We thank the commenters for their feedback. We recognize the challenges kidney transplant hospitals may face as a result of participation in the IOTA Model. However, as described in section III.C.3.b of the proposed rule, we believe that a mandatory model is necessary to ensure a sufficient number of kidney transplant hospitals participate in the IOTA Model such that CMS will be able to conduct a sound evaluation of the model's effects on cost and quality of care. For these reasons, we are finalizing our proposal without modification.

Comment: A commenter suggested that the IOTA Model has the same goals as the ETC Model, and the commenter stated that the ETC Model has not indicated any significant increase in kidney transplants or significant increase in patient placement on kidney transplant waitlists or reduced Medicare spending. The commenter stated that as a result, CMS should not implement a similar mandatory model.

Response: We thank the commenter for their feedback. As described in section III.A of the proposed rule, this model falls within a larger framework of activities initiated by the Federal Government during the past several years and forthcoming in the near future to enhance the donation, procurement, and transplantation of solid organs. Relatedly, as described in section III.B.3.b in this final rule, the IOTA Model proposes to complement the ETC Model and expand kidney model participation to kidney transplant hospitals, which are a key player in the transplant ecosystem, to test whether two-sided risk payments based on performance increase access to kidney transplants for ESRD patients placed on the waitlists of participating transplant hospitals. We disagree with the suggestion that the ETC Model and the IOTA Model have the same goals. No prior CMS models have focused squarely on transplant hospitals in the way the IOTA Model does. For these reasons, we are finalizing our proposal without modification.

Comment: Several commenters raised concerns about bias and disparities as a result of mandatory model participation, suggesting it could bias the model in favor of underperforming transplant hospitals or increase disparities for underserved populations, such as dual-eligible and low-income subsidy beneficiaries, or rural transplant hospitals already impacted by population variability that constricts the ease of access to transplant care.

Response: We thank the commenters for their feedback and concern. As described in section III.C.3.b of the

proposed rule, we believe that a mandatory model is necessary to ensure that a sufficient number of kidney transplant hospitals participate in the IOTA Model such that CMS will be able to conduct a sound evaluation of the model's effects on cost and quality of care. A mandatory model would also minimize the potential for selection bias, thereby ensuring that the model participants are a representative sample of kidney transplant hospitals. We believe a mandatory model is necessary to obtain relevant information about the effects of the model's proposed policies on Medicare savings, kidney transplant volume, kidney transplant acceptance rates, health equity, and quality of care. We also believe the burden on smaller kidney transplant hospitals will be minimized as a result of the low volume threshold of 11 adult kidney transplants performed during each of the baseline years, as described and finalized in section III.C.3.c of this final rule.

Additionally, we do not believe mandatory participation in the IOTA Model would increase disparities for underserved populations such as dual-eligibles or low-income subsidy beneficiaries, nor for rural transplant hospitals. Rather, we believe the IOTA Model will incentivize IOTA participants to perform a greater number of kidney transplants, including those for underserved populations. We believe that the IOTA Model will encourage IOTA participants to address access barriers low-income patients often face, such as transportation, remaining active on the kidney transplant waiting list, and making their way through the living donation process. Relatedly, while rural transplant hospitals face additional unique challenges, such as geographic difficulties in accessing care, we do not believe underserved populations will be negatively impacted by the IOTA Model's mandatory nature. Rather, as described in section III.B.3.e, differences among transplant hospitals in living donor kidney donation are correlated with geographic region and the number of deceased donor kidney transplantations performed. This underscores the need for initiatives and processes among transplant hospitals, such as the IOTA Model, to encourage living donations to reduce geographic disparities. For these reasons, we are finalizing our proposal without modification.

Comment: Several commenters suggested that a mandatory model has financial risks to model participants due to high upfront costs related to employees and IT support, and that it places model participants at significant financial risk regardless of their readiness for participation. Commenters stated that a mandatory model effectively cuts compensation for kidney transplant hospitals with insufficient resources to adequately participate, thereby exacerbating resource disparities and impacting the viability of some transplant programs. Commenters also stated that kidney transplant hospitals selected to participate in the model may opt out of performing kidney transplants rather than assume the costs of mandatory participation.

Response: We thank the commenters for their feedback and concern. As described in section III.C.3.b of the proposed rule, we believe that a mandatory framework is essential to ensure that a sufficient number of kidney transplant hospitals participate in the IOTA Model such that CMS will be able to conduct an adequate evaluation of the model's effects on cost and quality of care. Kidney transplant hospitals selected to participate in the model may have to make upfront investments to accommodate the IOTA Model's requirements, but we believe that the low volume threshold of 11 adult kidney transplants performed during each of the baseline years, as described and finalized in section III.C.3.c of this final rule, will substantially mitigate the demands placed on smaller kidney transplant hospitals. With several months of lead time until the IOTA Model's start date, we believe eligible kidney transplant hospitals selected to participate in the IOTA Model will be sufficiently equipped for participation and success in the model. We do not believe mandatory participation will cut compensation for smaller kidney transplant hospitals selected to participate in the IOTA Model. Rather, mandatory participation in the IOTA Model offers a strong financial incentive for those transplant hospitals chosen to participate. Finally, we believe the two-sided performance-based payment structure, as described and finalized in section III.C.6.a of this final rule, which rewards IOTA participants for high performance in the achievement, efficiency, and quality domains—and imposes financial accountability on IOTA participants that perform poorly on those domains—will encourage maximum engagement from IOTA participants. For these reasons, we are finalizing our proposal without modification.

Comment: Multiple commenters showcased the differing opinions regarding how the mandatory nature of the IOTA Model may impact kidney transplant hospitals based on size. Some commenters suggested that mandatory participation could benefit lower-volume or underperforming kidney transplant hospitals that have room to grow, while larger-volume kidney transplant hospitals with limited capacity to grow would incur financial and administrative burdens to reach their transplant targets. Other commenters suggested the IOTA Model could negatively impact small kidney transplant hospitals financially. or increase competition for available organs with higher-volume kidney transplant hospitals.

Response: We thank the commenters for their support and feedback. IOTA participant performance on the achievement domain in the IOTA Model is measured based on the number of transplants performed by the IOTA participant in the baseline years and the national growth rate as described and finalized in section III.C.5.c(1) of this final rule. As a result of this metric, we believe kidney transplant hospitals—including larger-volume programs in the IOTA Model—are on equal footing to improve their transplant rates in each consecutive PY. IOTA participants may have to make upfront investments to accommodate the IOTA Model's requirements, but we believe that the required low volume threshold of 11 adult kidney transplants performed for each kidney transplant hospital in each of the baseline years, as described and finalized in section III.C.3.c of this final rule, will substantially mitigate the demands placed on smaller kidney transplant hospitals. Additionally, we have found that many of these kidney transplant hospitals consistently perform between 11 and 50 kidney transplants annually. We direct readers to section III.C.3.c of this final rule for a full discussion on why we believe provisions within the IOTA Model will limit negative impacts to small kidney transplant hospitals.

We recognize that IOTA participants face varying challenges based on their kidney transplant volumes. However, we believe all IOTA participants, including high-volume kidney transplant hospitals, have opportunities to increase the number of kidney transplants performed. For example, high-volume kidney transplant hospitals could focus on improving deceased donor organ utilization or supporting more living donors. Regardless of each IOTA participant's approach or any potential competition, we intend to monitor the model for any unintended consequences. For these reasons, we are finalizing our proposal without modification.

Comment: A commenter suggested that mandatory participation in the IOTA Model may be undermined by the absence of any meaningful adverse consequences when an IOTA participant is terminated from the model.

Response: We thank the commenter for their feedback. As described and finalized in section III.C.16.a of this final rule, we may take a variety of one or more remedial actions. We believe the remedial actions we are finalizing at § 512.464(b) can meaningfully discourage noncompliance with the IOTA Model requirements. For these reasons, we are finalizing our proposal without modification.

Comment: A commenter claimed that CMS does not have the authority to institute IOTA as a mandatory model, while other commenters shared general concerns about requiring mandatory participation in the model.

Response: We thank the commenters for their feedback and concerns. CMS' testing of innovative payment and service delivery models, including the IOTA Model, complies with section 1115A of the Act and other governing laws and regulations, including the U.S. Constitution. Section 1115A of the Act and the Secretary's authority to operate the Medicare program authorize us to finalize mandatory participation in the IOTA Model for the selected IOTA participants. Section 1115A of the Act authorizes the Secretary to test innovative payment and service delivery models expected to reduce Medicare costs while preserving or enhancing quality of care. The statute does not require that models be voluntary or be tested first as a voluntary model, but rather gives the Secretary discretion to design and test models that meet certain requirements as to spending and quality. Section 1115A(b)(2)(B) of the Act describes a number of payment and service delivery models that the Secretary may test, but the Secretary is not limited to testing just those models. Rather, as specified in section 1115A(b)(2) of the Act, models to be tested under section 1115A of the Act must address a defined population for which there are either deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The IOTA Model addresses a defined population (kidney transplant waitlist patients) for which there are potentially avoidable expenditures arising from an inadequate number of kidney transplants performed each year.

We chose to make participation in the IOTA Model mandatory for the selected kidney transplant hospitals to avoid the selection bias inherent to any model in which providers may choose whether or not to participate. Such a design will ensure sufficient participation of kidney transplant hospitals, which is necessary to obtain a diverse, representative sample of hospitals that will allow a statistically robust test of the model.

Moreover, the Secretary has the authority to establish regulations to carry out the administration of the Medicare program. Specifically, the Secretary has authority under sections 1102 and 1871 of the Act to implement regulations as necessary to administer the Medicare program, including testing this Medicare payment and service delivery model. We note that IOTA is not a permanent feature of the Medicare program. Rather, IOTA will test innovative methods for delivering and paying for services covered under the Medicare program, which the Secretary has clear legal authority to regulate. The proposed rule went into detail about the provisions of the proposed IOTA Model, enabling the public to understand how IOTA was designed and could apply to affected kidney transplant hospitals. and sought comment on the proposed model design and policies. As permitted by section 1115A of the Act, we are testing IOTA within specified geographic areas. If the IOTA Model test meets the statutory requirements for expansion, and the Secretary determines that expansion is appropriate, we would undertake rulemaking to implement the expansion of the scope or duration of the IOTA Model to additional geographic areas or for additional time periods, as required by section 1115A(c) of the Act.

For these reasons, we are finalizing our proposal without modification.

Comment: Multiple commenters suggested the IOTA Model should begin with a voluntary trial period or be a purely voluntary model to minimize negative impacts on patients. They cautioned that an unintended consequence of this mandatory model could be a decrease the availability of marginal organs for transplantation. Several other commenters recommended the IOTA Model allow self-selection to encourage participation from motivated kidney transplant hospitals. These commenters suggested this would incentivize voluntary participation and enable kidney transplant hospitals to assess if the model is appropriate for their patients.

Response: We thank the commenters for their feedback. As described in section III.C.3.b of the proposed rule, we believe that a mandatory model is necessary to ensure that a sufficient number of kidney transplant hospitals participate in the IOTA Model such that CMS will be able to conduct a sound evaluation of the model's effects on cost and quality of care as required by section 1115A(b)(4) of the Social Security Act. We believe a voluntary trial period would inhibit this evaluation.

More specifically, we are concerned that a voluntary model would not be evaluable, result in insufficient numbers of IOTA participants, and not be representative of kidney transplant hospitals and ESRD patients nationally. These concerns reflect our expectation that the model's proposed payment approach, as described and finalized in section III.C.6 of this final rule, would disproportionately attract kidney transplant hospitals already performing well in kidney transplant volume, organ offer acceptance rate ratios, and quality of care pre- and post-transplantation. Kidney transplant hospitals already positioned to score high in the IOTA Model's achievement, efficiency, and quality domains may be more likely to join the model than other kidney transplant hospitals, as they would expect to receive upside risk payments. In the context of the IOTA Model, we believe that a voluntary model could result in selection bias and limit our ability to assess systematic differences in the IOTA Model's effects on kidney transplant disparities.

As a mandatory model, we also believe the IOTA Model will have positive impacts on patients and an increase in the availability of kidneys. Finally, we believe the transplant hospitals selected for mandatory participation would be motivated to increase the number of kidney transplants performed due to the financial incentives of the model. For these reasons, we are finalizing our proposal without modification.

Comment: Several commenters expressed concern with making participation in the IOTA Model mandatory, urging CMS to consider geographic factors or the impact of the model on smaller kidney transplant hospitals. For example, a commenter argued that the IOTA Model's mandatory participation component must consider geographic location. The commenter explained that if the model aims to address disparities in transplant access for patients of different races, ethnicities, socioeconomic statuses, or from rural areas, then these factors need to be accounted for. The commenter stated that they see these factors directly impacting their pool of potential living donors, who often suffer from the same medical and economic conditions as their recipients and thus get ruled out.

A commenter from a smaller, rural kidney transplant hospital expressed concerns about mandatory participation. They argued that population density varies greatly in their rural state, with an uneven distribution. The commenter noted this population variation impacts both access to transplant care and the available donor pool and would require additional staffing and resources to manage the model effectively.

Another commenter expressed concerns about the impact of the IOTA Model on small kidney transplant hospitals if participation was made mandatory. The commenter suggested that a low volume threshold of 100 kidney transplants, regardless of payer type, would be more appropriate. This, the commenter believed, would ensure small kidney transplant hospitals were excluded and protect access to kidney transplants in less populated areas.

Lastly, a commenter recognized that the IOTA participants would be kidney transplant hospitals. The commenter reiterated concerns about the challenges that mandatory payment models may pose for physician practices. The commenter explained that successful participation in alternative payment models often requires new investments in infrastructure and technical capabilities, such as sophisticated data management, dedicated performance assessment resources, and updates to electronic medical records. They argued that meeting these demands would be difficult, if not impossible, for many kidney transplant hospitals, especially smaller ones. This could set these kidney transplant hospitals up for failure. The commenter recommended that CMS apply exemptions or special accommodations, like upside-only risk, for small kidney transplant hospitals that lack experience with value-based payment arrangements, if CMS requires future participation in new models.

Response: We took into consideration geographic factors when proposing to stratify the DSAs into groups based on each DSA's Census Division and the total number of adult kidney transplants performed annually across all eligible kidney transplant hospitals in each DSA during the baseline years for the first PY, as described and finalized in section III.C.3.d(1). As discussed in the proposed rule, we believe selecting eligible kidney transplant hospitals from these groups of DSAs will ensure that the IOTA participants represent eligible kidney transplant hospitals nationwide, both geographically and in terms of annual adult kidney transplant volume (89 FR 43542). Additionally, as described and finalized in section III.C.3.d(1) of this final rule, CMS will then select approximately half of all DSAs nationwide using a stratified sampling methodology, and all eligible kidney transplant hospitals in the selected DSAs will be required to participate in the IOTA Model.

Additionally, we note that we intend to publicly post information regarding the selection process and how it resulted in the list of DSAs and kidney transplant hospitals selected to participate in the model.

Finally, as described and finalized in section III.C.3.c of this final rule, we will use a low volume threshold of 11 adult kidney transplants performed during each of the baseline years. This low volume threshold aligns with the minimum requirements for publishing CMS data, ensuring the confidentiality of Medicare and Medicaid beneficiaries by preventing the disclosure of information that could identify individual beneficiaries. As described at 89 FR 43541 in the proposed rule, we alternatively considered using a higher threshold, such as 30 adult kidney transplants or 50 adult kidney transplants during each of the three baseline years. However, we found that many kidney transplant hospitals consistently perform between 11 and 50 kidney transplants annually. For these reasons, we are finalizing our proposal without modification.

After careful consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposal to make the IOTA Model mandatory at § 512.412(c) without modification.

c. Participant Eligibility

We proposed kidney transplant hospital participant eligibility criteria that would increase the likelihood that: (1) individual kidney transplant hospitals selected as IOTA participants represent a diverse array of capabilities across the performance domains as discussed in section III.C.5 of this final rule; and (2) the results of the model test would be statistically valid, reliable, and generalizable to kidney transplant hospitals nationwide should the model test be successful and considered for expansion under section 1115A(c) of the Act.

We proposed that eligible kidney transplant hospitals would be those that: (1) performed 11 or more kidney transplants for patients aged 18 years or older annually, regardless of payer type, in each of the baseline years (the ''low volume threshold''); and (2) furnished more than 50 percent of its kidney transplants annually to patients over the age of 18 during each of the baseline years. We proposed to define ''baseline year'' as a 12-month period within a 3-year historical baseline period that begins 48 months (or 4 years) before the start of each model PY and ends 12 months (or 1 year) before the start of each model PY. For example, if the IOTA Model were to start on January 1, 2025, the 3-year historical baseline period would begin January 1, 2021, and end on December 31, 2023.[183] We proposed to define ''non-pediatric facility'' as a kidney transplant hospital that furnishes over 50 percent of their kidney transplants annually to patients 18 years of age or older. CMS would select approximately half of all DSAs nationwide using a stratified sampling methodology, and all eligible kidney transplant hospitals in the selected DSAs would be required to participate in the IOTA Model.

As described in the proposed rule at 89 FR 43541, the proposed low volume threshold of 11 or more kidney transplants for ESRD patients aged 18 years or older during each of the three baseline years (as described in section I.B.2.b of the proposed rule) would exclude low volume kidney transplant hospitals from the IOTA Model. We believed that these kidney transplant hospitals should be excluded from the model because they may not have the capacity to comply with the model's policies, and because the inclusion of this group of kidney transplant hospitals in the model would be unlikely to significantly alter the overall rates of kidney transplantation. We stated that we were also proposing a low volume threshold of 11 adult kidney transplants because it is consistent with the minimum thresholds for the display of CMS data to protect the confidentiality of Medicare and Medicaid beneficiaries by avoiding the release of information that can be used to identify individual beneficiaries. We alternatively considered using a higher threshold, such as 30 adult kidney transplants or 50 adult kidney transplants during each of the three baseline years. However, we found that many kidney transplant hospitals consistently perform between 11 and 50 transplants per year. We further believe that using a higher threshold would decrease the number, size and location of kidney transplant hospitals eligible to be selected for participation in the IOTA Model, thereby limiting the generalizability of the model test. We also recognize that the number of kidney transplants

[183] This example, which appeared in the notice of proposed rulemaking, has been clarified to specify that the baseline years for each PY would be each 12-month period beginning January 1, 2021, and ending December 31, 2023.

performed by a kidney transplant hospital may fluctuate from year to year, and looking back three years would help determine if a kidney transplant hospital has the capacity to consistently perform 11 or more transplants per year. We sought feedback on this approach for determining which kidney transplant hospitals would be eligible for selection under the model.

We considered including pediatric kidney transplant hospitals as eligible participants in the IOTA Model. However, pediatric kidney transplantation has significantly different characteristics, considerations, and processes from adult kidney transplantation. The number of pediatric kidney transplants performed each year is also exceedingly small, which would present difficulties in reliably determining the effects to the model in the pediatric population. Additionally, a much larger proportion of pediatric kidney transplants are living donor transplants than in the adult population. As such, we do not believe the proposed IOTA Model would function in the same way for both kidney transplant hospitals serving primarily adults and those serving primarily children, and we believe it is necessary to include only non-pediatric kidney transplant hospitals in the IOTA Model.

We sought comment on our proposed participant eligibility criteria for kidney transplant hospitals, including the requirement that a kidney transplant hospital perform 11 or more kidney transplants annually on patients aged 18 years or older during the baseline years. We also sought comment on the proposal to include only kidney transplant hospitals that meet the proposed definition for a non-pediatric facility during the baseline years.

The following is a summary of the comments received on our proposed participant eligibility criteria for kidney transplant hospitals, including the requirement that a kidney transplant hospital perform 11 or more kidney transplants annually on patients aged 18 years or older during each of the baseline years, and the proposal to include only kidney transplant hospitals that meet the proposed definition for a non-pediatric facility during the baseline years, and our responses:

Comment: Several commenters expressed support for the IOTA participant kidney transplant hospital eligibility criteria, as proposed, particularly noting the proposed eligibility criterion by which a kidney transplant hospital must furnish over 50 percent of their kidney transplants annually to patients 18 years of age or older.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern with the proposed low-volume kidney transplant threshold for IOTA participants. A commenter noted that there may be some unforeseen or unintended consequences of advantaging programs classified as ''low volume,'' where the volume is close to the dividing line, and vice versa. Additional commenters shared concerns that the low volume threshold of 11 kidney transplants performed will disadvantage kidney transplant hospitals that furnish a smaller number of kidney transplants, as these transplant programs do not meet the requirements for COE programs and have limited contracts with payers, and the low volume threshold does not ensure statistical significance. Several commenters recommended that CMS should increase the low volume threshold, setting the number of kidney transplants at a value such as 25, 50, or 100, to ensure statistical significance and avoid burden on kidney transplant hospitals that furnish a smaller number of kidney transplants. Finally, a commenter suggested CMS should only use the number of Medicare kidney transplants to determine eligibility, rather than 11 kidney transplants across all payers.

Response: We thank the commenters for their feedback. To protect the confidentiality of Medicare and Medicaid beneficiaries, we proposed a low volume threshold of 11 adult kidney transplants. We believe this low-volume threshold aligns with the minimum standards for CMS data display, preventing the release of information that could identify individual beneficiaries while ensuring statistical significance (89 FR 43541). We recognize that this could exclude smaller kidney transplant programs, which may not already meet COE [184] program criteria and have limited contact with payers. However, as described in the proposed rule, we proposed a low volume threshold of 11 adult kidney transplants to exclude low-volume kidney transplant hospitals that may lack the capacity to comply with the model's policies, as their inclusion would be unlikely to significantly impact overall kidney transplant rates (89 FR 43541). We considered, but did not propose, using a higher threshold, such as 30 adult kidney transplants or 50 adult kidney transplants during each of the three baseline years (89 FR 43541). However, we did not propose this, as we found that many kidney transplant hospitals consistently perform between 11 and 50 transplants annually. We maintain our belief that a higher threshold would reduce the number, size, and geographic diversity of kidney transplant hospitals eligible for the IOTA Model, limiting the model's broader applicability. Additionally, we recognize that kidney transplant volumes can fluctuate year-to-year. Furthermore, we believe looking at a 3-year historical baseline period will help assess if a kidney transplant hospital has the capacity to consistently perform 11 or more kidney transplants annually.

Relatedly, as described in section III.C.3.d(2) of this final rule, after the IOTA Model's start date, we do not anticipate making any additional participant selections, unless 10 percent or more of the selected participants are terminated during the model's performance period. If that occurs, we will address the selection of new IOTA participants through future notice and comment rulemaking, and we may reevaluate the low volume threshold.

Finally, as described in the proposed rule, we considered limiting IOTA waitlist and IOTA transplant patients to Medicare beneficiaries only, as Medicare covers over 50 percent of kidney transplants (89 FR 43544). However, we ultimately did not propose this limitation. We believe restricting the IOTA Model assessment to Medicare patients would reduce the sample size, potentially hindering our ability to detect performance changes due to model payments. Therefore, we proposed, and will be finalizing, that the IOTA Model reflect both Medicare beneficiaries and non-Medicare patients for performance assessment, with Medicare beneficiaries being a subset of the patient population attributed to each model participant. We direct readers to section III.C.5 of this final rule for a full discussion on the IOTA Model performance assessment methodology. We believe the same rationale applies for kidney transplant hospital eligibility criteria. For these reasons, we are finalizing our proposal without modification.

Comment: A commenter suggested that IOTA participants that furnish a smaller volume of kidney transplants would have little incentive to engage in the model if participant eligibility is

[184] A transplant center receives Center of Excellence (COE) designation from a private insurer when it meets transplant volume and performance thresholds. Without this designation, a transplant hospital may not be approved by certain private insurance companies to complete a transplant procedure, which limits the transplant center where patients may receive covered care.

based on all kidney transplants, but financial incentives and penalties only apply to Medicare kidney transplants.

Response: We thank the commenter for their feedback. We considered, limiting IOTA waitlist patients and IOTA transplant patients to Medicare beneficiaries only, as Medicare covers more than 50 percent of all kidney transplants from both deceased and living donors (89 FR 43544). However, we believe it's necessary to include all patients, regardless of payer type, in the IOTA participant's performance calculations. This protects against unintended consequences and problematic financial incentives that could arise if the IOTA Model only applied to specific payer types. Additionally, the eligible waitlist and transplant patient population attributed to each IOTA participant is already relatively small, in terms of both transplant candidates and recipients. Limiting the IOTA Model performance assessment, as described in section III.C.5 of this final rule, to only Medicare beneficiaries would further reduce the patient sample size, potentially affecting our ability to detect changes in performance due to model payments. For these reasons, we chose not to propose limiting IOTA waitlist patients and IOTA transplant patients to Medicare beneficiaries only and respectfully disagree with the commenter.

Lastly, as described in section III.C.5 of this final rule, the IOTA Model's performance assessment is inclusive of both Medicare and non-Medicare patients. We believe this will incentivize IOTA participants of all sizes and patient populations to fully engage in the model regardless of payer type. For these reasons, we are finalizing our proposal without modification.

Comment: Multiple commenters recommended that CMS exclude kidney transplant hospitals with high volume, high quality, and high efficiency from the IOTA Model, and provide additional provisions for newer kidney transplant hospitals.

Response: We thank the commenters for their feedback. As described in section I.B.2.b of the proposed rule, we proposed to select the kidney transplant hospitals that will be required to participate in the IOTA Model from the group of eligible kidney transplant hospitals using a stratified random sampling of DSAs to ensure that there is a fair selection process and representative group of participating kidney transplant hospitals. We believe the commenter's recommendation would inhibit a representative sampling necessary to the IOTA Model. For these reasons, we are finalizing our proposal without modification.

Comment: Several commenters suggested CMS should change multiple aspects of the proposed participant eligibility criteria. Recommendations included excluding kidney transplant hospitals that have had a transplant volume growth of 30 percent or more and expanding eligible kidney transplant hospitals to include pediatric kidney transplant hospitals.

Response: We thank the commenters for their feedback and suggestions. In section I.B.2.b of the proposed rule, we proposed to select the kidney transplant hospitals that will be required to participate in the IOTA Model from the group of eligible kidney transplant hospitals using a stratified random sampling of DSAs to ensure that there is a fair selection process and representative group of participating kidney transplant hospitals. We believe the commenter's recommendation would inhibit a representative sampling necessary to test the proposed model. For these reasons, we are finalizing our proposal without modification.

Additionally, regarding the comments that CMS consider including pediatric kidney transplant hospitals in the IOTA Model, we acknowledge the importance kidney transplantation for pediatric patients. As described at 89 FR 43541 in the proposed rule, we considered, including pediatric kidney transplant hospitals in the IOTA Model. However, for the reasons described in section III.C.5.c of this final rule, we ultimately decided not to propose their inclusion as eligible kidney transplant hospitals. pediatric kidney transplant hospitals as eligible participants in the model. As such, we respectfully disagree with commenters who argued that pediatric kidney transplant hospitals should be eligible to participate in the model.

Finally, as described in the proposed rule, we considered offering differential credit for transplants by type (89 FR 43553). With this alternative methodology, IOTA participants would receive bonus points and score higher for transplants that fit into categories that lead to more savings, such as living donor kidney transplants, high kidney donor profile index donors, or pre-emptive transplants, compared to other transplants. However, we chose not to propose a methodology that provides differential credit for transplants based on type, as we believe that counting all transplants equally will give IOTA participants the flexibility to meet their transplant targets. Furthermore, we think this approach of treating all transplants the same helps minimize the potential harm and unintended consequences that could arise from a methodology that offers differential credit based on transplant type. We direct readers to section III.C.5.c(2) of this final rule for a full discussion on alternative methodologies we considered for calculating points in the achievement domain. For these reasons, we are finalizing our proposal without modification.

Comment: A commenter acknowledged that CMS proposed to define a baseline year as a 12-month period within a 3-year historical baseline period, that begins 48 months (or 4 years) before the start of each model PY and ends 12 months (or 1 year) before the start of each model PY. For PY 1 (CY 2025), as proposed, the commenter highlighted that the proposed 3-year historical baseline period consists of CY 2021 through CY 2023. The commenter supported the proposed 3-year historical baseline period for PY 1, noting that 2020–2022 represented a low point in transplant activity due to the Public Health Emergency (''PHE'') declared in response to the COVID–19 pandemic, which reduced the number of kidneys transplanted nationally. Additionally, the commenter believed that starting from this low baseline would help ensure more attainable performance improvement targets for model participants, though they still had significant reservations about the proposed transplant targets.

Response: We thank the commenter for their support.

Comment: Multiple commenters expressed concern on the inclusion of 2021 in the baseline years. Specifically, a commenter suggested that the 3-year historical baseline period should exclude transplant data from 2021, as the COVID–19 public health emergency impacted this performance year.

Response: We thank the commenters for their feedback. As described in section III.C.3.c of this final rule, we proposed to define ''baseline year'' as a 12-month period within a 3-year historical baseline period that begins 48 months (or 4 years) before the start of each model PY and ends 12 months (or 1 year) before the start of each model PY. For example, if the IOTA Model were to start on July 1, 2025, the 3-year historical baseline period would begin July 1, 2021, and end on June 30, 2024. In this example, the baseline years for each PY would be 12-month periods beginning July 1, and ending on June 30.

Relatedly, in response to commenters requesting a later start date for the model, we are finalizing a July 1, 2025, model start date. This will result in the

inclusion of only the latter six months of 2021 into the baseline period for the first PY. Within the context of the COVID–19 pandemic, the non-utilization of deceased donor kidneys in 2020 rose to the highest level up to that time, 21.3 percent. Additionally, the number of newly added adult candidates to the waitlist increased 11.7 percent from 2020 to 2021, recovering from the pandemic related decline in the prior year, and exceeding the 2015–2019 CAGR of 9.2 percent. We do not believe inclusion of July through December of 2021 into the baseline year would inhibit the overarching goal of the IOTA Model. For these reasons, we are finalizing our proposal without modification.

After consideration of the public comments we received, we are finalizing our proposed provisions for participant eligibility criteria for kidney transplant hospitals at § 512.412(a) without modification. We received no comments for the proposed definition of non-pediatric facility and are finalizing the proposed definitions of non-pediatric facility, and baseline years at § 512.402 without modification.

d. Participant Selection

(1) Overview and Process for Participant Selection

In section III.C.c.3.d(1) of the proposed rule, we proposed to select eligible kidney transplant hospitals for participation in the IOTA Model using a stratified sampling of approximately half of all DSAs nationwide. We stated that all kidney transplant hospitals that meet the proposed participant eligibility criteria described in section III.C.3.c of the proposed rule and are located in the selected DSAs would be required to participate in the IOTA Model. As defined in 42 CFR 486.302, a ''Donation Service Area (DSA)'' means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area (MSA) or does not include any part of such an area and that meets the standards of subpart G. A DSA is designated by CMS, is served by one OPO, contains one or more transplant hospitals, and one or more donor hospitals. There were 56 DSAs as of January 1, 2024. A map of the DSAs can be found on the SRTR website.[185] CMS would use the list of DSAs as it appears on January 1, 2024, to select the DSAs, and therefore the eligible kidney transplant hospitals that would be required to participate in the IOTA Model.

We proposed this approach for selecting IOTA participants to obtain a group of eligible kidney transplant hospitals that is representative of kidney transplant hospitals from across the country in terms of geography and kidney transplant volume. We proposed to stratify the DSAs into groups based on each DSA's Census Division and the total number of adult kidney transplants performed annually across all eligible kidney transplant hospitals in each DSA during the baseline years for the first PY. Selecting eligible kidney transplant hospitals from these groups of DSAs would ensure that the IOTA participants are representative of eligible kidney transplant hospitals from across the nation in terms of geography and the volume of adult kidney transplants.

A second aim of our proposal to select eligible kidney transplant hospitals from stratified groups of DSAs is to prevent distortions on the effects of the model's policies and features on outcomes. Our analysis of kidney transplant hospital data shows that selecting only some eligible kidney transplant hospitals within a selected DSA to participate in the IOTA Model may shift the supply of deceased donor organs from non-IOTA participants to IOTA participants within the same DSA. The resulting distortions would make it difficult to attribute changes in outcomes to the model and would limit its evaluability.

Our proposed approach for selecting IOTA participants would involve stratifying DSAs into groups based on the average number of adult kidney transplants performed by all eligible transplant hospitals located in the DSA during the baseline years of PY 1. We proposed using this variable to stratify the DSAs into groups because increasing the total number of adult kidney transplants is the primary metric that we proposed to use to evaluate the IOTA participants' performance in the model.

The proposed approach for IOTA participant selection is as follows:

- *Assign all DSAs to a Census Division.*[186] The Census Bureau subdivides the United States into four Census Regions (Northeast, Midwest, South, and West) which are in turn divided into nine Census Divisions. CMS would assign each DSA to a single Census Division. Due to the New England region being both a DSA and a Census Division, CMS would combine the Middle Atlantic and New England Census Divisions for a total of eight Census Divisions. If CMS were to keep the New England Census Division separate, the New England DSA would be guaranteed participation in the model in subsequent steps. As such, we proposed to combine the Middle Atlantic and New England Census Divisions for the purposes of this selection methodology. Some DSAs may span several Census Divisions, but most DSAs will be assigned to the Census Division where the majority of the DSA's population resides according to the 2020 Census data. Puerto Rico is the only DSA which exists outside of a Census Division. This DSA would be assigned to the South Atlantic Census Division as it is the closest geographically. This step would create eight Census Division groups, one for each Census Division (with the exception of the combined Middle Atlantic and New England Census Divisions, which would be grouped together to create one Census Division group).
- *Determine the kidney transplant hospitals located within each DSA.* CMS would list out the kidney transplant hospitals located within each DSA and assigned Census Division group.
- *Identify the eligible kidney transplant hospitals located within each DSA.* CMS would use the criteria noted in section III.C.3.c of the proposed rule to identify the eligible kidney transplant hospitals within each DSA. This step is expected to yield approximately 180 to 200 eligible kidney transplant hospitals total across the eight Census Division Groups.
- *For each DSA, determine the average number of adult kidney transplants performed annually across all eligible kidney transplant hospitals during the baseline years for PY 1.* CMS would use data from the baseline years for PY 1 to determine the average number of adult kidney transplants performed annually across all of the eligible transplant hospitals located in each DSA. CMS would sum the number of adult kidney transplants performed by all of the eligible kidney transplant hospitals in a DSA during each of the baseline years for PY 1 and divide each DSA's sum by three to determine the average number of adult kidney transplants furnished annually during the baseline years by the eligible kidney transplant hospitals located within each DSA.
- *Within each Census Division group, create two mutually exclusive groups of DSAs using the average number of adult kidney transplants performed annually across the baseline years for PY 1.* CMS

[185] *https://www.srtr.org/reports/opo-specific-reports/interactive-report.*

[186] A complete list of DSAs in the United States as of 2022–2023 can be obtained using the data reporting tool found on the SRTR website (*https://www.srtr.org/reports/opo-specific-reports/interactive-report*).

would separate DSAs assigned to a Census Division group into two mutually exclusive groups of DSAs based on the average number of adult kidney transplants performed annually across the baseline years for PY 1. The two groups within each Census Division group would be: (1) DSAs having higher numbers of adult kidney transplants across the baseline years; and (2) DSAs having lower numbers of adult kidney transplants across the baseline years. Since the average number of adult kidney transplants will be different across each DSA, each Census Division group will have a different cut off to create these two groups. To ensure each DSA has a 50 percent chance of being chosen in step 7, each DSA group within a Census Division group should have the same number of DSAs. However, in the event of an odd number of DSAs within a Census Division group, CMS would proceed to step six.

- *For groups within a Census Division group that contain an odd number of DSAs, CMS would randomly select one DSA from the group. Each of these individual selected DSAs would have a 50 percent probability of being selected for the IOTA Model.* For groups within a Census Division group that contain an odd number of DSAs, CMS would randomly select one DSA from the group and determine that individual DSA's chance of selection for inclusion in the IOTA Model with 50 percent probability. Following this step, each group within a Census Division group would have an even number of DSAs.
- *Randomly select 50 percent of remaining DSAs in each group.* CMS would then take a random sample, without replacement, of 50 percent of the remaining DSAs in each group (the groups being DSAs having higher numbers of adult kidney transplants across the baseline years and DSAs having lower numbers of adult kidney transplants across the baseline years) within each Census Division group. All of the eligible kidney transplant hospitals located within the selected DSAs would be required to participate in the IOTA Model.

We proposed that CMS would notify IOTA participants of their selection to participate in the IOTA Model in a form and manner chosen by CMS, such as public notice and email, at least 3 months prior to the start of the model performance period. As described in section III.C.3.b of this final rule, we proposed that participation in the IOTA Model would be mandatory. As such, if an IOTA eligible transplant hospital is located within one of the DSAs that CMS randomly selects for the IOTA Model, the eligible kidney transplant hospital would not be able to decline participation in this model, nor would it be able to terminate its participation in the model once selected. Model termination policies are further discussed in section III.C.16 of this final rule.

We direct readers to section III.C.3.d(2) of this final rule for a summary of the comments received on our proposed approach for selecting IOTA participants and our responses.

(2) Consideration of Alternatives to Proposed Participant Selection Approach

We considered using other geographic units for stratified random sampling to choose IOTA participants, such as Core Based Statistical Areas (CBSAs), Metropolitan Statistical Areas (MSAs), Hospital Referral Regions (HRRs), or States (89 FR 43543). CBSAs, MSAs, HRRs, and States are commonly known geographic units, and have been used as part of participant selection for other Innovation Center models. We believe selecting participants by DSA significantly mitigates behavior that would artificially inflate the model's effects on kidney transplant volume for the reasons described in the preceding section. OPOs associated with selected DSAs would be expected to benefit from consistency in rules across most or all of their transplant hospitals. The Innovation Center found that selecting participants by DSA improved the ability to detect changes in kidney transplant volume to a level consistent with the anticipated change in kidney transplant volume associated with the model's payment rules. Participants from the same DSA are, for the most part, subject to similar levels of kidney supply, and, with the exception of kidneys from another DSA, the same rules for kidney allocation apply. While OPTN recently updated its organ allocation methodology to allow organs to go outside of the DSA in which an organ was procured, many kidney transplant hospitals still receive a plurality of kidneys from the local OPO in their DSA, ensuring that this is still a meaningful method to group kidney transplant hospitals. Using alternative geographic units would negate these advantages.

We also considered other random sampling techniques, including simple random sampling of transplant hospitals, simple random sampling of DSAs, and cluster sampling of DSAs (89 FR 43543). Simple random sampling of hospitals risks oversampling regions of the country where transplant hospitals are concentrated and under sampling areas with fewer eligible transplant hospitals. Using simple random sampling of DSAs may result in an unrepresentative sample of DSAs with a greater risk of oversampling regions where DSAs cover small geographic areas. We considered cluster random sampling where half of all DSAs would be sampled in a first step and half of eligible kidney transplant hospitals within selected DSAs would be sampled. However, because this approach would retain half of eligible kidney transplant hospitals in selected DSAs, we expect the model's effects on kidney transplant volume would be overstated because kidney supply flowing towards non-participant hospitals prior to the start of the model would be redirected towards IOTA participants. In addition, CMS' analyses of these alternative sampling approaches indicated the model would not be evaluable because these approaches were associated with lower precision in detecting changes in kidney transplant volumes due to the model compared to the increase in transplant volume anticipated from the model's payment rules.

As an alternative we also considered other variables to create DSA groups for stratified sampling of DSAs (89 FR 43543). Specifically, after assigning each DSA to a Census Division, we considered stratifying DSAs using the following DSA level variables:

- Number of eligible transplant hospitals in DSA.
- Annual adult kidney transplants per eligible transplant hospital in DSA.
- Average organ offer acceptance rate ratio across eligible kidney transplant hospitals in DSA.
- Average percent of Medicare kidney transplant recipients dually eligible for Medicare and Medicaid or who are LIS recipients.
- Percent of eligible transplant hospitals in DSA participating in the Kidney Care Choices or ESRD Treatment Choices Models.
- Average percent of kidney transplants from a living donor among eligible kidney transplant hospitals in DSA.

These variables were given consideration in the stratified selection approach because their use would create groups of DSAs whose eligible transplant hospitals are more similar to each other on the listed characteristics instead of only adult kidney transplant volume and Census Division. However, we opted to use the simpler stratified participant selection approach to provide greater transparency in the model's participant selection approach.

We also considered stratified random sampling of individual kidney

transplant hospitals using similar variables as those described in the preceding paragraph (89 FR 43543). Although this approach provided representativeness of sampled transplant hospitals along dimensions important for the model, it would be expected to result in a subset of eligible kidney transplant hospitals in at least a portion of DSAs being designated as participants. As we have described previously, we expect that allowing a portion of DSA kidney transplant hospitals to be model participants would result in an overstatement of the model's effects on kidney transplant volume and other outcomes of interest. As with the sampling approaches considered in the preceding paragraph, CMS' analyses indicated the IOTA Model would not be evaluable if stratified sampling of individual kidney transplant hospitals were used in participant selection for the reasons described previously.

As stated at 89 FR 43544 in the proposed rule, CMS expects that no additional participant selections would be made for the IOTA Model after its start date unless 10 percent or more of selected participants are terminated from the model during the model performance period. We stated that if this were to occur, we would address the selection of new participants in future rulemaking.

We sought comment on our proposed approach for selecting IOTA participants and on the alternative approaches considered, including perceived advantages and disadvantages of our proposed participant selection approach relative to alternatives.

The following is a summary of the comments received on our proposed approach for selecting IOTA participants, on the alternative approaches considered, including perceived advantages and disadvantages of our proposed participant selection approach relative to alternatives, and our responses:

Comment: Several commenters shared concerns about the participation selection method, with a commenter suggesting CMS would provide too short a notice of selection into the IOTA Model prior to the model start date and that this poses a challenge to smaller transplant programs. Additionally, a commenter shared a concern that the participant selection criteria highlights the significant variance in offer acceptance and transplant rates within DSAs, suggesting that it would be difficult to attribute outcome changes to the IOTA Model as a result.

Response: As described and finalized in section III.C.3.d(1) of this final rule, we proposed that CMS would notify IOTA participants of their selection to participate in the IOTA Model in a form and manner chosen by CMS, such as public notice and email, at least 3 months prior to the start of the model performance period. We believe this is in alignment with other Innovation Center models and an earlier notice would be provided if feasible. For these reasons, we are finalizing our proposal without modification.

Additionally, in section III.C.3.d(1) of this final rule, we described and finalized our approach for selecting IOTA participants to obtain a group of eligible kidney transplant hospitals that is representative of kidney transplant hospitals from across the country in terms of geography and kidney transplant volume. We proposed to stratify the DSAs into groups based on each DSA's Census Division and the total number of adult kidney transplants performed annually across all eligible kidney transplant hospitals in each DSA during the baseline years for the first PY. Selecting eligible kidney transplant hospitals from these groups of DSAs would ensure that the IOTA participants are representative of eligible kidney transplant hospitals from across the nation in terms of geography and the volume of adult kidney transplants.

A second aim of our proposal to select eligible kidney transplant hospitals from stratified groups of DSAs is to prevent distortions on the effects of the model's policies and features on outcomes. Our analysis of kidney transplant hospital data showed that selecting only some eligible kidney transplant hospitals within a selected DSA to participate in the IOTA Model may shift the supply of deceased donor organs from non-IOTA participants to IOTA participants within the same DSA. The resulting distortions would make it difficult to attribute changes in outcomes to the model and would limit its evaluability. As a result, we do not believe this would cause difficulty in attributing resulting impacts to the IOTA Model. For these reasons, we are finalizing our proposal without modification.

Comment: CMS received several comments and recommendations regarding participant selection for the IOTA Model. Specifically, commenters suggested CMS should modify the participant selection process in ways such as reconsidering the DSA as a quantifier, expanding the IOTA Model across all transplant programs, and providing eligible kidney transplant hospitals selected to participate in the IOTA Model more than a three-month notice prior to the start of the IOTA Model.

Response: We thank the commenters for their feedback and suggestions. We direct readers to section III.C.3.d(2) of this final rule for alternatives that we considered.

We believe that expanding accountability to kidney transplant hospitals and key stakeholders in the transplantation ecosystem for ESRD patients, aligns with the larger efforts across CMS and HRSA to improve performance and address disparities in kidney transplantation. As the most commonly transplanted organ, and its relationship with dialysis, of which Medicare is the primary payer, we believe focusing this model on kidney transplantation is prudent. Relatedly, as described in the proposed rule, we believe that it is necessary to include in the definition of kidney transplant those kidney transplants that occur in conjunction with other organ transplants to avoid creating a disincentive for multi-organ transplants within the IOTA Model (89 FR 43540).

Finally, regarding the comments we received about providing more than a three-month notice to eligible kidney transplant hospitals selected to participate in the IOTA Model, as described and finalized in section III.C.3.d(1) of this final rule, we proposed that CMS would notify IOTA participants of their selection to participate in the IOTA Model in a form and manner chosen by CMS, such as public notice and email, at least three months prior to the start of the model performance period. We believe this is in alignment with other Innovation Center models and an earlier notice would be provided if feasible. For these reasons, we are finalizing our proposal without modification at § 512.412(d).

Comment: Several commenters supported the use of stratified sampling in selecting IOTA participants. Specifically, several commenters supported the proposals to use DSAs, to group DSAs into Census Divisions, and to randomly select 50 percent of all eligible kidney transplant hospitals.

Response: We thank the commenters for their support.

Comment: In the context of the ETC Model, a commenter expressed concern that the use of stratified DSA sampling could penalize IOTA participants based on the DSA boundaries. Specifically, the commenter suggested that at times in the ETC Model, participants were penalized for circumstances that were largely based on zip code and compared to locales on the periphery of their DSA.

Response: As described and finalized in section III.C.3.c of this final rule, CMS will select approximately half of all DSAs nationwide using a stratified

sampling methodology, and all eligible kidney transplant hospitals in the selected DSAs will be required to participate in the IOTA Model. We proposed to stratify the DSAs into groups based on each DSA's Census Division and the total number of adult kidney transplants performed annually across all eligible kidney transplant hospitals in each DSA during the baseline years for the first PY (89 FR 43542). Within each Census Division group, we proposed to create two mutually exclusive groups of DSAs using the average number of adult kidney transplants performed annually across the baseline years for PY 1 (89 FR 43542). Selecting eligible kidney transplant hospitals from these groups of DSAs would ensure that the IOTA participants are representative of eligible kidney transplant hospitals from across the nation in terms of geography and the volume of adult kidney transplants. We recognize that kidney transplant hospitals in a DSA selected to participate in the IOTA Model could be adjacent to a DSA not selected to participate in the IOTA Model. The IOTA Model is looking to measure and test whether the provisions of the IOTA Model encourage more kidney transplants. We do not view this as potentially penalizing IOTA participants in close proximity to kidney transplant hospitals not participating in the IOTA Model. Rather, we believe this approach increases the ability to monitor performance improvements in metrics, such as an individual IOTA participants' transplant target or its organ offer acceptance rate ratio. It also helps us distinguish between DSAs and other similar geographical regions, ensuring accurate comparisons. For these reasons, we are finalizing our proposal without modification.

Comment: Several commenters asserted that the stratified sampling methodology should not use DSAs, as it could restrict organ allocation, and that average number of kidney transplants in a DSA does not provide a true representation of kidney transplant hospitals.

Response: We thank the commenters for their feedback and suggestions. We direct readers to section III.C.3.d(2) of this final rule for a full discussion of the alternatives that we considered. For these reasons, we will be finalizing our proposal without modification.

Comment: Several commenters expressed their concerns with the proposed stratified sampling methodology, suggesting that the proposed stratification may advantage transplant programs close to the low-volume threshold. A commenter specifically suggested CMS should revisit this low volume threshold across PYs, since the expectation is that the volume of kidney transplants performed would progressively increase for kidney transplant hospitals selected to participate in the IOTA Model.

Response: We thank the commenters for their feedback and recommendations. As described and finalized in section III.C.5.c(1) of this final rule, we proposed that the low volume threshold to be 11 kidney transplants performed for the purposes of calculating the national growth rate. We also proposed this approach for calculating the national growth rate to account for and reflect the growth in organ procurement by OPOs that has occurred, indicating potential growth in the number of available organs.

Specifically, as described and finalized in section III.C.5.c(1) of this final rule, we will calculate the national growth rate by determining the percent increase or decrease of all kidney transplants furnished to patients 18 years of age or older during the relevant baseline years, as described and finalized in section III.C.3.c of this final rule. We direct readers to section III.C.5.c(1) of this final rule for a full discussion on the calculation of the national growth rate.

Finally, as described in section III.C.3.d(2) of the proposed rule, we expect that no additional participant selections will be made for the IOTA Model after its start date unless 10 percent or more of selected participants are terminated from the model during the model performance period. If this were to occur, we will address the selection of new participants in future rulemaking and we may revisit the low volume threshold of 11 adult kidney transplants performed annually in each of the baseline years. We would not extend the model performance period of the IOTA Model. If we were to add any new model participants, the IOTA participants would participate in the model until the end of model performance period, as described and finalized in section III.C.1.a of this final rule. For these reasons, we will be finalizing our proposal without modification.

Comment: Several commenters requested that CMS provide clarification on the stratified sampling methodology. Specifically, how CMS would randomly select one DSA, the distinction between high transplant volume or low transplant volume groups, and the threshold for dividing DSAs by transplant volume.

Response: We thank the commenters for their feedback. As described and finalized in section III.C.3.d(1) of this final rule, for groups within a Census Division group that contain an odd number of DSAs, CMS would randomly select one DSA from the group. Each of these individual selected DSAs would have a 50 percent probability of being selected for the IOTA Model. For groups within a Census Division group that contain an odd number of DSAs, CMS would randomly select one DSA from the group and determine that individual DSA's chance of selection for inclusion in the IOTA Model with 50 percent probability. Following this step, each group within a Census Division group would have an even number of DSAs.

As described and finalized in section III.C.3.d(1) of this final rule, CMS would then randomly select 50 percent of remaining DSAs in each group. CMS would then take a random sample, without replacement, of 50 percent of the remaining DSAs in each group (the groups being DSAs having higher numbers of adult kidney transplants across the baseline years and DSAs having lower numbers of adult kidney transplants across the baseline years) within each Census Division group. All of the eligible kidney transplant hospitals located within the selected DSAs would be required to participate in the IOTA Model. For these reasons, we are finalizing our proposal without modification.

Comment: Several commenters recommended that CMS stratify kidney transplant hospitals based on their size and reassess the threshold separating low-volume and high-volume kidney transplant hospitals.

Response: As described in section III.C.3.d(2) of the proposed rule, we considered alternatives to the proposed participant selection methods. We believe selecting model participants by DSA significantly mitigates behavior that would artificially inflate the model's effects on kidney transplant volume for the reasons described in the preceding section. OPOs associated with selected DSAs would be expected to benefit from consistency in rules across most or all of their transplant hospitals.

We considered alternative variables to create DSA groups for stratified sampling of DSAs. One alternative consideration included stratifying DSAs by annual adult kidney transplants per eligible transplant hospital in DSA (89 FR 43543). This and other variables were given consideration in the stratified selection approach, however, we opted to use the simpler stratified participant selection approach to provide greater transparency in the

model's participant selection approach. We direct readers to section III.C.3.d(2) of this final rule for a full discussion of alternative participant selection approaches and variables that we considered.

Additionally, as described and finalized in section III.C.3.d(1) this final rule, two groups within each Census Division group would be: (1) DSAs having higher numbers of adult kidney transplants across the baseline years; and (2) DSAs having lower numbers of adult kidney transplants across the baseline years. Since the average number of adult kidney transplants would be different across each DSA, each Census Division group would have a different cut off to create these two groups. We believe this is an appropriate distinction between low-volume and high-volume kidney transplant hospitals. For these reasons, we will be finalizing our proposal without modification.

Comment: Multiple commenters suggested that CMS should establish control groups within the same geographical area in order to increase the ability to monitor performance improvements and distinguish within DSAs to ensure accurate comparisons.

Response: We thank the commenters for their feedback and suggestions. As described and finalized in section III.C.3.c of this final rule, CMS would select approximately half of all DSAs nationwide using a stratified sampling methodology, and all eligible kidney transplant hospitals in the selected DSAs would be required to participate in the IOTA Model. Selecting eligible kidney transplant hospitals from these groups of DSAs would ensure that the IOTA participants are representative of eligible kidney transplant hospitals from across the nation in terms of geography and the volume of adult kidney transplants. As described and finalized in section III.C.3.d(1) of this final rule, within each Census Division group, we would create two mutually exclusive groups of DSAs using the average number of adult kidney transplants performed annually across the baseline years for PY 1. CMS would separate DSAs assigned to a Census Division group into two mutually exclusive groups of DSAs based on the average number of adult kidney transplants performed annually across the baseline years for PY 1. We believe this approach increases the ability to monitor performance improvements and distinguish within DSAs and similar geographical areas to ensure accurate comparisons. For these reasons, we will be finalizing our proposal without modification.

After consideration of the public comments we received, we are finalizing our proposed provisions for the sampling methodology, participant selection process, and notifying IOTA participants of their selection to participate in the IOTA Model at §§ 512.412(b), 512.412(c) and 512.412(d) without modification. We are also finalizing as proposed the definition of donation service area (DSA) at § 512.402, with a minor technical correction to include the complete cross reference to subpart G.

4. Patient Population and Attribution

a. Proposed Attributed Patient Population

We proposed that the following patients who are alive at the time CMS conducts attribution would be attributed to an IOTA participant: (1) A kidney transplant waitlist patient, as defined in section III.C.4.a of this final rule, regardless of payer type and waitlist status, who is alive, 18 years of age or older, and is registered on a waitlist, as defined in section III.C.4.a of this final rule, to one or more IOTA participants, as identified by the OPTN computer match program (''IOTA waitlist patient''); and (2) A kidney transplant patient who receives a kidney transplant at the age of 18 years or older from an IOTA participant at any time during the model performance period (''IOTA transplant patient''). These patients would be referred to as IOTA waitlist patients and IOTA transplant patients, respectively, for purposes of assessing each IOTA participant's performance across the achievement domain, efficiency domain, and quality domain as discussed in section III.C.5 of this final rule. IOTA waitlist patients and IOTA transplant patients would factor into the model's performance-based payments to IOTA participants.

For the purpose of this model, we proposed to define ''waitlist'' as a list of transplant candidates, as defined in 42 CFR 121.2, registered to the waiting list, as defined in § 121.2, and maintained by a transplant hospital in accordance with 42 CFR 482.94(b). We proposed to define ''kidney transplant waitlist patient'' as a patient who is a transplant candidate, as defined in § 121.2, and who is registered to a waitlist for a kidney at one or more kidney transplant hospitals.

We understand that many patients on the waiting list are registered at multiple transplant hospitals. Therefore, we proposed attributing each of these waitlisted patients to every IOTA participant where they are registered on a waitlist during a given month in the applicable quarter. However, ''kidney transplant patient,'' defined as a patient who is a transplant candidate, as defined in § 121.2, and received a kidney transplant furnished by a kidney transplant hospital, regardless of payer type, would be attributed to the IOTA participant that furnished the kidney transplant.

We proposed attributing kidney transplant waitlist patients and kidney transplant recipients to IOTA participants for two reasons. First, we believe that by attributing these patients to IOTA participants it would ensure the full population of potential and actual kidney transplant candidates is represented when measuring participant performance. The waiting list captures most candidates except some living donor recipients. Transplant recipients include those who received deceased or living donor transplants. Second, because CMS is proposing to hold IOTA participants accountable for furnishing kidney organ transplants; focusing on kidney transplant waitlist patients and kidney transplant patients, and attributing them to IOTA participants, aligns with the model's goals of improving access to, and quality of, kidney transplantation, including post-transplant.

CMS proposed to determine an IOTA participant's performance across the achievement domain, efficiency domain, and quality domain based on all IOTA waitlist patients and IOTA transplant patients, regardless of payer type, as described in section III.C.5 of this final rule. That is, an IOTA participant's performance in terms of both Medicare beneficiaries and non-Medicare patients would be used to determine whether the IOTA participant would receive an upside risk payment from CMS, or owe a downside risk payment to CMS. As described in section III.C.6.c(2) of this final rule, demand for kidney transplants far exceeds supply, raising concerns that if the IOTA Model were limited to Medicare beneficiaries only, the model may inadvertently incentivize inappropriate diversion of donor organs to Medicare beneficiaries to improve their performance in the model, thereby limiting access to non-Medicare beneficiaries and potentially disincentivizing pre-emptive kidney transplants for patients not already covered by Medicare because their CKD has not progressed to ESRD. We believe that the change in care patterns that IOTA participants may undertake to be successful in the IOTA Model are unlikely to apply solely to Medicare beneficiaries under their care.

We considered limiting IOTA waitlist patients and IOTA transplant patients to Medicare beneficiaries only, as Medicare covers more than 50 percent of all kidney transplants from both deceased and living donors. However, we believe it is necessary to include all patients, regardless of payer type, in the IOTA participant's performance calculations to protect against unintended consequences and problematic financial incentives. Moreover, the group of eligible waitlist and transplant patients that would be attributed to each IOTA participant is already relatively small, both in terms of transplant candidates and transplant recipients. Limiting the IOTA Model performance assessment, as described in section III.C.5.b of this final rule, to Medicare beneficiaries would further limit the patient sample size, potentially affecting our ability to detect changes in performance due to model payments. Therefore, we proposed that the IOTA Model reflect both Medicare beneficiaries and non-Medicare patients for performance assessment, with Medicare beneficiaries just being a subset of the patient population attributed to each model participant.

We sought public comment on our proposals to include: (1) all kidney transplant waitlist patients, regardless of payer type and waitlist status, who are alive, 18 years of age or older, and registered on a waitlist to an IOTA participant, as identified by the OPTN computer match program; and (2) all kidney transplant patients who receive a kidney transplant, at 18 years of age or older, from an IOTA participant at any time during the model performance period, in each IOTA participant's population of attributed patients. We also sought public comment on our proposal to attribute IOTA waitlist patients and IOTA transplant patients, respectively, to IOTA participants for the purposes of assessing each IOTA participant's performance across the achievement domain, efficiency domain, and quality domain, and to determine performance-based payments to and from IOTA participants.

The following is a summary of the comments received and our responses:

Comment: We received several comments in support for the proposed attributed patient population, including the all-payer attribution approach and to allow patients to have multiple attributions when on the waitlist for one or more transplant hospitals, as this provision ensures the most patients can benefit from the model.

Response: We thank the commenters for their support.

Comment: We received a comment requesting CMS clarify if multi-organ transplants would be counted the same as single organ kidney transplants.

Response: We thank the commenter for their feedback. As described in section III.B.3.c of the proposed rule, the vast majority of kidney transplants are performed alone. However, we believe that it is necessary to include in the definition of kidney transplant those kidney transplants that occur in conjunction with other organ transplants to avoid creating a disincentive for multi-organ transplants within the IOTA Model. As defined at § 512.402, kidney transplant means the procedure in which a kidney is surgically transplanted from a living or deceased donor to a transplant recipient, either alone or in conjunction with any other organ(s).

Comment: We received a comment suggesting CMS should monitor for unintended consequences, such as systemic biases, as a result of including all payer types among attributed patients.

Response: We thank the commenter for their suggestion. We direct readers to comment responses noted previously for further discussion. For these reasons, we are finalizing our proposal without modification.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing these provisions at § 512.414 with slight modification. Specifically, we are modifying the regulatory text at § 512.414(a)(1)(iii) to specify determining performance-based payments paid to or by IOTA participants. We did not receive any comments on the proposed definition of IOTA waitlist patient, kidney transplant waitlist patient, kidney transplant patient or waitlist and therefore are finalizing these definitions without modification at § 512.402. We are also making a minor technical correction to the proposed definition of IOTA transplant patient at § 512.402 to update the cross reference. Specifically, we are removing the cross reference to § 512.412(b)(2) and replacing it with § 512.414(b)(2). As such, we are finalizing the definition of IOTA transplant patient at § 512.402 to mean a kidney transplant patient who receives a kidney transplant at the age of 18 years of age or older from an IOTA participant at any time during the model performance period and meets the criteria set forth in § 512.414(b)(2).

b. Patient Attribution Process

As described in section III.C.4.a of this final rule, we proposed to define ''attribution'' as the process by which CMS identifies patients for whom each IOTA participant is accountable during the model performance period. CMS would identify and assign a set of Medicare and non-Medicare patients to the IOTA participant through attribution. We proposed to define ''attributed patient'' as an IOTA waitlist patient or an IOTA transplant patient, as described in section III.C.4.a of this final rule. We proposed that a patient may not opt out of attribution to an IOTA participant under the model.

Section III.C.4.b(1) of this final rule outlines in more detail the attribution criteria to identify attributable kidney transplant waitlist patients and kidney transplant patients during initial attribution, quarterly attribution, and at annual attribution reconciliation using Medicare claims data, Medicare administrative data, and OPTN data. In advance of the model start date, we proposed to attribute patients to IOTA participants through an initial attribution process described in section III.C.4.b(2) of this final rule; quarterly attribution would be conducted thereafter to update the patient attribution list, as described in section III.C.4.b(3) of this final rule, to include the dates in which patient attribution changes occur. After the fourth quarter of each PY, we proposed to finalize each IOTA participant's annual attribution reconciliation list for that PY, including removing certain attributed patients, as described in section III.C.4.b(4) of this final rule. We proposed that once a patient is attributed to an IOTA participant, that attributed patient would remain attributed to the IOTA participant for the duration of the model, unless the patient is removed from the IOTA participant's list of attributed patients during the annual attribution reconciliation process, as described in section III.C.4.b(4) of this final rule.

We also considered proposing that once a patient is attributed to an IOTA participant, either through the initial attribution process or through quarterly attribution, that the patient would remain attributed only through the end of the PY. Initial attribution would then occur prior to the beginning of each PY. However, we choose to align with the attribution processes of our other kidney models to simplify operations.

We proposed to identify kidney waitlist patients and kidney transplant patients using SRTR data, OPTN data, Medicare claims data, and Medicare administrative data.

We sought comment on our patient attribution process proposals and alternatives considered.

The following is a summary of the comments received on our proposed patient attribution process proposals and alternatives considered and our responses:

Comment: We received several comments requesting clarity from CMS on certain categories of attributed patients, as well as seeking clarity on what CMS defines as an attributed patient. Specifically, we received comments requesting CMS to clarify if any patients are excluded from calculations related to the IOTA Model in the context of kidney/pancreas candidates and others such as those with a high panel reactive antibody test, re-transplanted patients, or safety-net kidney recipients.

Response: As described and finalized in section III.C.4.b of this final rule, we define attributed patient as an IOTA waitlist patient or an IOTA transplant patient. As described and finalized in section III.C.4.a of this final rule, an IOTA waitlist patient is a kidney transplant waitlist patient, as defined and finalized in section III.C.4.a of this final rule, regardless of payer type and waitlist status, who is alive, 18 years of age or older, and is registered on a waitlist, as defined and finalized in section III.C.4.a of this final rule, to one or more IOTA participants, as identified by the OPTN computer match program; and an IOTA transplant patient is a kidney transplant patient who receives a kidney transplant at the age of 18 years or older from an IOTA participant at any time during the model performance period.

Additionally, as described and finalized in section III.C.5.d(1)(a) of this final rule, we proposed to use and calculate the OPTN organ offer acceptance rate ratio in accordance with OPTN's measure specifications and SRTR's methodology as the metrics that would determine IOTA participants' performance on the efficiency domain outlined in equation 1 in paragraph (b)(1) of § 512.426. As it pertains to kidney/pancreas candidates, included in this organ offer acceptance ratio are offers to candidates on a single organ waitlist (except for kidney/pancreas candidates that are also listed for kidney alone). Excluded from this measure are offers to multi-organ candidates (except for kidney/pancreas candidates that are also listed for kidney alone).

In addition, paragraph (b)(1) at § 512.428 describes the composite graft survival rate equation used in determining the IOTA participant's quality domain score. As it pertains to kidney/pancreas candidates and re-transplant candidates, CMS excludes them from the numerator when calculating the composite graft survival rate.

As proposed, we do not exclude any patients with high panel reactive antibody tests or safety-net kidney recipients from IOTA Model measures. For these reasons, we are finalizing our proposal without modification.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing the patient attribution process at § 512.414(a) and the definitions of attribution and attributed patient at § 512.402 as proposed without modification.

(1) Attribution and De-attribution Criteria

(i) IOTA Waitlist Patient Attribution

We proposed that kidney transplant waitlist patients would be attributed as IOTA waitlist patients to one or more IOTA participants based on where the patient is registered on a kidney transplant waitlist, regardless of payer type and waitlist status, as identified by the OPTN computer match program. We proposed that CMS would conduct attribution on a quarterly basis, before each quarter of the model performance period. CMS is proposing to attribute a kidney transplant waitlist patient as an IOTA waitlist patient to an IOTA participant if the patient meets all of the following criteria:

- The patient is registered to one or more IOTA participant's kidney transplant waitlist during a month in the applicable quarter.
- The patient is 18 years or older at the time of attribution.
- The patient is alive at the time of attribution.

For purposes of attributing IOTA waitlist patients to IOTA participants, the proposed criteria must be met on the date that CMS runs attribution, as described in section III.C.4.b(1)(i) of this final rule.

As described in section III.C.4.b(1) of this final rule, a kidney transplant waitlist patient may be registered to more than one waitlist, which is why we proposed to attribute kidney transplant waitlist patients as IOTA waitlist patients to IOTA participants in a way that accurately reflects their waitlist registrations. A kidney transplant hospital should be actively engaged in coordinating the transplant process for kidney transplant waitlist patients on their waitlist, as they are responsible for accepting donor organs and furnishing transplants. As such, if a kidney transplant waitlist patient is registered on the waitlist of multiple IOTA participants, CMS would attribute that kidney transplant waitlist patient as an IOTA waitlist patient to all of the IOTA participants that have the kidney transplant waitlist patient on their waitlists.

We alternatively considered limiting IOTA waitlist patient attribution to only one IOTA participant based on ''active'' waitlist status. That is, the IOTA waitlist patient would be attributed to each IOTA participant where the patient is registered to a kidney transplant waitlist with an ''active'' status in a given quarter. A kidney transplant hospital designates patients on its waitlist with an ''active'' status to signal their readiness to receive a donor kidney offer when one becomes available. However, we anticipate that there would be operational challenges if CMS were to base patient attribution on waitlist ''active'' status, as doing so would require real-time and accurate information regarding each patient's waitlist status. There may be a time delay when changing a waitlist status from provisionally inactive to active once minor issues have been resolved. A kidney transplant waitlist patient may be made inactive or ineligible to receive an organ offer if, for example, they have an incomplete transplant evaluation to assess medical readiness, their BMI exceeds the transplant hospital's established threshold, due to infection or patient choice, or because of complications presented by other medical issues. Additionally, due to our inability to recognize differences in the contributions between kidney transplant hospitals in maintaining a patient's transplant readiness, we believe attributing kidney transplant waitlist patients as IOTA waitlist patients to all the IOTA participants where a kidney transplant waitlist patient is registered is the most appropriate approach to IOTA waitlist patient attribution, regardless of waitlist status.

As indicated in section III.C.3.c of this final rule, we are only proposing to include non-pediatric facilities as eligible participants in the IOTA Model. In alignment with this proposal, we proposed to exclude pediatric patients under 18 years of age from the population of attributed patients. According to national data from the OPTN, children under the age of 18 make up a small proportion of the kidney transplant candidates registered on the waiting list. However, pediatric patients have greater access to both deceased and living donor kidney transplant relative to adults. Pediatric patients under 18 years of age are also infrequently the recipient of organs at

high risk for non-use.[187] Thus, CMS did not propose to include pediatric patients under the age of 18 as part of the population that would be identified and attributed to IOTA participants. We alternatively considered including pediatric patients under the age of 18 in the IOTA Model patient population, but believe focusing on adults, given their unique challenges accessing kidney transplants, is a priority.

The waiting list often has a delay between when a patient's waitlist status changes and when that change is reflected in the data. For example, patients who have died are ineligible for transplant and must be removed from the waiting list, but there may be a time delay between a patient's death and their removal. Thus, we proposed to limit IOTA waitlist patient attribution to patients who are alive at the time of attribution.

We sought comment on our proposed criteria for identifying and attributing kidney transplant waitlist patients to one or more IOTA participants and alternatives considered.

The following is a summary of the comments received on our proposed criteria for identifying and attributing kidney transplant waitlist patients to one or more IOTA participants and alternatives considered and our responses:

Comment: A commenter recommended CMS change the proposed definition of a pediatric transplant to include a transplant performed on a patient who may be 18 years or older, but was listed on the kidney transplant waiting list prior to age 18. Specifically, a commenter recommended this change in definition because the commenter thought that its preferred definition would satisfy existing industry standards and better reflect the nature of a pediatric patient who may not receive a transplant until after turning 18 years old, but could remain under the care of a pediatric transplant program.

Response: We thank the commenter for their suggestion; however, we disagree as we did not propose to define a pediatric transplant. At 89 FR 43544 of the proposed rule, we proposed to define an IOTA transplant patient as a kidney transplant patient who receives a kidney transplant at the age of 18 years or older from an IOTA participant at any time during the model performance period. As we are including only non-pediatric facilities in our definition of eligible kidney transplant hospitals, as described and finalized in section III.C.3.c of this final rule, we believe that those that are listed prior to the age of 18 under the care of a pediatric facility would not be included in our definition of an IOTA transplant patient. Therefore, we will be finalizing our proposed definition of IOTA transplant patient without modification.

Comment: A commenter expressed support for CMS's proposal to attribute kidney transplant waitlist patients to one or more IOTA participants based on where the patient is registered on a kidney transplant waitlist.

Response: We thank the commenter for their support.

Comment: We received a comment voicing concern with the proposed IOTA waitlist patient and patient attribution process in that it could create competition among transplant hospitals due to the cross-listing of patients.

Response: We thank the commenter for their feedback. As described in section I.B.2.a of this final rule, we proposed that the IOTA Model would test whether performance-based incentive payments paid to or owed by participating kidney transplant hospitals increase access to kidney transplants for patients with ESRD while preserving or enhancing the quality of care and reducing Medicare expenditures. Specifically, we proposed to test whether performance based incentives (including both upside and downside risk) for participating kidney transplant hospitals can increase the number of kidney transplants (including both living donor and deceased donor transplants) furnished to ESRD patients, encourage investments in care processes and patterns with respect to patients who need kidney transplants, encourage investments in value-based care and improvement activities, and promote kidney transplant hospital accountability by tying payments to value. We believe a cross-listing of patients through the IOTA waitlist patient and patient attribution process is beneficial for patients and increases their likelihood of receiving a transplant. For these reasons, we are finalizing our proposal without modification.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed criteria for identifying and attributing kidney transplant waitlist patients as IOTA waitlist patients to one or more IOTA participants at § 512.414(b)(1) without modification.

(ii) IOTA Transplant Patient Attribution

We proposed that kidney transplant patients would be attributed as IOTA transplant patients to the IOTA participant that furnished a kidney transplant during the model performance period, if they meet the following criteria:

- The patient was 18 years of age or older at the time of their transplant; and
- The patient was alive at the time of attribution.

We note that an IOTA transplant patient who experiences transplant failure and is then de-attributed from an IOTA participant, as described in section III.C.4.b(1)(iii) of this final rule, could become attributed to an IOTA participant again at any point during the model performance period if they rejoined a kidney transplant waitlist for, or received a kidney transplant from, any IOTA participant and satisfied all of the criteria for attribution as described in section III.C.4.b(1)(i) or section III.C.4.b(1)(ii) of this final rule.

We proposed to attribute kidney transplant patients to the IOTA participant that furnished the transplant to hold the IOTA participant accountable for patient transplant and post-transplant outcomes. We alternatively considered attributing kidney transplant patients based on the plurality of post-transplant services, as identified in Medicare claims, because it would still result in attributing kidney transplant patients to only one IOTA participant and would base attribution on where the majority of services were furnished. We recognize that patients may choose to receive their pre-and post-transplant care from multiple IOTA participants in addition to the IOTA participant that performed their kidney transplant. However, the model's incentives do not support shifting accountability for post-transplant outcomes away from the IOTA participant that furnished the transplant. We believe that the IOTA participant that performed the transplant should remain accountable for any surgery related outcomes, both successes and failures.

We proposed not to attribute patients who are younger than 18 years of age at the time of their kidney transplant or who are deceased at the time of attribution due to the same reasons described in section III.C.4.b(1)(i) of this final rule.

We sought comment on our proposed criteria for identifying and attributing kidney transplant patients as IOTA

[187] Lentine, K.L., Smith, J.M., Miller, J.M., Bradbrook, K., Larkin, L., Weiss, S., Handarova, D.K., Temple, K., Israni, A.K., & Snyder, J.J. (2023). OPTN/SRTR 2021 Annual Data Report: Kidney. American journal of transplantation: official journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 23(2 Suppl 1), S21–S120. *https://doi.org/10.1016/j.ajt.2023.02.004.*

transplant patients to the IOTA participant that furnished their kidney transplant during the model performance period. We also sought comment on the alternative considered.

We received no comments on this proposal and therefore are finalizing the provisions for our proposed criteria for identifying and attributing kidney transplant patients as IOTA transplant patients to the IOTA participant that furnished their kidney transplant during the model performance period at § 512.414(b)(2) as proposed without modification.

(iii) De-Attribution Criteria

We proposed that CMS would only de-attribute attributed patients from an IOTA participant during annual attribution reconciliation, as described in section III.C.4.b(4) of this final rule. We proposed that CMS would de-attribute any attributed patient from an IOTA participant that meets any of the following criteria as of the last day of the PY being reconciled, in accordance with the annual attribution reconciliation list as described in section III.C.4.c of this final rule:

- The IOTA waitlist patient was not registered on an IOTA participant's kidney transplant waitlist on the last day of the PY being reconciled.
- The IOTA waitlist patient died at any point during the PY. We proposed that an IOTA waitlist patient who has died during the PY would be removed from the list of attributed IOTA waitlist patients effective on the last day of the PY that the death occurred.
- The IOTA transplant patient has died at any point during the PY. We proposed that an IOTA transplant patient who has died during the PY would be de-attributed from the list of attributed IOTA transplant patients effective on the last day of the PY that the death occurred.
- The IOTA transplant patient's kidney failed during the PY, and the patient is not included on the IOTA participant's waitlist. We proposed that an IOTA transplant patient who experiences transplant failure at any point during the PY and does not rejoin an IOTA participant's kidney transplant waitlist or receive another transplant from an IOTA participant before the last day of the same PY would be listed as de-attributed in the annual attribution reconciliation list. This IOTA transplant patient would no longer be attributed to the IOTA participant effective the last day of the PY in which the IOTA transplant patient's kidney transplant has failed.

We sought comment on our proposed methodology and criteria for identifying and de-attributing attributed patients from an IOTA participant.

The following is a summary of the comments received on our proposed methodology and criteria for identifying and de-attributing attributed patients from an IOTA participant and our responses:

Comment: A commenter expressed support for CMS's proposed de-attribution criteria.

Response: We thank the commenter for their support.

Comment: A commenter requested more information about the source of the data that would be used to verify the graft loss or death.

Response: We thank the commenter for their feedback. As noted in section V.C of the proposed rule, the SRTR data source includes data on all transplant donors, candidates, and recipients in the U.S. As described in the proposed rule, section III.C.4.b of the proposed rule outlines our proposal to use of SRTR data, OPTN data, Medicare claims data, and Medicare administrative data for the purposes of the IOTA Model. Additionally, section III.C.5.e(1) of this final rule describes and finalizes our proposal to use of OPTN follow-up forms to identify graft failure and re-transplant dates. We acknowledge that for the purposes of measuring graft survival using OPTN data, use of either concept would generate the same outcome measurement because OPTN data identify graft status as either functioning or failed. However, we aim to convey the importance of ongoing management to preserve the health of the transplanted graft and the health and quality of life of the attributed patients.

Finally, as described and finalized in section III.C.13.a of this final rule, we proposed that CMS, or its approved designees, would conduct compliance monitoring activities to ensure compliance by the IOTA participant and IOTA collaborators with the terms of the IOTA Model, including to understand IOTA participants' use of model-specific payments and to promote the safety of attributed patients and the integrity of the IOTA Model. One proposed monitoring activity would include audits of claims data, quality measures, medical records, and other data from the IOTA participant and its IOTA collaborators. For these reasons, we are finalizing our proposal without modification.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed methodology and criteria for identifying and de-attributing attributed patients from an IOTA participant at § 512.414(b)(3), as proposed without modification.

(2) Initial Attribution

We proposed that before the model start date, CMS would conduct an ''initial attribution'' to identify and prospectively attribute waitlist patients to an IOTA participant pursuant to § 512.414. The list of IOTA waitlist patients identified through initial attribution, namely the initial attribution list, would prospectively apply to the first quarter of PY 1, effective on the model start date. The purpose of this initial attribution list would be to prospectively provide IOTA participants with a list of their IOTA waitlist patients for the upcoming quarter.

We considered attributing patients to IOTA participants at different points in time, such as the day that a kidney transplant waitlist patient was added to the IOTA participant's kidney transplant waitlist, or the day that a kidney transplant patient received their kidney transplant. This approach would be more precise than considering all attributed patients to be attributed as of the start of the quarter. However, due to the limitations of data sources and the frequency with which these data are updated, we did not see this as a viable alternative.

We sought comment on our proposal to conduct initial attribution before the model start date and alternatives considered.

We received no comments on this proposal and therefore are finalizing the provisions as proposed without modification at § 512.414(c)(1) and the definition of initial attribution at § 512.402, without modification.

(3) Quarterly Attribution

We proposed that CMS would attribute patients to IOTA participants in advance of each quarter, after initial attribution, and distribute a ''quarterly attribution list'' to each IOTA participant that includes all their attributed patients, including newly attributed patients, on a quarterly basis throughout the model performance period, except in the event of termination as described in section III.C.16(b) of this final rule.

We considered monthly attribution for more frequent updates to the initial attribution list, but believe it would be operationally burdensome. We also considered annual attribution for less frequent updates to the initial attribution list, which would be less operationally burdensome than monthly or quarterly attribution. Annual attribution is common in other

Innovation Center models and CMS programs where the participant is managing total cost of care for a population. The benefits of annual attribution would include prospectively providing participants a stable list of patients for whom they would be held accountable, and, as the process would occur only once a year, would be associated with lower administrative burden. The downside of annual attribution, however, is that IOTA participants would have less frequent updates and understanding of their attributed population, potentially making it hard to plan and budget accordingly. We do not believe annual attribution would be appropriate for the IOTA Model's goal of improving access to kidney transplants and quality of care for a patient population that changes frequently. For example, kidney transplant hospitals add patients to their kidney transplant waitlist throughout the year. Were we to limit attribution to once a year, kidney transplant waitlist patients added during the year would not be attributed to an IOTA participant until the following year, delaying our ability to meet the minimum number of patients required to evaluate a model test. As such, we believe more frequent attribution would be necessary.

We sought comment on our proposal to conduct attribution on a quarterly basis during the model performance period and on the alternatives considered.

The following is a summary of the comments received on our proposal to conduct attribution on a quarterly basis during the model performance period and on the alternatives considered and our responses:

Comment: Several commenters voiced their support for the proposed quarterly attribution provisions, stating that it would ensure accuracy and fairness.

Response: We thank the commenters for their support.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed quarterly attribution provisions at § 512.414(c)(2), without modification. We received no comments on the proposed definition of quarterly attribution list and there are finalizing this definition without modification at § 512.402.

(4) Annual Attribution Reconciliation

We proposed that after the end of each PY, CMS would conduct annual attribution reconciliation. We proposed to define ''annual attribution reconciliation'' as the yearly process by which CMS would: (1) create each IOTA participant's final list of attributed patients for the PY being reconciled by retrospectively de-attributing from each IOTA participant any attributed patients that satisfied a criterion for de-attribution pursuant to § 512.414(c); and (2) create a final list of each IOTA participant's attributed patients who would remain attributed for the PY being reconciled, subject to the attribution criteria in §§ 512.414(b)(1) and (2). For the purposes of this model, we proposed to define ''annual attribution reconciliation list'' as the final cumulative record of attributed patients that would be generated annually for whom each IOTA participant was accountable for during the applicable PY.

For example, after PY 1, CMS would rerun attribution for the entire PY to finalize the list of attributed patients that met the criteria specified in sections III.C.4.b(1) and (2) of this final rule. Once the fourth quarter is complete, CMS would use the fourth quarter attribution list to determine and de-attribute any attributed patients that meet a criterion for de-attribution, as described in section III.C.4.b(1)(iii) of this final rule, from the IOTA participant, as described in section III.C.4.b(1)(iii) of this final rule, and remove those attributed patients from the quarterly attribution list to create the annual attribution reconciliation list. Before the second quarter of the following PY, CMS would distribute the annual attribution reconciliation list to IOTA participants. We proposed that these lists, at a minimum, would identify each attributed patient, identify reasons for de-attribution in the previous PY, and the dates in which attribution began, changed, or ended, where applicable.

We sought comment on our proposal to conduct annual attribution reconciliation.

The following is a summary of the comments received on our proposal to conduct annual attribution reconciliation and our responses:

Comment: Several commenters expressed support for CMS's proposal to conduct annual attribution reconciliation.

Response: We thank the commenters for their support.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing the policy for annual attribution reconciliation as proposed in § 512.414(c)(3), with a minor technical correction to update the cross references in the regulation text at §§ 512.414(c)(3)(ii)(A) and 512.414(c)(3)(ii)(C–F). We are also finalizing the definitions of annual attribution reconciliation and annual attribution reconciliation list at § 512.402 without modification.

c. IOTA Patient Attribution Lists

We proposed that no later than 15 days prior to the start of the first model performance period, CMS would provide the IOTA participant the ''initial attribution list.'' For the purposes of the model, we proposed to define ''days'' as calendar days, as defined in 42 CFR 512.110, unless otherwise specified by CMS. On a quarterly basis thereafter, CMS would provide the IOTA participant the ''quarterly attribution list'' no later than 15 days prior to the start of the next quarter. The annual attribution reconciliation list for a given PY would be provided to the IOTA participants after the conclusion of the PY, before the second quarter of the following PY.

We proposed that the initial, quarterly, and annual attribution reconciliation lists would be provided in a form and manner determined by CMS.

We sought comment on our proposed attribution list policies.

The following is a summary of the comments received on our proposed attribution list policies and our responses:

Comment: Several commenters requested that CMS provide the patient attribution lists be provided well in advance of the performance period to allow IOTA participants to prepare accordingly and assess performance impacts. Specifically, a commenter suggested providing attribution lists at least one quarter in advance of the start of the performance period.

Response: We thank the commenters for their feedback. As described and finalized in section III.C.4.c of this final rule, we proposed that 15 days prior to the start of the first model performance period, CMS would provide the IOTA participant the initial attribution list. On a quarterly basis thereafter, CMS would provide the IOTA participant the quarterly attribution list no later than 15 days prior to the start of the next quarter. The annual attribution reconciliation list for a given PY would be provided to the IOTA participants after the conclusion of the PY, before the second quarter of the following PY. This sequence for patient attribution lists follows the same pattern as other Innovation Center models—such as the KCC Model—and, therefore, we are finalizing this provision without modification.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing, as proposed, our provisions at §§ 512.414(c)(1)(ii),

512.414(c)(2)(ii), 512.414(c)(3)(ii) and the definition of days at § 512.402 without modification.

5. Performance Assessment

a. Goals and Proposed Data Sources

As described in section III.B. of the proposed rule, CMS and the OPTN each have roles in assessing the performance of kidney transplant hospitals. CMS' regulations in 42 CFR part 482 subpart E require certain conditions of participation for kidney transplant hospitals to receive approval to perform Medicare transplant services. Under 42 CFR part 121, the OPTN is required to implement a peer review process by which OPOs and transplant hospitals are periodically reviewed for compliance with the bylaws of the OPTN and the OPTN final rule (63 FR 16332). The OPTN MPSC is charged with performing these evaluations; including the identification of threats to patient safety and public health.[188]

As described in section III.C.5.a. of the proposed rule, CMS and the OPTN have each acknowledged the limitations of transplant hospital performance assessment based on the one-year patient and transplant survival measure alone. In 2018, CMS eliminated its assessment of one year patient and transplant survival for the purposes of transplant hospital re-approval in the final rule, ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51732), leaving assessment of the one year patient and transplant survival measure only for initial Medicare approval, due to concerns that the measure was causing conservative behavior in transplant hospitals.[189] In 2021, the OPTN disseminated a proposal to enhance the MPSC's performance monitoring process by expanding the number of measures used to identify transplant hospital underperformance.[190] In that proposal, the OPTN acknowledged the potential for transplant hospital risk aversion due to the MPSC's evaluations of performance based on the one year patient and transplant survival metric alone and proposed transplant hospital assessment based on a holistic set of measures encompassing aspects of care across the transplant journey.[191]

As described in section III.C.5.a. of the proposed rule, strengthening and improving the performance of the organ transplantation system is a priority for HHS, including CMS and HRSA. In accordance with this priority and joint efforts with HRSA, the IOTA Model would aim to improve performance and equity in kidney transplantation by testing whether performance-based payments to IOTA participants increases access to kidney transplants for kidney transplant waitlist and kidney transplant patients attributed to IOTA participants in the model, thereby reducing Medicare program expenditures while preserving or enhancing quality of care. For the IOTA Model, we proposed a broader set of metrics which aligns with the trends that we believe would encourage IOTA participants to meet the model goals as described in section III.A of this final rule.

As described in section III.C.5.a of the proposed rule, the IOTA Model would assess performance on a broad set of metrics that were selected to align with all of the following model goals:

- Increase number of, and access to, kidney transplants.
- Improve utilization of available deceased donor organs.
- Support more donors through the living donation process.
- Improve quality of care and equity.

In section III.C.5.a of the proposed rule, we proposed using Medicare claims and administrative data about beneficiaries, providers, suppliers, and data from the OPTN, which contains comprehensive information about transplants that occur nationally, to measure IOTA participant performance in the three model domains: (1) achievement domain; (2) efficiency domain; and (3) quality domain. Medicare administrative data refers to non-claims data that Medicare uses as part of regular operations. This includes information about beneficiaries, such as enrollment information, eligibility information, and demographic information. Medicare administrative data also refers to information about Medicare-enrolled providers and suppliers, including Medicare enrollment and eligibility information, practice and facility information, and Medicare billing information.

We solicited comment on our proposal for selecting performance metrics and performance domains. We also solicited comment on our proposed use of Medicare claims data, Medicare administrative data, and OPTN data to calculate the performance across the three proposed domains, as described in section III.C.5. of this final rule.

The following is a summary of comments received on our proposal for selecting performance metrics and performance domains, in addition to our proposed use of Medicare claims data, Medicare administrative data, and OPTN data to calculate the performance across the three proposed domains and our responses:

Comment: A commenter conveyed their concern that the OPO and transplant performance metrics are misaligned and as a result will minimize the impact of the IOTA Model.

Response: We appreciate the commenter's feedback; however, we do not believe that it is appropriate to directly compare the performance metrics of OPOs and kidney transplant hospitals. Both OPOs and kidney transplant hospitals have unique roles in the transplant ecosystem, requiring different focuses, skills sets and responsibilities. We acknowledge the different responsibilities of these two parties along the continuum of care for organ transplantation. Overall, performance metrics, are meant to understand current state, to set goals to create improvement, to ensure unintended consequences of changes are identified, and to allow for analysis and evaluation to pivot and modify metrics when appropriate. With overarching goals to improve kidney transplant volume while maintaining quality organs and patient care, we believe that HRSA and CMS do not have misaligned goals.

Comment: A few commenters stated that they believe the three domains will lead to a successful solution and are acceptable.

Response: We appreciate the commenters' support. We believe that including the achievement, efficiency and quality domain are an ideal combination to ensure that while IOTA participants are increasing kidney transplants, we are also monitoring acceptance patterns and post-transplant outcomes.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing the proposed provisions for selecting performance metrics and performance domains at § 512.422(a), without modification. We did not receive any comments regarding

[188] *https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/.*

[189] *https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/* and Burden Reduction. **Federal Register**. *https://www.federalregister.gov/d/2018-19599/p-215.*

[190] *https://optn.transplant.hrsa.gov/media/4777/transplant_program_performance_monitoring_public_comment_aug2021.pdf.*

[191] *Ibid.*

our proposed use of Medicare claims data, Medicare administrative data, and OPTN data to calculate the performance across the three proposed domains and therefore are finalizing this provision without modification at § 512.422(b).

b. Method and Scoring Overview

In accordance with our proposed goals of the IOTA performance assessment, as described in section III.C.5.a of the proposed rule, we proposed to assess performance across three domains: (1) achievement domain; (2) efficiency domain; and (3) quality domain. We proposed to use one or more metrics within each domain to assess IOTA participant performance. We proposed at § 512.422(a)(2) that CMS would assign each set of metrics within a domain a maximum point value, with the total possible points awarded to an IOTA participant being 100 points. We proposed to define ''final performance score'' as the sum total of the scores earned by the IOTA participant across the achievement domain, efficiency domain, and quality domain for a given PY. We also proposed that the combined sum of total possible points would determine whether and how the IOTA Model performance-based payments, as described and finalized in section III.C.6.c of this final rule, would apply and be calculated. We proposed the following point allocations for each of these three domains:

- The achievement domain would make up 60 of 100 maximum points. The achievement domain would measure the number of kidney transplants performed relative to a participant-specific target, as described in section III.C.5.c of the proposed rule. The achievement domain would represent a large portion (60 percent) of the maximum total performance score. We weighted the achievement domain performance score more than the efficiency and quality domain because we believe it aligns with the primary goal of the IOTA Model, to increase the overall number of kidney transplants. Additionally, because increasing the number of kidney transplants performed is the primary goal of the model, we believe weighing performance on this measure more than the efficiency domain and quality domain is necessary to directly incentivize participants to meet their target.
- The efficiency domain would make up 20 of 100 maximum points. The efficiency domain would measure performance on a kidney organ offer acceptance rate ratio, as described in section III.C.5.d of the proposed rule.
- The quality domain would make up 20 of 100 maximum points. As described in section III.C.5.e. of the proposed rule, the quality domain would measure performance on a set of quality metrics, including post-transplant outcomes, and on three proposed quality measures—CollaboRATE Shared Decision-Making Score, Colorectal Cancer Screening, and 3-Item Care Transition Measure.

We believed that many prospective IOTA participants may already be familiar with the approach of assigning points up to a maximum in multiple domains. This structure is similar to other CMS programs, including the Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program. For MIPS, we assess the performance of MIPS eligible clinicians (as defined in 42 CFR 414.1305) across four performance categories—one of which is quality—and then determine a positive, neutral, or negative MIPS payment adjustment factor that applies to the clinician's Medicare Part B payments for professional services. Similar to MIPS, we proposed that the IOTA Model would use a performance scoring scale from zero to 100 points across performance domains, and apply a specific weight for each domain. We believed using wider scales of 0 to 100 points would allow us to calculate more granular performance scores for IOTA participants and provide greater differentiation between IOTA participants' performance. In the future, we believed this methodology for assessing performance could be applied with minimal adaptation to future IOTA participants if CMS adds other types of organ transplants to the model through rulemaking. We believed that the approach of awarding points in the achievement, efficiency, and quality domains for a score out of 100 points represented the best combination of flexibility and comparability that would allow us to assess participant performance in the IOTA Model.

As discussed in section III.C.5.b of the proposed rule, the proposed performance domains and scoring structure would also allow us to combine more possible metric types within a single framework. We believed that this approach allows for more pathways to success than performance measurement based on relative or absolute quintiles, which were also alternatively considered, as it would reward efforts made towards achievable targets.

As discussed in section III.C.5.b of the proposed rule, we considered more than three domains to assess performance, which would potentially offer IOTA participants more opportunity to succeed due to the ability to maximize points in different combinations of domains. The more domains there are, the more the maximum points possible in each domain are spread out. However, we limited the number of domains to three to ensure the model is focused and goal-oriented, thus promoting, encouraging, and driving improvement activity and care delivery transformation across IOTA participants that evidence suggest may help achieve desired outcomes. Desired outcomes include delaying or avoiding dialysis, improving access to kidney transplantation by reducing barriers and disparities, reducing unnecessary deceased donor discards, increasing living donors, and improving care coordination and quality of care pre and post transplantation. We believed that the three domains and the proposed performance scoring structure would offer IOTA participants multiple paths to succeed in the proposed IOTA Model due to the ability to maximize points in different combinations of domains.

In section III.C.5.b of the proposed rule, we also considered not using the three performance domains and scoring structure, instead opting for alternative methods. We considered a performance assessment methodology in which an IOTA participant's performance on a metric would be divided by an expected value for each metric, which would indicate whether an IOTA participant is performing better or worse on a given measure than expected. We would then calculate a weighted average of all performance scores to reach a final score. However, we believed that setting appropriate targets of expected performance for each IOTA participant for each metric would be unrealistic to implement. The additional methodological complexity necessary for this approach would be difficult for an IOTA participant to incorporate into its operations and data systems, thereby limiting an IOTA participant's ability to understand the care practice changes it would need to make to succeed in the IOTA Model.

As discussed in section III.C.5.b of the proposed rule, we also considered assessing IOTA participant performance solely on magnitude of increased transplants over expected transplants. Under this approach, an IOTA participant's number of transplants furnished in a given PY subtracted from expected transplants would show a numeric net gain or loss in total transplants. This net value would be multiplied by an IOTA participant's kidney transplant survival rate to generate a total score for each IOTA

participant. This option would reward successfully completed transplants. This methodology reflects the goals of the IOTA Model and acknowledges that kidney transplant failures are an undesirable outcome. In addition, the methodology is simple to evaluate and understand, requiring only two inputs and a simple calculation. However, this approach does not account for efficiency and quality domain metrics, as proposed in sections III.C.5.d. and III.C.5.e of the proposed rule, which we believed to be important goals of the model. Thus, we did not propose this method to assess IOTA participant performance.

As discussed in section III.C.5.b of the proposed rule, we also considered directly translating the benefits of a kidney transplant by measuring the net effect of increased transplants and post-transplant care at the IOTA participant level. In a performance scoring methodology focused on the net effect of increased transplants and post-transplant care, the number of kidney transplants performed in a given PY would be compared to a benchmark year for the IOTA participant. Each additional kidney transplant would then be multiplied by the expected number of years of dialysis treatment the transplant averted, based on organ quality. Post-transplant care would analyze observed versus expected kidney transplant failures. For IOTA participants that achieved fewer kidney transplant failures than expected, the difference in volumes would be translated into life-years. Each marginal additional year of averted dialysis care would be used to determine the performance-based payment. Because calculating expected transplant failures is a complicated calculation with assumptions based on organ quality, donor age, and donor health conditions, a scoring system of this type would require us to make multiple broad assumptions about individual transplants or average scores across all transplants performed by the IOTA participant to create an accurate estimate of the total number of years of dialysis treatment the kidney transplant averted. This level of complexity would also introduce operational risks and burden. This approach would be aligned with the goals of the IOTA Model as it relates to increasing the number and access to kidney transplants but would still require CMS to separately assess performance on proposed performance measures for the IOTA Model, as discussed in sections III.C.5.c, III.C.5.d, and III.C.5.e of the proposed rule.

We solicited feedback from the public on our proposal to assess IOTA participant performance in three domains: (1) achievement domain; (2) efficiency domain; and (3) quality domain. We also sought feedback on our proposed performance scoring approach that would weigh the achievement domain higher than the efficiency and quality domain, and our proposed use of a 0 to 100 performance scoring approach to determine if and how performance-based payments would apply. Additionally, we invited feedback on the alternatives considered.

The following is a summary of the comments received on our proposal to assess IOTA participant performance in three domains (achievement domain, efficiency domain and quality domain), our proposed performance scoring approach, and on our proposed use of a 0 to 100 performance scoring approach to determine if and how performance-based payments would apply and our responses:

Comment: A few commenters supported the three proposed domains for assessing an IOTA participant's performance. A commenter specifically stated they supported the 100-point structure made up of 3 domains and another specifically stated their support for the emphasis on the achievement domain.

Response: We thank the commenters for their support.

Comment: A commenter stated that the performance metrics are conflicting because while volume is incentivized, achieving a high organ offer acceptance rate ratio would require more conservative transplants.

Response: We appreciate the commenters feedback. We believe that counterbalanced performance metrics are needed to create checks and balances within the IOTA Model. The inclusion of the organ offer acceptance rate ratio metric and the composite graft survival rate discourages IOTA participants from strictly considering volume and encourages IOTA participants to also prioritize long term outcomes. We direct readers to sections III.C.5.d(1) and III.C.5.e(1) of this final rule for further discussion on the organ offer acceptance rate ratio and the composite graft survival rate. The collection of metrics encourages IOTA participants to understand specific components of their transplant program that may be optimized such as utilizing filters, understanding what organs they are accepting or deferring and identifying what workflows and resources may help them optimize their transplant program. While IOTA participants may believe it is contradictory to weight achievement higher, we believe that kidney transplant volume can be increased while being mindful of post-transplant outcomes for both living donor and deceased donor transplant recipients. There are a variety of ways for IOTA participants to reach final performance point totals that are incentivized (score greater than 60). For example, growth of a living donor program could increase volume without impacting the offer acceptance ratio entirely.

Comment: Many commenters stated that the performance should include other factors that could impact an IOTA participant's performance, such as the IOTA participant's history.

Response: We appreciate the commenters' feedback. We believe that IOTA participant history is incorporated into many features and performance measurements of the IOTA Model. An IOTA participant's past performance is included in the achievement domain of the IOTA Model, by using baseline year data to calculate kidney transplant volume goals in the IOTA Model. While there is not an improvement scoring component within the achievement domain, we intend to consider this for future rulemaking. The organ offer acceptance rate ratio performance metric, which is part of the efficiency domain, is evaluated either through overall achievement or improvement. Inclusion of an improvement scoring system within the efficiency domain, takes the IOTA participant's history into consideration. The quality domain utilizes composite graft survival over a 6-year period as a performance metric. While use of this metric in the first 1–2 years of the model will not take IOTA participant history into consideration, the latter years will include earlier model data years (IOTA participant history) in its calculation.

Comment: Many commenters suggested that risk adjustment should be included in the performance measures, with a couple of commenters stating specifically that the lack of adjustment incentivizes transplanting healthier individuals and avoiding higher risk organs. Another commenter relayed their concern about the lack of scientific validation for the metrics, from the transplant community.

Response: We thank the commenters for submitting their concerns. The data and methodology utilized for the offer acceptance ratio utilizes OPTN data and SRTR methodology and is risk adjusted. As mentioned in section III.C.5.e(1)(a) of this final rule, we considered whether donor demographic characteristic risk adjustments such as race, gender, age, disease condition and geographic location would be significant and clinically appropriate for our approach

in calculating the composite graft survival rate measure, however, we are unsure which specific adjustments would be most appropriate. We believe that further analysis of the impact of the donor's characteristics on graft survival is necessary prior to incorporating a risk adjustment methodology. Additionally, given that the IOTA Model is 6 years, and the measure is rolling, we want to make sure that we continue discussions to ensure that this measure eventually includes a robust and appropriate risk adjustment methodology. We direct readers to section III.C.5.e(1)(a) of this final rule, for further discussion regarding calculation of the composite graft survival rate.

While the achievement domain does not utilize risk adjustment, it assigns points for volume of kidneys transplanted, based on an IOTA participant's prior performance and national growth rate. We did not originally consider how volume goals could be risk adjusted, however, we are open to ongoing feedback as to how this could be integrated into the achievement domain metric.

We acknowledge the concerns raised by a commenter about the scientific validity of some performance measures, but we do not believe any of the measures are entirely novel. For example, the OPTN has previously used an offer acceptance rate ratio in their metrics. Although the proposed composite graft survival rate measure is new, analyzing 1-year graft survival is an established performance metric familiar to kidney transplant hospitals. We will consider risk-adjusting this metric in future rulemaking. The IOTA Model intends to closely monitor metrics new to the transplant community and adjust as indicated throughout its performance years.

Comment: A couple of commenters mentioned that performance assessment should include a measure of additional relevant factors, such as the donor's risk factors.

Response: We agree and note that the SRTR calculation, which is used for the organ offer acceptance rate ratio calculation, includes numerous donor factors that contribute to the acceptance predictors.[192] While the composite graft survival rate metric is not risk adjusted, we will stratify the data from the composite graft survival rate measure and consider public comments to inform a risk adjustment methodology for this measure and intend to address a new or updated policy pursuant to future rulemaking. We direct readers to section III.C.5.e(1) of this final rule for further discussion on the composite graft survival metric.

Comment: Several commenters stated that measures of transplant outcomes should be a reliable and valid measure and that a SRTR metric is an example of a metric that should be used.

Response: We agree and note that the SRTR calculation, which is used for the organ offer acceptance rate ratio calculation, includes numerous donor factors that impact the acceptance predictors.[193] While the composite graft survival rate metric is not risk adjusted, we will stratify the data from the composite graft survival rate measure and consider public comments to inform a risk adjustment methodology for this measure and intend to address a new or updated policy pursuant to future rulemaking. We direct readers to section III.C.5.e(1) of this final rule for further discussion on the composite graft survival metric.

Comment: Several commenters conveyed concern that CMS should exclude hospice patients from the one-year mortality rate.

Response: We appreciate the commenters' concern. The IOTA Model does not currently include a one-year mortality performance measure, and therefore discussion about hospice patient exclusions from this metric is not applicable. For clarification, the IOTA Model does include a composite graft survival rate metric, but this metric is based on graft survival, not patient survival. Any specifications on exclusions for calculating the composite graft survival rate metric would be addressed in detail in future IOTA Model methodology reports.

Comment: Several commenters conveyed concern that assessment scoring places a heavy weight on the volume of transplants and the subsequent possibility that this may incentivize IOTA participants to use ''sub-par'' organs and increase disparities.

Response: We agree that there is a heavy focus on increasing volume of transplants as this is one of the primary goals of the IOTA Model. There are a variety of ways to increase kidney transplant volume (for example, expanding a living donor program, increasing volume of patients active on the kidney transplant list, utilizing filters to ensure appropriate offers for risk thresholds, or using kidney transplants from underutilized categories, if reasonable). While some kidney transplant hospitals may prioritize increasing kidney transplants from underutilized categories such those with a high KDPI or donation after circulatory death (DCD) kidneys, that decision may hinge on resources, and is not a requirement.

The IOTA Model was designed to create balance by requiring that IOTA participants perform well in the efficiency and quality domains to reach positive performance incentives. This ensures that kidney transplant volume does not grow unchecked, and IOTA participants remain responsible for long term outcomes of patients. We believe that increasing kidney transplants will result in increases in patient access to transplant along the continuum of care—ranging from being referred for transplant, to waitlisting, to transplant. Given the disparities that exist in all phases of transplant, we believe that changes made to increase kidney transplant volume will also help reduce disparities. Additionally, we believe the proposed transparency measures, which include publishing the criteria used to select transplant patients and reviewing the acceptance criteria as described and finalized in sections III.C.8.a(1) and (2) of this final rule, complement the performance-based metrics and will help to reduce disparities by increasing patient awareness and encouraging shared decision-making. We direct readers to section III.C.8(a) of this final rule for a full discussion on the transparency requirements. We intend to monitor throughout the entirety of the model for any unintended consequences that would impact disparities.

Comment: Numerous commenters expressed concern regarding the weighting of points for each domain. Several commenters stated that the point allocation for each performance domain should be spread equally across domains or that more points should be allocated to the quality domain (one example specified 50 achievement points, 30 quality points, 20 efficiency points). A commenter suggested that quality should have the highest weight, while another recommended equal weighting of achievement and quality due to resources needed for post-transplant care, which they felt was not reimbursed. A commenter suggested that during PY 3 or later, CMS should consider the point breakdown of 50, 25, 25 for the achievement, efficiency and quality domains. There were many specific concerns that there is too much incentive placed on volume rather than quality and this may incentivize poor long-term outcomes for patients. A commenter was specifically concerned

[192] Scientific Registry of Transplant Recipients. (n.d.). *Risk Adjustment Model: Offer Acceptance.* Offer acceptance. *https://www.srtr.org/tools/offer-acceptance/.*

[193] Ibid.

about the risk of increased performance reviews.

Response: We appreciate the commenters' concerns but respectfully disagree. We believe that the domain with the heaviest weighting, will also be the domain that sees greatest behavioral changes. Therefore, the achievement domain is more heavily weighted to increase access to transplant, a primary goal of the IOTA Model. If an IOTA participant prioritizes growth of their living donor program, for example, this would have a high likelihood of better post-transplant outcomes, given the longer graft lives of living donor kidney transplants. IOTA participants that may be restricted to expanding living donation could consider, for example, how to optimize their organ filters to ensure that they receive more of the transplant offers they are willing to accept and transplants they can help maintain long term. IOTA participants can earn up to 60 points for performance in the achievement domain and up to 40 combined points for performance metrics in the efficiency and quality domains. We do not believe this is imbalanced given the reasoning previously mentioned. Additionally, as described and finalized in section III.C.5.e of this final rule, we are modifying the metrics proposed for inclusion in the quality domain. As such, we do not believe that weighting the quality domain metrics more heavily is appropriate at this time. We direct readers to section III.C.5.e of this final rule for further discussion on the quality domain. We will continue to monitor our performance assessment strategy across all performance domains and may consider proposing an updated performance scoring approach through future rulemaking. We will be finalizing our performance scoring approach in section III.C.5.b of this final rule, as proposed, which designates 3 performance domains and the performance scoring approach as follows: 60 points for the achievement domain, 20 points for the efficiency domain and 20 points for the quality domain.

Comment: A couple of commenters stated their concerns that prioritizing kidney transplant volume in the achievement domain may discourage IOTA participants from taking on more complex cases, because patients may need more assistance throughout transplant evaluation or may be at risk of worse outcomes.

Response: We appreciate the commenters' feedback but believe that kidney transplant hospitals have different skill sets and resources. The IOTA Model encourages IOTA participants to work at the top of their scope and encourages them to identify ways that they can optimize their program without compromising post-transplant care. Approaches may look very different depending on the size, location and resources of an IOTA participant. For example, well-established IOTA participants may focus on improving outcomes for patients receiving kidneys with a KDPI greater than 85, whereas small IOTA participants may decide to focus on pre-emptive transplant or living donation transplant. Risk thresholds may also vary considerably based on the established networks between community nephrologists and transplant teams. Community nephrologists are an extension of the transplant team and can have significant impact on helping their patients successfully receive a transplant and maintain graft life, after transplant. The IOTA Model challenges the pre-existing framework of kidney transplant hospitals to evolve.

While we believe that increasing access to transplant and subsequent increase in volume is a fundamental goal of the IOTA Model, we believe there is also opportunity to encourage and reward IOTA participants that excel in the efficiency and quality domains as they adapt their programs for growth. It is ideal for IOTA participants to excel across all three performance domains throughout the model test; however, we understand that IOTA participants may perform better in specific performance domains due to year-to-year variations in available resources. The IOTA Model scoring was designed to include post-transplant measures to prevent poor outcomes from increased kidney transplant volume.

Comment: A commenter recommended that CMS include nutritional care in their performance metrics to address needs of patients.

Response: While we acknowledge the importance of nutrition and nutritional resources for patients across the CKD to ESRD to transplant care continuum, we do not currently believe that that nutritional care directly aligns with the goals of the IOTA Model or its performance metrics. We invite ongoing input on how nutritional care may fit into an alternative quality metric utilized in future iterations of the IOTA Model.

Comment: A commenter stated that safety net kidney transplant hospitals in remote regions will be disadvantaged by the three domains.

Response: We acknowledge that remote and safety net kidney transplant hospitals have different challenges in their transplant programs than kidney transplant hospitals that may be in highly populated areas. We encourage IOTA participants to consider the numerous approaches that they may take to increase kidney transplant volume. This may be achieved by increasing living donor kidney transplants (LDKTs), deceased donor kidney transplant (DDKTs) or both. If an IOTA participant struggles to increase their volume initially, there are opportunities to excel in the efficiency and quality domains. We understand that any model can have unintended consequences and we intend to monitor the model impacts on IOTA participants.

Comment: A couple of commenters suggested that the IOTA Model should have been weighted to encourage use of kidneys with a KDPI greater than 85 and improving quality of care for those transplant recipients, rather than prioritize increasing total number of transplants performed.

Response: Thank you for submitting feedback, however, we disagree. While there is opportunity to optimize use of kidneys with a KDPI greater than 85, we believe this may not be the most ideal way for all IOTA participants to increase volume or general performance. Prioritizing an increase in any DDKTs or LDKTs of a specific classification allows each IOTA participant to have flexibility in adapting their program to meet this goal.

While the IOTA Model is not finalizing a performance metric measuring utilization of kidneys with a KDPI greater than 85, we intend to assess and monitor the utilization of this category of kidney transplants by IOTA participants.

Comment: A commenter was concerned that the IOTA Model does not account for recovered kidneys that are not used for transplant or for non-utilization.

Response: We thank the commenter for their feedback. The organ offer acceptance rate ratio is calculated by excluding donor kidneys that are not utilized. While no metric in the IOTA Model specifically looks at the total non-utilization number, this may be an important metric to further research as it may be impacted differently as kidney transplant hospitals adjust their offer acceptance filters. We believe there may be opportunity for future collaboration with the OPTN to ensure non-utilization data is captured and accessible for review.

Comment: A commenter mentioned concern that CMS is basing kidney transplant hospital percentile rankings against both participating and non-

participating kidney transplant hospitals.

Response: We thank the commenter for submitting their concern. IOTA participants are awarded points in the achievement domain based on performance improvement relative to historical performance for volume of kidneys transplanted. We direct readers to section III.C.5.c of this final rule for a full discussion of the achievement domain.

As described and finalized in section III.C.5.d.(1).(b). of this final rule, the efficiency domain applies a two-scoring system (achievement score and improvement score) based on its performance on the OPTN organ offer acceptance rate ratio; awarding points equal to the higher of the two scores to the IOTA participant. For achievement scoring in the quality domain, as described and finalized in section III.C.5.d.(1).(b). of this final rule, points earned will be based on the IOTA participants' performance on the organ offer acceptance rate ratio relative to national ranking, including all eligible kidney transplant hospitals (both those selected and not selected as IOTA participants), and awarded based on national quintiles. For improvement scoring in the efficiency domain, as described and finalized in section III.C.5.d.(1).(b). of this final rule, points earned will be based on the IOTA participants' performance on organ offer acceptance rate ratio during a PY relative to their performance during the third baseline year for the PY that is being measured. We direct readers to section III.C.5.d of this final rule for a full discussion on the efficiency domain.

Lastly, as described and finalized in section III.C.5.e(1)(b) of this final rule, IOTA participants will earn points in the quality domain based on its performance on the composite graft survival rate, as described and finalized in section III.C.5.e(1)(a) of this final rule, ranked nationally, inclusive of all eligible kidney transplant hospitals. IOTA participants will be awarded points on the composite graft survival rate based on the national quintiles, as outlined in Table 1 to Paragraph (d) at § 512.428. We direct readers to section III.C.5.e of this final rule for a full discussion on the quality domain.

The IOTA Model incentivizes high performance through a point-based system, which we anticipate will drive IOTA participants to outperform non-participating kidney transplant hospitals, which we view as a notable strength of the model.

Comment: A commenter stated the IOTA Model methodology does not account for kidney transplant hospitals that already perform a high-volume of kidney transplants, and instead is based solely on improvement.

Response: We thank the commenter for expressing their concern. Many high-volume kidney transplant hospitals have a combination of well-developed living donor programs, resources such as perfusion pumps, and the volume that allows higher risk thresholds both for accepting certain donors and accepting candidates with more co-morbidities. These qualities and resources allow ongoing opportunity for growth. We recognize that IOTA participants with varying kidney transplant volumes will have unique challenges. However, we believe the methodology's built-in flexibility enables IOTA participants to adapt their kidney transplant hospital to best serve their patient populations. We intend to closely monitor kidney transplant volume growth and outcomes for IOTA participants of all kidney transplant volume sizes and take this into consideration in future rulemaking.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed provisions to assess IOTA participants in the achievement domain, efficiency domain and quality domain and performance scoring approach at § 512.422(a), without modification. We are also codifying the proposed definition of final performance score at § 512.402, without modification. We direct readers to sections III.C.5.c, III.C.5.d, and III.C.5.e of this final rule for further discussion on our proposed achievement domain, efficiency domain, and quality domain. We also direct commenters to section III.C.6.c of this final rule for further discussion on our proposed performance-based payment methodology.

c. Achievement Domain

In section III.C.5.b of the proposed rule, we proposed measuring IOTA participant performance across three domains, one of which is the achievement domain. We proposed to define ''achievement domain'' as the performance assessment category in which CMS assesses the IOTA participant's performance based on the number of transplants performed on patients 18 years of age or older, relative to a target, subject to a health equity performance adjustment, as described in section III.C.5.c.(3) of this final rule, during a PY. We proposed to use OPTN data, regardless of payer, and Medicare claims data to calculate the number of kidney transplants performed during a PY by an IOTA participant on patients 18 years of age or older at the time of transplant, as described in section III.C.5.c(2) of this final rule.

In section III.C.5.c of the proposed rule, we proposed to set the participant-specific target for the achievement domain based on each IOTA participant's historic number of transplants. A central goal of the proposed IOTA Model test is to increase the number of kidney transplants furnished by IOTA participants, which we believed would be possible via care delivery transformation and improvement activities, including donor acceptance process improvements to reduce underutilization and discards of donor kidneys. We believed IOTA participants may also increase the number of kidney transplants furnished to patients by improving or implementing greater education and support for living donors.

As discussed in section III.C.5.c of the proposed rule, we considered constructing and using a transplant waitlisting rate measure or using SRTR's transplant rate [194] rather than measuring number of transplants performed relative to a participant-specific target for the achievement domain. Research has suggested that including such a metric could demonstrate the need for both living and deceased donor organs for a particular transplant hospital and be less reliant on organ availability for a particular geographical area.[195] Research also suggested that the inclusion of a pretransplant measure, such as waitlisting rate, may allow for a more complete assessment of transplant hospital performance and provide essential information for patient decision-making.[196] However, for the IOTA Model, we proposed to test the effectiveness of the model's incentives to change outcomes, rather than on processes. The relevant outcome for purposes of the IOTA Model is the receipt of a kidney transplant, not

[194] For additional information on SRTR's transplant rate measure, please see *https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports#figurea2.*

[195] Paul, S., Melanson, T., Mohan, S., Ross-Driscoll, K., McPherson, L., Lynch, R., Lo, D., Pastan, S.O., & Patzer, R.E. (2021). Kidney transplant program waitlisting rate as a metric to assess transplant access. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 21*(1), 314–321. *https://doi.org/10.1111/ajt.16277.*

[196] Paul, S., Melanson, T., Mohan, S., Ross-Driscoll, K., McPherson, L., Lynch, R., Lo, D., Pastan, S.O., & Patzer, R.E. (2021). Kidney transplant program waitlisting rate as a metric to assess transplant access. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 21*(1), 314–321. *https://doi.org/10.1111/ajt.16277.*

getting on and remaining on the kidney transplant waitlist. Additionally, the SRTR transplant rate measure calculates the number of those transplanted as a share of the kidney transplant hospital's waitlist, which we believed does not reflect the variety of ways that kidney transplant hospitals construct their waitlist practices. For example, for some kidney transplant hospitals, the number of kidneys transplanted as a share of their ''active'' waitlist transplant candidates may be a more accurate representation of their waitlist practices. Thus, we did not believe this was appropriate to propose for the IOTA Model.

We sought comment on our proposed achievement domain performance metric and alternative methodologies considered for assessing transplant rates.

The following is a summary of the comments received on our proposed achievement domain performance metric and alternative methodologies considered for assessing transplant rates and our responses:

Comment: A couple of commenters supported the achievement domain performance metric. A commenter specifically agreed with not including a waitlisting measure.

Response: We thank the commenters for their support of the achievement domain.

Comment: Several commenters stated their concern that there is a heavy weight placed on the volume of transplants and that this may incentivize participants to use ''sub-par'' organs and increase disparities.

Response: We agree that there is a heavy focus on increasing volume of transplants as this is one of the primary goals of the IOTA Model. There are a variety of methods that IOTA participants may choose to increase kidney transplant volume including, but not limited to, expanding a living donor program, increasing volume of patients active on the kidney transplant list, utilizing filters to ensure appropriate offers for risk thresholds, or using kidney transplants from underutilized categories. While some kidney transplant hospitals may prioritize increasing kidney transplants from underutilized categories such those kidneys with a KDPI greater than 85 or DCD kidneys, that decision may hinge on resources, and is not a requirement. We are unsure if the commenters are defining ''sub-par'' organs as organs that should not be offered to any candidates or as organs that are only acceptable in specific scenarios. We believe it will be important for IOTA participants to further consider what is a ''sub-par'' kidney. While certain kidneys may not be ideal for some waitlist candidates, they may be a potential opportunity in another scenario.

Comment: Commenters voiced concerns about how the achievement domain would impact high performing IOTA participants. Some commenters worried the proposed scoring system would penalize IOTA participants who have historically been top performers. Another commenter suggested CMS credit the top 20 percent of IOTA participants to maintain their kidney transplant volume, while using different incentives for lower-performing IOTA participants.

Additionally, a commenter expressed concern that increasing kidney transplant volume often involves transplanting more high-risk organs. While SRTR accounts for how this impacts outcomes, the commenter argued that it does not consider the added strain on resources at high performing kidney transplant hospitals. Lastly, another commenter worried the achievement domain would penalize IOTA participants who are already operating at full kidney transplant capacity, unless they made substantial new investments.

Response: We appreciate the concerns that the commenters have submitted, and we acknowledge the efforts exerted by transplant hospitals to reach their status. We believe that IOTA participants can potentially become ''high performing'' through a variety of practices such as utilizing kidneys of all KDPI scores when appropriate, adjusting filters, or expanding their living donor program. We believe that with the number of ways that an IOTA participant can become more efficient and have higher kidney transplant volumes, that they have additional opportunities to improve their performance and to continue increasing kidney transplants. We believe that the updated methodology for setting transplant targets, as described and finalized in section III.C.5.c(1) of this final rule, and the updated scoring methodology in the achievement domain, as described and finalized in section III.C.5.c(2) of this final rule, will make it more achievable for IOTA participants of all sizes to achieve maximum points in the achievement domain. We direct readers to section III.C.5.c(1) and III.C.5.c(2) of this final rule for a full discussing on the updated methodology for calculating the transplant target and the updated scoring methodology in the achievement domain. We also note that, as described and finalized in section III.C.6.c(2) of this final rule, there is no downside risk payment in PY 1 of the IOTA Model.

Comment: A couple of commenters stated that CMS should act to eliminate constraints on transplant availability due to both kidney transplant hospital and hospital capacity and organ availability before implementing transplant targets in the achievement domain.

Response: We appreciate the commenters' feedback; however, we do not have control over the capacity of kidney transplant hospitals and hospitals or organ availability. We encourage kidney transplant hospitals to work with their leadership if they have concerns about capacity limitations. Organ availability is impacted by a variety of factors, including, but not limited to identification of organ donors, allocation practices, location of kidney transplant hospitals and donors and utilized organs. Improving kidney transplant volumes will require multi-pronged efforts. We believe the IOTA Model will help increase the number of kidney transplants performed.

Comment: A few commenters suggested that CMS should engage with stakeholders to refine goals and focus more narrowly on certain aspects of increasing transplant volume in the achievement domain, especially increasing living donation and utilizing high-risk kidneys. Similarly, a commenter suggested that CMS should focus its efforts on increasing kidney volume in categories where there is opportunity for growth such as high KDPI kidneys, donor kidneys with acute kidney injury (AKI) and DCD kidneys.

Response: We thank the commenters for their suggestions and believe that there are a variety of practices that IOTA participants can choose to utilize when increasing their kidney transplant volume. Because kidney transplant hospitals vary significantly, we disagree with the commenters, and do not believe it would be appropriate to be prescriptive about how an IOTA participant decides to increase their kidney transplant volume. While living donation, for example, has had relatively unchanged transplant rates over the last few years, indicating opportunity for improvement, we acknowledge that not every kidney transplant hospital has the same resources or characteristics.[197] Furthermore, we believe the IOTA Model design provides flexibility that enables IOTA participants to increase

[197] United States Renal Data System. 2022. USRDS Annual Data Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 7: Transplantation. Figure 7.10b.

their kidney transplant volume in a way that best suits their transplant program and community.

Comment: A couple of commenters voiced concern that success in the achievement domain is contingent upon a multitude of uncontrollable factors, such as limited organs and matching challenges. Additionally, a few commenters mentioned concern that increasing kidney transplant volume requires expansion of many other resources for successful post-transplant care, which are not reimbursed through the Medicare cost report.

Response: We appreciate the commenters' feedback about their concern about limitations of resources. We acknowledge the multitude of factors that can impact kidney transplant hospital volume—from a community level to a nationwide level, and also acknowledge that kidney transplant volume expansion may require increased resources, particularly staffing. There are intrinsic components of the IOTA Model intended to offset challenges of the achievement domain, such as two other performance domains (efficiency and quality). Additionally, the achievement domain calculates transplant targets for IOTA participants based on an IOTA participant's own prior kidney transplant volume in their baseline years and based on a national growth rate that accounts for changes year to year (as described in section III.C.5.c.2 of this final rule). We also note that there are not prescriptive specifications in the achievement domain requiring IOTA participants to meet transplant volumes in one specific way. This flexibility allows IOTA participants to identify what method is best to optimize their kidney transplant volume. Notably, as described and finalized in section III.C.6.c(1) of this final rule, PY 1 does not include any downside risk payments regardless of an IOTA participant's final performance score. Furthermore, we believe the neutral zone has a reasonable final performance score range for PYs 2–6, as described and finalized in section III.C.6.c(1) of this final rule. As such, we believe the absence of downside risk payment in of PY 1 creates a buffer for IOTA participants to anticipate resources needed to succeed in PY 2.

The achievement domain scoring methodology accounts for Medicare and non-Medicare patients who receive a kidney transplant. We anticipate that since IOTA participants will aim to increase kidney transplants for all kidney transplant waitlist patients, this will create opportunities to accumulate payment through the IOTA Model incentives and through payment by both Medicare and private payers for kidney transplant related services. We believe these payments should assist in costs that IOTA participants may encounter while participating in the IOTA Model.

Comment: A commenter conveyed concern that the achievement domain, which focuses on increasing kidney transplant volume, is contradictory since the Innovation Center's goals have traditionally been to improve value versus volume. A few commenters were concerned that volume does not equate with better outcomes and even with counterbalances in the model, will pressure IOTA participants to complete riskier transplants, which may have worse outcomes.

Response: We disagree and believe that the achievement domain simultaneously supports increasing kidney transplant volume and value. There are almost 5,000 patients who die annually while being on the kidney transplant waitlist.[198] It is well known the life span of and lifestyle of those patients on dialysis is drastically different from those patients who receive kidney transplants. Not only does the model aim to improve access, kidney transplant volumes and quality of life, but also reduce spending. The cost of yearly dialysis far exceeds the average cost of immunosuppression and post-transplant care. The IOTA Model is not encouraging IOTA participants to transplant non-viable organs or organs where risks outweigh the benefits. The IOTA Model design, does however, challenge kidney transplant hospitals to optimize all components of care from waitlisting to transplant to post-transplant. Growth in living donor programs is a prime example of how increasing volume should not compromise outcomes and should improve overall outcomes. As for increases in DDKT volume, we plan to carefully monitor volume, organ offer acceptance ratios and composite graft survival independently and collectively to monitor for unintended consequences and will consider this for future rulemaking for PY 2. We encourage commenters to provide feedback in the future about (1) what they define as ''riskier'' transplants from the perspective of the donor and recipient (2) whether this is specific to KDPI values or qualities of the donor kidney and (3) if this exceeds the risk of being on dialysis.

Comment: A few commenters believe that the achievement domain disadvantages smaller transplant programs due to their lack of COE designation and overlooks challenges to gain this designation. Another commenter was concerned that small transplant programs will have to accept higher risk kidneys. A commenter suggested that smaller programs should have separate performance metrics.

Response: We thank the commenters for their feedback and acknowledge that kidney transplant hospitals of different sizes, will have different challenges in increasing kidney transplant volume. Kidney transplant hospitals that fall below the low volume threshold would be excluded from the IOTA Model, as described and finalized in section III.C.3(c) of this final rule. Based on the updated scoring methodology in the achievement domain, as described and finalized in section III.C.5.c(2) of this final rule, an IOTA participant with 20 kidney transplants during the baseline years (with an example growth rate of 8 percent) would need a total of 27 kidney transplants to earn maximum achievement points (60), or approximately 23 kidney transplants to earn 40 points in the achievement domain. We believe that offering wide neutral margins for final performance scores and offering a variety of opportunities to gain points in the achievement domain, efficiency domain and quality domain creates balances for a different size kidney transplant hospital. We believe that increasing kidney transplant volume will create opportunities for smaller kidney transplant hospitals to qualify for COE designation in the future.

Comment: A couple of commenters raised concerns that the achievement domain disproportionately impacts large transplant programs due to the demand on resources it would require and the general volume requirements.

Response: We thank the commenters for submitting their concerns. As stated in response to small kidney transplant hospital concerns, offering wide neutral margins for final performance scores and offering a variety of opportunities to gain points in the achievement, efficiency and quality domains creates balances for IOTA participants. Many large kidney transplant hospitals have significant resources, COE designation, and paired donation opportunities that may not be available to smaller kidney transplant hospitals. We believe that while volume goals may be higher, they are proportionately similar for kidney transplant hospitals of different sizes.

[198] Penn Medicine News. (2020, December 16). *Too Many Donor Kidneys Are Discarded in U.S. Before Transplantation—Penn Medicine. www.pennmedicine.org. https://www.pennmedicine.org/news/news-releases/2020/december/too-many-donor-kidneys-are-discarded-in-us-before-transplantation.*

Comment: A commenter suggested that IOTA participant specific volume targets should match local population needs along economic lines, racial lines and payer sources to increase equitable access to underserved groups.

Response: We thank the commenter for their feedback. While this is not a specific requirement that we originally proposed, we are interested to receive more information about this suggestion, as we consider future rulemaking. First, we would want to consider how to do this equitably and how kidney transplant hospitals would identify their local population needs.

Comment: A commenter suggested that CMS track achievement domain volume scores to ensure IOTA participants do not utilize the scoring system at the expense of patient risk.

Response: We appreciate the commenter's response. The IOTA Model has thoughtfully been designed to create counterbalances between measures. For example, although the achievement score is based on kidney transplant volume, the efficiency score is based on offer to acceptance ratios and the quality domain includes a composite graft calculation for a 6-year period post-transplant. While innovation models are not perfect, and are corrected for optimization over time, we believe that IOTA participants that have combined accountability for IOTA Model requirements, OPTN metrics and regulatory and ethical requirements, will be mindful of avoiding inappropriate patient risk.

Comment: A commenter recommended that CMS differentiate between more established kidney transplant hospitals and newer kidney transplant hospitals with shorter track records and transplant volume. Established kidney transplant hospitals often have decades-long waitlists, referral networks, and stable staffing of transplant nephrologists. In contrast, newer, smaller kidney transplant hospitals can experience large swings in transplant volume due to growing pains. Furthermore, the commenter argued, the loss of a single transplant nephrologist can halt kidney transplants at these newer kidney transplant hospitals while they recruit replacements, leading to a penalty at a time when the kidney transplant hospital can least afford it.

Response: We thank the commenter for their feedback. We acknowledge that there are differences between well-established and, newer, smaller kidney transplant hospitals with smaller transplant volume. As described in section III.C.5.c(1) of this final rule, the updated methodology for measuring performance in the achievement domain will be based on the average number of kidney transplants performed in the baseline years trended forward by the national growth rate. Therefore, we disagree with the commenter and believe all IOTA participants can improve their kidney transplant rates, regardless of size. We recognize that some IOTA participants may have to make upfront investments, but the low volume threshold of 11 adult kidney transplants for each kidney transplant hospital in every baseline year, as described and finalized in section III.C.3.c of this final rule, will substantially mitigate the demands placed on, newer, smaller kidney transplant hospitals.

After consideration of the public comments, for the reasons set forth in this rule, we are finalizing, as proposed, our provisions for setting an IOTA participant's transplant target based on each IOTA participant's historic number of transplants at § 512.424(b)(1), as described and finalized in section III.C.5.c(1) of this final rule. We direct readers to section III.C.5.c(1) of this final rule for further discussion on the transplant target methodology. As described and finalized in section III.C.5.c(2) of this final rule, we are also finalizing our proposed provision for identifying kidney transplants performed by an IOTA participant using OPTN data, regardless of payer, and Medicare claims data at § 512.424(d), without modification.

Furthermore, after consideration of the public comments we received, we will not be finalizing a health equity performance adjustment provision, as described in section III.C.5.c(3) of this final rule. Therefore, we are modifying regulatory text for the achievement domain definition at § 512.402, to remove references to a health equity performance adjustment and make minor technical corrections in punctuation. We direct readers to section III.C.5.c(3) of this final rule for further discussion on our proposed health equity performance adjustment. While we are finalizing our provision for setting IOTA participants' transplant target based on each IOTA participant's historic number of transplants as mentioned in section III.C.5.c, we note that the methodology for utilizing an IOTA participant's historic number of transplants for calculating transplant targets has changed in section § 512.424(b)(1) and is described in detail and finalized in section III.C.5.c(1) of this final rule. We direct readers to section III.C.5.c(1) of this final rule for further discussion on the transplant target methodology. In addition, as described and finalized in section III.C.5.c(2) of this final rule, we are finalizing our proposed provision for identifying kidney transplants performed by the IOTA participant using OPTN data, regardless of payer, and Medicare claims data at § 512.424(d), without modification.

(1) Calculation of Transplant Target

In the proposed rule, we proposed that for each model PY, CMS would calculate a ''transplant target'' for each IOTA participant, which would determine performance in the achievement domain. For the purposes of the model, we proposed to define ''transplant target'' as the target number of transplants set for each IOTA participant to measure performance in the achievement domain as described in the proposed rule and section III.C.5.c of this final rule. We proposed that CMS would notify each IOTA participant of their transplant target by the first day of each PY, in a form and manner determined by CMS.

For each PY, we proposed in section III.C.5.c(1) of the proposed rule, that CMS would calculate the transplant target for the achievement domain by first determining the highest number of deceased donor kidney transplants and living donor kidney transplants furnished to patients 18 years of age or older in a single year during the baseline years, as defined and finalized in section III.C.3.c. of this final rule. CMS would then sum the highest number of deceased donor kidney transplants and living donor kidney transplants furnished in a single year during the baseline years calculate the transplant target for an IOTA participant, even if those transplant numbers were achieved during different baseline years. We believed that choosing the highest transplant numbers during the baseline years would illustrate the capabilities and capacities of the IOTA participant, and, when combined, would be an appropriate target for number of transplants performed during the PY. We also understood that living donation and deceased donor donation involve different processes by the IOTA participant, so we chose each of those numbers separately to recognize the potential capacity for each IOTA participant for both living and deceased donor transplantation.

In section III.C.5.c(1) of the proposed rule, we proposed that the sum of the highest number of deceased donor and living donor transplants across the baseline years of the IOTA participant would then be projected forward by the national growth rate, as described in section III.C.5.c(1) of this final rule, or

zero should the national growth rate be negative, resulting in the transplant target for a given PY. We proposed to define ''national growth rate'' as the percentage increase or decrease in the number of kidney transplants performed over a twelve-month period by all kidney transplant hospitals except for pediatric kidney transplant hospitals and kidney transplant hospitals that fall below the low volume threshold described and finalized in section III.C.3. of this final rule. We proposed to define ''pediatric kidney transplant hospitals'' as a kidney transplant hospital that performs 50 percent or more of its transplants in a 12-month period on patients under the age of 18. We also proposed that the low volume threshold to be 11 kidney transplants performed for the purposes of calculating the national growth rate. We also proposed this approach for calculating the national growth rate to account for and reflect the growth in organ procurement by OPOs that has occurred, indicating potential growth in the number of available organs.

In section III.C.5.c(1) of the proposed rule, we proposed that CMS would calculate the national growth rate by determining the percent increase or decrease of all kidney transplants furnished to patients 18 years of age or older from two years prior to the PY to one year prior to the PY. Because the proposed national growth rate includes IOTA participants and non-IOTA participant kidney transplant hospitals, we acknowledge that it could make achieving the transplant target number harder. This is why, if the national growth rate becomes negative for a PY, we proposed treating it as zero and CMS would not apply the national growth rate to project forward the sum of the highest number of deceased and living donor kidney transplants furnished in a single year during the baseline years. In other words, an IOTA participant's transplant target would equal the sum of its own highest deceased and living donor transplants furnished across the baseline years if the national growth rate were to be negative for a PY. We also want to be able to share model performance targets with IOTA participants before the start of each PY and are prioritizing ensuring prospectivity over ensuring the most up-to-date trend figures. We also proposed that if the model begins on an any date after January 1, 2025, the trend would also be adjusted.

For example, as described in section III.C.5.c(1) of the proposed rule, to calculate the national growth rate for PY 1 using the proposed model start date of January 1, 2025, CMS would first subtract the total number of kidney transplants furnished to patients 18 years of age or older in 2022 from the total number of kidney transplants furnished to patients 18 years of age or older in 2023. Next, CMS would then divide that number by the total number of kidney transplants furnished to patients 18 years of age or older in 2022 to determine national growth rate. To create the transplant target for each IOTA participant for PY 1 CMS would do the following:

- If the national growth rate is positive, CMS would trend the national growth rate forward for an IOTA participant by multiplying the national growth rate by the sum of the highest number of deceased donor and living donor transplants furnished to patients 18 years of age or older across the baseline years for the IOTA participant.
- CMS would take the product of step 1 and add it to the sum of the highest living donor and deceased donor kidney transplants furnished to patients 18 years of age or old across the baseline years for an IOTA participant.
- The sum of step 2 would be the transplant target for an IOTA participant. However, if the national growth rate were negative, CMS would not trend the growth rate forward for PY 1 and the transplant target would be the sum of the highest living donor and deceased donor kidney transplants across the baseline years.

In section III.C.5.c(1) of the proposed rule, we proposed that when calculating the national growth rate for each PY, CMS would look to the relevant baseline years for that PY, as depicted in Table 1. This approach would mitigate our concern that a static baseline may reward a one-time investment, rather than continuous improvement. The model PYs, as proposed in the proposed rule, would not factor into an IOTA participant's transplant target calculation until PY 3 of the model (January 1, 2027, to December 31, 2027) and the baseline years would not be based exclusively on PYs until PY 5 of the model (January 1, 2029, to December 31, 2029), which may represent an effective phase-in approach to drive improved performance and savings for the Medicare trust fund. We believe that using baseline years to calculate the transplant targets would also account for kidney transplant hospitals that experience changes in strategy or staffing that may affect their capacity to perform transplants at the level that they did in previous years.

TABLE 1: EXAMPLE – PROPOSED BASELINE YEARS FOR CALCULATION OF TRANSPLANT TARGET (FOR PROPOSED MODEL START DATE)

Performance Year	Calendar Year	Highest Number of Living + Highest Number of Deceased from Baseline Years	Trended by National Growth Rate from
1	Jan 1, 2025 — December 31, 2025	CY 2021: January 1, 2021 – December 31, 2021 CY 2022: January 1, 2022 – December 31, 2022 CY 2023: January 1, 2023 – December 31, 2023	CY 2023/CY 2022
2	Jan 1, 2026 — December 31, 2026	CY 2022: January 1, 2022 – December 31, 2022 CY 2023: January 1, 2023 – December 31, 2023 CY 2024: January 1, 2024 – December 31, 2024	CY 2024/CY 2023
3	Jan 1, 2027 — December 31, 2027	CY 2023: January 1, 2023 – December 31, 2023 CY 2024: January 1, 2024 – December 31, 2024 CY 2025: January 1, 2025 — December 31, 2025	CY 2025/ CY 2024
4	Jan 1, 2028 — December 31, 2028	CY 2024: January 1, 2024 – December 31, 2024 CY 2025: January 1, 2025 – December 31, 2025 CY 2026: January 1, 2026 – December 31, 2026	CY 2026/ CY 2025
5	Jan 1, 2029 — December 31, 2029	CY 2025: January 1, 2025 – December 31, 2025 CY 2026: January 1, 2026 – December 31, 2026 CY 2027: January 1, 2027 – December 31, 2027	CY 2027/ CY 2026
6	Jan 1, 2030 — December 31, 2030	CY 2026: January 1, 2026 – December 31, 2026 CY 2027: January 1, 2027 – December 31, 2027 CY 2028: January 1, 2028 – December 31, 2028	CY 2028/ CY 2027

Should we finalize a model start date other than January 1, 2025, we proposed in section III.C.5.c(1) of the proposed rule that the baseline years, as defined and finalized in section III.B.2.c of this final rule, would shift accordingly, as illustrated in Table 2.

TABLE 2: EXAMPLE - PROPOSED BASELINE YEARS FOR CALCULATION OF TRANSPLANT TARGET, FOR POTENTIAL ALTERNATIVE MODEL START DATE

Performance Year	Alternative Year	Highest Number of Living + Highest Number of Deceased from Baseline Years	Trended by National Growth Rate from
1	July 1, 2025 — June 30, 2026	July 1, 2021 – June 30, 2022 July 1, 2022 – June 30, 2023 July 1, 2023 – June 30, 2024	July 1, 2023 – June 30, 2024 / July 1, 2022 – June 30, 2023
2	July 1, 2026 — June 30, 2027	July 1, 2022 – June 30, 2023 July 1, 2023 – June 30, 2024 July 1, 2024 – June 30, 2025	July 1, 2024 – June 30, 2025 / July 1, 2023 – June 30, 2024
3	July 1, 2027 — June 30, 2028	July 1, 2023 – June 30, 2024 July 1, 2024 – June 30, 2025 July 1, 2025 – June 30, 2026	July 1, 2025 – June 30, 2026 / July 1, 2024 – June 30, 2025
4	July 1, 2028 — June 30, 2029	July 1, 2024 – June 30, 2025 July 1, 2025 – June 30, 2026 July 1, 2026 – June 30, 2027	July 1, 2026 – June 30, 2027 / July 1, 2025 – June 30, 2026
5	July 1, 2029 — June 30, 2030	July 1, 2025 – June 30, 2026 July 1, 2026 – June 30, 2027 July 1, 2027 – June 30, 2028	July 1, 2027 – June 30, 2028 / July 1, 2026 – June 30, 2027
6	July 1, 2030 — June 30, 2031	July 1, 2026 – June 30, 2027 July 1, 2027 – June 30, 2028 July 1, 2028 – June 30, 2029	July 1, 2028 – June 30, 2029 / July 1, 2027 – June 30, 2028

We stated in section III.C.5.c(1) of the proposed rule that we believe that IOTA participants could improve on this metric in several ways. For example, IOTA participants could increase the number of kidney organ offers they accept, which would also potentially lead to greater efficiency domain scores. IOTA participants could also invest in a living donation program or modify their OR schedules to facilitate fewer discards due to physician scheduling.

We considered basing the transplant target on the total number of all organ transplants performed by the IOTA participant over the baseline years (89 FR 43518). However, we did not believe this was appropriate because the total would not reflect the specific capabilities of the IOTA participant's kidney transplant program. We also considered adjusting the transplant target by IOTA participant revenue from hospital cost reports. In this scenario, our consideration was to look at historical kidney transplant data as the best predictor, since this reveals the demonstrated capacity for each IOTA participant to complete kidney transplants.

We also considered setting each IOTA participant's transplant target by determining the IOTA participant's average total kidney transplant volume from the three previous years instead of using the sum of the highest living and deceased donor kidney transplant volumes during the baseline years (89 FR 43518). We believe that this methodology would be simpler and result in a transplant target that is potentially more attainable for IOTA participants, assuming that the average kidney transplant volume is lower than the sum of the highest volumes of deceased and living donor kidney transplants. However, we do not believe that this would reflect the potential highest capacity for transplant that we would otherwise like the target to reflect.

We alternatively considered a static or fixed baseline approach for purposes of determining the transplant target for each IOTA participant, as it would minimize operational burden for CMS due to less frequent updates to the transplant target and ensure that the model does not set a moving target year-over-year (89 FR 43518). However, we believe that a fixed baseline may reward a one-time investment, rather than continuous improvement, and may not

account for kidney transplant hospitals that experience changes in strategy or staffing that may affect their capacity to perform transplants at the level that they did in historical years. The rolling baseline approach we proposed uses historical kidney transplant volumes pre-dating the model start date through the first two model PYs, ensuring a phased-in approach before any improvements made during the model performance period are accounted for in the baseline.

We also considered setting the transplant target for IOTA participants based on two baseline years, rather than the proposed methodology of three (89 FR 43518). For the proposed model start date of January 1, 2025, this approach would look at the highest living and deceased volumes from 2022 and 2023, trended by the national growth rate from 2024, to set the transplant target for PY 1. We believe this methodology would be more reflective of recent transplantation volume and account for the changes to the kidney allocation system that were implemented in 2021. However, we believe that using two baseline years to set a transplant target would be more susceptible to temporary market disruptions or fluctuations that may impact IOTA participants capability or capacity to furnish kidney transplants, such as: if the transplant hospital experiences a shortage in transplant surgeons or other critical staff; if the transplant hospital is acquired; or, the occurrence of a natural disaster, pandemic, or other public health emergency or other extreme and uncontrollable circumstance that would require the transplant hospital to temporarily suspend operations. Any of these disruptions or fluctuations could result in an inaccurate transplant target that would not accurately reflect an IOTA participant's volume capability.

We considered determining the national growth rate by calculating separately; (1) the growth rate of the deceased donor target number by the growth in organs procured, and (2) the living donor target number by the national growth rate in living donor transplants (89 FR 43518). However, procurement rates vary nationally depending on variables unique to each geography and local OPO policies.[199] Because we want the model to inspire kidney transplant hospitals to expand living donor programs, not just match national growth rates, we did not believe this alternative methodology was appropriate to propose.

We also considered determining the national growth rate using the following information: (1) the total growth rate in kidney transplants; (2) the change in rate of organs procured by OPOs; (3) the growth rate in kidney transplants in the non-selected portions of the country; and (4) calculating the average growth rate across multiple baseline years (89 FR 43518). However, we believe that the national growth rate in kidney transplants makes the most sense to use as the basis for the model's growth factor because it best reflects volume trends in the kidney transplant ecosystem overall, as it considers all kidney transplant hospitals, not just IOTA participants.

Finally, we also considered a performance assessment methodology for IOTA participants already achieving higher rates of kidney transplantation by assessing each such IOTA participant's total transplant volume as compared to all IOTA participants, rather than on an IOTA participant specific transplant target (89 FR 43518). We believe this methodology is both easy to understand and simple to administer because it rewards IOTA participants for the total number of transplants performed. However, we thought that this methodology would not be fair to IOTA participants that are smaller in size or achieving lower rates of kidney transplantation.

We solicited comment on our proposal to set unique transplant targets for each IOTA participant, the methodology for setting transplant targets, and any alternatives considered.

The following is a summary of the comments received on our proposal to set unique transplant targets for each IOTA participant, the methodology for setting transplant targets, any alternatives considered and our responses:

Comment: Commenters expressed concern over the proposed methodology for calculating unique transplant targets each PY for each IOTA. Many commenters expressed concern that the proposed methodology is impractical as it overestimates a transplant programs capability to increase transplantation throughput unilaterally, such as without significant improvements in organ procurement and distribution by the OPTN and OPOs, factors beyond hospitals' control, does not take into consideration year over year variability in overall donor volume, and could not be achieved without potentially compromising the quality of care and patient safety. Many commenters stated that the proposed transplant target methodology was unsustainable throughout the model, as increasing kidney transplant volume would make it increasingly difficult for IOTA participants to meet ever-higher targets in subsequent PYs, potentially leading to penalties.

Many commenters believed that the proposed methodology for calculating the transplant target for each IOTA participant would be unattainable for high performing transplant hospitals. For example, while a commenter supported comparing a kidney transplant hospital's transplant rates to the national average, they believed that they would be held to an impractically high expectation for growth. The commenter also argued that kidney transplant hospitals already performing in the top 20 percent should not be penalized for failing to reach an unrealistically high transplant rate. Another commenter suggested that they would need to increase their annual adult transplant numbers by 75 to 150 each year. They felt that the ability to achieve this increase would rely on the availability of a sufficient number of viable organs and a significantly increased waitlist. Consequently, they believed that their kidney transplant hospital could potentially achieve that goal and clear their waiting list in the first year; however, this assumption relied on the premise that every patient could be successfully transplanted with an appropriate donor match, which they considered highly unlikely. A commenter believed that the proposed methodology advantages smaller kidney transplant hospitals disproportionately. The commenter argued that it was impractical to require a larger kidney transplant hospital, already performing over 400 transplants annually, to do an additional 200 or more transplants to earn full points and could not be done without compromising quality of care and patient safety. The same commenter also noted that acquiring the necessary staff, space, and resources to accommodate such a rapid and significant increase would pose a substantial obstacle.

Commenters also raised specific concerns over the proposal to trend the transplant target forward by the national growth rate, as described in section III.C.5.c(1) of this final rule. Many commenters indicated that the more an IOTA participant increases its transplant volume, the harder it will be for them to achieve their transplant target in the future PY because the methodology, as proposed, also trends the baseline transplant volume forward

[199] Potluri, V.S., & Bloom, R.D. (2021). *Effect of Policy on Geographic Inequities in Kidney Transplantation. https://doi.org/10.1053/j.ajkd.2021.11.005;* Hanaway, M.J., MacLennan, P.A., & Locke, J.E. (2020). Exacerbating Racial Disparities in Kidney Transplant. *JAMA Surgery, 155*(8), 679. *https://doi.org/10.1001/jamasurg.2020.1455.*

each PY. Many commenters suggested that IOTA participants may be unfairly penalized for responding to the model's goals and incentives. Specifically, that if IOTA participants meet their transplant target during a performance year, the rising national growth rate could make transplant targets harder to achieve in future PYs. A couple commenters suggested that the growth rate should be regionally indexed or calculated separately by region because regional factors affect the potential for increased transplantation. Lastly, a commenter recommended that CMS determine the national growth rate by calculating the average growth rate across multiple baseline years instead of the proposed approach. This commenter believed that this alternative approach for calculating the national growth rate would take into consideration the natural variability in the annual volume of both living and deceased donor transplants performed at kidney transplant hospitals, resulting in a transplant target that may be more attainable for IOTA participants.

Response: Given the numerous concerns from stakeholders regarding the proposed methodology for calculating transplant targets, we recognized an updated methodology may be necessary to strengthen the model. As indicated in the proposed rule (89 FR 43518) and discussed in the preamble of this final rule, we considered setting each IOTA participant's transplant target by determining the IOTA participant's average total kidney transplant volume from the three previous years instead of using the sum of the highest living and deceased donor kidney transplant volumes during the baseline years. Ultimately, we decided against this approach, as we did not believe it would accurately reflect the IOTA participants' full transplant capacity. Instead, we constructed, and proposed, a methodology to illustrate the individual capabilities and capacities of the IOTA participants, which when combined, would serve as an appropriate transplant target for the program year. However, we recognize that there may be a better balance in including a simpler methodology and result in a transplant target that is potentially more attainable for IOTA participants, assuming that the average kidney transplant volume is lower than the sum of the highest volumes of deceased and living donor kidney transplants while still limiting complexity.

We conducted additional analysis that examined one of the methodologies that we considered for calculating the transplant target as described in section III.C.5.c(1) of the proposed rule. Specifically, based on public comment, we reexamined setting each IOTA participant's transplant target by determining the IOTA participant's average total kidney transplant volume from the three previous years instead of using the sum of the highest living and deceased donor kidney transplant volumes during the baseline years (89 FR 43518). Using historical transplant data, we compared this methodology to what we proposed, as described in this final rule, to determine whether an alternative methodology for setting the transplant target would be potentially more attainable.

Based on additional analysis and the commenters concerns about the proposed transplant target methodology, we are finalizing an updated methodology for setting transplant targets as follows:

For each PY, CMS will calculate the transplant target for the achievement domain by first determining the mean of the total number of deceased donor kidney transplants and living donor kidney transplants furnished to patients 18 years of age or older across the baseline years, as defined and finalized in § 512.402 of this final rule.

The mean number of deceased donor and living donor transplants across the baseline years of the IOTA participant would then be projected forward by the national growth rate, as described in section III.C.5.c(1) of this final rule, or zero should the national growth rate be negative, resulting in the transplant target for a given PY.

For example, to calculate the national growth rate for PY 1 using the proposed model start date of January 1, 2025, CMS would first subtract the total number of kidney transplants furnished to patients 18 years of age or older in 2022 from the total number of kidney transplants furnished to patients 18 years of age or older in 2023. Next, CMS would then divide that number by the total number of kidney transplants furnished to patients 18 years of age or older in 2022 to determine national growth rate. To create the transplant target for each IOTA participant for the relevant PY CMS would do the following: 1. If the national growth rate is positive, CMS would trend the national growth rate forward for an IOTA participant by multiplying the national growth rate by the mean number of deceased donor and living donor transplants furnished to patients 18 years of age or older across the baseline years for the IOTA participant.

2. CMS would take the product of step 1 and add it to the mean number of the highest living donor and deceased donor kidney transplants furnished to patients 18 years of age or old across the baseline years for an IOTA participant.

3. The sum of step 2 would be the transplant target for an IOTA participant. However, if the national growth rate were negative, CMS would not trend the growth rate forward for PY 1 and the transplant target would be the sum of the mean number of living donor and deceased donor kidney transplants across the baseline years. For example, when determining individual transplant targets for PY 1 of the model, if an IOTA participant had a mean of 50 living donor and deceased donor kidney transplants furnished to patients 18 years of age or older across the relevant baseline years, and the national growth rate was negative, then the transplant target for that IOTA participant would be 50.

However, we will monitor IOTA participant performance throughout the model performance period and, if warranted, will propose alternative or updated policies in future notice and comment rulemaking.

Comment: Commenters encouraged CMS to reconsider how the proposed transplant target is calculated and suggested a variety of alternative options. Many commenters urged CMS to set each IOTA participant's transplant target by determining the IOTA participant's average total kidney transplant volume from the three previous years. Several of these commenters urged CMS to set each IOTA participant's transplant target by determining the IOTA participant's average total kidney transplant volume from the three previous years across the relevant baseline years. Specifically, a commenter believed that using the average number of transplants across the relevant baseline years would ensure that transplant programs are not penalized for their efforts in increasing transplant volumes prior to program initiation. Another commenter expressed concern that the proposed approach does not take into account the natural year-to-year variability in overall and living donor and deceased donor volume of transplants performed within a kidney transplant hospital. Thus, they recommended that each IOTA participant's transplant target be calculated by determining the IOTA participant's average total kidney transplant volume from the three previous years. The commenter stated that the three-year averaging approach is frequently used by the Innovation Center in other payment methodologies, which could help reduce year-to-year variability and mitigate the impact of potential outliers for transplants from

deceased or living donors in a given year.

A couple commenters suggested CMS use the average kidney transplant volume and a fixed baseline. Specifically, a commenter felt that using the average kidney transplant volume would be more reflective of an IOTA participant's expected performance. A commenter also recommended that CMS take the average of kidney transplant volumes over a 5-year historical period, as it would more accurately reflect past performance. Another commenter believed that the transplant target should be calculated based on the average number of kidney transplants performed during a fixed historical period to ensure that IOTA participants are not penalized for their success in increasing transplant volumes.

A commenter also suggested that CMS select the year with the highest total volume of living and deceased donor kidney transplants combined in relation to the three prior years as the historical benchmark. The commenter felt that this was especially crucial if the historical benchmark is then multiplied by a national growth rate, as proposed, to ensure IOTA participants have a realistic chance of meeting the target. This same commenter also suggested that CMS could consider identifying in the relevant baseline years the highest number of combined deceased donor and living donor kidney transplants and then measure and reward subsequent growth in each transplant type, deceased donor and living donor. However, the commenter acknowledged that this methodology would be more complex and move away from the simplicity originally proposed, which is a strength of the model. Finally, a commenter recommended that CMS use a weighted benchmark based on the actual number of kidney transplants for three years, with the most recent year being weighted the most.

Response: We appreciate the commenters' suggestions on alternative methodologies for setting the transplant target. As mentioned in comment responses noted previously, we recognize that there could be a more favorable balance by adopting a simpler methodology that could result in a transplant target that is more feasible for IOTA participants, assuming that the average kidney transplant volume is lower than the total of the highest volumes from both deceased and living donor kidney transplants, while still keeping complexity to a minimum. As such, we are finalizing an updated methodology for setting transplant targets at § 512.424(b). Specifically, CMS will calculate the transplant target for the achievement domain by first determining the mean of the total number of deceased donor kidney transplants and living donor kidney transplants furnished to patients 18 years of age or older across the baseline years, as defined and finalized in section III.C.3.c of the preamble in this final rule.

Comment: A couple commenters suggested that CMS create a fixed baseline year period, rather than changing the baseline every PY. For example, one of these commenters stated that a permanent baseline would be particularly beneficial for larger institutions, for which year-over-year growth is more difficult. Another commenter felt that CMS should use a fixed baseline year period of five to ten years. The commenter noted that a kidney transplant hospital's annual volume is often limited to factors beyond their control and may vary year to year. Thus, they believed that an average of transplant volumes over a five-to-ten-year period would more accurately reflect a participant's past performance. The same commenter also acknowledged that the model performance years would not factor into an IOTA participant's transplant target calculation until the third PY; however; they argued that transplant target methodology as proposed penalizes IOTA participants for their earlier successes by making it more difficult to exceed the target in the future. Therefore, using a fixed baseline would ensure IOTA participants are able to realistically meet their transplant targets and would not be penalized for variations in transplant volumes.

Response: We thank the commenters for their feedback. As described at 89 FR 43552 in the proposed rule, we considered a static or fixed baseline approach, as it would minimize operational burden for CMS due to less frequent updates to the transplant target and ensure that the model does not set a moving target year-over-year. However, for the reasons described in section III.C.5.c(1) of this final rule, we disagree with the commenters that the baseline years should be fixed. We maintain our belief that the proposed rolling baseline approach, which uses historical kidney transplant volumes pre-dating the model start date through the first two model PYs, ensures a phased-in approach before any improvements made during the model performance period are accounted for in the baseline. Thus, we are finalizing our proposal to calculate the transplant target using the relevant baseline years, as defined and finalized in section III.C.3.c of the preamble in this final rule, as proposed.

Comment: Several commenters raised concerns about using CY 2021 when calculating the IOTA participant specific transplant target. Given that transplant hospitals across the U.S. were impacted by COVID–19 at different points throughout the year, a couple commenters believed that CY 2021 data may inadvertently skew the baseline performance, either increasing or decreasing it, obscuring the true performance of programs required to participate in the IOTA Model. Another commenter conveyed that while they recognized the importance of analyzing past performance over multiple years, they suggested that CMS should concentrate exclusively on CY's 2022 and 2023.

A few commenters argued that CY 2021 was an outlier in various aspects and might not reflect the usual practices, or the current and anticipated practices, of numerous transplant hospitals. These aspects included the COVID–19 pandemic and the change in kidney allocation. These commenters specifically noted that the COVID–19 pandemic had a profound influence on kidney transplant volumes during 2021. They suggested that some transplant hospitals lowered their transplant rates, whereas others actually ramped up their operations. They believed that this situation arose in part because transplant hospitals that conducted fewer transplants allowed for a greater availability of high-quality kidneys for the transplant hospitals that remained operational. Additionally, 2021 was the first year the new KAS250 policy took effect, and transplant hospitals were still adjusting to the significant increase in organ offers.

Response: We thank commenters for their feedback and for raising some concerns about the proposed methodology for setting specific transplant targets. We acknowledge the commenters' concerns regarding the inclusion of CY 2021 in the baseline years as it pertains to setting specific transplant targets. We considered setting the transplant target for IOTA participants based on two baseline years, rather than the proposed methodology of three, as described at 89 FR 43552 in the proposed rule. In light of the commenters' concerns, we considered the potential impact of including CY 2021 in the proposed methodology for setting specific transplant targets, as described in section III.C.5.c(1) of the proposed rule. We still believe that using two baseline years to set a transplant target would make the target more susceptible to

temporary market disruptions or fluctuations, such as those discussed at 89 FR 43552 in the proposed rule, which could result in an inaccurate transplant target that does not accurately reflect the IOTA participant's true volume capabilities. As such, we disagree with excluding CY 2021 from the relevant baseline years when setting specific transplant targets. However, as mentioned in comment responses noted previously in this section, we are finalizing a modified methodology for setting specific transplant targets. Specifically, we are finalizing at § 512.424(b) that CMS would calculate the transplant target for the achievement domain by first determining the mean of the total number of deceased donor kidney transplants and living donor kidney transplants furnished to patients 18 years of age or older across the baseline years, as defined and finalized in section III.C.3.c of this final rule. We will analyze and monitor the performance of IOTA participants to ensure they are not unfairly disadvantaged by the model. If our analysis indicates the need for a new or revised policy, we will address it through future notice and comment rulemaking.

Comment: A commenter requested that CMS clarify whether the transplant number used for the transplant target calculation would be based on kidney transplants performed for all payors, or just Medicare kidney transplants.

Response: As discussed in the proposed rule at 89 FR 43550, CMS would calculate the transplant target for the achievement domain by first determining the highest number of deceased donor kidney transplants and living donor kidney transplants furnished to patients 18 years of age or older in a single year during the baseline years, as defined in section III.C.3.c. of the proposed rule. We clarify that the transplant target would be calculated based on the number of applicable kidney transplants performed across all payors. However, as mentioned in comment responses noted previously, we are finalizing an updated methodology for setting transplant targets. Specifically, we will be finalizing at § 512.424(b) that CMS would calculate the transplant target for the achievement domain by first determining the mean of the total number of deceased donor kidney transplants and living donor kidney transplants furnished to patients 18 years of age or older across the baseline years, as defined and finalized in section III.C.3.c of this final rule. We note that this would still be inclusive across all payors and not just Medicare.

Comment: A commenter suggested that CMS provide each IOTA participant with their transplant target three months or at least one month prior to the start of a performance year rather than by the first day of a performance year. Knowing the transplant target ahead of time will allow participants to prepare for the model.

Response: We appreciate the commenter's suggestion. We note that it is our intent to provide each IOTA participant with their transplant target prior to the first day of each PY. However, we acknowledge that operational delays could occur which is why we proposed to provide each IOTA participant with their transplant target by the first day of each PY. Thus, to account for potential operational delays, we are finalizing as proposed.

Comment: A commenter stated that they did not agree with our proposed definition of national growth rate. Specifically, the commenter disagreed with eliminating low-volume kidney transplant hospitals when assessing the national growth rate. Given transplant programs can close and new transplant programs can enter the market, the commenter felt that the national growth rate should be based on all adult kidney transplants performed in the country as this represents a true reflection of growth in kidney transplants performed. The commenter went on to express that they agreed with CMS that the national growth rate in kidney transplants makes the most sense to use as the basis for the model's growth factor but felt that the national growth rate should reflect the total growth rate in kidney transplants as measured across all adult transplants performed at adult transplant programs (with due consideration of the definition of an IOTA transplant patient).

Response: We appreciate the commenter's suggestion and acknowledge their concerns for excluding kidney transplant hospitals that fall below the low volume threshold from the proposed national growth rate, as defined at 89 FR 43617 in the proposed rule. We note that at 89 FR 43550 we proposed that CMS would calculate the national growth rate by determining the percent increase or decrease of all kidney transplants furnished to patients 18 years of age or older from two years prior to the PY to one year prior to the PY. We also stated at 89 FR 43550 that because the proposed national growth rate includes IOTA participants and non-IOTA participant kidney transplant hospitals, we acknowledged that it could make achieving the transplant target number harder. This is why, if the national growth rate becomes negative for a PY, we proposed treating it as zero and CMS would not apply the national growth rate to project forward the sum of the highest number of deceased and living donor kidney transplants furnished in a single year during the baseline years. However, upon further consideration, CMS agrees with this commenter's suggestion. As such, we will be finalizing a modified definition of national growth rate at § 512.402 to eliminate the exclusion of kidney transplant hospitals that fall below the low volume threshold from the national growth rate calculation.

Comment: A commenter indicated that CMS proposed to calculate the national growth rate by determining the percent increase or decrease of all kidney transplants furnished to patients 18 years of age or older from two years prior to the PY to one year prior to the PY. However, the commenter suggested that CMS should provide clarification around whether the national growth rate would be rounded. Specifically, the commenter wanted to know if, when, and how rounding would be applied to these calculations. Additionally, the commenter also wanted to know if the national growth rate would be rounded, and if so, to what extent. The commenter believed that this is important for the calculation of each IOTA participant's transplant target. The commenter also suggested that providing more clarity here could help improve understanding as the IOTA Model is implemented.

Response: We thank the commenter for highlighting the need for clarity regarding whether any of the proposed calculations for setting a transplant target would be rounded. We clarify that once all calculations for setting a transplant target have been made, CMS would do the following:

- Round the transplant target down for decimals less than 0.500; and
- Round the transplant target up for decimals of 0.500 or greater.

For example, if an IOTA participants transplant target is 57.44, CMS would round the transplant target down to 57. Whereas, if an IOTA participants transplant target was 57.54, CMS would round the transplant target up to 58.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed provisions on setting unique transplant targets for each IOTA participant and the methodology for setting transplant targets, with modification. We are codifying in our regulation at § 512.424(b) that for each PY, CMS will determine the transplant

target for the achievement domain, as proposed.

We are codifying in our regulation at § 512.424(b)(1) that CMS analyzes the baseline years for the relevant PY, without modification. In response to comments received, we are replacing the methodology for setting unique transplant targets we had proposed to use for purposes of determining performance in the achievement domain. Specifically, we are codifying in our regulation in sections § 512.424(b)(1)(i) and (ii) that CMS identifies the mean number of deceased donor kidney transplants furnished by the IOTA participant to patients 18 years of age or older across the relevant baseline years, as defined at § 512.402 and the mean number of living donor kidney transplants furnished by the IOTA participant to patients 18 years of age across the baseline years, as defined at § 512.402.

We are finalizing our regulation at § 512.424(b)(2) that CMS sums the numbers in sections §§ 512.424(b)(1)(i) and (ii), without modification. We are also finalizing as proposed our provisions for calculating the national growth rate at § 512.424(b)(3), calculation of transplant target at § 512.582(b)(4), notification of transplant target at § 512.424(c) and the definitions of transplant target, and pediatric kidney transplant hospitals at § 512.402. In response to public comments, we are finalizing our proposed definition of national growth rate at § 512.402 with slight modification to remove the exclusion of kidney transplant hospitals that fall below a low-volume threshold of 11. Specifically, we are codifying at § 512.402 that national growth rate means the percentage increase or decrease in the number of kidney transplants performed over a 12-month period by all kidney transplant hospitals except for pediatric kidney transplant hospitals, as defined at § 512.402. We note that we will analyze and monitor IOTA participant performance throughout the model performance period to ensure we do not unduly disadvantage IOTA participants. If analysis results warrant a new or updated policy, we will address it pursuant to future notice and comment rulemaking.

(2) Calculation of Points

In section III.C.5.c(2) of the proposed rule, we proposed that the achievement domain would be worth 60 points. We chose this domain for the highest number of points because we believe that driving an increase in the number of transplants should be the main incentive for change in the model. We considered allocating fewer points to this domain, such as 50 points, but we believe that performance in this domain should impact the overall performance score more than the other domains given its centrality to the model.

In section III.C.5.c(2) of the proposed rule, we proposed that an IOTA participant's performance would be assessed relative to their transplant target, with those performing at less than 75 percent of the transplant target receiving no points and those performing at 150 percent of the transplant target or above receiving the maximum number of points (60 points). That is, at the highest end of the scale, IOTA participants performing at or above 150 percent of the transplant target would earn the maximum 60 points, while at the lowest end of the scale, IOTA participants performing at less than 75 percent of the transplant target would earn no points for the achievement domain; performance that falls in between 75 percent and 150 percent of the transplant target may earn the IOTA participant 45, 30, or 15 points in the achievement domain. Table 3 illustrates our proposal for how an IOTA participant's performance would be assessed against its transplant target. We chose 150 percent as the maximum performance level based on the theoretical capability of growth in one year and analysis in trends of transplant over time. We recognized that an IOTA participant might exceed 150 percent of its transplant target, but this was not expected given the investment needed for substantiable transplant infrastructure to consistently support that number of transplants over time.

TABLE 3: PROPOSED ASSESSMENT OF ACHIEVEMENT DOMAIN

Performance Relative to Transplant Target	Lower Bound Condition	Upper Bound Condition	Points Earned
150% of transplant target	Equals 150%	Greater than 150%	60
125% of transplant target	Equals 125%	Less than 150%	45
100% of transplant target	Equals 100%	Less than 125%	30
75% of transplant target	Equals 75%	Less than 100%	15
75% of transplant target	N/A	Less than 75%	0

We stated in the proposed rule that we believe that a methodology based on performance improvement relative to historical performance is important and would allow us to test whether the model's performance-based payments drive increased behavior from IOTA participant, as opposed to just rewarding IOTA participants based on the status quo (89 FR 43518). IOTA participants that are achieving a high rate of kidney transplantation, and already have robust transplant programs at the start, can more easily scale up to achieve the additional growth required for excellent performance under the model. Also, given our statutory requirements to achieve savings, the CMS Office of the Actuary (OACT) estimates, as described in section VI of the proposed rule, suggested that savings would be driven by the effects of increased transplants. We believed that the model's performance-based payments need to be tied to a policy that aims to create and drive Medicare savings.

We considered offering differential credit for transplants by type (89 FR 43518). With this methodology, IOTA participants would receive bonus points and score higher for transplants that fit into categories that lead to more savings, such as living donor kidney transplants (LDK), high KDPI donors, or pre-emptive transplants, compared to other transplants. However, we believed that counting all transplants the same, except for transplants furnished to underserved populations, would maximize flexibility for IOTA

participants in meeting their targets and minimize the potential harm and unintended consequences the alternative system would create.

As an alternative, we considered including gradient points instead of points based on bands (that is, between X and Y) (89 FR 43518). Scoring closer to a performance minimum would result in increased points rather than remaining static throughout the band. We considered the following formula: Percent Performance Relative to Transplant Target * (100/2.5), not to exceed 60 points. However, we decided that a narrower range of results would better differentiate performance among IOTA participants and allow for easier comparison across IOTA participants.

We also considered smaller point brackets of improvement, requiring IOTA participants to achieve a flat number increase of kidney transplants, such as to a 140 percent, 125 percent, or 120 percent, to achieve the highest performance in this category, and asymmetric point brackets that would make the magnitude of performance required to achieve the highest performance rate a flat number increase in addition to a percentage increase (89 FR 43518). However, we wanted the percentage of the transplant target necessary to achieve the highest number of points to be large enough to incentivize behavior while still being achievable.

We also considered improvement-only scoring, based on year-over-year IOTA participant transplant growth, without inclusion of national rates (89 FR 43518). In this methodology, positive improvement rates less than 5 percent would be scored 15 points, rates over 5 percent would be scored 30 points, rates over 20 percent would be scored 45 points, and rates over 50 percent would be scored 60 points. We also considered using combinations of potential transplant target or scoring methods, with the final score being whichever score was highest to ensure low-volume IOTA participants are not penalized and to mitigate unrealistic transplant targets. We considered an improvement-only scoring methodology to reflect the historical performance of each IOTA participant. However, because we want a methodology that sets more of a national standard for expected growth rate to assess volume trends in the transplant space overall, we chose not to propose improvement-only scoring. As organ supply continues to increase year-over-year, we wish to set the expectation for IOTA participants to grow their transplant volumes at least at the cadence of the national growth rate.

We solicited comment on our proposed achievement domain scoring methodology and alternative methodologies considered.

The following is a summary of the comments received on our proposed achievement domain scoring methodology, alternative methodologies considered and our responses:

Comment: Numerous commenters expressed concerns that the achievement domain requires an impractically significant increase in kidney transplant volume, especially in the later PYs of the IOTA Model. In particular, they felt it would be virtually impossible for IOTA participants to earn the maximum points in this domain, and that the proposed approach would undermine the overall model test.

Response: We recognize the validity of this critique from commenters and believe in updating the achievement domain in two key areas. The first is that the transplant target for each IOTA participant will be calculated based on a rolling average of transplants, as described and finalized in section III.C.5.c(a) of this final rule, rather than taking the highest number of living and deceased transplants across the relevant baseline years, as discussed previously. The second is to modify our scoring methodology for allocating points for the achievement domain at Table 1 under § 512.424(f)(2), as illustrated in Table 4 of this section.

Comment: Several commenters expressed concern that the proposed thresholds for increasing transplant rates are aggressive such that they could negatively impact performance score metrics for all IOTA participants, recommending that CMS set more realistic performance goals by lowering the points thresholds in the achievement domain. For instance, a commenter supported the proposed methodology of awarding points based on percentage relative to transplant target thresholds. However, they believed the proposed points thresholds exceeded reasonable expectations for eligible kidney transplant hospitals. The commenter recommended that CMS set the highest points threshold (60 points) at greater than 125 percent of the transplant target, and drop the lowest points threshold (0 points) to less than 50 percent of the transplant target. This, the commenter felt, would ease IOTA participants' ability to receive achievement domain points, help alleviate resource disparities between participant hospitals, and reduce the potential for financial considerations to cloud clinical judgment when matching organs to recipients.

Another commenter recommended that CMS use a volume growth trend that better recognizes the potential limits of transplant programs to expand capacity in a more reliable, realistic, and safe manner. The commenter felt that having a transplant goal that is more achievable would also incentivize the growth the IOTA Model is trying to achieve. Setting transplant targets too high could discourage IOTA participants from growing their kidney transplant programs at all if the targets are unrealistic and not achievable. As such, this same commenter recommended that CMS allow IOTA participants to achieve the maximum 60 points for the achievement domain with performance equal or greater than 110 percent of the transplant target.

Another commenter stated that to achieve a 10 percent increase in kidney transplants, a large-volume kidney transplant hospital performing 400 transplants annually would need to do an additional 40 per year. While the increase would be less for smaller kidney transplant hospitals, any additional transplants may strain their personnel and infrastructure. The commenter also suggested that kidney transplant hospitals of any size need appropriate lead time to estimate and accommodate the increase in transplant volume. Expanding transplant capacity requires significant infrastructures investments, such as for higher-risk candidates and donor organs, infusion bays, access to inpatient and outpatient dialysis for higher volumes of recovering recipients with delayed graft function, and additional personnel. The commenter warned that disregarding these infrastructure needs would put undue stress on the healthcare system and could prevent IOTA participants from meeting mandated targets. For these reasons, they recommended that the achievement domain points thresholds be lowered to a more realistic performance metric (for example, 110 to 125 percent relative to transplant target).

Lastly, a commenter believed that the proposed achievement domain points thresholds are too aggressive and would sharply curtail the opportunity for IOTA participants to achieve more than 30 points in any PY. The commenter suggested an alternative approach that would allow IOTA participants to earn the maximum 60 points in the achievement domain if their performance exceeded the transplant target by 125 percent or more.

Response: We thank the commenters for expressing their concerns and for their suggestions on our proposed methodology for awarding points for performance in the achievement

domain. As described in the proposed rule at 89 FR 43553, we considered smaller point brackets of improvement to achieve the highest performance in this category but chose not to propose smaller point brackets of improvement as we wanted the percentage of the transplant target necessary to achieve the highest number of points to be large enough to incentivize behavior while still being achievable. However, in response to comments received, we are updating the methodology for points allocation in the achievement domain. Specifically, we are finalizing, with modification, Table 1 to Paragraph (f)(2) at § 512.424(f)(2) to reflect the updated points allocation, as illustrated in Table 4.

TABLE 4: ASSESSMENT OF ACHIEVEMENT DOMAIN

Performance Relative to Transplant Target	Lower Bound Condition	Upper Bound Condition	Points Earned
125% of transplant target	Equals 125%	Greater than 125%	60
120% of transplant target	Equals 120%	Less than 125%	55
115% of transplant target	Equals 115%	Less than 120%	50
105% of transplant target	Equals 105%	Less than 115%	40
95% of transplant target	Equals 95%	Less than 105%	30
85% of transplant target	Equals 85%	Less than 95%	20
75% of transplant target	Equals 75%	Less than 85%	10
75% of transplant target	N/A	Less than 75%	0

We believe that the updated scoring system reflects our partial agreement with commenters. Specifically, we are lowering the maximum performance threshold from 150 percent to 125 percent of the transplant target. Moreover, in combination with the updated methodology for setting transplant targets, as described and finalized section III.C.5.c(1) of this final rule, we believe that this revised standard is more achievable for IOTA participants and strikes a balance—it aims to incentivize performance, while also recognizing the challenges that IOTA participants may face in increasing their kidney transplant volume.

Lastly, because we are updating achievement domain performance thresholds and points allocation, we are keeping the performance threshold for earning 0 points at 75 percent of the transplant target as proposed at 89 FR 43553. This is to ensure a minimum level of performance from IOTA participants and keep the focus on ensuring that the number of kidney transplants performed by IOTA participants does not significantly decrease.

Comment: A commenter suggested that CMS adopt a more graduated scoring scale, providing additional opportunities for IOTA participants to earn points in the achievement domain.

Response: We appreciate the feedback from the commenter. As mentioned in comment responses noted previously, in light of the comments received, we are updating the methodology for points allocation in the achievement domain, as illustrated in Table 4 of this section. The updated methodology for point allocation includes additional gradations, which we believe will provide IOTA participants with greater opportunities to earn points compared to the four scoring ranges we originally proposed at 89 FR 43553 in the proposed rule.

Comment: A commenter expressed concerns that the proposed methodology for calculating transplant targets would have compounding negative effects on performance over time, making it increasingly difficult for IOTA participants to earn maximum points in the achievement domain in later years of the model.

Response: We thank the commenter for raising their concern. We recognize that the proposed methodology may have set a standard that may have been too difficult for IOTA participants to meet. We believe that our updated methodology for setting the transplant target, as described and finalized in section III.C.5.c(1) of this final rule, sets a balance between trying to incentivize improvement over time with allowing IOTA participants to recognize the benefits of investment in increasing their number of kidney transplants. Moreover, as described in the proposed rule at 89 FR 43550, the model PYs would not factor into an IOTA participant's transplant target calculation until PY 3 of the model and the baseline years would not be based exclusively on PYs until PY 5 of the model. We maintain our belief that using baseline years to calculate the transplant targets could represent an effective phase-in approach to drive improved performance and savings for the Medicare trust fund, while also accounting for kidney transplant hospitals that experience changes in strategy or staffing that may affect their transplant capacity compared to previous years.

Comment: We received a comment that the only way that IOTA participants can increase their supply is by using marginal organs which would result in increased rates of graft failure for transplanted patients.

Response: We disagree with this commenter and would like to provide clarification. We did not specify how IOTA participants should increase their number of kidney transplants, nor do we believe that the only way that IOTA participants can increase their number of transplants is by using marginal organs. In the proposed rule at 89 FR 43551, we expressed our belief that IOTA participants could improve on this metric and provided several possible ways that they might be able to. We acknowledge that some IOTA participants may choose to increase their utilization of DCD kidneys or kidneys with a KDPI greater than 85, however, the IOTA Model does not prescribe that they do. Additionally, the CoPs for transplant hospitals require that the transplanting surgeon at the transplant program is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient (42 CFR 482.92).

Furthermore, we believe that many organs that are not used today have a clinical profile similar to organs that are ultimately transplanted. As such, we expect that IOTA participants will exercise their medical judgement appropriately when determining whether or not to accept a DCD kidney organ offer.

Comment: We received a comment that there is not enough available transplant supply to increase numbers, particularly at the thresholds that CMS set in the proposed scoring for the achievement domain.

Response: We believe that the updated transplant target methodology and scoring methodology make the transplant targets more achievable for IOTA participants. We also recognize the growth in organs being procured by OPOs since the 2020 CfC update and believe that there is an opportunity for transplant hospitals to take advantage of the updated supply being procured by OPOs. Additionally, we believe that living donation represents an untapped supply of potential kidney transplants that is not dependent on procurement practices.

Comment: A commenter expressed their disagreement with the proposed achievement domain performance thresholds, as they do not take into account the inability of transplant programs to scale up the volume of the number of transplants performed in a given year. The commenter believed that some transplant programs may have excess capacity to perform more transplants annually, but others would face significant fixed costs to expand their transplant operations beyond their current volume. Additionally, the commenter noted that in the current labor market, it would be challenging to recruit and retain the highly specialized staff, including transplant physicians, needed to expand the capacity of their transplant program to meet these transplant targets.

Response: We recognize that there will be some need for IOTA participants to scale up, which is why we are not finalizing the proposed model start date of January 1, 2025. As described and finalized in section III.C.1.a of this final rule, we are finalizing a model start date of July 1, 2025. We also note that there is no downside risk payment in PY 1, as described and finalized in section III.C.6.c(2)(b) of this final rule. As such, it will be over 18 months from the publication of this final rule until an IOTA participant is held liable for their number of transplants with the potential for a downside risk payment. Furthermore, as mentioned in comment responses in this section, we will be finalizing an updated methodology for points allocation in the achievement domain, as illustrated in Table 4 in this section, and our methodology for setting transplant targets, as described and finalized in section III.C.5.c(1) of this final rule. For these reasons, we believe this will give time for IOTA participants to make investments to expand their transplant program, resulting in a transplant target that is potentially more attainable for IOTA participants and providing additional opportunities to be awarded points.

Comment: Multiple commenters expressed concern that the proposed scoring methodology was too difficult for large kidney transplant hospitals, given that a significant percentage increase for them represents a higher number of additional transplants. We also received comments pointing out that the scoring methodology could be punitive to IOTA participants that already invested to increase their number of transplants before the start of the model.

Response: We thank the commenters for expressing their concerns regarding the proposed scoring methodology. We note that, as described and finalized in section III.C.5.c(1) of this final rule, that we are finalizing an updated methodology for setting transplant targets. We direct readers to section III.C.5.c(1) of this final rule for further discussion on our updated methodology for setting transplant targets. As such, we believe that this updated methodology for setting transplant targets will make top performance in the achievement domain more achievable for all kidney transplant hospitals participating in the model. We also recognize that larger kidney transplant hospitals have already invested in additional capacity and resources to help more patients through the transplant process, which means that they have experience in increasing their transplant numbers that they can leverage as IOTA participants.

Comment: We received comments that the proposed scoring methodology was too difficult for smaller kidney transplant hospitals. Commenters pointed out that smaller kidney transplant hospitals may experience fluctuations in their transplant volume. Given their lower volume of kidney transplants, a small numerical decrease in the number of kidney transplants they perform could translate to a large percentage drop, potentially resulting in a loss of all points in the achievement domain.

Response: We believe that the updated methodology for setting transplant targets, as described and finalized in section III.C.5.c(1) of this final rule, will help smaller kidney transplant hospitals selected to participate in the model deal with fluctuations. We direct readers to section III.C.5.c(1) of this final rule for further discussion on our updated methodology for calculating transplant targets. The updated scoring methodology, as shown in Table 4, will provide more gradation in scoring. As such, we believe that this should prevent small kidney transplant hospitals from being significantly impacted if they fall short of their transplant targets by a small margin. The increased number of scoring thresholds means IOTA participants will have more opportunities to earn points, minimizing the effect of minor shortfalls.

Comment: Several commenters proposed including a living donor performance adjustment, which would award additional points for living donor kidney transplants. A commenter suggested that, in the absence of adequate risk adjustment, a performance adjustment, similar to the proposed health equity adjustment, with a weighting greater than 1 should also be considered for living donor transplants. Another commenter suggested that CMS should consider including an incentive multiplier in the achievement domain point calculation for living donor kidney transplants, as this is the optimal treatment for patients with end-stage kidney disease (ESKD). Lastly, a commenter praised CMS's efforts to improve the organ transplantation system, but recommended giving greater weight to living donor kidney transplants over deceased donor kidneys for several reasons. For example, the commenter cited that living donor kidneys typically have a lower risk of graft failure compared to deceased donor kidneys. This results in longer lifespans for living donor kidney recipients, fewer complications, better post-transplant outcomes, and reduced burden on the healthcare system—ultimately enhancing overall patient health. Additionally, they noted that there is a reduced need for immunosuppressive medications because patients receiving a living donor kidney often require less immunosuppressive drugs. For these reasons, the commenter proposed that CMS either assign a larger weight to living donor kidney transplants or apply a multiplier akin to the proposed health equity performance adjustment.

Response: We thank the commenters for their suggestions to include a living donor performance adjustment. We recognize the benefits of living donor

transplantation and views it as an important part of the transplant process. However, the IOTA Model test prioritizes flexibility, allowing IOTA participants to determine the best way to perform. We also acknowledge that IOTA participants may have varying comfort levels with promoting living donation. As such, we want to prioritize flexibility for IOTA participants rather than specifically promoting any particular transplant type. Additionally, we believe that the composite graft survival rate measure, as described and finalized in section III.C.5.e(1) of this final rule, in the quality domain accounts for the potential long-term survival benefits of living donation for patients.

Comment: A commenter suggested that IOTA participants receive additional points in the proposed achievement domain scoring methodology for preemptive kidney transplants, as they offer considerable survival and quality of life benefits for patients, as well as major cost savings. Given the substantial benefits to patients and the substantial savings as compared to dialysis, the commenter recommended that CMS consider creating a preemptive bonus or preemptive multiplier, which could be scaled proportionately with savings to the Medicare program pre-emptive transplants provide relative to maintenance dialysis. However, the commenter emphasized that carefully calibrating and closely monitoring such a bonus or multiplier would be crucial. Ideally, this process should involve input from the community to ensure the incentive expands access to pre-emptive kidney transplants rather than exacerbating existing disparities.

Response: We thank the commenter for their suggestion but disagree with the commenter. We recognize the benefits of preemptive transplantation. However, we are unsure whether the inclusion of a preemptive kidney transplant performance adjustment would be effective at incentivizing preemptive transplantation. We plan to monitor the effects of the model on preemptive transplantation as part of the evaluation process and may consider potential changes to the model through future notice and comment rulemaking, depending on performance by IOTA participants.

Comment: A couple commenters suggested that CMS should use two metrics to score IOTA participants in the achievement domain: percentage growth in kidney transplants and a flat threshold for increased kidney transplant volume. For instance, a commenter proposed that IOTA participants earn maximum points if they achieve 150 percent of their transplant target or perform 25 additional kidney transplants.

Response: We thank the commenters for their suggestions to include an additional flat threshold scoring methodology. We understand the merits of this idea as it recognizes that it may be more difficult for IOTA participants that are already performing more transplants to further increase their number of transplants. As described at 89 FR 43553 in the proposed rule, we considered a methodology based on year-over-year IOTA participant transplant growth, excluding national growth rates. We also considered using combination of potential transplant target or scoring methodologies, taking the highest resulting score to avoid penalizing low-volume IOTA participants and prevent unrealistic transplant targets. However, for the reasons described in section III.C.5.c(2) of this final rule, we chose not to propose either of the methodologies discussed previously.

We believe that the updated methodology for setting transplant targets, as described and finalized in section III.C.5.c(1) of this final rule, and the updated scoring methodology in the achievement domain, as illustrated in Table 4 in comment responses noted previously, will make it more achievable for IOTA participants of all sizes to achieve maximum points in this domain.

Comment: A commenter expressed their concern over the number of proposed points for the achievement domain (60 points) and quality domain (20 points). Specifically, the commenter was concerned that, in the context of resource scarce kidney transplant hospitals, resources would be pulled from efforts to help patients succeed in the long-term (post one-year) period in order to deliver success on increasing transplant rates. As such, the commenter believed that greater emphasis was needed to encourage focus on, and investment in, supporting patients' longer-term (post-one-year and longer) outcomes post-transplant, recommending that CMS allocate a maximum of 50 points for the achievement domain instead of the proposed 60 points.

Response: We appreciate the commenter's recommendation and acknowledge their concerns. The achievement domain performance score was weighted more heavily than the efficiency and quality domains because we believe this aligns with the IOTA Model's primary objective of increasing the total number of kidney transplants (89 FR 43548). Moreover, recognizing that the main goal of the model is to increase the number of kidney transplants performed, we maintain that weighing performance on this measure more than the efficiency domain and quality domain is necessary to directly incentivize participants to meet their target, as increasing the number of kidney transplants performed is the primary goal of the model. For these reasons, we disagree with the commenter that CMS should decrease the number of proposed points allocated for the achievement domain and are finalizing our proposal to allocate 60 out of a maximum 100 points to the achievement domain, as described and finalized in section III.C.5(b) of this final rule. Regarding our proposed point allocations across the achievement domain, efficiency domain, and quality domain, and alternatives we considered, we direct readers to section III.C.4.b of this final rule. We note that we intend to monitor the impacts of the quality domain and efficiency domain throughout the model test and will consider whether adjustments in the maximum number of points awarded in each domain are necessary in future notice and comment rulemaking.

After consideration of the public comments, for the reasons set forth in this rule, we are finalizing our proposed achievement domain scoring methodology, with modification. As described in section III.C.5.c(3) of the preamble in this final rule, we will not be finalizing a health equity performance adjustment provision. As such, we are finalizing the provisions at § 512.424(a) with slight modification. Specifically, we are modifying the regulatory text at § 512.424(a)(2) to remove references to a health equity performance adjustment and make minor technical corrections in punctuation.

We are codifying in our regulation at § 512.424(f) that for each PY, CMS awards the IOTA participant zero to 60 points for its performance in the achievement domain, as proposed. We are also making a minor technical correction to update the cross reference in our regulation at § 512.424(f)(1). In particular, we are removing the cross reference to the health equity performance adjustment and replacing it to reflect § 512.424(d)(2). We direct readers to section III.C.5.c(3) of this final rule for further discussion on the health equity performance adjustment.

We are also finalizing § 512.424(f)(2) as proposed, which states that for each PY, CMS will calculate the transplant target for the achievement domain, as proposed. Lastly, in response to

comments received, we are replacing the methodology for points allocation in the achievement domain. Specifically, we are finalizing, with modification, Table 1 to Paragraph (f)(2) at § 512.424(f)(2) to reflect the updated points allocation, as illustrated in Table 4 above. However, we will analyze and monitor IOTA participant performance through the model test to ensure we do not unduly disadvantage kidney transplant hospitals selected for the model. If analysis results indicate that a change in policy is warranted, we will address it pursuant to future notice and comment rulemaking.

(3) Health Equity Performance Adjustment

Socioeconomic factors impact patient access to kidney transplants. Patients with limited resources or access to care may require more assistance from kidney transplant hospitals to overcome barriers to transplantation. To incentivize IOTA participants to decrease disparities in the overall transplant rate among patients of various income levels, we proposed to include a health equity performance adjustment in the methodology for calculating the overall number of transplants furnished to patients attributed to an IOTA participant during the PY. We proposed to define the ''health equity performance adjustment'' as the multiplier applied to each kidney transplant furnished to a low-income population IOTA transplant patient when calculating the transplant target (as described in § 512.424 of the proposed rule). For purposes of the model, we proposed to define the ''low-income population'' to mean an IOTA transplant patient in one or more of the following groups:

- The uninsured.
- Medicaid beneficiaries.
- Medicare-Medicaid dually eligible beneficiaries.
- Recipients of the Medicare low-income subsidy.
- Recipients of reimbursements from the Living Organ Donation Reimbursement Program administered by the National Living Donor Assistance Center (NLDAC).

In the proposed rule, we proposed to apply a health equity performance adjustment, a 1.2 multiplier, to each kidney transplant furnished by an IOTA participant to a patient, 18 years of age or older at the time of transplant, that meets the low-income population definition. That is, each kidney transplant that is furnished to a patient who meets the low-income population definition would be multiplied by 1.2, thus counting that transplant as 1.2 instead of 1. The resulting count of the overall number of kidney transplants performed during the PY, after the health equity performance adjustment is applied, would then be compared to the transplant target. In effect, the health equity performance adjustment would be a reward-only adjustment to the performance score in the achievement domain. We also considered basing the multiplier on the difference between rates of transplantation for Medicare beneficiaries with ESRD who are dual eligible and those who are not. In 2019, 47 percent of Medicare beneficiaries with ESRD were dually eligible for Medicare and Medicaid. However, only 41 percent of Medicare transplants recipients were dually eligible, which would yield a multiplier of 1.1.[200]

We chose 1.2 as the health equity performance adjustment multiplier because, according to USRDS data, 78.6 percent of patients living with ESRD have some form of Medicare and or Medicaid coverage; however, only 65.1 percent of patients who received transplants in 2020 were on Medicare, Medicaid, or both.[201] [202] The 1.2 multiplier represents the ratio of those living with ESRD and those who received transplants. We theorized that providing this incentive for IOTA participants to increase their transplant rate among low-income populations would ultimately reduce disparities in access to kidney transplants, as it would encourage IOTA participants to address access barriers low-income patients often face, such as transportation, remaining active on the kidney transplant waiting list, and making their way through the living donation process.

We believed that the health equity performance adjustment would be a strong incentive to promote health equity, as the multiplier earned would help IOTA participants meet or exceed their kidney transplant target, thereby potentially resulting in upside risk payments given the heavy weighted scoring applied to the achievement domain. We also believed it would ensure IOTA participants that serve disproportionately high numbers of low-income populations are not penalized in the achievement performance scoring.

We considered not applying a health equity performance adjustment to the achievement performance scoring, which would ensure all kidney transplants, regardless of the low-income status of individual patients, are counted as one transplant. The concern with the health equity performance adjustment may be that it may incentivize shifting of kidney transplants from one type of patient to another. However, we believed the incentive is to promote improvement activities that would increase access to all patients while recognizing that low-income patients may face more barriers to care outside of the IOTA participants' control. It also recognizes that disparities already exist in access to kidney transplants for low-income patients, so, by addressing inequities, IOTA participants would focus efforts on tackling inequities for patients outside the Medicare population.

For purposes of the health equity performance adjustment, we also considered using the area deprivation index (ADI) to define the low-income population. ADI ranks neighborhoods based on socioeconomic disadvantage in the areas of income, education, employment, and housing quality. Areas with greater disadvantage are ranked higher, and they correlate with worse health outcomes in measures such as life expectancy.[203] The areas used in the ADI are defined by Census Block Group, which presents a number of challenges.[204] However, because address information for Medicare beneficiaries may be incomplete, and not available at all for patients who have private insurance or the uninsured, we opted to not use ADI to define the low-income population. We believed that this would leave an incomplete picture of the transplant population for a given IOTA participant. Furthermore, the socioeconomic status of individuals within a given ADI can vary greatly. Those that are underserved in a Census Block Group with a low ADI may be overlooked.

We also considered including ''rural resident'' as one of the groups that define a low-income population in the IOTA Model, as rural transplant patients face numerous barriers to care, including transportation, food, housing, and income insecurity, and no or

[200] Gillen, E.M., Ganesan, N., Kyei-Baffour, B., & Gooding, M. (2021, August 30). *Avalere analysis of disparities in Kidney Care Service Utilization.* Avalere Health. *https://avalere.com/insights/avalere-analysis-of-disparities-in-kidney-care-service-utilization.*

[201] United States Renal Data System. (2020). *2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases.* Bethesda, MD.

[202] Lentine, K.L., Smith, J.M., Hart, A., Miller, J., Skeans, M.A., Larkin, L., Robinson, A., Gauntt, K., Israni, A.K., Hirose, R., & Snyder, J.J. (2022). OPTN/SRTR 2020 Annual Data Report: Kidney. *American Journal of Transplantation, 22*(S2), 21–136. *https://doi.org/10.1111/ajt.16982.*

[203] *Neighborhood Atlas—Home.* (2018). *Wisc.edu. https://www.neighborhoodatlas.medicine.wisc.edu/.*

[204] *https://www2.census.gov/geo/pdfs/reference/GARM/Ch11GARM.pdf.*

limited access to kidney transplant hospitals within or close to their rural communities. We considered defining rural beneficiaries consistent with the criteria used for identifying a rural area when determining CAH eligibility at 42 CFR 485.610(b)(1)(i), that is, beneficiaries living outside an MSA. However, we were unsure if it was appropriate to include this group to define a low-income population to determine if a health equity adjustment would apply to the achievement performance score, particularly as the proposed low-income definition may already capture the majority of rural kidney transplant patients.

We sought comment on our proposed health equity performance adjustment, including on the adjustment multiplier and calculation method, the definition of low-income population and alternatives considered, including consideration of ADI as an alternative definition, or including rural resident in the low-income population definition.

The following is a summary of the comments received on our proposed health equity performance adjustment, including on the adjustment multiplier and calculation method, the definition of low-income population and alternatives considered, including consideration of ADI as an alternative definition, or including rural resident in the low-income population definition and our responses:

Comment: A couple commenters advised CMS against finalizing the proposed HEPA provision for a variety of reasons, arguing that it prioritizes non-medical factors and prompts IOTA participants to unfairly favor certain patients over others for reasons unrelated to clinical needs.

Response: We appreciate the feedback from commenters, but we respectfully disagree with their position. We originally proposed this provision out of concern for the existing disparities in access to transplants. The proposed HEPA was not intended to incentivize a focus on any particular patient group, but rather to encourage kidney transplant hospitals to identify and address the barriers faced by their underserved patient populations, with the goal of overcoming issues related to SDOH. Moreover, we believe that IOTA participants will leverage their medical expertise to deliver the best outcomes for patients. However, in light of all the comments we received and about the potential for unintended consequences, we will not be finalizing the proposed HEPA at this time. As part of the evaluation process, we intend to monitor how the model impacts low-income individuals' access to kidney transplants and may consider proposing a new or updated policy through future notice and comment rulemaking.

Comment: While a commenter appreciated CMS' focus on promoting health equity in this model, they did not support the proposed HEPA due to broader concerns about using transplant volume as a performance measure. Specifically, the commenter noted that although the HEPA aims to encourage IOTA participants to provide transplants for uninsured patients, the bonus payments are insufficient to cover the extensive, long-term care required for successful transplant outcomes. Transplant patients need a wide range of services beyond just the surgery itself, including preoperative testing and monitoring, dietary counseling, and ongoing medications. However, a lack of insurance coverage presents a major challenge for both patients and kidney transplant hospitals in achieving better kidney care outcomes. For these reasons, the commenter argued that CMS' proposed health equity multiplier approach to incentivize organ transplantation services for underserved patients is an inadequate solution to this complex issue.

Response: We appreciate the feedback and believe that the increased payment amounts in the model could provide additional resources for IOTA participants to support the necessary interventions required to overcome barriers for underserved patients. However, as mentioned in comment responses noted previously in this section, we will not be finalizing the HEPA as we are concerned about the potential for unintended consequences and will keep this feedback in mind as we consider alternatives in future notice and comment rulemaking.

Comment: A commenter expressed concern that the proposed HEPA incentivizes out-of-sequence allocation of kidneys by IOTA participants, giving preferential treatment to low-income candidates, in order to maximize the number of points they receive in the achievement domain. Given these concerns and the pressing disparities in access to living donor transplants, the commenter urged CMS to consider increasing the HEPA, but limiting the availability of the HEPA to living donor transplants.

Response: We appreciate this feedback. As mentioned in commented responses previously in this section, we will not be finalizing the proposed HEPA at this time. Additionally, as described and finalized in section III.C.13.c of this final rule, we will monitor the rates of out-of-sequence allocation that may result from the model. This is to ensure the model does not have unintended consequences. Accordingly, we do not anticipate any potential impact of out-of-sequence allocation as a way to prioritize transplants for underserved populations.

Comment: A commenter strongly agreed with CMS' intended goal of using financial incentives to encourage IOTA participants to improve health equity and reduce disparities in overall transplant rates for lower-income patients. However, the commenter expressed significant concerns about the potential unintended consequences of this design. Specifically, they believed that financially incentivizing the use of lower-quality kidneys for lower-income patients, while also incentivizing more transplants for this group, could inadvertently link these factors and entrench a two-tiered system. The commenter stated that this could result in lower-income patients being offered lower-quality kidneys, further exacerbating health disparities among kidney transplant recipients. Additionally, the commenter was concerned that while the proposed model would increase kidney transplantation rates for those already on the waitlist, it overlooked the broader barriers in healthcare access that prevent low-income patients from being placed on the transplant waitlist in the first place. As such, the commenter recommended that CMS not finalize the HEPA.

Response: We thank the commenter for sharing their support and concerns. We acknowledge potential concerns about the proposed HEPA policy, but also recognize the substantial benefits of kidney transplantation over dialysis, even for complex organs. Furthermore, we believe IOTA participants will exercise their medical expertise to ensure the best possible outcomes for patients. However, as mentioned in comment responses noted previously in this section, we will not be finalizing the proposed HEPA provision at this time due to the potential for unintended consequences. We intend to monitor how the model impacts low-income individuals' access to kidney transplants and may consider proposing a new or updated policy through future notice and comment rulemaking.

Comment: A commenter suggested that the proposed HEPA would bias IOTA Model results toward larger kidney transplant hospitals with the financial resources to overcome the challenges of serving low-income patients. The commenter also believed that any effort to shift transplantation decisions away from purely clinical

considerations would necessarily produce adverse results, such as higher rates of unsuccessful transplants. Specifically, IOTA participants may take greater risks by transplanting kidneys into HEPA-eligible patients rather than better clinically-matched recipients, leading to increased failure rates. For these reasons, the commenter strongly recommended that CMS reduce the multiplier for the HEA from 1.2 to 1.05 or 1.1. Additionally, the commenter suggested lowering the achievement domain points thresholds commensurately, setting the highest threshold (sixty points) at greater than 125% of target and dropping the lowest (zero points) to less than 50% of target. This, they believed, would help address the resource gap between IOTA participants. Additionally, the commenter felt this change would also reduce the potential adverse consequences of clouding clinical judgment with financial considerations when matching organs to recipients. Finally, the commenter noted that making these suggested changes would further recognize the sometimes-severe disparity of available organs from one PY and its relevant baseline years to the next.

Response: We thank the commenter for sharing their concerns; however, we disagree that the proposed HEPA would bias larger kidney transplant hospitals. We believe all transplant hospitals, not just larger ones, should focus on overcoming barriers for underserved populations. Moreover, many of the interventions needed to address these barriers are covered by organ acquisition costs. However, in response to the public comments we received on our proposed HEPA, we will not be finalizing this provision at this time.

Comment: Several commenters urged CMS to include rural residents as a population group in the proposed definition of low-income population that is eligible for the proposed HEPA; given the limited access to transplant services in rural areas and additional challenges that rural residents, regardless of income, face throughout the transplant process. For example, a commenter appreciated that CMS considered including rural residents in the proposed low-income patient definition eligible to receive the proposed HEPA. However, the commenter urged CMS to reconsider this factor, arguing that it would help address the unique challenges rural residents face throughout the transplant process. Another commenter recommended that CMS consider including ''rural resident'' as a group in the proposed definition of low-income population for the purposes of the IOTA Model, since rural residency is associated with significant barriers to transplantation, a situation only made worse by the increasingly precarious hospital footprint in rural areas of the country. Due to the significant barriers to transplantation faced by rural residents, which are exacerbated by the increasingly limited availability of hospitals in rural areas, a commenter recommended that CMS should include rural resident as a group in the proposed low-income population definition for the IOTA Model.

A commenter strongly supported the proposed HEPA and applauded CMS for recognizing that some patients require more assistance from kidney transplant hospitals to overcome barriers to transplantation. This commenter felt CMS correctly identified that rural transplant patients face barriers to care, some of which are income related such as food, housing, and income insecurity. The commenter believed that patients facing these barriers would almost certainly qualify for the proposed health equity performance adjustment (HEPA) through Medicaid eligibility or the Medicare Low Income Subsidy (LIS). According to the commenter, patients confronting these barriers would likely qualify for the proposed HEPA through Medicaid eligibility or the Medicare Low Income Subsidy (LIS). However, the commenter stated that they could attest that two of the barriers identified by CMS—transportation issues and ''limited access to kidney transplant hospitals within or close to rural communities''—complicate transplant care for patients, regardless of their income level. The commenter argued that by including rural residents in the groups qualifying for the proposed HEPA, CMS would ensure that the additional assistance kidney transplant hospitals must provide to help rural patients of all income levels overcome barriers to transplantation is properly accounted for. Lastly, this commenter stated their belief that the criteria used for identifying a rural area when determining CAH eligibility at 42 CFR 485.610(b)(1)(i) would sufficiently capture rurality.

Lastly, a commenter greatly supported CMS' efforts to strengthen health equity in value-based care, but believed CMS should expand the proposed definition of low-income population eligible for the HEPA to also include rural residents, given the limited access to transplant services in rural areas. The commenter argued that rural patients face significant barriers to accessing transplant services, as they are less likely to be added to transplant waitlists or referred for transplant by dialysis providers due to the limited availability of transplant services in rural areas. Therefore, the commenter felt CMS should incentivize IOTA participants to care for rural patients through the HEPA for low-income populations, in order to address the disproportionate challenges faced by the rural population in accessing transplant care. The commenter suggested that if CMS is hesitant to label all rural patients as low-income, they could rename the adjustment to more accurately reflect the vulnerable populations it includes.

Response: We thank the commenters for their support and recommendation to include rural residents in our proposed definition of low-income population eligible to receive the proposed HEPA. We recognize that rural patients may face additional barriers and challenges throughout the transplant process. However, as mentioned in comment responses noted previously, we will not be finalizing the proposed HEPA at this time. Additionally, we will consider additional adjustments to the model that may account for the barriers faced by patients living in rural areas in future notice and comment rulemaking.

Comment: A commenter noted that they have dialysis patients that get assistance to enroll in commercial plans. The commenter argued that these individuals should be classified as low-income, citing their frequent socioeconomic barriers, and urged CMS to revise the proposed definition of low-income population to encompass these individuals.

Response: We thank the commenter for their suggestion. We chose the specific designations in an effort to use insurance status as a proxy for underserved status for beneficiaries and the statuses we proposed at 89 FR 43553 in the proposed rule (uninsured, Medicaid beneficiaries, Medicare-Medicaid dually eligible beneficiaries, recipients of the Medicare LIS, or recipients of reimbursements from the Living Organ Donation Reimbursement) only apply to lower-income beneficiaries, whereas beneficiaries with commercial insurance may not be low-income. As such, we disagree with the commenter.

Comment: A commenter expressed strong support for reducing health inequities but felt that the proposed methodology for identifying low-income populations, although clear, may not be comprehensive in gathering the intended information. Specifically, the commenter cited three concerns: (1) The commenter was unaware of transplant hospitals that would knowingly

transplant someone without insurance who lacked the means to cover the costs out-of-pocket. Therefore, the uninsured criteria may identify patients with significant means, unless CMS examines people who have lost some or all insurance after transplant.; (2) Transplant hospitals do not know which patients receive LIS benefits, and many patients are unaware that they receive this benefit, based on the commenter's experience.; and (3) NLDAC benefits are attached to the donor, not the recipient, so CMS may not have access to this information.

Response: We thank the commenter for their feedback. We believe that all patients with kidney disease deserve equitable care and access to the transplant process. We urge transplant hospitals to think about how to overcome barriers for patients, regardless of insurance status, and to think about how to best care for patients' needs. Although we will not be finalizing the proposed HEPA at this time, we will consider the comments that were received during the public comment period and may make future proposals during the course of the model test in future notice and comment rulemaking.

Comment: Multiple commenters supported the proposed HEPA but urged CMS to increase the amount of the proposed HEPA multiplier. For example, a commenter expressed their strong support for the proposed HEPA and believed that it is an appropriate incentive to encourage IOTA participants to address barriers that low-income populations face in the transplant process and to help reduce disparities in access to transplant. Furthermore, the commenter felt that the proposed HEPA is also an important tool to ensure IOTA participants are not unfairly penalized if they serve a high number of low-income populations. As such, they recommend that CMS consider increase the health equity performance adjustment.

Additionally, a commenter encouraged CMS to increase the proposed HEPA multiplier to 1.25. Another commenter supported the precision of the IOTA Model's approach, which proposed to apply an adjustor for each individual kidney transplant furnished to a patient meeting the proposed low-income population definition. This individualized method, they argued, would more effectively address health equity compared to the broader approach used in the ETC Model. However, the commenter expressed concerns that the proposed 1.2 multiplier was insufficient to cover the increased costs kidney transplant hospitals would face in expanding transplants for low-income populations. Therefore, the commenter believed it is critical for CMS to consider increasing the multiplier to at least 1.5 in order to incentivize and enable greater transplant access for this underserved group.

Response: We appreciate the commenters' support and recommendations. As described in comment responses noted previously, we will not be finalizing the proposed HEPA. Although we are not finalizing the proposed HEPA at this time, we will take the comment but will consider the appropriate magnitude of any potential adjustment via future rulemaking, as we are not finalizing this provision.

Comment: We received multiple comments supporting the proposed inclusion of a HEPA. For example, several commenters commended CMS's emphasis on and approach to implement a reward only HEPA. They believed the proposed HEPA would be a major stride toward promoting equity in access to organ transplants and motivate IOTA participants to address the barriers faced by low-income individuals in the transplant process. In their comments supporting the proposed HEPA, a couple commenters also expressed gratitude to CMS. They thanked CMS for acknowledging inequities in the transplant process and recognizing that low-income patients may require additional resources to receive a transplant and overcome social barriers to health. These commenters further appreciated CMS for recognizing the extra challenges and burden faced by transplant programs when treating low-income patients, and for its continued efforts to improve service delivery for this population. Lastly, another commenter strongly supported the inclusion of a HEPA, asserting that it serves as an important mechanism to protect IOTA participants from being unduly penalized for serving a high volume of low-income populations.

Response: We appreciate the feedback from commenters. As mentioned in comment responses noted previously in this section, we are not finalizing the proposed HEPA out of the potential for unintended consequences. We plan to monitor the effects of the model on low-income individuals' access to kidney transplants as part of the evaluation process and may consider proposing a new or updated policy through future notice and comment rulemaking, depending on performance by IOTA participants.

Comment: Multiple commenters suggested that CMS only apply the proposed HEPA to living donor transplants. For example, a commenter commended CMS for including the proposed HEPA, noting its structure as a reward-only mechanism. The commenter further suggested that CMS implement a similar ''reward-only'' multiplier based on donor characteristics, which could be integrated into IOTA participants' transplant counts in a similar way. Additionally, the commenter could also envision a multiplier for living donations from historically disadvantaged groups, such as rural and underserved areas. To avoid incentivizing IOTA participants to prioritize deceased donor transplants for low-income candidates out-of-sequence, a commenter suggested that CMS apply the proposed HEPA policy only to living donor transplants.

Response: We thank the commenters for their suggestions. We will not be finalizing the proposed HEPA at this time, as described in comment responses noted previously in this section, but may consider this idea in future notice and comment rulemaking as we continue to assess ways to address inequities in the transplant process.

Comment: A commenter expressed their appreciation for CMS' focus on low-income patients but noted that these individuals frequently arrive at transplant hospitals with more advanced disease, often due to delayed referrals. Accordingly, the commenter urged CMS to explore alternative models that would facilitate earlier kidney health screenings and improve primary care access for these underserved populations.

Response: We appreciate the commenters' feedback. However, we believe that the IOTA Model works alongside other CMS initiatives aimed at earlier intervention for patients with kidney disease, such as the KCC Model, which focuses on managing care for Medicare beneficiaries with chronic kidney disease and end-stage renal disease.

Comment: Multiple commenters agreed with CMS' decision to not use ADI, pointing out many of the limitations in using ADI to measure inequity in the transplant process. For example, a commenter argued that using the ADI is less optimal than the approach proposed by CMS. The commenter stated that the ADI is a more difficult criterion for transplant hospitals to apply when identifying patients who would qualify for and benefit from interventions. This added complexity would undermine one of the key strengths of the IOTA Model—simplicity. As a result, the commenter

felt that the ADI would be less effective than the clearly defined socioeconomic status (SES) eligibility criteria put forth by CMS in driving behavioral changes at the transplant hospital level. Additionally, the commenter noted that while the ADI is a valuable tool, transplant hospitals typically have a more granular understanding of individual patients' SES, allowing them to easily and immediately identify those who should receive additional support. While another commenter accepted the proposed low-income population definition for this model, recognizing the limitations of the ADI, noting that it fails to adequately capture low-income populations across all regions.

Response: We thank the commenters for their support and do not plan to use the ADI as a way to identify underserved populations in the IOTA Model.

After consideration of public comments received, for the reasons set forth in this rule, CMS is not finalizing the Health Equity Performance Adjustment to the achievement domain, due to the potential for unintended consequences, some of which were pointed out by commenters. We still recognize that there are many inequities in the transplant process and may propose alternative approaches in future notice and comment rulemaking that could address some of the potential consequences laid out by commenters. We also plan to monitor and evaluate the results of the IOTA Model in an effort to see which patients receive transplants in an effort to monitor for any impact of the model based on patient insurance status. However, we are finalizing our proposed methodology for calculating the number of kidney transplants performed during the PY at § 512.424(d) with slight modification. Specifically, since we are not finalizing the proposed health equity performance adjustment at this time, we are modifying our regulation at §§ 512.424(d)(1)(i) and (2) to remove the cross reference to the health equity performance adjustment.

d. Efficiency Domain

At § 512.402 of the proposed rule, we proposed to define the ''efficiency domain'' as the performance assessment category in which CMS assesses the IOTA participant's performance using the organ offer acceptance rate ratio as described in § 512.426. In section III.C.5.d(1) of the proposed rule, we stated that the efficiency domain is focused on improving the overall efficiency of the transplant ecosystem.

In section III.C.5.d(1) of the proposed rule, we proposed including OPTN's organ offer acceptance rate ratio measure in the efficiency domain. The organ offer acceptance rate ratio measure is a ratio of observed organ offer acceptances versus expected organ offer acceptances, as described in section III.C.5.d.(1) of the proposed rule.

(1) Organ Offer Acceptance Rate Ratio

As reviewed in section III.C.5.d(1) of the proposed rule, with over 90,000 unique patients on the waiting list for a kidney transplant, the need to effectively use every available donor organ is critical. However, despite the new allocation system introduced in 2021, and more organs being offered over a wider geographic area, the kidney discard rate has risen to over 24.6 percent and continues to trend upwards.[205] There is a significant shortage of organs available for transplantation, and many patients die waiting for a kidney transplant. Moreover, there are large disparities in organ offer acceptance ratio performance. A 2020 national registry study found that the probability of receiving a deceased donor kidney transplant within three years of placement on the waiting list varied as much as 16-fold amongst different kidney transplant hospitals across the U.S.[206] The study also found that large variations were still present between kidney transplant hospitals that utilized the same OPO and that the probability of transplant was significantly associated with transplant hospitals' offer acceptance rates.[207] By incentivizing kidney organ offer acceptance, we aimed to optimize the use of available organs, thereby reducing underutilization and discards of quality donor organs.

For purposes of assessing the performance of IOTA participants in the achievement domain, we proposed in section III.C.5.d(1) of the proposed rule to include the organ offer acceptance rate ratio as one of the two metrics of performance. We believed that including this measure in the efficiency domain would encourage IOTA participants to increase the utilization of available organs. We also believed that this measure would encourage IOTA participants to improve efficiency in the organ offer process, improve acceptance practices for offers received, and allow for maximal utilization of available organs. We believed that the organ offer acceptance rate ratio is an important system-wide metric, as improved performance by an IOTA participant would also improve opportunities for other kidney transplant hospitals that would not have to wait as long for an available donor kidney. We recognized that all kidney transplant hospitals are already assessed on the organ offer acceptance rate ratio metric under the OPTN, however, we believed that the IOTA Model sets a higher bar for performance, as discussed in section III.C.5.d.(1)(a) of the proposed rule, rather than clearing the threshold that the OPTN sets at 0.30.[208]

As stated in section III.C.5.d(1) of the proposed rule, in the United States, kidney transplant waitlist candidates face considerable disparities in access to kidney transplant, such as in who is referred and placed on the waiting list, who remains ''active'' on the waiting list, and how waitlisted patients are managed by kidney transplant hospitals.[209] Additionally, kidney

[205] MN, 1Scientific R. of T.R., Hennepin Healthcare Research Institute, Minneapolis. (n.d.). *Kidney. Srtr.transplant.hrsa.gov*. Retrieved June 19, 2023, from *https://srtr.transplant.hrsa.gov/annual_reports/2021/Kidney.aspx.*

[206] King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. *Journal of the American Society of Nephrology, 31*(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335.*

[207] King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. *Journal of the American Society of Nephrology, 31*(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335.*

[208] *Enhance Transplant Program Performance Monitoring System OPTN Membership and Professional Standards Committee.* (n.d.). *https://optn.transplant.hrsa.gov/media/4777/transplant_program_performance_monitoring_public_comment_aug2021.pdf.*

[209] Schold, J.D., Gregg, J.A., Harman, J.S., Hall, A.G., Patton, P.R., & Meier-Kriesche, H.-U. (2011). Barriers to Evaluation and Wait Listing for Kidney Transplantation. *Clinical Journal of the American Society of Nephrology, 6*(7), 1760–1767. *https://doi.org/10.2215/cjn.08620910;* Hod, T., & Goldfarb-Rumyantzev, A.S. (2014). *The role of disparities and socioeconomic factors in access to kidney transplantation and its outcome. Renal Failure, 36*(8), 1193–1199. *https://doi.org/10.3109/0886022x.2014.934179;* Stolzmann, K.L., Bautista, L.E., Gangnon, R.E., McElroy, J.A., Becker, B.N., & Remington, P.L. (2007). Trends in kidney transplantation rates and disparities. *Journal of the National Medical Association, 99*(8), 923–932. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2574300/;* Paul, S., Melanson, T., Mohan, S., Ross-Driscoll, K., McPherson, L., Lynch, R., Lo, D., Pastan, S.O., & Patzer, R.E. (2021). Kidney transplant program waitlisting rate as a metric to assess transplant access. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 21*(1), 314–321. *https://doi.org/10.1111/ajt.16277;* Cheng, X.S., Busque, S., Lee, J., Discipulo, K., Hartley, C., Tulu, Z., Scandling, J.D., & Tan, J.C. (2018). A new approach to kidney wait-list management in the kidney allocation system era: Pilot implementation and evaluation. *Clinical Transplantation, 32*(11), e13406. *https://doi.org/10.1111/ctr.13406.*

transplant hospital performance is commonly measured by post-transplant outcomes. We recognized that including pre-transplant measures could allow for a more thorough evaluation of transplant hospital performance and provide insight for patient decision-making.

In section III.C.5.d(1) of the proposed rule, we considered several waitlist management metrics for assessing performance in the efficiency domain, such as the number of patients registered to a waitlist, the number or percentage of attributed patients registered on a waitlist with an active waitlist status, or the number or percentage of attributed patients on a waitlist with active waitlist status to inactive waitlist status. Metrics focused on the waitlist could help assess how effectively kidney transplant hospitals are managing their kidney transplant waitlist patients. Organ offers to waitlist kidney transplant patients are made directly to the kidney transplant hospital where they are waitlisted. Once a kidney transplant hospital receives an organ offer for one of their kidney transplant waitlist patients, it is ultimately its decision to accept or decline an organ offer on the patient's behalf. Kidney transplant hospitals are not required to inform kidney transplant waitlist patients for whom an offer was received when an organ offer was received or why an organ offer was declined. While we understood the importance of a transplant surgeon's clinical decision-making and respected the clinical judgement of transplant surgeons, declining an offer without involving the affected patient in the decision-making can be detrimental to the patient, as additional time on the waitlist can negatively impact the patient's quality of life.[210]

As stated in section III.C.5.d(1) of the proposed rule, we also considered including a waitlist mortality metric for assessing efficiency domain performance, so as to incentivize improvements in mortality outcomes of attributed patients on a waitlist. On average, as many as 20 patients on the waitlist for a kidney transplant die each day waiting for a kidney transplant in the United States.[211] While a waitlist mortality metric may help assess patient outcomes and experience while waiting for an organ offer,[212] and provide insight into differences in waitlist management practices across kidney transplant hospitals, we recognize that waitlist mortality rate is also influenced by the insufficient supply of donor organs available for transplantation. We also recognized that IOTA participants may not have a direct effect on, or ability to improve, mortality metrics, as nephrologists are also closer to the direct care of waitlist patients and would have a greater ability to affect their care and mortality rate. Furthermore, we believed that we are already testing the ability of nephrologists to manage care for Medicare beneficiaries with ESRD or CKD via the KCC Model.

We also considered several other metrics for assessing efficiency domain performance related to time to transplant, as outlined in section III.C.5.d(1) of the proposed rule, such as—

- Time from initial evaluation to transplant;
- Time from initial referral to transplant;
- Time from initial placement on a waitlist to transplant; and
- Time from when a patient was initially referred to time of initial evaluation to time of initial placement on a waitlist to time to transplant.

As discussed in section III.C.5.d(1) of the proposed rule, before a patient can be considered for, and placed on, the waiting list for a kidney transplant, they must first be referred by either a nephrologist or dialysis facility, at which point they undergo a comprehensive evaluation process by a transplant hospital.[213] Studies have shown long-standing barriers and disparities to access to transplantation by patient demographics, such as racial/ethnic, sex, socioeconomic, and insurance factors.[214] Disparities are driven by various factors, but we recognized that delays or lack of referrals for evaluation, evaluation criteria that may unintentionally deem a patient not eligible to be placed on a waitlist, and organ acceptance rate variations across kidney transplant hospitals, may exacerbate disparities. Thus, measuring time to transplant was considered an appropriate potential performance metric that could incentivize IOTA participants to improve. However, we chose not to propose this type of measure due to concerns about how to properly measure start and end points and unintended consequences that may harm patients, as it may create opportunities for kidney transplant hospitals to manipulate average times by only adding patients to the waitlist when they are certain of imminent transplant, which could exacerbate waitlist inequities.

We also considered including a transplantation referral to evaluation conversion rate measure, as discussed in section III.C.5.d(1) of the proposed rule. For patients with ESRD, access to transplantation is influenced by both referral patterns of pre-transplantation providers and transplant hospital processes of care and evaluation criteria.[215] Additionally, some studies found considerable variation in referral rates to transplantation by dialysis facilities, proposing significant regional and facility-level variation in care.[216]

[210] Husain, S.A., King, K L., Pastan, S., Patzer, R.E., Cohen, D.J., Radhakrishnan, J., & Mohan, S. (2019). Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. *JAMA Network Open, 2*(8), e1910312. *https://doi.org/10.1001/jamanetworkopen.2019.10312.*

[211] Delmonico, F.L., & McBride, M.A. (2008). Analysis of the Wait List and Deaths Among Candidates Waiting for a Kidney Transplant. *Transplantation, 86*(12), 1678–1683. *https://doi.org/10.1097/tp.0b013e31818fe694.*

[212] Shepherd, S., & Formica, R.N. (2021). *Improving Transplant Program Performance Monitoring. 8*(4), 293–300. *https://doi.org/10.1007/s40472-021-00344-z;* Wey, A., Gustafson, S.K., Salkowski, N., Kasiske, B.L., Skeans, M., Schaffhausen, C.R., Israni, A.K., & Snyder, J.J. (2019). *Association of pretransplant and posttransplant program ratings with candidate mortality after listing. 19*(2), 399–406. *https://doi.org/10.1111/ajt.15032.*

[213] Paul, S., Plantinga, L.C., Pastan, S.O., Gander, J.C., Mohan, S., & Patzer, R.E. (2018). Standardized Transplantation Referral Ratio to Assess Performance of Transplant Referral among Dialysis Facilities. *Clinical Journal of the American Society of Nephrology, 13*(2), 282–289. *https://doi.org/10.2215/cjn.04690417;* Redeker, S., Massey, E.K., van Merweland, R.G., Weimar, W., Ismail, S.Y., & Busschbach, J.J.V. (2022). Induced demand in kidney replacement therapy. *Health Policy, 126*(10), 1062–1068. *https://doi.org/10.1016/j.healthpol.2022.07.011;* Knight, R.J., Teeter, L.D., Graviss, E.A., Patel, S.J., DeVos, J.M., Moore, L.W., & Gaber, A.O. (2015). Barriers to Preemptive Renal Transplantation. *Transplantation, 99*(3), 576–579. *https://doi.org/10.1097/tp.0000000000000357;* Schold, J.D., Patzer, R.E., Pruett, T.L., & Mohan, S. (2019). Quality Metrics in Kidney Transplantation: Current Landscape, Trials and Tribulations, Lessons Learned, and a Call for Reform. *American Journal of Kidney Diseases, 74*(3), 382–389. *https://doi.org/10.1053/j.ajkd.2019.02.020.*

[214] Shepherd, S., & Formica, R.N. (2021). *Improving Transplant Program Performance Monitoring. 8*(4), 293–300. *https://doi.org/10.1007/s40472-021-00344-z;* Ernst, Z., Wilson, A., Peña, A., Love, M., Moore, T., & Vassar, M. (2023). Factors associated with health inequities in access to kidney transplantation in the USA: A scoping review. *Transplantation Reviews,* 100751. *https://doi.org/10.1016/j.trre.2023.100751.*

[215] Schold, J.D., Patzer, R.E., Pruett, T.L., & Mohan, S. (2019). Quality Metrics in Kidney Transplantation: Current Landscape, Trials and Tribulations, Lessons Learned, and a Call for Reform. *American Journal of Kidney Diseases, 74*(3), 382–389. *https://doi.org/10.1053/j.ajkd.2019.02.020.*

[216] Ibid; Alexander, G. Caleb., & Sehgal, A.R. (2002). Variation in access to kidney transplantation across dialysis facilities: Using process of care measures for quality improvement. *American Journal of Kidney Diseases, 40*(4), 824–831. *https://doi.org/10.1053/ajkd.2002.35695;* Patzer, R.E., Plantinga, L.C., Paul, S., Gander, J., Krisher, J., Sauls, L., Gibney, E.M., Mulloy, L., & Pastan, S.O. (2015). Variation in Dialysis Facility Referral for

However, because dialysis facilities are often the primary referrer and are not IOTA participants, we did not propose this measure. We also had concerns about how this data would be collected.

Finally, we also considered a living donor rate as one of the metrics used to assess performance in the efficiency domain to measure percentage of potential living donors who are evaluated to donate a kidney and that actually donated a kidney. This metric could help assess success towards addressing living donor concerns and improvements in education on the living donor process. However, we did not propose this metric because we have concerns about our ability to access data needed for measurement.

Ultimately, as discussed in section III.C.5.d(1) of the proposed rule, we chose not to propose to include waitlist management metrics when assessing IOTA participant performance in the efficiency domain because we believed that waitlist costs are already accounted for in the Medicare cost report. Transplant waitlist measures also do not capture living donation, which is an additional path to a successful kidney transplant that CMS already incentivizes living donations in the ETC Model. Moreover, studies have shown that organ acquisition costs have been rising and were not solely attributable to the cost of procurement, suggesting that an increased focus on the waiting list could further increase Medicare expenditures.[217] Also, for some of the measures considered (that is, waitlist mortality, transplantation referral to evaluation rate), nephrologists and dialysis facilities play large roles in maintaining the patient's health, and we did not believe it is appropriate to include a measure that would depend largely upon the behavior and actions of physicians and facilities other than the IOTA participant. We also thought this type of measure could distract from increasing rates of transplant and provide false expectations for time to transplant for kidney transplant waitlist patients. We are also concerned that a waitlist measure could have unintended consequences and potentially lead to those most in need of transplant not being listed to receive a transplant.

We solicited comment on our proposed organ offer acceptance rate ratio metric for purposes of assessing performance in the efficiency domain, and the alternatives considered.

The following is a summary of the comments received on our proposed use of the organ offer acceptance rate ratio in the efficiency domain and our responses:

Comment: A commenter was specifically opposed to including the OPTN organ offer acceptance rate measure in the efficiency domain. A few other commenters were concerned with using the organ offer acceptance rate ratio because it may be inflated by a high use of out-of-sequence kidneys, or it may promote kidney transplant hospitals to perform more DDKTs.

Response: We thank the commenters for their feedback. While there is no downside risk for out-of-sequence allocation we acknowledge commenters' concerns that an unintended consequence of using the organ offer acceptance rate ratio performance metric could be a rise in out-of-sequence allocation. We encourage the transplant community to continue providing feedback about appropriately capturing out-of-sequence organ offers, as we will consider this for future rulemaking and performance years. While we agree with the commenter who stated that the organ offer acceptance rate ratio metric may increase DDKTs, we do not believe that this automatically means that transplants will be of lesser quality. There are currently underutilized subsets of deceased donor kidneys and high rates of organ non-use [218] due to a number of reasons including, but not limited to, systematic inefficiencies [219] and lack of organ filters.[220] We refer readers to sections III.B and III.C.5.d(1) of this final rule for further discussion on organ acceptance patterns. Pre-existing OPTN mortality metrics and the new composite graft survival metric that we mention in section III.C.5.e of this final rule discourage transplant programs from transplanting kidneys that are very obviously not viable.

Comment: A few commenters suggested that if CMS is using the organ offer acceptance rate ratio measure, that they need to address out-of-sequence allocation, should utilize SRTRs risk adjustment, and should modify OPTN codes to develop more targeted responses to the discard rate.

Response: We thank the commenters for their suggestions. As previously mentioned in comment responses in this section, while there is no downside risk for out-of-sequence allocation in the IOTA Model, we acknowledge commenters concern that an unintended consequence of using the organ offer acceptance rate ratio performance could be an increase in out-of-sequence allocation. We encourage the transplant community to continue providing feedback about appropriately capturing out-of-sequence organ offers, as we will consider this for future rulemaking and performance years.

We intend to use the SRTR risk adjustment model for the offer acceptance metric; see section III.C.5.e of this final rule for more details.

Comment: A commenter stated that offers should be analyzed via validated metrics.

Response: We thank the commenter for their response. The organ offer acceptance rate ratio has been utilized by SRTR since 2023 and while lacking formal validation, is not unknown to the transplant community.[221] With the use of this measure by SRTR and CMS by way of the IOTA Model, we believe this creates opportunity to better understand its validity and adapt risk-adjustment.

Comment: A commenter requested clarification around what is considered an ''unsuitable kidney'' in the list of exclusions for the expected organ offer acceptance.

Response: We recommend the commenter review Table 6 in section III.C.5.d(1)(a) of this final rule, for a full list of exclusions from the measure. While an ''unsuitable kidney'' is not specifically listed in the exclusion list, we believe that the exclusion criteria of a kidney having a ''match run with no acceptances'' would apply.

Comment: A commenter was concerned that the organ offer acceptance metric was too broad and should be calculated based on offers within and outside of a 250-mile radius given the variation in regional importing of organs and the variation in kidney transplant hospital wait times.

Response: We appreciate the commenter's feedback. This was not a

Kidney Transplantation Among Patients With End-Stage Renal Disease in Georgia. *JAMA, 314*(6), 582. *https://doi.org/10.1001/jama.2015.8897.*

[217] Cheng, X.S., Han, J., Braggs-Gresham, J.L., Held, P.J., Busque, S., Roberts, J.P., Tan, J.C., Scandling, J.D., Chertow, G.M., & Dor, A. (2022). Trends in Cost Attributable to Kidney Transplantation Evaluation and Waitlist Management in the United States, 2012–2017. *JAMA Network Open, 5*(3), e221847. *https://doi.org/10.1001/jamanetworkopen.2022.1847.*

[218] Mohan, S., Yu, M., King, K.L, & Husain, S.A. (2023) Increasing discards as an unintended consequence of recent changes in United States kidney allocation policy. *Kidney International Reports,* 8(5): 1109–1111. *https://doi.org/10.1016/j.ekir.2023.02.108.*

[219] Wood, N.L., VanDerwerken, D.N., Segev, D.L., & Gentry, SE (2022). Increased logistical burden in circle-based kidney allocation. *Transplantation,* 106(10): 1885–1887. *https://doi.org/10.1097/tp.0000000000004127.*

[220] UNOS. (2023, September 5). Research in focus: Examining organ offers. Retrieved October 11, 2024 from *https://unos.org/news/in-focus/organ-offers/#Impact.*

[221] OPTN. (2023, September 14). New pre-transplant performance metric now in effect, offer acceptance rate ratio. Retrieved August 15, 2024 from *https://optn.transplant.hrsa.gov/news/new-pre-transplant-performance-metric-now-in-effect-offer-acceptance-rate-ratio/.*

consideration made during proposed rulemaking in order to align our metric with the pre-existing SRTR methodology. We are, however, interested in considering this for future rulemaking.

Comment: Many commenters stated their support for the use of OPTN's organ offer acceptance rate measure in the efficiency domain.

Response: We thank the commenters for their support.

Comment: A commenter conveyed concern that listing practices could penalize them in the efficiency domain. For example, if a transplant program listed all patients for high KDPI kidneys, resulting in passing on kidneys for offers sometimes, their organ offer acceptance rate ratio could be impacted.

Response: We appreciate the commenter's feedback. While IOTA participants may choose to encourage all their patients to enroll for kidneys with a KDPI greater than 85 to increase their offer opportunity, as the commenter points out, this may have risks. The purpose of selecting organ offer acceptance rate ratio as a metric is to increase utilization of available organs. If frequent ''passing'' is occurring for patients listed for kidneys with a KDPI greater than 85, there may be additional opportunities for utilizing filters. We also acknowledge that no transplant program will accept every offer they receive due to outliers and offers that may not be ideal due to comorbidities/risks of the donor kidney and recipient or both. Results in PY 1 will be monitored closely, to help identify reasonable and achievable organ offer acceptance ratio goals for future performance years and rulemaking.

Comment: A commenter was concerned that organ offer acceptance rate metric will encourage more conservative choices, which contradicts increasing overall kidney transplant volume, another goal of the IOTA Model.

Response: We appreciate your feedback; however, we believe the three performance domains counterbalance each other. The three performance domains challenge IOTA participants to consider if there is opportunity for growth in their kidney transplant hospital and how to navigate the task of increasing volume while offering a good quality of life for patients and appropriate long-term outcomes while minimizing non utilization of organs when possible. We would argue that the organ offer acceptance rate ratio measure does not encourage conservative choices but rather choices that better align with organs they will accept, to prevent overall organ non-use. We are asking IOTA participants to consider fine-tuning their organ offer filters and general processes.

Comment: A commenter suggested that the performance measures include a metric assessing performance in excluded communities, awarding IOTA participants more points who have organ offer acceptance rate ratios matching population needs and showing evidence of improved access to underserved populations. Similarly, a commenter suggested stratifying organ offer acceptance rate ratios by the beneficiary's payer, race, ethnicity and the income of the local population.

Response: Thank you for your responses. We did not consider further stratifying organ offer acceptance rate ratio goals. This approach could aid in identifying disparities across kidney transplant waitlist patients and organ offer acceptance patterns; however, it may be challenging to create adjusted metrics specific to each IOTA participant and their local population needs. This would also require IOTA participants to annually identify their local population to formulate baselines. These calculations would then need to be utilized to determine how to award points to IOTA participants who exceed expectations for underserved populations. We are interested in considering how the organ offer acceptance rate ratio could be tailored to local populations and underserved communities during future rulemaking.

Comment: A couple of commenters suggested CMS use a living donor metric. They had specific concerns that a domain dependent on DDKTs may not help to increase LDKTs. A commenter stated that CMS should include a living donor metric such as converting potential to actual living donors, and another stated CMS should implement a living donor and pre-emptive transplant measure given the significant benefits with living donation.

Response: We thank the commenters for their suggestions. We intend to further consider how living donor metrics could be included in future rulemaking. Setting a target number for the number of living donor evaluations versus the actual number of living donor evaluations who proceed with a surgery creates numerous risks. This could inadvertently cause kidney transplant hospitals to change their practices for those patients they accept for evaluations (potentially lowering criteria thresholds) or who they approve to be donors. Either result could cause reduced access to donation and create ethical concerns or both. While we do not believe that this would be an appropriate metric for the IOTA Model, we do however, encourage ongoing feedback about other opportunities for metrics specific to living donation.

Comment: A commenter requested use of a measure that does not incentivize acceptance of organ offers for the sole purpose of reaching a target number.

Response: We appreciate the commenter's feedback. We acknowledge that almost all metrics are imperfect. The purpose of including organ offer acceptance rate as a metric is to increase utilization of available organs in the system. The efficiency domain, as proposed, is not dependent on volume of kidney transplants performed but how well kidney transplant hospitals can prevent receiving offers they will knowingly decline, how kidney transplant hospitals can optimize filters to meet their individual needs and minimize organ non-use. We believe that performing well in the efficiency domain will result in more efficient utilization of organs, which can impact the number of organs transplanted.

Comment: A commenter recommended following adjusted non-use rates to account for different donor pools year-to-year.

Response: We appreciate the commenter's response. In the context of organ offer acceptance rate ratio, as described and finalized in III.C.5.d (1)(a) of this final rule, we are utilizing a risk adjustment model from year-to-year to account for consistent measurement between PYs.

Comment: A commenter suggested adding a metric that specifically follows non-utilization, particularly for kidneys with a KDPI greater than 85.

Response: We thank the commenter for their suggestion. While kidneys with a KDPI greater than 85 have high non-use rates, we recognize that there is underutilization of kidneys in all categories. Furthermore, in PY 1 we believe it is ideal to improve utilization broadly, which allows IOTA participants the flexibility to focus on improving access to groups of donors and recipients that may vary between regions and IOTA participants.

Comment: A commenter suggested routine reviews of the organ offer acceptance rate ratio metric to guarantee high quality outcomes.

Response: We thank the commenter for their feedback and agree that the organ offer acceptance rate ratio calculations and goals will need to be monitored closely to ensure their use improves the performance of IOTA participants without unintended consequences. If analysis results warrant a new or updated policy, we

will address it pursuant to future rulemaking.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing, as proposed, our provisions to assess performance in the efficiency domain using the organ offer acceptance rate ratio metric at §§ 512.426(a) and (b), as described and finalized in section III.C.5.d(1) of this final rule. We direct readers to section III.C.5.d(1)(a) of this final rule for a full discussion on the organ offer acceptance rate ratio methodology. As described and finalized in section III.C.5.d(1)(c) of this final rule, we are finalizing the proposed provisions for the point allocation and calculation methodology for the efficiency domain scoring and scoring for organ offer acceptance rate ratio for the IOTA Model at § 512.426(c), with slight modifications. We direct readers to section III.C.5.d.(1).(b). of this final rule for a full discussion on the point allocation and calculation methodology for the organ offer acceptance rate ratio metric.

We are also codifying at § 512.402 the definition of efficiency domain as the performance assessment category in which CMS assesses the IOTA participant's performance using the organ offer acceptance rate ratio as described in § 512.426. We intend to analyze and monitor IOTA participant performance to ensure we do not unduly disadvantage IOTA participants selected for the IOTA Model. If analysis warrants a new or updated policy, we will address it pursuant to future rulemaking.

(a) Calculation of Metric

In section III.C.5.d(1)(a) of the proposed rule, we proposed calculating organ offer acceptance rates for an IOTA participant using OPTN's offer acceptance rate ratio performance metric (see Equation 1). Per OPTN's new offer acceptance rate ratio, a rate ratio for a kidney transplant hospital that is greater than 1 indicates that the kidney transplant hospital usually accepts more offers than expected. A rate ratio that is less than 1 conveys a kidney transplant hospital's tendency to accept fewer offers than expected compared to national offer acceptance practices.[222] The OPTN MPSC has reported that this metric assesses kidney transplant hospitals' rate of observed organ offer acceptances to expected acceptances and is intended to answer the following question: Given the types of offers received to the specific candidates, does this program accept offers at a rate higher/lower than national experience for similar offers to similar candidates.[223]

Equation 1: Organ Offer Acceptance Rate Ratio [224]

$$Organ\ Offer\ Acceptance\ Rate\ Ratio\ = \frac{Number\ of\ Acceptances\ +\ 2}{Number\ of\ Expected\ Acceptances\ +\ 2}$$

As discussed in section III.C.5.d(1)(a) of the proposed rule, expected acceptances are based solely on kidneys that are accepted and transplanted by a kidney transplant hospital, so unsuitable kidneys are excluded from this measure, and are calculated using logistic regression models to determine the probability that a given organ offer will be accepted. The measure, as specified by SRTR methodology, is inherently risk adjusted as it only counts organs that are ultimately accepted by a kidney transplant hospital.[225] We proposed to use SRTR data to calculate the OPTN organ offer acceptance rate ratio, as described in section III.C.5.d.(1)(a) of the proposed rule.

Per the SRTR measure, we proposed in section III.C.5.d(1)(a) of the proposed rule, dividing the number of kidney transplant organs accepted by each IOTA participant (numerator) by the risk-adjusted number of expected organ offer acceptances (denominator).[226] This measure utilizes a logistic regression and risk adjusts for the following: donor quality and recipient characteristics; donor-candidate interactions, such as size and age differences; number of previous offers; and, distance of potential recipient from the donor.[227] We proposed to use SRTR's adult kidney model strata risk adjustment methodology and most recently available set of coefficients to calculate the number of expected organ offer acceptances.

For example, suppose we have a model for predicting the probability a kidney offer will be accepted, and this model adjusts for the number of years the candidate has been on dialysis, whether the kidney was biopsied, and the distance between the donor hospital and the candidate's transplant center (89 FR 43557). Consider the offer of a biopsied kidney 150 nautical miles (NM) away to a candidate who has been on dialysis for 2 years. As described in section III.C.5.d(1)(a) of the proposed rule, to calculate the probability of acceptance, we would first multiply these values by their respective model coefficients and then sum up those products with the model's intercept, as illustrated in Table 5.[228]

[222] OPTN. (2022). *OPTN Enhanced Transplant Program Performance Metrics. https://optn.transplant.hrsa.gov/media/r5lmmgcl/mpsc_performancemetrics_3242022b.pdf.*

[223] *Mpsc-enhance-transplant-program-performance-monitoring-system_srtr-metrics.pdf.* (n.d.). Retrieved December 28, 2022, from *https://optn.transplant.hrsa.gov/media/qfuj3osi/mpsc-enhance-transplant-program-performance-monitoring-system_srtr-metrics.pdf.*

[224] Ibid.

[225] Scientific Registry of Transplant Recipients. (n.d.). *Risk Adjustment Model: Offer Acceptance.* Offer acceptance. *https://www.srtr.org/tools/offer-acceptance/.*

[226] Ibid.

[227] SRTR. (2023). Srtr.org. *https://tools.srtr.org/OAModelApp_2205/;* Ibid.

[228] CMS notes that some risk adjustment factors in the SRTR models may only apply in certain ranges of a continuous variable. For example, a term that applies if the patient's age at the time of listing is >35 may be named ''can_age_at_listing_right_spline_knot_35''. In these cases, obtain the product using this formula if the patient's age at listing was >35: product = (Age − 35)*(model coefficient). Others may apply if the value is less than (<) a specified value. For example, for a term like ''can_age_at_listing_left_spline_knot_18'', obtain the product for a patient younger than 18 as: product = (18 − Age)*(model coefficient).

TABLE 5: EXAMPLE OF SUMMING UP COEFFICIENTS

Risk Adjustment Factor	Value	Coefficient	Product
Kidney Biopsied	Yes (use 1 for yes)	-1.750	-1.750
Years on Dialysis	2	0.250	0.500
Distance (NM)	150	-0.0035	-0.525
Intercept	(use 1 for intercept)	-0.255	-0.225
Total			-2

We would then plug that total into the following equation (see Equation 2) to get that the probability of acceptance is approximately 0.119 (that is., 11.9 percent chance of acceptance).

Equation 2: Probability of Organ Offer Acceptance

$$Probability\ of\ Organ\ Offer\ Acceptance\ = \frac{e^{-2}}{1+e^{-2}}$$

To determine the number of offers a transplant program was expected to accept, we would add up the probability of acceptance for every offer that transplant program received (89 FR 43557). The final organ offer acceptance rate ratio (OAR) is then constructed from the observed (O) number of acceptances and the expected (E) number of acceptances using Equation 1 as described in section III.C.5.d(1)(a) of this final rule. In this example we showed a simple logistic regression model that only included three risk-adjusters. The actual models used by the SRTR adjust for many more variables, but the process demonstrated here is the same.

As discussed in section III.C.5.d(1)(a) of the proposed rule, a kidney may be transplanted into a candidate who did not appear on the match run, usually to avoid discard if the intended recipient is unable to undergo transplant. If the eventual recipient was not a multi-organ transplant candidate and was blood type compatible per kidney allocation policy, then these transplants would be included in the organ offer acceptance rate. For purposes of the IOTA Model, we proposed to define ''match run'' as a computerized ranking of transplant candidates based upon donor and candidate medical compatibility and criteria defined in OPTN policies.

Per OPTN's new organ offer acceptance rate ratio, as described in section III.C.5.d(1)(a) of the proposed rule, Table 6 summarizes the types of organ offers that we proposed be included and excluded in the calculation of this metric. For the purposes of organ offers excluded from the organ offer acceptance rate ratio, we proposed to define ''missing responses'' as organ offers that the kidney transplant hospital received from the OPO but did not submit a response (accepting or rejecting) in the allotted time frame from the time the offer was made per OPTN policy 5.6.B.[229] For purposes of organ offers excluded from the organ offer acceptance rate ratio measure, we proposed to define ''bypassed response'' as an organ offer not received due to expedited placement [230] or a decision by a kidney transplant hospital to have all of its waitlisted candidates skipped during the organ allocation process based on a set of pre-defined filters matching the characteristics of the potential organ to be transplanted.[231]

[229] OPTN. (2023). *OPTN Policies. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.*

[230] Expedited placement has the potential to minimize delays in organ allocation by directing organs that may not be ideal to transplant centers that have demonstrated a willingness to utilize such organs. Currently, expedited placement, also known as ''accelerated placement'' or ''out-of-sequence'' allocation, permits OPOs to deviate from the standard match run, which determines the priority of patients on the waiting list for organ offers, under exceptional circumstances. This discretionary tool of expedited placement is employed by OPOs when there are suboptimal donor characteristics associated with donor disease or recovery-related issues, in order to prevent the organ from going unused. For numerous years, expedited organ placement has played a crucial role in organ allocation, enabling OPOs to promptly allocate organs that they believe are at risk of not being utilized for transplantation.

[231] King, K.L., S Ali Husain, Cohen, D.J., Schold, J.D., & Mohan, S. (2022). The role of bypass filters in deceased donor kidney allocation in the United States. *American Journal of Transplantation, 22*(6), 1593–1602. *https://doi.org/10.1111/ajt.16967; Transplant Quality Corner | The New MPSC Metric.* (n.d.). The Organ Donation and Transplantation Alliance. Retrieved February 23, 2024, from *https://www.organdonationalliance.org/insights/quality-corner/new-mpsc-metric/.*

TABLE 6: ORGAN OFFERS INCLUDED AND EXCLUDED FROM MEASURE[232]

Offers Included in Measure	Offers Excluded from Measure
• Organ offers that are ultimately accepted and transplanted. • Offers to candidates on a single organ waitlist (except for Kidney/Pancreas candidates that are also listed for kidney alone).	• Multiple match runs from same donor combined and duplicate offers. • Match run had no acceptances. • Offer occurred after last acceptance in a match run. • Missing or bypassed response. • Offers to multi-organ candidates (except for Kidney/Pancreas candidates that are also listed for kidney alone).

As discussed in section III.C.5.d(1)(a) of the proposed rule, we believed that IOTA participants could improve on the organ offer acceptance rate ratio metric in at least two ways. First, IOTA participants could increase the number of organ offers they accept, which would also potentially lead to greater performance scores in the achievement domain. Second, IOTA participants could also decrease the number of expected acceptances by adding better filters so that they are only receiving offers that they are likely to accept. Stricter filters may help ensure that an IOTA participant is not delaying the allocation of organs that they are uninterested in that could otherwise be accepted by another kidney transplant hospital. Since there are multiple ways to improve the offer acceptance ratio, the IOTA Model is not requiring increased utilization of higher KDPI kidneys that some IOTA participants may not want to use due to their clinical protocols. Additionally, the IOTA Model is not prescribing or requiring specific care delivery transformation or improvement activities of IOTA participants, so as to allow for flexibility and innovation.

In section III.C.5.d(1)(a) of the proposed rule, we considered calculating the organ offer acceptance rate by dividing the number of organs each IOTA participant accepts by the number offered to that transplant hospital's patients that are ultimately accepted elsewhere; however, the lack of risk adjustment in this metric may be unfair to some IOTA participants (89 FR 43558).

As mentioned in section III.C.5.d(1)(a) of the proposed rule, we also considered updating the calculation for organ offer acceptance rate ratio to account for the benefits of living donation by increasing the number of organs in the system because the proposed organ offer acceptance rate ratio only shows improvement in deceased donor utilization. This modification would add a single 1 in the numerator and a single 1 in the denominator for each living donation a transplant hospital completes. However, we did not propose updating the organ offer acceptance rate ratio because we decided to focus on deceased donor acceptance to remain aligned with the SRTR calculation. We also did not believe this was appropriate to propose because we believe that IOTA participants with an established or high performing living donation program would be able to gain points more easily in the achievement domain, which has a larger percent of overall points, which we thought may be unfair to IOTA participants that do not.

We sought comment on our proposal to use and calculate the OPTN organ offer acceptance rate ratio in accordance with OPTN's measure specifications and SRTR's methodology as the metrics that would determine IOTA participants' performance on the efficiency domain. We also sought comments on the alternatives we considered. Additionally, we sought comment on our proposed definitions.

The following is a summary of the comments received on our proposed utilization of the organ offer acceptance rate ratio using OPTN measure specifications and SRTR metrics for the efficiency domain and our responses:

Comment: Several commenters requested clarification for how organ offer filters will be used when calculating the organ offer acceptance rate ratio. They were concerned that using filters may create conflicts between kidney transplant volume and offer acceptances.

Response: We appreciate the commenters' feedback. Organ offer filters allow kidney transplant hospitals to specify characteristics of donors or donor-recipient matches they would not transplant at their transplant program, to prevent unnecessary organ offers and to allow the organ to go to another kidney transplant hospital who may accept the offer, more expeditiously. Organ filter use does not directly contribute to the organ offer acceptance rate ratio calculation. Use of filters, however, can impact the calculation result. Kidney transplant hospitals may choose to use less filters, allowing increased offers; or they may choose to use more strict filters to ensure that they are very likely to accept the offers they receive. We acknowledge that kidney transplant hospitals will not accept every organ offer and that they must maintain some flexibility to keep some filter criteria liberal to meet the needs of some of their beneficiaries, however, we believe these practices will be relatively consistent between kidney transplant hospitals to create comparable results. We also agree that it may take kidney transplant hospitals time to optimize their organ offer filters and their increase in kidney transplants, which is one of the reasons that we ensured that PY 1 does not have any downside risk, regardless of final performance score.

Comment: A few commenters requested clarification as to whether CMS would create a new organ acceptance rate measure, stating it must be validated, if so.

[232] OPTN. (2022). *OPTN Enhanced Transplant Program Performance Metrics. https://optn.transplant.hrsa.gov/media/r5lmmgcl/mpsc_performancemetrics_3242022b.pdf; For Transplant Center Professionals.* (n.d.). *www.srtr.org.* Retrieved February 22, 2023, from *https://www.srtr.org/faqs/for-transplant-center-professionals/#oaconsideration.*

Response: As outlined in section III.C.5.d(1)(a) of this final rule, we proposed OPTN's measure specifications and SRTR's methodology.

Comment: Several commenters stated their concerns about the CMS calculations for organ offer acceptance rate ratio. Each commenter within this group had a different concern, including the lack of risk adjustment, unfair comparison of large and small kidney transplant hospitals, how calculations are applied to beneficiaries that are toward the bottom of the waitlist and if the methodology will make a kidney transplant hospital's waitlist criteria more strict.

Response: We thank the commenters for their feedback. The SRTR methodology outlined in section III.C.5.d.(1).(a). of this final rule includes a risk-adjusted number of expected organ offer acceptances in its calculation.

While we acknowledge the different challenges of IOTA participants with variable volumes of kidney transplants, we also believe that each category of IOTA participants has different opportunities to impact their organ offer acceptance rate ratio. An IOTA participant with high volume of kidney transplants may focus on accepting higher score kidneys, whereas an IOTA participant with low volume of kidney transplants may be able to have more strict filter criteria to ensure the organ offers they receive are those that they will accept.

The SRTR methodology is based on a match run, if the IOTA participant accepts an organ offer and whether the IOTA participant was expected to accept the offer, based on the methodology and risk adjustment as described in section III.C.5.d.(1).(a). of this final rule. If a kidney transplant waitlist patient is not at the top of the waiting list and does not match, this calculation would not be applicable.

Finally, we agree that if a kidney transplant hospital uses very strict filter criteria this could impact their waitlist, however, we also believe it is important to consider having organ offer filter criteria reflect the organ offers that their transplant programs actually accept. The organ offer acceptance rate ratio methodology and subsequent use of organ offer filters encourages IOTA participants to minimize non-use of organs and minimize cold ischemic times.

Comment: A commenter requested clarification around what is considered an ''unsuitable kidney'' in the list of exclusions for the expected organ offer acceptance rate ratio.

Response: We recommend the commenter review III.C.5.d.(1)(a) Table 6 for a full list of exclusions from the measure. If a kidney transplant organ is not used by any kidney transplant hospital, that kidney is excluded from the organ offer acceptance rate ratio calculation.

Comment: A commenter stated they agreed with the inclusion and exclusion criteria for organ offers included in the calculation of the organ offer acceptance rate ratio.

Response: We thank the commenter for their support.

Comment: A commenter was concerned that out-of-sequence kidney offers are included in the measurement of success. Similarly, another commenter suggested CMS monitor the rate of out-of-sequence allocation that occurs.

Response: We appreciate the commenter's feedback. The commenter is correct that the SRTR methodology does not account for out-of-sequence kidney offers. Given the historic rise of out-of-sequence allocation over the last few years, we intend to monitor this closely.[233] If analysis results warrant a new or updated policy, we will address it pursuant to future rulemaking.

Comment: A commenter asked that CMS clarify filter use and how it would impact those patients that remain after filtering.

Response: We appreciate the commenter's feedback. Organ offer filters allow kidney transplant hospitals to specify characteristics of donors or donor-recipient matches they would not transplant at their transplant program, to prevent unnecessary organ offers and to allow the organ to go to another kidney transplant hospital who may accept the offer, more expeditiously. By utilizing filters that more closely match what offers a kidney transplant hospital is likely to accept for their waitlisted patients, the kidney transplant hospital will have a higher likelihood of organ offer acceptance. Furthermore, this would increase their organ offer acceptance rate ratio.

Comment: A commenter was concerned that the SRTR methodology does not account for non-viable kidneys.

Response: We appreciate the commenters concern and agree that not all offers are viable and acknowledges this in section III.C.5.d.(1).(a). of this final rule, Table 6, where exclusions for the organ offer acceptance rate ratio metric are included. Kidney match runs that have no acceptances are excluded in this metric. The calculation leaves ''viability'' judgment to the kidney transplant hospitals. If the commenter is concerned that there are too many non-viable kidney organ offers occurring, this would be a matter that may need to be discussed with OPOs and is outside the scope of the IOTA Model.

Comment: A commenter disagreed with use of the SRTR data because the c-statistic of their tool has not been published.

Response: We thank the commenter for their feedback. Availability of the published c-statistic of the SRTR data is not something we took into consideration, however, we believe that the SRTR methodology and OPTN data is appropriate for use in the IOTA Model given its risk adjustment, as outlined in section III.C.5.d.(1).(a). of this final rule. If analysis results warrant a new or updated policy, we will address it pursuant to future rulemaking.

Comment: A commenter suggested CMS modify its organ offer acceptance rate ratio calculation methodology by dividing accepted organs by organs offered elsewhere that are accepted.

Response: We thank the commenter for their suggestion. We previously considered this as an option for the efficiency domain performance metric; however, we were concerned that the lack of risk adjustment would be unfair to IOTA participants.

Comment: A few commenters suggested that CMS not use the SRTR methodology. Each individual commenter had a different concern, including that this methodology follows unproven outcomes, that the UNOS data is more up to date than SRTR data, and that using SRTR methodology conflicts with the achievement domain.

Response: We appreciate the commenters' suggestions and concerns and hope to provide some clarification. We are not using SRTR data and note that there is not ''UNOS data''. The SRTR methodology is calculated with OPTN data. By using the same methodology and data as the OPTN's organ offer acceptance rate ratio metric, the IOTA Model results will align with those tested by OPTN/UNOS, as recommended by the MPSC. As previously mentioned, the organ offer acceptance rate ratio has been utilized by SRTR since 2023 and while lacking formal validation, is not unknown to the transplant community.[234] If analysis

[233] Liyanage, L.N., Akizhanov, D., Patel, S.S., Segev, D.L., Massie, A.B., Stewart, D.E., & Gentry, S.E. (in press). Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. *American Journal of Transplantation. https://doi.org/10.1016/j.ajt.2024.08.016.*

[234] OPTN. (2023, September 14). New pre-transplant performance metric now in effect, offer acceptance rate ratio. Retrieved August 15, 2024

results warrant a new or updated policy, we will address it pursuant to future rulemaking.

Additionally, we believe SRTR methodology, or more generally the organ offer acceptance rate ratio, ensures balance in the model. While the achievement domain focuses on increasing kidney transplant volume, the efficiency domain metrics focuses on efficient utilization of kidney transplants to reduce organ non-use. By optimizing filters, IOTA participants are ensuring that their kidney transplant waitlist patients that are active on the transplant waitlist will actually be transplanted. Additionally, we believe organ filters allow kidneys to be directed to the appropriate kidney transplant hospital to improve quality of organs (lesser cold ischemic time) and potentially increase volume of transplants due to a more efficient process.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing, without modification, at § 512.426(b)(1) our proposals to use and calculate the OPTN organ offer acceptance rate ratio in accordance with OPTN's measure specifications and SRTR's methodology as the metrics that would determine IOTA participants' performance on the efficiency domain. Additionally, we are finalizing as proposed the definitions of match run, missing responses, and bypassed response at § 512.402.

(b) Calculation of Points

As described in section III.C.5.b. of the proposed rule, we proposed that performance on the efficiency domain would be worth up to 20 points of 100 maximum points. As indicated in section III.C.5.c.(2). of this final rule, the efficiency domain is weighted lower than the achievement domain but equal to the quality domain to ensure performance measurement is primarily focused on increasing number of kidney transplants, while still incentivizing efficiency and quality. Within the efficiency domain, we proposed that the OPTN organ offer acceptance rate ratio would account for the entirety of the 20 allocated points in that domain.

In section III.C.5.d.(1).(b) of the proposed rule, we proposed applying a two-scoring system to award up to 20 points to the IOTA participant based on its performance on the OPTN organ offer acceptance rate ratio. Under this two-scoring system, we would determine two separate scores for an IOTA participant: an ''achievement score'' reflecting its current level of performance, and an ''improvement score'' reflecting changes in its performance over time. We proposed that the IOTA participant would be awarded points equal to the higher of the two scores, up to a maximum of 20 points. We believed that this approach would recognize both high achievement among high performing IOTA participants as well as IOTA participants that make marked improvement in their performance. We believe that average or low-performing IOTA participants would likely require multiple years of transformation to catch up with those who have a high organ offer acceptance rate ratio.

In section III.C.5.d.(1).(b). of the proposed rule, for achievement scoring, we proposed that points earned would be based on the IOTA participants' performance on the organ offer acceptance rate ratio ranked against a national target,[235] inclusive of all eligible kidney transplant hospitals, both those selected and not selected as IOTA participants. Currently, there is a large disparity in organ offer acceptance ratio performance. As previously noted, a 2020 national registry study found that the probability of receiving a deceased donor kidney transplant within 3 years of waiting list placement varied 16-fold between different kidney transplant hospitals across the U.S.[236] Large variations were still present between kidney transplant hospitals that utilized the same OPO.[237] The probability of transplant was significantly associated with transplant hospitals' offer acceptance rates.[238]

We proposed that achievement scoring points be awarded based on the national quintiles, as outlined in Table 7 of section III.C.5.d.(1).(b). of this final rule. Utilizing quintiles aligns with the calculation of the upside and downside risk payments in relation to the final performance score, as detailed in section III.C.6.c.(2). of this final rule, where average performance yields half the number of points. The scoring is normalized, meaning an average performing IOTA participant earns 10 points out of 20, 50 percent of the total possible points. We recognized that there was an upper limit to the benefits of efficiency, and quintiles combine the highest 20 percent of performers in a point band. Due to the current disparity among kidney transplant hospitals on this metric, we did not expect every IOTA participant to reach top-level performance.

In the proposed rule, we proposed the following Organ Offer Acceptance Rate Achievement point allocation for IOTA participants, as illustrated in Table 7 of section III.C.5.d.(1).(b). of this final rule:

- IOTA participants in the 80th percentile and above, 20 points.
- IOTA participants in the 60th to below the 80th percentile of performers, 15 points.
- IOTA participants in the 40th to the 60th percentile of performers, 10 points.
- IOTA participants in the 20th to below the 40th percentile of performers, 6 points.
- IOTA participants who are below the 20th percentile of performers, 0 points.

from *https://optn.transplant.hrsa.gov/news/new-pre-transplant-performance-metric-now-in-effect-offer-acceptance-rate-ratio/*.

[235] Subsequent to the publication of the proposed rule, we found that.

[236] King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. *Journal of the American Society of Nephrology, 31*(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335*.

[237] King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. *Journal of the American Society of Nephrology, 31*(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335*.

[238] Ibid.

TABLE 7: ORGAN OFFER ACCEPTANCE RATE ACHIEVEMENT SCORING

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
80th Percentile relative to target OR for comparison	Equals 80th percentile	Greater than 80th percentile	20
60th Percentile	Equals 60th percentile	Less than 80th percentile	15
40th Percentile	Equals 40th percentile	Less than 60th percentile	10
20th Percentile	Equals 20th percentile	Less than 40th percentile	6
20th Percentile	N/A	Less than 20th percentile	0

As discussed in section III.C.5.d.(1).(b). of the proposed rule, we considered the approach used by the MPSC, that would yield maximum points if transplant hospitals have at least a .35 organ offer acceptance rate ratio. However, we do not believe that this approach fits with the IOTA Model's goals. MPSC metrics are more focused on highlighting and improving performance for the lowest performers, whereas the model seeks to improve performance across the board, not just avoid poor performance.

For improvement scoring, we proposed in section III.C.5.d.(1).(b). of the proposed rule, that points earned would be based on the IOTA participants' performance on organ offer acceptance rate ratio during a PY relative to their performance during the third baseline year for the PY that is being measured. We proposed to use the same baseline year definition used for participant eligibility, as described in section III.C.3. of the proposed rule, including the rationale for doing so. We separately proposed to calculate an ''improvement benchmark rate,'' defined as 120 percent of the IOTA participants' performance on the organ offer acceptance rate ratio during the third baseline year for each PY. We would award points by comparing the IOTA participant's organ offer acceptance rate ratio during the PY to the IOTA participant's improvement benchmark rate to determine the improvement scoring points earned. Specifically:

- IOTA participants whose organ offer acceptance rate ratio during a PY is at or above the improvement benchmark rate would receive 12 points.
- IOTA participants whose organ offer acceptance rate ratio during a PY is at or below the organ offer acceptance rate ratio during the third baseline year for that respective PY would receive no points.
- IOTA participants whose organ offer acceptance rate ratio during a PY is greater than the organ offer acceptance rate ratio during the third baseline year for that respective PY, but less than the improvement benchmark rate, would earn a maximum of 12 points in accordance with Equation 3.

Equation 3: Proposed Improvement Scoring for Organ Offer Acceptance Rate Ratio

$$Organ\ Offer\ Acceptance\ Rate\ Ratio\ Improvement\ Scoring\ =$$

$$12\ x \frac{Rate\ Earned\ in\ Performance\ Year\ -\ Rate\ Earned\ in\ Third\ Baseline\ Year}{Benchmark\ Rate\ -\ Third\ Baseline\ Year\ Rate}$$

As discussed in section III.C.5.d.(1).(b). of the proposed rule, we proposed using Equation 3 to mirror the methodology used in the Hospital Value Based Purchasing (VBP) Program, with the only modification being the number of points available for this metric. Equation 3 would also allow for a maximum of 12 points to be earned by IOTA participants whose organ offer acceptance rate ratio during the PY is greater than the baseline year organ offer acceptance rate ratio but less than the improvement benchmark rate. We did not want the improvement score to be worth more than, or equal to, the achievement score, as proposed for the organ offer acceptance rate ratio performance scoring, so as to reserve the highest number of points (15 points) for top performers in the metric.

Once both the achievement score and the improvement score were calculated, we proposed, in section III.C.5.d.(1).(b). of the proposed rule, comparing the two scores and applying the higher of the two values as the performance score or points earned (of 20 possible points) for the organ offer acceptance rate ratio metric within the efficiency domain.

In section III.C.5.d.(1).(b). of the proposed rule, we considered setting the improvement benchmark rate to be 200 percent of the IOTA participant's third baseline year for a given PY to measure performance on the organ offer acceptance rate ratio. The scoring structure would be the same, with 12 or 0 points to be awarded depending on whether the benchmark is met. However, we believed this would be too strict and risk penalizing already high-achieving IOTA participants.

In section III.C.5.d.(1).(b). of the proposed rule, we considered simplifying the performance scoring for the organ offer acceptance rate ratio metric within the efficiency domain by only awarding performance points based on the proposed achievement scoring methodology, rather than also calculating an improvement score for the IOTA participant and comparing the scores. However, given the variation that is present amongst kidney transplant hospitals, we thought it might be difficult for some IOTA participants to achieve top tier points for the first two model PYs. Thus, incorporating an improvement scoring method would ensure that IOTA participants are still rewarded for improvements made towards the efficiency domain goal.

We considered using the scoring method proposed for the post-transplant outcomes metric within the quality domain, as described in section III.C.5.e.(1)(b) of the proposed rule, as it would award full points if the hazard ratio or confidence interval of the metric includes the number one or higher. We believed this scoring method would honor the intent of the organ offer acceptance rate ratio metric, which is to determine if an IOTA participant is accepting more organs than expected. However, given the variation in

performance on this metric across all kidney transplant hospitals, we believe improvement opportunities exist in this metric. We also believe that our proposed approach rewards both achievement and improvements and is a more rigorous scoring methodology.

As discussed in section III.C.5.d.(1).(b). of the proposed rule, we considered a continuous scoring range from zero to 20, where IOTA participants may earn a score of any point value instead of bands. We thought that a continuous scoring range could provide more flexibility for IOTA participants and greater variety of scores. However, we believe grading using bands provides a more favorable scoring system for IOTA participants by grouping performance. We also recognize there is diminishing marginal efficiency for higher and higher organ offer acceptance rate ratios.

We considered using the lower and upper bounds of the offer acceptance odds ratio within a confidence interval, like we proposed in the quality domain for post-transplant outcomes, as described in section III.C.5.e.(1).(b). of the proposed rule. However, the organ offer acceptance rate ratio metric, unlike post-transplant outcomes, had wider disparity in performance than in post-transplant outcomes. We believe that there is a clear benefit to patients and the transplantation ecosystem overall by continuing to increase performance on this metric and promoting better performance than the national average. Under this alternative, IOTA participants would be evaluated based on whether the lower bound, acceptance ratio, and upper bound all crossed 1. Doing so would indicate the IOTA participant's true offer acceptance ratio with 95 percent probability. We did not propose this approach, however, as our analyses using SRTR data indicated that the majority of kidney transplant hospitals had either all three bounds cross 1 or all three never cross 1. Thus, scoring would largely not have differed from utilizing the offer acceptance ratio alone.

Finally, in section III.C.5.d.(1).(b). of the proposed rule, we also considered stratifying offer acceptance by KDRI status, with different score targets based on KDRI status ranges, such as KDRI of less than 1.05, between 1.05 and 1.75, and more than 1.75. We thought that this scoring method may potentially prevent IOTA participants from narrowing their criteria to only receive selected offers. However, we believed that it was already risk adjusted for organ status inherently in the measure because only organs that are ultimately transplanted are counted in the denominator.

We sought comment on our proposed organ offer acceptance rate ratio performance scoring methodology for purposes of assessing efficiency domain performance for each IOTA participant, including on the achievement and improvement score calculation and point allocation method. We also seek comments on alternatives considered.

The following is a summary of comments received on our proposed scoring methodology for the organ offer acceptance rate ratio performance in the efficiency domain and our responses:

Comment: Several commenters relayed concern that there may be a typo in the proposed rule, which stated the highest amount of points for the efficiency domain is 15.

Response: We thank the commenters for identifying a typo in the proposed rule. The highest amount of points available for IOTA participants to earn is 20 points if they are in the highest quintile of the organ offer acceptance rate ratio achievement score.

Comment: There were numerous comments about scoring methodology. Several commenters requested clarification as to why the improvement component of the efficiency domain does not provide more than 12 points. A couple of commenters had specific concerns that quintile methodology is not ideal and creates uncertainty. A commenter was concerned that improvement score of the efficiency domain does not account for high performers who may have challenges improving every year.

Response: Thank you for seeking clarification. An improvement goal was selected in addition to an achievement goal to account for the variation among kidney transplant hospitals and in acknowledgement that it may be challenging for some kidney transplant hospitals to reach high performance levels in the achievement component of the efficiency domain. In the proposed rule, we chose not to provide maximum points in the improvement domain, in order to reward the top-tiered programs in efficiency performance. Additionally, if some kidney transplant hospitals newly utilize filters, while others have already been utilizing filters, this will increase their improvement score significantly. By limiting improvement points, this prevents mismatch in recognizing those who newly and previously utilize filters.

We note that we are finalizing these policies as proposed but with a minor technical correction to update the maximum number of points awarded for improvement scoring from 12 points to 15 points. In the proposed rule at 89 FR 43560, we proposed to award IOTA participants whose organ offer acceptance rate ratio during a PY is at or above the improvement benchmark rate would receive 12 points. We also proposed at 89 FR 43560 that IOTA participants whose organ offer acceptance rate ratio during a PY is greater than the organ offer acceptance rate ratio during the third baseline year for that respective PY, but less than the improvement benchmark rate, would earn a maximum of 12 points in accordance with equation 1 to paragraph (c)(1)(ii)(B)(*1*) of § 512.426. However, we also stated at 89 FR 43560 that we did not want the improvement score to be worth more than, or equal to, the achievement score, as proposed for the organ offer acceptance rate ratio performance scoring, so as to reserve the highest number of points (15 points) for top performers in the metric. Thus, we are updating the regulation text at § 512.426(c)(1)(ii)(B)(1) to reflect 15 points instead of 12 points and equation 1 to paragraph (c)(1)(ii)(B)(*1*) of § 512.426, as illustrated in equation 4 below, to reflect a multiplier of 15 instead of 12.

Equation 4: Improvement Scoring for Organ Offer Acceptance Rate Ratio

$$Organ\ Offer\ Acceptance\ Rate\ Ratio\ Improvement\ Scoring\ = 15\ x \frac{Rate\ Earned\ in\ Performance\ Year - Third\ Baseline\ Year\ Rate}{Improvement\ Benchmark\ Rate - Third\ Baseline\ Year\ Rate}$$

Additionally, the commenters are correct that the methodology creates a moving target for rankings within the scoring quintiles, year to year. This method was chosen to ensure that targets reflect current practices and

trends across kidney transplant hospitals.

We also note that we are finalizing this policy as proposed but with a minor technical correction to update the terminology used to provide points for achievement scoring in the efficiency domain. In the proposed rule at 89 FR 43559, we proposed that achievement scoring, would be based on the IOTA participant's performance on the organ offer acceptance rate ratio ranked against a national target, inclusive of all eligible kidney transplant hospitals, both those selected and not selected as IOTA participants. However, we also stated at 89 FR 43559 that achievement scoring points be awarded based on the national quintiles, as outlined in Table 6 of section III.C.5.d.(1).(b). of the proposed rule. Thus, we are updating our regulation text at § 512.426(c)(2)(i) to remove the reference to performance being measured against a national target and instead based on national ranking.

Based on PY 1 and ongoing feedback, we will consider in future rulemaking if there should be alternative point opportunities for the efficiency improvement scoring scale in later performance years. If analysis results warrant a new or updated policy, we will address it pursuant to future rulemaking.

Comment: A couple of commenters were concerned that IOTA participants may accept deceased donor organs more aggressively or make their waitlist criteria more stringent, to have a high score in the efficiency domain due to the percentile scoring.

Response: We agree that some IOTA participants with higher risk thresholds may accept deceased donor organs more aggressively, if they believe they have the resources and support for their patients post-transplant. While this may apply to some kidney transplant hospitals, however, we do not believe that this will be a common approach. IOTA participants have the opportunity to consider utilizing filters that more closely match their risk threshold and waitlist patient population. While we do not believe that the efficiency domain will make waitlist criteria more stringent, we do believe that paired with the transparency notification requirement in section III.C.8.a(2), IOTA participants may be more inclined to remove patients from their active waitlist who are not potential kidney transplant candidates. Should we notice an adverse effect of the efficiency domain, such as reduction in access to waitlisting or being active on the waitlist, we will take this into consideration for future rulemaking. Additionally, as mentioned in the comments noted previously in this section, we are we are updating our regulation text at § 512.426(c)(2)(i) and in Table 1 to Paragraph (c)(1)(i) at our regulation at § 512.426 to remove reference to performance being measured against a national target and is instead based on national ranking.

Comment: A few commenters suggested considerations for the efficiency domain scoring. These considerations included ensuring not to penalize IOTA participants that are already accepting more organs than expected, moderating the proposed expectations for performance in the achievement and improvement scores, and aligning the efficiency domain point system to SRTR's upcoming method of creating performance tiers. Several commenters also provided suggestions for alternative criteria for kidney transplant hospitals to receive the full 20 points in the efficiency domain. The suggestions included awarding full points for meeting the OPTN's minimum ratio, having an organ offer acceptance ratio of 1.0, and meeting organ acceptance expectations. There were also a few suggestions that kidney transplant hospitals that meet the improvement component criteria should be awarded the full 20 points as well; this could potentially be accomplished by having programs opt in to either an achievement or improvement track. Finally, a commenter pointed out that because the organ offer acceptance rate ratio is compared to national performance for the achievement component of the efficiency domain, a program may improve its rate but not its ratio depending on the national rate. They same commenter suggested considering relative acceptance rate. Similarly, a commenter stated the scoring system, as proposed, is too harsh.

Response: We thank the commenters for their feedback. As mentioned in the proposed rule, we do not expect every IOTA participant to reach top-level performance. If an IOTA participant is already accepting more organs than expected, they will likely have a high scoring ratio as well. An IOTA participant that scores in the 50th percentile of performance for the organ offer acceptance rate achievement score would receive 10 out of 20 points. Alternatively, if an IOTA participant improves their organ offer acceptance rate ratio by 120 percent of their benchmark rate, as proposed, they can earn 15 points. As mentioned in the comments noted previously in this section, we are finalizing our proposed organ offer acceptance rate ratio improvement scoring methodology to reflect that the maximum number of points awarded for improvement scoring is 15 points, rather than 12 points.

For PY 1, we believe it is appropriate to carve out more points for those IOTA participants who have the highest performance. We do not believe the OPTNs minimum ratio is high enough to nudge transplant programs to continue to improve on this performance metric. As mentioned in the comments noted previously in this section, we are finalizing our proposed organ offer acceptance rate ratio achievement scoring methodology with slight modifications to reflect that points earned will be based on national ranking rather than a national target.

Although we did not consider the SRTRs performance tier assessment in the proposed rule, we are interested to learn more about this methodology once implemented and to further consider this for future rulemaking. We will also continue to consider if the improvement maximum score should be equivalent to the achievement maximum score and if achieving upper quintile ranks is too challenging. This, in addition to ongoing feedback and performance during PY 1 will help guide us in future rulemaking.

Comment: A commenter was concerned that the organ offer acceptance rate ratio would be impacted by transplant programs completing dual organ transplants, who may receive priority offers.

Response: We thank the commenter for their feedback and recommends reviewing Table 6 of section III.C.5.d(1)(a) of this final rule, which includes organ offers included and excluded from the organ offer acceptance rate ratio metric. This specifically identifies that offers to multi-organ candidates (except kidney pancreas candidates that are also listed for kidney alone) are excluded from the measure.

Comment: A few commenters were concerned about overall impact of risks and costs of the organ offer acceptance ratio methodology. A couple of commenters were concerned that point allocation for the organ offer acceptance rate ratio and kidney transplant volume will increase marginal kidney use and have higher financial costs and risks to patients. A commenter specifically asked whether there will be subsequent increase in reimbursement and SRTR adjustments. Similarly, another commenter stated that the organ offer acceptance ratio incentivizes IOTA participants to accept offers they may not ordinarily accept and is concerned that the IOTA Model needs to minimize

the risk of adverse outcomes when evaluating participating hospitals fairly.

Response: We thank the commenters for sharing their concerns. We agree that some IOTA participants may choose to increase their utilization of DCD kidneys or kidneys with a KDPI greater than 85, however, this is a choice for each IOTA participant based on their comfort level and resources and is not the only way for an IOTA participant to perform well in the IOTA Model. Regardless of the approach of each IOTA participant, we intend to monitor for unintended consequences that my occur with the model. We bring attention to the fact that while IOTA participants who achieve a final performance score of 60 or more points will receive an upside risk payment, as described and finalized in section III.C.6.c(1) of this final rule, there is also a neutral zone for IOTA participants who achieve a final performance score between 0 and 59 points in PY 1 and a final performance score of 40–59 points in PY 2 through PY 6, as described and finalized in section III.C.6.c(1) of this final rule. We direct readers to sections III.C.6 of this final rule for a full discussion on payment. With increasing resources and knowledge such as access to timely donor biopsies and research on what factors prompt kidneys to be designated as high KDPI kidneys, there are growing opportunities in the transplant ecosystem to identify kidneys that may or may not be ideal to transplant.

As for as modifications to SRTR adjustments and reimbursement, we will continue to collaborate with other groups in OTAG to work on aligning goals across the transplant ecosystem.

Comment: A few commenters had concerns that IOTA participants may change their habits or manipulate their listing or transplant practices to improve their organ offer acceptance rate. Specifically, a couple of commenters conveyed their concern that kidney transplant hospitals will use organ offer filters to have a better offer acceptance rate ratio, whereas kidney transplant hospitals that utilize marginal kidneys and try to have higher volumes will have worse performance for this ratio. They requested clarification on how CMS will prevent IOTA participants from being rewarded if they choose to use filters for this metric. Another commenter stated their concern that to achieve a better organ offer acceptance ratio, IOTA participants may inactivate patients, causing subsequent disadvantages. Additionally, a commenter was concerned that OPOs may start bypassing IOTA participants if they scrutinize whether the organ is an optimal match for a recipient.

Response: We appreciate the commenters' feedback and believe that organ offer filters are often an underutilized resource that help minimize organ non-use, out-of-sequence allocation, and prolonged cold ischemic times. Therefore, we disagree with the commenter views and encourage kidney transplant hospitals to use filters to reduce unnecessary offers to their transplant programs, when appropriate, for categories of offers that the transplant program will definitively not accept. We recognize this may be challenging due to high thresholds for marginal kidneys or different risk thresholds for different rotating surgeons in the same transplant program. However, we believe that given the rise in organ offers made by OPOs, there is opportunity to reduce administrative burden and organ non-use, by way of using filters and impacting their organ offer acceptance rate.

We acknowledge that there are some unique cases that are very high risk and require specific donor and recipient criteria, which may impact acceptance practices. We also acknowledge that it is unrealistic for kidney transplant hospitals to accept every offer they receive.

If OPOs start bypassing IOTA participants due to in depth analysis of whether an organ is optimal for their patients, we believe this would be important model feedback for IOTA participants to relay to us. If analysis results warrant a new or updated policy, we will address it pursuant to future rulemaking.

Comment: A commenter suggested CMS mandate the use of organ offer filters by a certain date.

Response: We appreciate the commenter's suggestion. Currently, we do not believe mandating organ filters is appropriate for the IOTA Model. While the performance domains and performance metrics in the IOTA Model do indirectly encourage use of organ offer filters, we believe IOTA participants should have the opportunity to identify what organ offer filters are appropriate for their transplant program and the populations they serve, as they participate. This is a topic for the entire transplant ecosystem to collectively consider in the future.

Comment: A few commenters conveyed concerns that unique situations may impact post-transplant outcomes and impact acceptance rates. For example, a commenter stated that CMS should consider patient characteristics and how they impact a successful transplant. Another commenter is concerned that not all offers are viable. A commenter conveyed concern that filter settings for distance may conflict with allocation registered distance. For example, a kidney available in Alaska may show as local per UNOS assignment but will show as 2500 miles away from a kidney transplant hospital in Washington per filters, which would require liberal filters for distance, to capture donors in that region.

Response: We appreciate the commenters bringing these concerns to our attention. We acknowledge that there are unique donor and recipient characteristics that may impact offer acceptances. We do not expect that any IOTA participant will accept every organ offer it receives since there are scenarios that are difficult to predict.

We agree with the second commenter who stated that not all offers are viable and acknowledges this in section III.C.5.d.(1)(a), Table 6, where exclusions for the organ offer acceptance rate ratio metric are included. Kidney match runs that have no acceptances are excluded in this metric.

We appreciate the commenter bringing UNOS and offer filter distance criteria mismatch to our attention. This was not considered at the time of the proposal of the IOTA Model. We plan to further discuss this internally and analyze how this can appropriately be accounted for in future performance years.

Comment: A commenter requested that CMS consider how IOTA participants using organ offer filters prior to the model will be compared to IOTA participants that newly utilize organ offer filters and receive higher scores in the efficiency domain.

Response: We appreciate the commenter's feedback. The proposed organ offer acceptance rate ratio achievement scoring methodology is independent of pre-existing or new filter use and is strictly dependent on a ratio compared to national ranking. As mentioned in the comments noted previously in this section, we are finalizing our proposed achievement scoring methodology with slight modifications to reflect that points earned will be based on national ranking rather than a national target. Additionally, the organ offer acceptance rate ratio improvement scoring methodology has a ceiling of 15 points, which prevents IOTA participants that are new to using filters from having an unfair advantage over IOTA participants who previously utilized this resource. As mentioned in the comments noted

previously in this section, we are finalizing our proposed improvement scoring methodology to reflect that the maximum number of points awarded for improvement scoring is 15 points, rather than 12 points.

Comment: A commenter encouraged CMS to consider that not all kidney transplant hospitals have the same capabilities, and this contradicts the achievement component of the efficiency domain since kidney transplant hospitals are not uniform.

Response: We appreciate the commenter's concerns and acknowledge the differences between kidney transplant hospitals but also believe that these unique variations create flexibility in how an IOTA participant may choose to adapt practice to impact their organ offer acceptance rate ratio. For those IOTA participants who prioritize improving their own score year-to year, the organ offer acceptance rate ratio improvement scoring methodology, as described in section III.C.5.d.(1).(b). of this final rule, allows them to earn points independent of comparison to other IOTA participants.

Comment: A commenter relayed concern that keeping track of potential offers and acceptances is burdensome.

Response: We appreciate the commenter's feedback and will take this into consideration when planning for and implementing the IOTA Model in addition to identifying appropriate intervals for IOTA participants to have access to interim results. The IOTA Model does not mandate that IOTA participants keep track of their potential organ offers and acceptances but understands that IOTA participants may want to have access to this information for personal tracking purposes.

Comment: A couple commenters expressed their support for CMS' proposal to include the organ offer acceptance rate ratio as a performance measure in the efficiency domain. They contended that the organ offer acceptance rate ratio metric motivates kidney transplant hospitals to utilize filters that reflect their acceptance practices, while also providing the flexibility to modify these filters. Furthermore, they suggested that this metric would encourage increased acceptance rates.

Response: We appreciate the support received from commenters for our proposal to include the organ offer acceptance rate ratio metric as a performance measure in the efficiency domain.

After consideration of the public comments, for the reasons set forth in this rule, we are finalizing the proposed provisions for the point allocation and calculation methodology for efficiency domain scoring and scoring for organ offer acceptance rate ratio for the IOTA Model at § 512.426(c), with slight modifications. In the proposed rule at 89 FR 43559, we proposed that achievement scoring points be awarded based on the national quintiles, as outlined in Table 6 of section III.C.5.d.(1).(b). of the proposed rule. As such, we are updating our regulation text at § 512.426(c)(2)(i) and in Table 1 to Paragraph (c)(1)(i) at our regulation at § 512.426 to remove reference to performance being measured against a national target and is instead based on national ranking. Additionally, we are updating the regulation text at § 512.426(c)(1)(ii)(B)(1) to reflect 15 points instead of 12 points and updating the multiplier in equation 1 to paragraph (c)(1)(ii)(B)(*1*) at § 512.426, as illustrated in Equation 4 in this section, to reflect 15 instead of 12. Lastly, we are updating our regulation text language at § 512.402 to clarify our definition for improvement benchmark rate, which we modified to 120 percent of the IOTA participants' performance on the organ offer acceptance rate ratio, as specified under § 512.426(c)(1)(ii)(A) rather than 120 percent of the IOTA participants' performance on organ offer acceptance rate ratio, as specified under § 512.426(c)(1)(ii)(A).

e. Quality Domain

In the proposed rule, we proposed to define ''quality domain'' as the performance assessment category in which CMS assesses the IOTA participant's performance using a performance measure and quality measure set focused on improving the quality of transplant care, as described in section III.C.5.e of the proposed rule and section III.C.5.e. of this final rule. We proposed that performance on the quality domain would be worth up to 20 points out of the proposed 100 points. The quality domain is focused on monitoring post-transplant care and quality of life for IOTA transplant patients.

In section III.C.5.e of the proposed rule, we stated that our goal for the quality domain within the IOTA Model is to achieve acceptable post-transplant outcomes while incentivizing increased kidney transplant volume. We believed that transplant hospital accountability for patient-centricity and clinical outcomes continues post-transplantation. While transplant outcomes have historically received the most attention, often at the exclusion of other factors, we sought to encourage a better balance in the system to offer the benefits of transplant to more patients. Therefore, we proposed to include one post-transplant outcome measure, as described in section III.C.5.e(1) of this final rule, and a quality measure set that includes two patient-reported outcome-based performance measures (PRO–PM) and one process measure, as described in section III.C.5.e(2) of this final rule.

We sought comment on the proposed definition of the quality domain.

We did not receive any comments on the proposed definition of the quality domain and are finalizing the proposed definition for quality domain at § 512.402, with slight modification to remove the following words from the definition: and quality measure set. Since we are not finalizing our proposal to include our proposed quality measure set that includes two patient-reported outcome-based performance measures (PRO–PM) and one process measure, as described in the section III.C.5.e(2) of this final rule, we modified the quality domain definition and removed reference to the quality measure set. As such, we are also finalizing the general provisions for the quality domain as proposed, with a minor technical correction to update the cross reference in the regulation text at § 512.424(a). Specifically, we are removing the cross reference to the proposed quality measure set at § 512.424(a). We direct readers to section III.C.5.e(2) of this final rule for further discussion on our proposed quality measure set methodology. We are also finalizing our regulation as proposed without modification at § 512.424(b) that for each PY, CMS assesses each IOTA participant using the specified quality metrics. Lastly, we direct readers to section III.C.5.e(1) of this final rule for further discussion on our proposed post-transplant outcome measure.

(1) Post-Transplant Outcomes

In the proposed rule, we proposed using an unadjusted rolling ''composite graft survival rate,'' defined as the total number of functioning grafts relative to the total number of adult kidney transplants performed, as described in the proposed rule (89 FR 43518) and section III.C.5.e(1)(a) of this final rule, to assess IOTA participant performance on post-transplant outcomes. In this measure, the numerator (observed functioning grafts) and denominator (number of kidney transplants completed) would increase each PY of the IOTA Model to include a cumulative total.

In section III.C.5.e(1) of the proposed rule, we stated that over the past few decades, advances in immunosuppressive therapies, surgical techniques, and organ preservation

methods have resulted in significant improvements in kidney transplantation outcomes.[239] According to the OPTN, the overall 1-year survival rate for kidney transplantation recipients in the United States is over 90 percent, and the 5-year survival rate is around 75 percent. However, even with the advances that have been made to improve kidney outcomes, the success of kidney transplantation is still dependent upon factors such as the age and health of the donor and recipient, the presence of comorbidities (for example, diabetes), and the effectiveness of the immunosuppressive regimen. Kidney transplant outcomes can also be affected by possible post-transplant complications, including infection, cardiovascular disease, and kidney failure.[240]

More recently, CMS received feedback from transplant hospitals, patient advocacy groups, and transplant societies, including on the recent rule making (''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction'' (83 FR 47686)), that the 1-year measure was causing transplant centers to be risk averse about the patients and organs they would transplant while being simultaneously topped out (83 FR 47706).[241] Notably, even the lowest ranked programs, as measured by the SRTR, achieved a result of 90 percent of transplanted patients have a functioning graft at one year.[242]

To safeguard patient outcomes under the IOTA Model, we proposed to include this measure as a checkpoint (89 FR 43518). Because there is significant variation in post-transplant outcomes across kidney transplant hospitals, we believed the IOTA Model should promote improvement in outcomes for the benefit of attributed patients. We also believed that this measure would build upon, and complement, existing OPTN and SRTR measures to the maximum extent possible. Additionally, we believed that this approach could be applied with minimal adaptation to other organs were they to be added to the model through future rulemaking. Furthermore, we believed that this measure would enhance patient understanding of clinically important post-transplant outcomes beyond existing 90-day, 1-year and 3-year post transplant outcomes.

We considered measuring post-transplant outcomes using SRTR's methodology at 90 days,[243] and constructing 5-year and 10-year post-transplant measures (89 FR 43518). However, we did not select these measures because post-transplant outcomes are already measured at 90-days by SRTR. Additionally, because the IOTA Model as proposed spans only 6 years, we did not believe we could appropriately measure post-transplant outcomes at 5 or 10 years.

We considered constructing an ongoing post-transplant outcome measure that would continuously evaluate post-transplant outcomes at 1-year throughout the model performance period of the IOTA Model. In this measure the numerator (observed graft failures) and denominator (number of transplants completed) would increase each PY of the model to a cumulative total (89 FR 43518). For example, in PY 1 of the model an IOTA participant could have five 1-year observed graft failures and complete 20 transplants, resulting in a graft failure rate of 0.25. In PY 2 of the model, the same IOTA participant could have eight 1-year observed graft failures and complete 30 transplants. To calculate the IOTA participant's graft failure rate for PY 2 of the model, we would divide the cumulative total of 13 1-year observed graft failures by the cumulative total of 50 completed transplants. However, we felt it was important to measure post-transplant outcomes in terms of graft survival rather than in terms of graft failure. We acknowledged that for the purposes of measuring graft survival using OPTN data, use of either concept would generate the same outcome measurement because OPTN data identify graft status as either functioning or failed. However, we aim to convey the importance of ongoing management to preserve the health of the transplanted graft and the health and quality of life of the attributed patients.

We considered constructing a continuous patient survival measure that would evaluate patient survival throughout the entirety of the IOTA Model (89 FR 43518). Similar to the considered measure mentioned in the previous paragraph, the numerator (number of patients alive) and denominator (number of received kidney organ offers) would increase each PY of the model to a cumulative total. For the denominator, we considered only including organ offers where the sequence number was less than 100 or less than 50. In other words, under that rationale we would only include offers that came within a certain point of time that could have potentially benefited the patient or should not have been turned down. We believed that this type of measure would not disincentivize waitlisting and could potentially increase equity within this population. Additionally, we believed that this type of measure would indirectly encourage living donor transplants because those would only hit the numerator (number of people alive) but not the denominator (number of kidney organ offers received). However, we felt that this measure would be somewhat duplicative of other parts of the model where we are already evaluating organ offer acceptance. We also chose not to propose this measure due to logistical concerns, and felt that it could be difficult to determine how many people were offered a specific organ and determining what an appropriate sequence number cutoff should be.

We considered measuring estimated glomerular filtration rate (eGFR) at the 1-year anniversary of the date of transplant (89 FR 43518). Glomerular filtration rate (GFR) is a way to assess renal function, and eGFR is the test used to assess renal function in primary

[239] Stewart, D.E., Garcia, V.C., Rosendale, J.D., Klassen, D.K., & Carrico, B.J. (2017). Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States. *Transplantation, 101*(3), 575–587. *https://doi.org/10.1097/tp.0000000000001539;* Vinson, A., Kiberd, B.A., & Karthik Tennankore. (2021). *In Search of a Better Outcome: Opting Into the Live Donor Paired Kidney Exchange Program. 8,* 205435812110174–205435812110174. *https://doi.org/10.1177/2054358121101741 2;* Shepherd, S., & Formica, R.N. (2021). *Improving Transplant Program Performance Monitoring. 8*(4), 293–300. *https://doi.org/10.1007/s40472-021-00344-z.*

[240] Gioco, R., Sanfilippo, C., Veroux, P., Corona, D., Privitera, F., Brolese, A., Ciarleglio, F., Volpicelli, A., & Veroux, M. (2021). Abdominal wall complications after kidney transplantation: A clinical review. *Clinical Transplantation, 35*(12), e14506. *https://doi.org/10.1111/ctr.14506;* Wei, H., Guan, Z., Zhao, J., Zhang, W., Shi, H., Wang, W., Wang, J., Xiao, X., Niu, Y., & Shi, B. (2016). Physical Symptoms and Associated Factors in Chinese Renal Transplant Recipients. *Transplantation Proceedings, 48*(8), 2644–2649. *https://doi.org/10.1016/j.transproceed.2016.06.052;* Mehrabi, A., Fonouni, H., Wente, M., Sadeghi, M., Eisenbach, C., Encke, J., Schmied, B.M., Libicher, M., Zeier, M., Weitz, J., Büchler, M.W., & Schmidt, J. (2006). Wound complications following kidney and liver transplantation. *Clinical Transplantation, 20*(s17), 97–110. *https://doi.org/10.1111/j.1399-0012.2006.00608.x.*

[241] Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction (September, 20, 2018) *https://www.federalregister.gov/documents/2018/09/20/2018-19599/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and.*

[242] Scientific Registry of Transplant Recipients. Request for Information. Requested on 05/02/2023. *https://www.srtr.org/.*

[243] Mpsc-enhance-transplant-program-performance-monitoring-system_srtr-metrics.pdf. (n.d.). Retrieved December 28, 2022, from *https://optn.transplant.hrsa.gov/media/qfuj3osi/mpsc-enhance-transplant-program-performance-monitoring-system_srtr-metrics.pdf.*

clinical care.[244] Despite the fact that studies indicate eGFR's potential as a reliable predictor of long-term post-transplant prognosis, our goal is to adopt a measure that resonates more with the transplant community's evaluation of post-transplant outcomes.[245] We recognized that the equation for calculating eGFR was revised in 2021 to not include race, but we still have some concerns over the potential for bias and inaccurate results and the limitations that still exist with the updated equation and did not believe it was appropriate to propose.[246]

We considered constructing several hospital-based post-transplant outcome measures such as those that measure: the number of days spent out of the hospital post-transplant, how many days spent at home post-transplant before returning to work, and number of hospital readmissions post-transplant (89 FR 43518). However, we do not want to penalize the use of moderate-to-high KDPI kidneys, as we recognize that utilizing these organs carries an increased risk of transplant recipient hospitalizations. Additionally, we had concerns over how we would assess and measure this type of metric.

We considered proposing a phased-in approach to measuring post-transplant outcomes, in which no post-transplant outcome metrics would be included until PY 3 of the model (89 FR 43518). In this alternative methodology, the quality domain for the first two PYs would only include our proposed quality measure set, as described in section III.C.5.e(2) of the proposed rule and this final rule. Starting PY 3 of the model, IOTA participants would be evaluated on two post-transplant outcome measures (SRTR's 1-year post-transplant outcome conditional on 90-day survival measure and 3-year post-transplant outcome measure) in addition to our proposed quality measure set. This approach incorporates a time delay, allowing us to assess the post-transplant outcomes of IOTA participants using SRTR's measures. Because we felt that it was critical to include a post-transplant measure from the onset of the model to check for unintended consequences throughout the entirety of the model performance period, we did not believe that this alternative was appropriate to propose.

We also considered using SRTR's new ''1-year post-transplant outcome conditional on 90-day graft survival'' measure and including a 3-year post-transplant outcome measure, such as the one currently used by SRTR (89 FR 43518). We also considered constructing our own 3-year post-transplant outcome measure conditional on 1-year survival. However we chose not to propose SRTR's conditional 1-year or 3-year post-transplant outcome measures or our own measure for the following reasons: (1) because SRTR's conditional 1-year metric has a 2.5 year lookback period, it would require us to evaluate IOTA participants on post-transplant outcomes prior to starting the model for at least the first two PYs; (2) because SRTR does not currently have a 3-year conditional post-transplant outcome measure, we would not be in alignment with SRTR if we constructed our own; (3) including SRTR's 3-year post-transplant outcome measure would include time outside of the model for at least the first three PYs and we want to evaluate IOTA participants based on their performance within the model; and (4) we recognize there may be some logistical issues and difficulty in measuring performance in that time. We may consider incorporating a 3-year post-transplant outcome measure into the model in the future, through rulemaking.

We sought public comment on our proposal to evaluate IOTA participants on post-transplant outcomes using our new composite graft survival rate metric, as well as on the alternatives we considered. We were also interested in public comment on how we may be able to use OPTN data to characterize different clinical manifestations of graft survival, as we understand that not all surviving grafts are clinically equivalent or have the same impact on the patient and graft health. We were further interested to hear from the public on which factors involved in graft survival are modifiable by the care team.

The following is a summary of the comments received on our proposal to evaluate IOTA participants on post-transplant outcomes using our new composite graft survival rate metric, as well as on the alternatives we considered and our responses:

Comment: There were many commenters requesting CMS use alternative metrics for graft survival rate that include risk adjustment methodologies in place of the proposed composite graft survival rate. For example, a commenter suggests that CMS develop additional post-transplant outcome measures that could be utilized to measure the quality of care provided, surrogates for long term allograft function, in addition to early indicators for allograft function. This commenter additionally recommended measures of kidney function at 12 months or new onset albuminuria (for example, urine albumin to creatinine ratio [ACR]). A couple commenters that suggested that CMS reconsider using eGFR at 12 months. Specifically, a commenter stated that, on a population level, the data suggests that eGFR at 12 months is predictive of long-term outcomes. Taking into consideration the dual goals of increasing organ utilization and patient outcomes, as well as outcomes that are superior to the dialysis, the same commenter recommended that an appropriate gauge of success in such a measure could be an eGFR superior to dialysis initiation or listing for re-transplant (for example, greater than 20 mL/min) such as 25 or 30 mL/min. Another commenter suggested that eGFR more accurately conveys long-term patient outcomes and incorporating granular measures of allograft function into performance metrics instead of using a binary (functioning/failed) indicator could improve patient care by prioritizing allograft function as a measure of program quality.

Several commenters urged CMS to reconsider current SRTR outcome measures. For example, although a commenter agreed with CMS that it may not be possible to use SRTR's 1-year graft survival conditional on 90-day survival or 3-year survival for short term evaluations of transplant program outcomes, they noted that SRTR has available models to assess 90-day outcomes along with the first full year posttransplant. The same commenter suggested that the 90-day models could be used to assess near-term success of the transplants in a risk-adjusted framework, and the full 1-year models could be used as the model develops and more performance years are

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[244] Mayne, T.J., Nordyke, R.J., Schold, J.D., Weir, M.R., & Mohan, S. (2021). Defining a minimal clinically meaningful difference in 12-month estimated glomerular filtration rate for clinical trials in deceased donor kidney transplantation. *Clinical Transplantation, 35*(7), e14326. *https://doi.org/10.1111/ctr.14326.*

[245] Ibid; Wu, J., Li, H., Huang, H., Wang, R., Wang, Y., He, Q., & Chen, J. (2010). Slope of changes in renal function in the first year post-transplantation and one-yr estimated glomerular filtration rate together predict long-term renal allograft survival. *Clinical Transplantation, 24*(6), 862–868. *https://doi.org/10.1111/j.1399-0012.2009.01186.x;* Schold, J.D., Nordyke, R.J., Wu, Z., Corvino, F., Wang, W., & Mohan, S. (2022). Clinical events and renal function in the first year predict long-term kidney transplant survival. *Kidney360,* 10.34067/KID.0007342021. *https://doi.org/10.34067/kid.0007342021;* Hariharan, S., Mcbride, M.A., Cherikh, W.S., Tolleris, C.B., Bresnahan, B.A., & Johnson, C.P. (2002). Post-transplant renal function in the first year predicts long-term kidney transplant survival. *Kidney International, 62*(1), 311–318. *https://doi.org/10.1046/j.1523-1755.2002.00424.x.*

[246] Majerol, M., & Hughes, D.L. (2022, July 5). CMS Innovation Center Tackles Implicit Bias. *Health Affairs.* Retrieved January 16, 2024, from *https://www.healthaffairs.org/content/forefront/cms-innovation-center-tackles-implicit-bias.*

included to also incorporate risk adjustment into the evaluations.

This commenter also stated that the 90-day and 1-year models conditional on 90-day survival are currently used by the MPSC to evaluate transplant program outcomes. Therefore, they believed that not only is it feasible to use the 90-day and 1-year adjusted evaluations following the SRTR methodology, but it was also imperative to achieve the goals of the IOTA Model. Several commenters also urged CMS to use the outcomes already available from the SRTR, as it is well-established. Although the data is delayed, these commenters argued for CMS to include SRTR outcome measures citing reasons such as that it is well-established, accepted, and tested nationally and offers a comprehensive evaluation of graft survival that accounts for the complexities of both donors and recipients. A commenter believed CMS should remove the proposed measure and instead continue to use the existing SRTR post-transplant survival measures if CMS wants to increase the number of kidney transplants in part by encouraging kidney transplant hospitals to accept higher risk organs. This would also reduce the additional reporting burden associated with a new quality measure. Alternatively, a commenter suggested that CMS could utilize SRTR's CUSUM data as it could provide more real-time measurements.

Response: We thank the commenters for their suggestions on additional risk-adjusted measures that could be considered for measuring post-transplant outcomes in the model. As described at 89 FR 43562 in the proposed rule, we considered measuring eGFR at the 1-year anniversary of the date of transplant. However, our goal is to adopt a measure that better resonates with the transplant community's evaluation of post-transplant outcomes. As a result, we did not propose including eGFR at the 1-year anniversary. Additionally, we have ongoing concerns about potential bias, inaccurate results, and limitations with the updated eGFR equation. Given these issues, we did not believe it was appropriate to propose using eGFR at the 1-year mark.[247]

We also considered using SRTR's 1-year graft survival conditional on 90-day survival or 3-year post-transplant outcome measure. However, for the reasons stated at 89 FR 43562 in the proposed rule, we chose not propose using SRTR's 1-year graft survival conditional on 90-day survival or 3-year post-transplant outcome measure. As such, we will be finalizing our proposed composite graft survival rate metric to measure post-transplant outcomes in the IOTA Model. We will take into consideration the suggested post-transplant outcome metrics for IOTA and, if we determine that a new measure post-transplant outcome measure should be included, we would do so through future notice and comment rulemaking.

Comment: A commenter opposed the proposed graft survival rate measure given that the transplant community already has statistically valid measurements for outcomes utilizing a rolling 2.5-year cohort. Thus, the commenter felt relying on a raw calculation was not a reasonable replacement.

Response: We appreciate commenters recommendation to use an existing post-transplant outcome measure in place of the proposed composite graft survival rate. We will take the recommendation into consideration for future rulemaking and direct the commenter to comment responses noted previously in this section for further discussion on alternative metrics considered.

Comment: Several commenters expressed support for using the unadjusted Composite Graft Survival Rate as proposed—notably, that the proposed unadjusted composite graft survival rate is simple and would be easy for the patients to understand. For example, a commenter reported that their kidney patients frequently expressed confusion about transplant data metrics and appreciated CMS's efforts to establish a clearer measure for assessing graft survival. Furthermore, the commenter voiced support for using a graft survival metric rather than a graft failure metric, citing the reasons outlined in the proposed rule. A commenter also agreed with using this measure as a checkpoint to help ensure patient safety and improve understanding of post-transplant outcomes for patients. Another commenter concurred with CMS's proposal to calculate post-transplant outcomes using a rolling, unadjusted, composite graft survival measure. Although they believed that many commenters would argue for an urgent need to add ''risk adjustment'' to the measure, they felt that the proposed measure had the virtues of being straightforward, unambiguous, easy to understand, and easy to explain to patients and their families. This same commenter also stated their belief that these virtues are, too often, underemphasized.

Response: We thank the commenters for their support.

After consideration of the public comments received, for the reasons set forth in this rule, we are finalizing our proposed provision to assess IOTA participant performance on post-transplant outcomes using the composite graft survival rate at § 512.428(b)(1), without modification. We are also finalizing without modification the definition of composite graft survival rate at § 512.402.

(a) Calculation of Metric

In section III.C.5.e(1)(a) of the proposed rule, we proposed that for each model PY, CMS would calculate a composite graft survival rate for each IOTA participant, as defined and finalized in section III.C.5.e(1) of this final rule, to measure performance in the quality domain as described in section III.C.5.e. of this final rule.

In section III.C.5.e(1)(a) of the proposed rule, we proposed to use our own unadjusted composite graft survival rate equation to evaluate post-transplant outcomes. We proposed to calculate the composite graft survival rate by taking the total number of functioning grafts an IOTA participant has and dividing that by the total number of kidney transplants furnished to patients 18 years of age or older at the time of the transplant in PY 1 and all subsequent PYs (see Equation 4) to evaluate post-transplant outcomes during the IOTA Model performance period.

For example, as described in section III.C.5.e(1)(a) of the proposed rule, if in PY 1 of the model, an IOTA participant had 20 observed functioning grafts and furnished 25 kidney transplants to patients 18 years of age or older at the time of transplant, the composite graft survival rate for that IOTA participant would be 0.8 (20 from PY 1 divided by 25 from PY 1). Continuing this example, for PY 2 of the model if the same IOTA participant had 30 observed functioning grafts and furnished 35 kidney transplants to patients 18 years of age or older at the time of transplant, and two functioning kidney grafts failed from PY 1, CMS would calculate its composite graft survival rate for PY 2 as follows. CMS would divide the cumulative total of 48 observed functioning grafts (30 from PY 2 + 20 from PY 1—2 from PY 1) by the cumulative total of 60 completed kidney transplants (35 from PY 2 + 25 from PY 1), resulting in a

[247] Majerol, M., & Hughes, D.L. (2022, July 5). CMS Innovation Center Tackles Implicit Bias. *Health Affairs*. Retrieved January 16, 2024, from *https://www.healthaffairs.org/content/forefront/cms-innovation-center-tackles-implicit-bias.*

composite graft survival rate of 0.8 (48 divided by 60).

Equation 4: Composite Graft Survival Rate

$$Composite\ Graft\ Survival\ Rate\ = \frac{\#\ of\ Functioning\ Grafts}{\#\ of\ Completed\ Kidney\ Transplants}$$

In the proposed equation, the numerator (number of functioning grafts) is defined as the total number of living adult kidney transplant patients with a functioning graft. The numerator, functioning grafts, would exclude grafts that have failed, as defined by SRTR. SRTR counts a graft as failed when follow-up information indicates that one of the following occurred before the reporting time point: (1) graft failure (except for heart and liver, when re-transplant dates are used instead); (2) re-transplant (for all transplants except heart-lung and lung); or 3) death.[248] OPTN follow-up forms are used to identify graft failure and re-transplant dates.[249] We also proposed to use OPTN adult kidney transplant recipient follow-up forms [250] to identify graft failure and re-transplant dates for all transplants furnished to kidney transplant patients 18 years of age or older at the time of the transplant. In the proposed equation, we noted that the numerator and denominator would not be limited to the attributed IOTA transplant patients. By this, we meant that it could include IOTA transplant patients who have been de-attributed from an IOTA participant due to transplant failure. We believed that IOTA participants could improve on this metric by working with IOTA collaborators to coordinate post-transplant care.

We considered incorporating a risk adjustment methodology to our proposed composite graft survival equation, such as the one used by SRTR for 1-year post-transplant outcomes conditional on 90-day survival or constructing our own (89 FR 43518). While we recognized that risk adjustment methodologies may help account for patient and donor traits, we could not find a risk adjustment approach that has consensus agreement within the kidney transplant community. We also believed that our proposed measure is inherently risk adjusted as it only counts organs that are ultimately transplanted to patients 18 years of age or older by a kidney transplant hospital.

We invited public comment on our proposed methodology to calculate post-transplant outcomes in the IOTA Model, and on alternatives considered. Although we proposed an unadjusted composite graft survival rate to measure post-transplant outcomes, we were interested in comments on whether risk risk-adjustments are necessary, and which ones, such as donor demographic characteristics (*i.e.,* race, gender, age, disease condition, geographic location), would be significant and clinically appropriate in the context of our proposed approach.

The following is a summary of the comments received on our proposed methodology to calculate post-transplant outcomes in the IOTA Model, on whether risk risk-adjustments are necessary, and which ones, such as donor demographic characteristics (*i.e.,* race, gender, age, disease condition, geographic location), would be significant and clinically appropriate in the context of our proposed approach, alternatives considered and our responses:

Comment: Commenters expressed concern that the lack of risk adjustment in the proposed composite graft survival rate metric could have adverse consequences and would add additional administrative burden. Many commenters expressed concern that the unadjusted composite graft survival rate does not account for the clinical risk factors of the recipient or the donor, therefore, it may inadvertently lead to disparities in transplant by incentivizing participants to select healthier patients. For example, a commenter felt that the absence of risk adjustment in the IOTA Model was problematic and could be detrimental to patient care; stating that without accounting for the varying complexities of patients' health conditions, hospitals might avoid referring higher-risk patients who could benefit most from transplants. Another commenter suggested that the lack of risk adjustment to the composite graft survival measure would incentivize IOTA participants to choose the healthiest patients to transplant and would reject those who are sensitized. Highly sensitized patients have high levels of anti-HLA antibodies, making them more likely to reject a kidney from a donor. These highly sensitized patients are more likely to be African American. This same commenter cited a study published in the Nephrology Dialysis Transplantation journal that found that highly sensitized kidney transplant recipients were more frequently African American compared to non-sensitized patients.[251] Thus, the commenter believed that failure to risk-adjust this measure could lead to outcomes that run counter to CMS's stated desire to reduce disparities. A commenter believed that the inclusion of a post-transplant graft survival metric is innate and relevant to the IOTA Model. However, the commenter stated that one of the longstanding frustrations of transplant programs is that various regulatory bodies use different definitions and standards for graft survival. As proposed, this would represent another new definition and benchmarking system for kidney graft survival. The same commenter also found the lack of risk-adjustment concerning, as they would be taking on donor organs and recipients of progressively higher complexity, particularly for those programs that wish to pursue the greater-than-150 percent volume target.

Several commenters felt that the proposed measure misaligns with the model's goal of increasing kidney transplants in a more complex population without risk adjusting for allograft and recipient factors. Without proper risk adjustment, these commenters suggested it could cause IOTA participants to be more risk averse with the types of organs they accept or disincentivizing IOTA participants from transplanting candidates who have a higher likelihood of graft failure, such as older candidates or those with more comorbid conditions.

[248] *Technical Methods for the Program-Specific Reports.* (n.d.). *www.srtr.org.* Retrieved December 3, 2022, from *https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/;* OPTN. (2022). *OPTN Enhanced Transplant Program Performance Metrics. https://optn.transplant.hrsa.gov/media/r5lmmgcl/mpsc_performancemetrics_3242022b.pdf.*

[249] *Technical Methods for the Program-Specific Reports.* (n.d.). *www.srtr.org.* Retrieved December 3, 2022, from *https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/.*

[250] *https://unos.org/wp-content/uploads/Adult-TRF-Kidney.pdf.*

[251] Zhang, R. (2017). Donor-Specific Antibodies in Kidney Transplant Recipients. *Clinical Journal of the American Society of Nephrology, 13*(1), 182–192. *https://doi.org/10.2215/cjn.00700117.*

Some commenters suggested specific donor and recipient characteristics that CMS should risk adjust for when calculating the proposed composite graft survival rate. For example, a commenter recommended that CMS risk adjust for how sick the patient is or the health of the kidney. Another commenter urged CMS to use SRTR's risk adjustment methodology, as it undergoes regular testing and is updated annually. This commenter also stated that the current SRTR model recommends adjusting for both donor and recipient characteristics, including (1) donor and recipient demographic characteristics such as age, gender, and race, (2) donor and recipient clinical characteristics such as BMI, past behavior, medication history, and (3) history of certain conditions. A commenter suggested CMS consider risk-adjusting the composite graft rate using age, sex, major comorbidities, and neighborhood disadvantage index or similar (for example, CDC Social Vulnerability Index [252]). Lastly, a commenter appreciated CMS's emphasis on encouraging focus on post-transplant outcomes beyond the one- (and three-) year time horizon that currently receive the most focus. The commenter also broadly supported the proposed rolling composite graft survival metric as a mechanism to do so, and in particular, appreciated the simplicity of the proposed approach. However, they believed that CMS should risk-adjust for at least a small number of variables that would allow for a simple model that is understandable by including the biggest drivers for variation in outcomes and thereby disincentivize the creation of additional hurdles for more complex patients. For example, a model that includes age, ESRD vintage, and diabetes mellitus (y/n) the same commenter felt would leverage currently available data and remain easily measurable and understood.

Response: We appreciate the concerns and suggestions from the commenters. We recognize the importance of providing a risk adjustment methodology, but we disagree with modifying how the composite graft survival rate, as proposed, is calculated for PY 1. As discussed in section III.C.5.e(1)(a) of this final rule, we proposed to include this measure as a checkpoint to safeguard patient outcomes under the IOTA Model and sought to convey the importance of ongoing management to preserve the health of the transplanted graft and the health and quality of life of the attributed patients. As discussed at 89 FR 43536 in the proposed rule, 1-year post-transplant outcomes are markedly stable while long term post-transplant outcomes have historically been unchanged. In addition, research has shown that kidney transplant recipients, on average, experience one-year graft and patient survival rates above 95 percent.[253] As such, we believe the composite graft survival rate measure, as proposed, will reflect that for PY 1. We also maintain our belief that this measure would build upon, and complement, existing OPTN and SRTR measures to the maximum extent possible and enhance patient understanding of clinically important post-transplant outcomes beyond existing 90-day, 1-year and 3-year post transplant outcomes.

In light of commenters suggestions, we considered finalizing a risk adjustment methodology that adjusted for donor age, recipient age and recipient diabetes. However, we do not believe that adjusting for these three alone are appropriate. Organ availability is affecting the kidney transplantation in its entirety, leading to transplant teams expanding the criteria for accepting organ donors. In these circumstances, we believe that analysis of the impact of the donor's characteristics on graft survival becomes mandatory before incorporating a risk adjustment methodology. Additionally, given that the IOTA Model is 6 years, and the measure is rolling, we want to make sure that we continue discussions to ensure that this measure eventually includes a robust and appropriate risk adjustment methodology. Furthermore, we believe that the lack of risk adjustment for PY 1 will be minimal in terms of impacting IOTA participants scores and note that IOTA participants would not owe a downside risk payment in PY 1, as described and finalized in section III.C.6 of this final rule.

Therefore, we will be finalizing our composite graft survival methodology, as proposed, to calculate post-transplant outcomes in the IOTA Model. However, in light of comments received, we will be stratifying the data from the composite graft survival rate measure and will work with stakeholders to inform a risk adjustment methodology for this measure and intend to address a new or updated policy pursuant to future notice and comment rule making. We also note that since we are not finalizing our proposed quality measure set or quality measure set scoring methodology, as described in sections III.C.5.e(2) and III.C.5.e(2)(e) of this final rule, and based on public comment, we will be modifying our proposed points allocation. We direct readers to section III.C.5.e(1)(b) for further discussion on the points allocation for the composite graft survival rate measure.

Comment: Several commenters expressed concern over the proposed composite graft survival rate outcome measure. In particular, some commenters felt that the measure contradicts the primary objective of the IOTA Model, which is to increase the number of kidney transplants performed. For instance, a commenter believed that because this proposed measure would evaluate post-transplant outcomes during the IOTA Model performance period that the added requirement to provide six-year data detracts from what should be an unerring and resolute focus on increasing transplant volumes. A commenter also urged CMS to modify or remove this measure from the model in order for the model to succeed in achieving its primary objective. A couple commenters argued that this proposed measure would deter IOTA participants from transplanting lower-quality organs, which are significantly less likely to maintain function for six years post-transplant. Therefore, the commenters felt that the proposed outcome measure is inconsistent with the main objectives of the IOTA Model.

Some commenters also shared that they felt collecting the data required for the proposed composite graft survival rate metric would add additional administrative burden for IOTA participants. Specifically, a commenter suggested that finalizing this measure as proposed would significantly increase the data collection burden on participating transplant programs, as no existing database contains six-year post-transplant graft function data. A commenter also argued that the proposed six-year outcome measure conflicts with the existing monitoring and reporting framework, and introducing a significant unfunded change would be illogical, as it is incongruent with the model's strategic goals. A few commenters felt that this measure, as proposed, increases the time horizon for post-transplant graft survival accountability for transplant

[252] *CDC/ATSDR Social Vulnerability Index (CDC/ATSDR SVI).* (2024, June 14). *cdc.gov. https://www.atsdr.cdc.gov/placeandhealth/svi/index.html.*

[253] Poggio, E.D., Augustine, J.J., Arrigain, S., Brennan, D.C., & Schold, J.D. (2021). Long-term kidney transplant graft survival—Making progress when most needed. *American Journal of Transplantation, 21*(8). *https://doi.org/10.1111/ajt.16463;* Meier-Kriesche, H.U., Schold, J.D., & Kaplan, B. (2004). Long-Term Renal Allograft Survival: Have we Made Significant Progress or is it Time to Rethink our Analytic and Therapeutic Strategies? *American Journal of Transplantation, 4*(8), 1289–1295. *https://doi.org/10.1111/j.1600-6143.2004.00515.x.*

programs that participate. They noted that after the first-year post-transplant, the recipient's nephrologist, rather than the transplant facility, is primarily responsible for the patient's ongoing care. Thus, they felt the six-year timeline was unreasonable, as it would hold transplant programs accountable for ensuring graft function long after the period for which they can be held responsible.

Response: We thank commenters for their input and acknowledge their recommendations and concerns around the proposed composite graft survival rate. As mentioned in comment responses noted previously in this section, we will be finalizing the composite graft survival rate as proposed. However, we will take these insights and recommendations into consideration as we continue to assess our composite graft survival rate measure methodology and, if warranted, will propose a new or updated policy through future notice and comment rulemaking. We also note that in light of comments received, we intend to incorporate a risk adjustment methodology into our proposed approach for calculating post-transplant outcomes in the IOTA Model in future notice and comment rulemaking.

Comment: Several commenters expressed support for using the unadjusted composite graft survival rate as proposed.

Response: We thank the commenters for their support. We direct readers to section III.C.5.e(1)(a) of this final rule for the full discussion of the comments received in support of our proposed composite graft survival rate measure.

After consideration of the public comments received, for the reasons set forth in this rule, we are finalizing the proposed provisions for calculating the composite graft survival rate as proposed at § 512.428(b)(1), without modification. While we are finalizing our provision for calculating the composite graft survival rate as proposed, we will be stratifying the data from the composite graft survival rate measure to inform a risk adjustment methodology for this measure and may consider future notice and comment rulemaking on this topic.

(b) Calculation of Points

As described in section III.C.5.e of the proposed rule, performance on the quality domain would be worth up to 20 points. Within the quality domain, we proposed that the composite graft survival rate would account for 10 of the 20 allocated points. We proposed that the points earned would be based on the IOTA participants' performance on the composite graft survival rate metric ranked against a national target, inclusive of all eligible kidney transplant hospitals, both those selected and not selected as IOTA participants. We believe that using percentiles would create even buckets of scores among the continuum of IOTA participants.

We proposed that points would be awarded based on the national quintiles, as outlined in Table 8, such that IOTA participants that perform—

- At or above the 80th percentile would earn 10 points;
- In the 60th percentile to below the 80th percentile would earn 8 points;
- In the 40th to below the 60th percentile would earn 5 points;
- In the 20th percentile to below the 40th percentile would earn 3 points; and
- Below the 20th percentile would receive no points for the composite graft survival rate.

TABLE 8: COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance Relative to Target	Points Earned
80^{th} Percentile $\leq$	10
$60^{th} \leq$ and $< 80^{th}$ Percentile	8
$40^{th} \leq$ and $< 60^{th}$ Percentile	5
$20^{th} \leq$ and $< 40^{th}$ Percentile	3
$< 20^{th}$ Percentile	0

Utilizing quintiles aligns with the calculation of the upside and downside risk payments in relation to the final performance score as detailed and finalized in section III.C.6.c(2) of this final rule, where average performance yields half the number of points. The scoring is normalized, meaning an average performing IOTA participant earns 5 points out of 10, or about 50 percent of possible points. We recognize that there is an upper limit to the benefits of efficiency, and quintiles combine the highest 20 percent of performers in a point band. Due to the current disparity among kidney transplant hospitals, we do not expect every IOTA participant to reach top-level performance on this metric.

We considered a strategy similar to the proposed organ offer acceptance methodology which would apply a two-scoring system in which we would determine an achievement score and improvement score and award the point equivalent to the higher value between the two scores. We also considered proposing just an improvement score, in which we would evaluate IOTA participants' performance on composite graft survival during a PY relative to their performance the previous CY. We considered both approaches because we recognize that if an IOTA participant does not do well one year in our proposed methodology, that it may be difficult for it to improve during the model performance period. However, we chose not to propose either of these other methodologies (achievement and improvement or just improvement scoring) because we had concerns over our ability to measure improvement year over year due to potentially small numbers.

We sought public comment on the proposed point allocation and calculation methodology for post-transplant outcomes within the quality domain for the IOTA Model and alternatives considered.

The following is a summary of the comments received on our proposed point allocation and calculation methodology for post-transplant outcomes within the quality domain for the IOTA Model and our responses:

Comment: A few commenters expressed concern over the proposed points allocation. Specifically, a commenter indicated that, despite performing as expected on one-year outcomes, they would receive zero points based on the proposed points allocation, as the observed survival is

ranked low. The commenter attributed this to the transplant hospitals willingness to take on riskier waitlist patients and accept donors that other transplant hospitals may otherwise not. A commenter expressed concern that a small number of adverse scores could significantly skew a transplant hospital's data. They argued that with the relatively low volume of transplants, just a few outlier scores could make it challenging to draw meaningful conclusions or implement impactful changes. As a result, the commenter believed these widely used quality metrics were better suited for evaluating large patient populations, such as in primary care settings. Lastly, a commenter also recommended that CMS adjust the eligibility to obtain maximum points downward in the composite graft survival rate points allocation. Specifically, the commenter suggested that full points be awarded to IOTA participants at the 60th percentile and above instead of the proposed 80th percentile and above.

Response: We thank the commenters for raising concerns around the potential difficulties IOTA participants may face in achieving a top score on the composite graft survival rate metric. Regarding the concerns that a small number of adverse scores could significantly skew a transplant hospital's data, we believe that is difficult for us to approach with so little data. However, we recognize there have been significant improvements in kidney transplantation outcomes over time due to advances in immunosuppressive therapies, surgical techniques, and organ preservation methods. We also recognize that post-transplant outcomes are already incentivized through private payers' COE programs and OPTN metrics. Additionally, we acknowledge that IOTA participants will need time to establish relationships with IOTA collaborators, as described and finalized in section III.C.11.c of this final rule, and we want to allow time for those to be established.

Thus, given this myriad of issues, and in light of public comment, we are finalizing an alternate scoring system for PY 1. Points will be awarded based on the national quintiles, as outlined in Table 9, such that IOTA participants that perform:

- At or above the 80th percentile would earn 20 points;
- In the 60th percentile to below the 80th percentile would earn 18 points;
- In the 40th percentile to below the 60th percentile would earn 16 points;
- In the 20th to below the 40th percentile would earn 14 points;
- In the 10th to below the 20th percentile would earn 12 points; and
- Below the 10th percentile would receive 10 points for the composite graft survival rate.

TABLE 9: COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance Relative to Target	Points Earned
80^{th} Percentile $\leq$	20
$60^{th} \leq$ and $< 80^{th}$ Percentile	18
$40^{th} \leq$ and $< 60^{th}$ Percentile	16
$20^{th} \leq$ and $< 40^{th}$ Percentile	14
$10^{th} \leq$ and $< 20^{th}$ Percentile	12
$< 10^{th}$ Percentile	10

We recognize that for PY 2 and future PYs there will be more events and a longer time horizon and plan to implement a more robust methodology that can account for both the likelihood of graft failure based on the donor and the recipient and can account for relative benefits of transplantation over remaining on dialysis. We will continue to assess our quality domain methodology and how to best balance incentives in the efficiency domain and quality domain and address a new or updated policy pursuant to future notice and comment rule making.

Comment: A commenter expressed support for the proposed point allocation and calculation methodology for post-transplant outcomes within the quality domain for the IOTA Model.

Response: We thank the commenter for their support. As mentioned in comment responses noted previously, since we are not finalizing our proposed quality measure set or quality measure set scoring methodology, as described in sections III.C.5.e(2) and III.C.5.e(2)(e) of this final rule, and based on public comment, we will be modifying our proposed points allocation, as illustrated in Table 9 in this section. We will continue to assess our quality domain methodology and how to best balance incentives in the efficiency domain and quality domain and address a new or updated policy pursuant to future notice and comment rule making and provide further specification based on commenters suggestions, if warranted.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed composite graft survival rate scoring methodology within the quality domain at § 512.428(d), as proposed with minor technical corrections to update language to reflect what we proposed at 89 FR 43518 of the proposed rule. Specifically, at § 512.428(d) we are updating the language to reflect that CMS awards points to the IOTA participant based on the IOTA participant's performance on the composite graft survival rate, as described in paragraph (b)(1) of this section, ranked nationally, inclusive of all eligible kidney transplant hospitals.

We are also finalizing our proposal for the proposed point allocation for post-transplant outcomes within the quality domain for the IOTA Model with slight modifications. In section III.C.5.e(2)(e) of the proposed rule, we proposed that the IOTA participant would receive up to 10 points for performance on our three proposed measures within the quality domain while also noting in the proposed rule at 89 FR 43564, that if we finalized fewer measures, then we proposed to allocate the points accordingly within the remaining measures. We acknowledge that by not finalizing any of the proposed quality measures for inclusion in the quality measure set of the quality domain, as described in section III.C.5.e(2) of this final rule, there is a need to account for

the points that we proposed to allocate to them, as described in section III.C.5.e(2)(e) of the preamble in this final rule. Therefore, we are finalizing our proposal with slight modification in Table 1 to paragraph (d) at our regulation at § 512.428(d) to allot a maximum of 20 points for performance on the composite graft survival rate measure.

Additionally, after consideration of the public comments we received, we are also finalizing, with modification, Table 1 to paragraph (d) at § 512.428(d) to reflect the updated points allocation, such that IOTA participants that perform—

- At or above the 80th percentile would earn 20 points;
- In the 60th percentile to below the 80th percentile would earn 18 points;
- In the 40th percentile to below the 60th percentile would earn 16 points;
- In the 20th to below the 40th percentile would earn 14 points;
- In the 10th to below the 20th percentile would earn 12 points; and
- Below the 10th percentile would receive 10 points for the composite graft survival rate.

(2) Quality Measure Set

In section III.C.5.e(2) of the proposed rule, we proposed to select and use quality measures to assess IOTA participant performance in the quality domain. Performance on the proposed IOTA Model quality measure set would be used to assess the performance of an IOTA participant on aspects of care that we believe contribute to a holistic and patient-centered journey to receiving a kidney transplant.

In section III.C.5.e(2) of the proposed rule, we proposed the following three measures for inclusion in the IOTA Model quality measure set: (1) CollaboRATE Shared Decision-Making Score (CBE ID:3327), (2) Colorectal Cancer Screening (COL) (CBE ID: 0034), and (3) the 3-Item Care Transition Measure (CTM–3) (CBE ID: 0228).[254] [255] [256] The quality measures that we proposed share common features. We proposed measures that have been or are currently endorsed by the CMS Consensus-Entity (CBE) through the CMS Consensus-Based Process. This ensures that the measures proposed have been assessed against established evaluation criteria of importance, acceptability of measure properties, feasibility, usability, and competing measures.[257] Our proposed measure set is patient-centered, reflecting areas that we have heard from patients are important and for which there is significant variation in performance among transplant hospitals. We proposed measures that would incentivize improvements in care that we would otherwise not expect to improve based on the financial incentives in the model alone. We are also proposing a measure set that would allow us to make a comprehensive assessment of post-transplant outcomes. The composite graft survival rate that we proposed in section III.C.5.e(1) of the proposed rule and this final rule would provide an essential, albeit limited, assessment of the success of a kidney transplant. Finally, we proposed measures that we believe would incentivize improvement in aspects of post-transplant care that are important to patients and modifiable by IOTA participants.

We stated in the proposed rule at section III.C.5.e(2) that on March 2, 2023, Jacobs et al. published *Aligning Quality Measures across CMS—The Universal Foundation,* which describes CMS leadership's vision for a set of foundational quality measures known as the Universal Foundation. This measure set would be used by as many CMS value-based and quality programs as possible, with other measures added based on the population or healthcare setting.[258] CMS selected measures for the Universal Foundation that are meaningful to a broad population, reduce burden by aligning measures, advance equity, support automatic and digital reporting, and have minimal unintended consequences.[259]

We considered only including two measures in the initial quality measure set and pre-measure development because we were concerned about the potential added reporting burden placed on IOTA participants (89 FR 43518). However, we chose to propose three measures and pre-measure development because we want to use them to incentivize and improve patient care. We sought additional feedback on which of the proposed measures have the highest potential to impact changes in behavior, while minimizing provider burden.

We also considered only including COL in the quality measure set and allotting this measure 4 points, with the remaining 16 points allotted to the composite graft survival rate (89 FR 43518). It is worth noting that if we choose fewer measures, then we proposed allocating the points accordingly within the remaining measures.

We considered several alternative measures for the quality domain performance assessment (89 FR 43518). We considered the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey because hospitals are already required to report that survey in the Hospital VBP Program, thereby reducing or limiting burden to IOTA participants burden since it is already in use. We did not propose the HCAHPS measure for the IOTA Model because HCAHPS data is based on survey results from a random sample of adult patients across medical conditions. We believe that the HCAHPS would present sample size issues for purposes of calculation.

We considered the Gains in Patient Activation Measure (PAM®) (CBE ID: 2483) (89 FR 43518). The PAM® measure is being used in the voluntary KCC Model and was included on the 2022 Measures Under Consideration (MUC) List for the ESRD Quality Incentive Program (QIP) and MIPS.[260] We considered whether the PAM® Measure could encourage IOTA participants and IOTA Collaborators, as defined and finalized in section III.C.11.d of this final rule, to activate IOTA waitlist patients to work in collaboration with IOTA participants to complete requirements to maintain active waitlist status; however, we were unable to locate any peer-reviewed literature to support this hypothesis.

As described in section III.C.5.e(2) of the proposed rule, we also considered the Depression Remission at 12 Months measure (CBE ID: 0710e). Studies have shown that depression and anxiety are common amongst people on dialysis and suggested that incorporating patient reported outcome measures (PROs) that

[254] *collaboRATE.* (2019). Glyn Elwyn. *http://www.glynelwyn.com/collaborate.html.*

[255] *Colorectal Cancer Screening—NCQA.* (2018). NCQA. *https://www.ncqa.org/hedis/measures/colorectal-cancer-screening/* https://www.ncqa.org/hedis/measures/colorectal-cancer-screening/.

[256] *THE NATIONAL QUALITY FORUM Specifications for the Three-Item Care Transition Measure—CTM–3.* (n.d.). Retrieved May 28, 2023, from *https://mhdo.maine.gov/_pdf/NQF_CTM_3_%20Specs_FINAL.pdf.*

[257] Supplemental Material to the CMS Measures Management System (MMS) Hub CMS Consensus-Based Entity (CBE) Endorsement and Maintenance. (2022). *https://www.cms.gov/files/document/blueprint-nqf-endorsement-maintenance.pdf.*

[258] Jacobs, D.B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L.A. (2023). Aligning quality measures across CMS—the Universal Foundation. *New England Journal of Medicine, 388*(9), 776–779. *https://doi.org/10.1056/nejmp2215539.*

[259] Jacobs, D.B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L.A. (2023). Aligning quality measures across CMS—the Universal Foundation. *New England Journal of Medicine, 388*(9), 776–779. *https://doi.org/10.1056/nejmp2215539.*

[260] *Pre-Rulemaking | The Measures Management System.* (n.d.). *Mmshub.cms.gov.* Retrieved May 12, 2023, from *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/overview.*

focus on depression can improve health-related quality of life in patients with ESRD.[261] One study found that, at the time of kidney evaluation, over 85 percent of patients exhibited at least minimal depressive symptoms and that patients with depressive symptoms were less likely to gain access to the waitlist.[262] Although the waitlist offers some hope to patients, being waitlisted for a kidney transplant is also psychologically distressing, with patients reporting disillusionment, moral distress, unmet expectations, increasing vulnerability, and deprivation.[263] These factors are likely contributors to high rates of stress and anxiety observed among waitlisted patients.[264] The conditions of participation (CoPs) for transplant hospitals require that prospective transplant candidates receive a psychosocial evaluation prior to placement on a waitlist (42 CFR 482.90(a)(1)), if possible, and OPTN bylaws specify that transplant hospitals must include team members to coordinate a transplant candidate's psychosocial needs; however, neither the CoP nor the OPTN bylaws require specific assessment of, or intervention into, patients' behavioral health. The ESRD QIP measure set includes the Clinical Depression Screening and Follow-Up measure; however, performance on the measure requires only documentation that an attempt at screening and follow up was made.[265] Additionally, this measure is already being used in the KCC Model.

We stated in the proposed rule that while we understand the importance of including measures focused on depression, we believe that IOTA participants may have limited experience diagnosing and treating depression and may struggle to make referrals due to limited behavioral health providers (89 FR 43518). We also believe that this measure may be duplicative with other policies in this model that strive to improve the health and post-transplant outcomes of attributed patients. Additionally, based on the KCC Model experience, the Depression Remission measure is operationally complex due to the 10-month reporting period and novel collection and reporting processes. We believe that IOTA participants would experience similar challenges due to the mandatory nature of the model and unfamiliarity with reporting quality measure data to the Innovation Center.

In section III.C.5.e(2) of the proposed rule, we considered the Depression Remission at 12 Months measure (CBE ID: 0710e) because major depression is prevalent in the dialysis population and most kidney transplant recipients spend some time on a dialysis modality.[266] Depression measures are included in the Universal Foundation because successfully treating depression can improve physical health outcomes, in addition to behavioral health outcomes.[267] A depression measure would align with the behavioral health domain of Meaningful Measures 2.0. We considered a depression remission measure over a depression screening measure because we believed a depression remission measure would incentivize IOTA participants to work with the other clinicians and providers involved in the care of attributed patients to resolve or improve the depressive symptoms rather than only identifying them. Our review of the literature found that presence of behavioral health symptoms affected the ability of patients to get on the kidney transplant waiting list, but did not affect likelihood of receiving a kidney transplant.[268] We did not propose the Depression Remission at 12 Months Measure because we were unable to locate any publications that found depression remission affected access to a kidney transplant. We also chose not to propose this type of measure because the IOTA Model does not target pre-waitlist patients for attribution to model participants. We also believe that IOTA participants may have limited experience in diagnosis and treating depression and may struggle to make referrals due to limited behavioral health providers. Additionally, behavioral health management is not under the purview of a kidney transplant hospital that might see a kidney transplant waitlist patient perhaps only a handful of times, but may be more appropriate for the patient's nephrologist or dialysis center.

We sought comment on our proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening) for purposes of measuring performance in the quality domain. We also sought comment on alternative quality measures considered.

The following is a summary of the comments received on our proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening) for purposes of measuring performance in the quality domain and alternative quality measures considered and our responses:

Comment: We received many responses from commenters who did not agree with the proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening), as described in the preamble of this final rule, in the IOTA Model and highlight several reasons. Commenters stated that the proposed measures have not been

[261] Feroze, U., Martin, D., Kalantar-Zadeh, K., Kim, J.C., Reina-Patton, A., & Kopple, J.D. (2012). Anxiety and depression in maintenance dialysis patients: Preliminary data of a cross-sectional study and brief literature review. *Journal of Renal Nutrition, 22*(1), 207–210. *https://doi.org/10.1053/j.jrn.2011.10.009;* Mclaren, S., Jhamb, M., & Unruh, M. (2021). Using Patient-Reported Measures to Improve Outcomes in Kidney Disease. *Blood Purification,* 1–6. *https://doi.org/10.1159/000515640;* Cukor, D., Donahue, S., Tummalapalli, S.L., Bohmart, A., & Silberzweig, J. (2022). Anxiety, comorbid depression, and dialysis symptom burden. *Clinical Journal of the American Society of Nephrology, 17*(8), 1216–1217. *https://doi.org/10.2215/cjn.01210122.*

[262] Chen, X., Chu, N.M., Basyal, P.S., Vihokrut, W., Crews, D., Brennan, D.C., Andrews, S.R., Vannorsdall, T.D., Segev, D.L., & McAdams-DeMarco, M.A. (2022). Depressive symptoms at kidney transplant evaluation and access to the kidney transplant waitlist. *Kidney International Reports, 7*(6), 1306–1317. *https://doi.org/10.1016/j.ekir.2022.03.008.*

[263] Tong, A., Hanson, C.S., Chapman, J.R., Halleck, F., Budde, K., Josephson, M.A., & Craig, J.C. (2015). 'suspended in a paradox'—patient attitudes to wait-listing for Kidney Transplantation: Systematic review and thematic synthesis of qualitative studies. *Transplant International, 28*(7), 771–787. *https://doi.org/10.1111/tri.12575.*

[264] Ibid.

[265] *CMS ESRD Measures Manual for the 2023 Performance Period.* (2022). *https://www.cms.gov/files/document/esrd-measures-manual-v81.pdf.*

[266] Cukor, D., Donahue, S., Tummalapalli, S.L., Bohmart, A., & Silberzweig, J. (2022). Anxiety, comorbid depression, and dialysis symptom burden. *Clinical Journal of the American Society of Nephrology, 17*(8), 1216–1217. *https://doi.org/10.2215/cjn.01210122.*

[267] Jacobs, D.B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L.A. (2023). Aligning quality measures across CMS—the Universal Foundation. *New England Journal of Medicine, 388*(9), 776–779. *https://doi.org/10.1056/nejmp2215539.*

[268] Szeifert, L., Bragg-Gresham, J.L., Thumma, J., Gillespie, B.W., Mucsi, I., Robinson, B.M., Pisoni, R.L., Disney, A., Combe, C., & Port, F.K. (2011). Psychosocial variables are associated with being wait-listed, but not with receiving a kidney transplant in the dialysis outcomes and Practice Patterns Study (dopps). *Nephrology Dialysis Transplantation, 27*(5), 2107–2113. *https://doi.org/10.1093/ndt/gfr568;* Chen, X., Chu, N.M., Basyal, P.S., Vihokrut, W., Crews, D., Brennan, D.C., Andrews, S.R., Vannorsdall, T.D., Segev, D.L., & McAdams-DeMarco, M.A. (2022). Depressive symptoms at kidney transplant evaluation and access to the kidney transplant waitlist. *Kidney International Reports, 7*(6), 1306–1317. *https://doi.org/10.1016/j.ekir.2022.03.008.*

developed, validated, or evaluated for use in this patient population and expressed uncertainty to how effective they would be in the model. A few commenters noted that the CollaboRATE Shared Decision-Making measure and CTM–3 are not currently being utilized by transplant hospitals and lack any evidence base for use in kidney transplantation or in patients with CKD and ESRD. Thus, including PRO–PMs without any convincing evidence base for efficacy could be counterproductive and discourage support for PRO measurements generally. Additionally, because the proposed quality measures are not currently used in any CMS program, a commenter anticipated that IOTA participants would face additional costs to implement these new requirements.

Response: We thank commenters for expressing their concerns with the proposed quality measures. While we recognize that the CollaboRATE measure, COL and CTM–3 are not specific to transplantation, we believe they are helpful measures for assessing hospital quality and performance for the reasons set forth in sections III.C.5.e(2)(b), (c), and (d) of this final rule. However, in response to public comments, we will not be finalizing our proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening) at this time.

Comment: A commenter agreed with the importance of assessing both patient's level of SDM and readiness for self-care at the time of discharge but did not support the use of patient report survey-based measures. The commenter suspected that adding another survey would likely result in low response rates and survey fatigue. Patients are already overwhelmed by the numerous surveys from hospitals, doctors, dialysis centers, and post-acute care providers. Additionally, the commenter argued that transplant patients, who already face significant demands on their time and energy, would likely not prioritize completing survey measures.

Response: We appreciate the commenters' concerns regarding the use of patient-report survey measures, but we disagree. Chronic kidney disease is complex and demands thorough medical management, even after transplantation. Thus, when taking into consideration the lasting impact of CKD, symptom burden and its correlation to mental health and psychosocial difficulties, we believe it is essential that we understand the entirety of the patient experience and take steps to improve it using the policy levers available in the IOTA Model. We maintain that failure to address what is important to patients could result in continued, or the development of, decreased quality of life in addition to psychosocial distress, increased symptom burden and new physical problems or both to arise and be left untreated. We also acknowledge that it is equally important that any PROM included be relevant to the population being measured. To date, there are not only no kidney transplant specific PROs that are endorsed by NQF but there also remains a shortage of kidney transplant specific validated measures. However, given commenters concerns, we are persuaded not to finalize our proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening) at this time. We still believe in the importance of using validated, person-centered, measures of quality of care to support a holistic and patient-centered kidney transplant process, but acknowledge the challenges presented by commenters in the proposed quality measures set. We intend to propose additional quality measures which may include a focus on health-related quality of life (HRQoL) for kidney transplant recipients or address pre-transplant processes of care through future notice and comment rule making. We believe these measures will support the goals of the IOTA Model to improve quality and equity of care. In the interim, we have been convinced the other requirements that enforce SDM in the pre-transplant process (for example, Transplant Hospitals' CoP) are adequate and mitigate the challenges posed by the proposed measures. Although we are not finalizing any of the proposed measures in our quality measure set, we think that the IOTA Model promotes SDM through some of our other policies, such as the proposed transparency requirements as described and finalized in section III.C.8(a) of the preamble in this final rule.

Comment: Some commenters encouraged CMS to include the PAM® in the IOTA Model. A couple commenters noted that while the PAM® is not validated for use in transplantation it would serve as continuity with other models. A few commenters acknowledged that we considered whether the PAM® Measure could encourage IOTA participants and IOTA Collaborators, as defined at § 512.402 of the proposed rule, to activate IOTA waitlist patients to work in collaboration with IOTA participants to complete requirements to maintain active waitlist status; however, we were unable to locate any peer-reviewed literature to support this hypothesis. One of these commenters recommended that CMS reevaluate possible inclusion of the PAM in the IOTA Model quality measure set after the public release of data on the PAM® use in the voluntary KCC Model. While a couple commenters disagreed with CMS, suggesting that there was ample evidence to support the inclusion of PAM® in the IOTA Model. Specifically, they asserted that the PAM® is well established, in use, valid and reliable across the kidney care journey, including specific peer reviewed studies on the proposed IOTA population. Moreover, they asserted that the evidence demonstrates the crucial importance of patient activation for patients diagnosed with CKD, particularly within the transplant population. Furthermore, the findings suggest that clinical teams could have a profound impact on supporting the main objectives of the IOTA Model.

Response: We appreciate the suggestion from commenters to include the PAM® in the IOTA Model and will consider the suggestion for future rulemaking, where appropriate. Given the concerns raised by commenters about participant burden associated with PRO–PMs, including PAM®, we are not proposing to add it at this time. Rather, as mentioned in comment responses noted previously, we will consider future PRO–PMs use in the model.

Comment: Many commenters suggested alternative measures that the IOTA Model should include in place of those proposed quality measure set. For example, a commenter recommended that CMS consider implementing stronger quality protections during the first two years of the model; suggesting that this could include assessing performance on additional process measures that reflect appropriate care delivery, rather than relying solely on pay-for-reporting. To align with the updates to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, a commenter suggested that CMS should replace the retired CTM–3 measure with the proposed ''Care Coordination'' Sub-Measure.

Several commenters suggested that CMS include more specific health screening measures in place of the COL. For example, a commenter stated that colon cancer rates are similar between kidney transplant and non-transplant patients. Whereas skin cancer has a much higher prevalence in transplant

patients compared to non-transplant patients. Thus, they suggested that there would be more value in creating a skin cancer measure. The commenter also mentioned that they contemplated suggesting that CMS consider using a vaccination rate measure in place of the COL, since being current on vaccinations is more directly relevant to transplant candidate readiness and transplant recipient well-being regardless of age than colorectal cancer screening. However, they suggested that vaccination rates could present an evolving challenge for IOTA participants to achieve given the growing skepticism of vaccinations in the post-COVID–19 pandemic era. The same commenter also believed that many programs exclude individuals who refuse vaccinations who would otherwise be good transplant candidates, and such a metric could further encourage the exclusion of these patients. A couple of commenters suggested that addressing post-transplant cardiovascular risk factors could lead to better long-term outcomes. This is because multiple adverse cardiac events are more common causes of death than cancer or infection after transplant, noting that nearly 25 percent of deaths in the first-year post-transplant are related to cardiovascular reasons. Therefore, the commenters recommended that CMS include measures to screen for post-transplant diabetes mellitus and manage hyperlipidemia.

A few commenters mentioned that CMS should include the Hemoglobin A1c poor control (≤9%) (CBE #0559) and Advance Care Plan (CBE #0326) measures to the quality domain to align with the Universal Measures. A commenter suggested that the Advance Care Plan and CollaboRATE score align with the program's other measures, collectively upholding a high standard of care for transplant patients. Specifically, the commenter proposed that the Advance Care Plan and CollaboRATE score could work together to facilitate a comprehensive, patient-informed decision-making process. Another commenter encouraged CMS to consider the 15-item Care Transition Measure (CTM–15), proposing that it could facilitate a better understanding of post-transplant expectations for patients due to its incorporation of components like a written care plan and a list of scheduled appointments.

Response: We would like to thank all commenters that closely reviewed and shared their suggestions for with the IOTA Model proposed quality measures, and recognize the efforts made by commenters to align measures relevant to the target population and to align to the Universal Foundation, a key CMS priority. We are committed to including quality measures in the IOTA quality domain to further the model goals for improving quality of care and supporting a holistic, patient-centered kidney transplant process. Responsive to comments, we will not be finalizing our proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening). We will consider future measures aligned to the priority areas of the kidney transplant process and will align, where possible, with CMS priorities and other CMS programs.

Comment: Numerous commenters expressed concerns about the proposed quality measure reporting requirements. They cited challenges with data collection, administrative burden, and unfamiliarity with the measures; ultimately suggesting that the data collected would not justify the added administrative burden. For example, a commenter stated that if patients are attributed to multiple transplant hospitals, collecting quality measures data on the entire attributed population could be duplicative and burdensome. The same commenter also believed that allowing for quality measures to change each PY that it would cause confusion and lost revenue, and that more consideration should be put into the process for data collections so that it does not unduly burden programs in a way that compromises clinical outcomes and organ transplant access. A commenter stated that SDM and patient involvement in transplant care, as well as patient autonomy, are respected and assessed in the evaluation process but do not directly support the goal of improving patient outcomes. Thus, they felt that the that administering the CollaboRATE Shared Decision-Making Score and CTM–3 would cause unnecessary administrative burden. Another commenter expressed their belief that administering and documenting the CollaboRATE Shared Decision-Making Score and CTM–3 would be laborious due to the volume of patients on the waitlist and questioned how this would be accomplished in a consistent manner.

Response: We appreciate and acknowledge the commenters' concern and challenges with the proposed quality measures. We recognize the difficulties associated with patient reported outcome measures and the underlying data collection tools used in a clinical domain. At this point, as mentioned in comment responses noted previously, we are not finalizing any of the three quality measures that we proposed. In the future we plan to propose additional quality measures which may include a focus on HRQoL for kidney transplant recipients or address pre-transplant processes of care. We suggest these measures would support the goals of the IOTA Model to improve quality and equity of care and acknowledge the burden of data collection in measures using EHR or survey data. However, it is a CMS priority to incorporate person-centered measures, including patient-reported measures, where possible. We will continue to consider EHR reporting challenges when selecting quality measures to account for future performance and intends to propose new quality measures for inclusion in the IOTA Model through future notice and comment rulemaking.

Comment: A few commenters supported the inclusion of patient-reported outcome (PRO) measures in the IOTA Model. For example, a commenter believed that including PROs is essential for evaluating the quality of care and patient satisfaction but believed that the quality measure set scoring methodology, as described at § 512.428(e) of the proposed rule could inaccurately reflect the quality of care or patient satisfaction and lacked transparency and consistency; suggesting that it could cause discrepancies in evaluating IOTA participant performance. A commenter strongly supported the use of quality measures to evaluate transparency and SDM. This commenter also voiced their belief that the proposed quality measure was good because it did not significantly increase administrative burden but thought the measures' simplicity might limit their ability to provide meaningful insights into the quality of care these patients receive. Another commenter voiced their appreciation for CMS's inclusion of PROMs in the IOTA Model. The same commenter agreed that increasing patient involvement in the kidney transplant process is a critical objective but expressed concern over the inclusion of CollaboRATE and CTM–3. Specifically, the commenter felt that administering and documenting these measures, which have not been validated for this specific patient population, would increase burden on both IOTA participants and its attributed patients, without improving quality of care.

Response: We thank the commenters for expressing their support. We agree that when taking into consideration the lasting impact of CKD, symptom

burden, and its correlation to mental health and psychosocial difficulties, it is important that the patient perspective and voice be included through the use of patient-reported outcome measures (PROMs) to truly grasp how CKD impacts their lives.[269] As described at 89 FR 43603 in the proposed rule, we also recognize that in spite of the growing recognition over the past two decades that this is paramount to advancing the quality of care at both the patient and policy levels, there remains significant information gaps in understanding how PROMs are, and can be utilized across different domains, especially within nephrology to enrich patient-centered care, and measure other important quality components, such as access to transplantation, shared-decision making and quality of life post-transplantation, to provide a comprehensive understanding.[270] However, given commenters concerns, we are persuaded not to finalize the three quality measures proposed for inclusion in the IOTA Model at this time. It is a CMS priority to incorporate person-centered measures, including patient-reported measures, where possible and CMS believes in the importance of elevating patient's voice in their care. We plan, in future notice and comment rulemaking, to propose additional quality measures which may include a focus on HRQoL for kidney transplant recipients or address pre-transplant processes of care. We suggest these measures will support the goals of the IOTA Model to improve quality and equity of care.

Comment: Lastly, many commenters urged CMS to focus on new measure development and collaborate with stakeholders, clinicians, and patients to develop meaningful quality measures in this space that can be validated in this setting. For example, many commenters encouraged CMS to eliminate the proposed quality measure and pursue new measure development. These commenters also stated that it is critical that CMS include all relevant stakeholders when developing new measures to ensure that any new measure is appropriate, reliable, and representative of the diverse patient population. A commenter appreciated CMS's interest in developing a PROM pertaining to HRQoL in the context of kidney transplant especially given the relative paucity of measures of quality of care for kidney transplant; nothing that no validated PROMs of quality of life currently exist, much less any PROMs that are appropriate for use in the IOTA Model. A commenter strongly supported the development of a HRQoL PROM and suggested CMS invest in developing a measure(s) along these lines for inclusion in the IOTA Model as soon as possible. Some commenters voiced their belief that CMS should work with relevant stakeholders and focus on, and invest, in new measure development, provided it is rigorously tested and developed using the highest standards. One of these commenters suggested that it be used as a reporting measure initially before rewarding performance against quality performance benchmarks and should assess SDM about patient-focused risk tolerance regarding organ offer quality.

Response: We acknowledge commenters suggestions for CMS to focus on new measure development for use in the IOTA Model, including support for a future PROM related to HRQoL for kidney transplant recipients. Appropriately evaluating the change in quality of care is an essential goal of the IOTA Model and we will consider future measure development, potentially in the areas of HRQoL and pre-transplant processes of care.

After considering public comments, for the reasons set forth in this rule, we are not finalizing our proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening) for purposes of measuring performance in the quality domain at this time. We continue to note that quality of care is an important element of the IOTA Model, and we will be monitoring quality through other care delivery requirements and through the required independent evaluation of the model. We also will continue to evaluate the changing inventory of quality measures, considering public input, and have already begun developing new measures more clinically and setting appropriate. Because of the uncertain nature of timing of developing new quality measures we will not specify a timeline for incorporation but may in future rulemaking.

(a) Quality Measure Set Selection, Reporting and Changes

In section III.C.5.e(2) of the proposed rule, we proposed that CMS select and use quality measures to assess IOTA participant performance in the quality domain. We proposed that each PY, IOTA participants would be required to report quality measure data during survey and reporting windows to CMS in a form and manner, and at times, established by CMS. We also proposed that, where applicable, IOTA participants would be required to administer any surveys or screenings relevant to the quality measures selected for inclusion in the IOTA Model to attributed patients. We proposed to define ''survey and reporting windows'' as two distinct periods where IOTA participants would be required to administer a quality measure-related survey or screening to attributed patients or submit attributed patient responses to CMS pursuant to § 512.48(b)(2)(ii). We proposed that CMS would notify, in a form and manner as determined by CMS, IOTA participants of the survey and reporting window for applicable quality measures by the first day of each PY.

In section III.C.5.e(2)(a) of the proposed rule, we proposed that CMS would use future rulemaking to make substantiative updates to the specifications of any of the quality measures in the IOTA Model. Additionally, we proposed that the quality measures finalized for inclusion in the IOTA Model would remain in the quality measure set unless CMS, through future rulemaking, removed or replaced them.

In section III.C.5.e(2)(a) of the proposed rule, we proposed that CMS could remove or replace a quality measure based on one of the following factors:

- A quality measure does not align with current clinical guidelines or practice.
- Performance on a quality measure among IOTA participants is so high and unvarying that meaningful distinctions

[269] Schick-Makaroff, K., Thummapol, O., Thompson, S., Flynn, R., Karimi-Dehkordi, M., Klarenbach, S., Sawatzky, R., & Greenhalgh, J. (2019). Strategies for incorporating patient-reported outcomes in the care of people with chronic kidney disease (PRO kidney): a protocol for a realist synthesis. *Systematic Reviews, 8*(1). *https://doi.org/10.1186/s13643-018-0911-6;* Brett, K.E., Ritchie, L.J., Ertel, E., Bennett, A., & Knoll, G.A. (2018). Quality Metrics in Solid Organ Transplantation. *Transplantation, 102*(7), e308–e330. *https://doi.org/10.1097/tp.0000000000002149;* Mendu, M.L., Tummalapalli, S.L., Lentine, K.L., Erickson, K.F., Lew, S.Q., Liu, F., Gould, E., Somers, M., Garimella, P.S., O'Neil, T., White, D.L., Meyer, R., Bieber, S.D., & Weiner, D.E. (2020). Measuring Quality in Kidney Care: An Evaluation of Existing Quality Metrics and Approach to Facilitating Improvements in Care Delivery. *Journal of the American Society of Nephrology, 31*(3), 602–614. *https://doi.org/10.1681/ASN.2019090869;* Tang, E., Bansal, A., Novak, M., & Mucsi, I. (2018). Patient-Reported Outcomes in Patients with Chronic Kidney Disease and Kidney Transplant—Part 1. *Frontiers in Medicine, 4. https://doi.org/10.3389/fmed.2017.00254;* Anderson, N.E., Calvert, M., Cockwell, P., Dutton, M., Aiyegbusi, O.L., & Kyte, D. (2018). Using patient-reported outcome measures (PROMs) to promote quality of care in the management of patients with established kidney disease requiring treatment with haemodialysis in the UK (PROM–HD): a qualitative study protocol. *BMJ Open, 8*(10), e021532. *https://doi.org/10.1136/bmjopen-2018-021532.*

[270] Ibid.

and improvement in performance can no longer be made (''topped out'' measure), as defined in 42 CFR 412.140(g)(3)(i)(A).

- Performance or improvement on a quality measure does not result in better patient outcomes.
- The availability of a more broadly applicable quality measure (across settings or populations) or the availability of a quality measure that is more proximal in time to desired patient outcomes for the particular topic.
- The availability of a quality measure that is more strongly associated with desired patient outcomes for the particular topic.
- Collection or public reporting of a quality measure leads to negative unintended consequences other than patient harm.
- It is not feasible to implement the quality measure specifications.
- The costs associated with a quality measure outweigh the benefit of its continued use in the IOTA Model.

In section III.C.5.e(2)(a) of the proposed rule, we proposed that CMS would assess the benefits of removing or replacing a quality measure from the IOTA Model on a case-by-case basis. We proposed that CMS would use the future rulemaking process to add, remove, suspend, or replace quality measures in the IOTA Model to allow for public comment, unless a quality measure raises specific safety concerns. We proposed that if CMS determines that the continued requirement for IOTA participants to submit data on a quality measure raises specific patient safety concerns, CMS could elect to immediately remove the quality measure from the IOTA Model quality measure set. Finally, we proposed that CMS would, upon removal of a quality measure, and in a form and manner determined by CMS, do the following:

- Provide notice to IOTA participants and the public at the time CMS removes the quality measure, along with a statement of the specific patient safety concerns that would be raised if IOTA participants continued to submit data on the quality measure.
- Provide notice of the removal in the **Federal Register**.

We sought comment on the requirement that IOTA participants report quality measure data to CMS. We additionally sought comment on our proposed process for adding, removing, or replacing quality measures in the IOTA Model.

The following is a summary of the comments received on our proposal to require that IOTA participants report quality measure data to CMS and our proposed process for adding, removing, or replacing quality measure in the IOTA Model and our responses:

Comment: Several commenters felt that more consideration should be put into the process for data collection and reporting requirements so that it does not unduly burden IOTA participants in a way that could compromise clinical outcomes and transplant access. A commenter felt that CMS's proposed rule lacked key logistical details necessary to understand how IOTA participants would collect the required quality measures and how CMS would evaluate them. Specifically, the proposed rule did not specify what patient information IOTA participants must collect and report alongside the measure results, nor whether hospitals should provide patient-level or aggregate data.

Response: We understand the need for IOTA participants understand any quality measure set survey and reporting requirements finalized for inclusion in the IOTA Model. Additionally, we acknowledge the importance of, are committed to, providing key logistical details, where warranted, to mitigate administrative burdens for IOTA participants. As discussed in section III.C.5.e(2) of this final rule, we are not finalizing our proposed quality measure set. We intend to propose new quality measures for inclusion in the IOTA Model in future notice and comment rule making. As such, we will not be finalizing our proposed quality measure set survey and reporting requirements at § 512.428(b)(2)(ii), our proposed process for adding, removing or replacing a quality measure at § 512.428(b)(3) or the definition of survey and reporting windows at § 512.402 as described in the proposed rule. While we are not finalizing any of the aforementioned provisions, we will continue to assess our quality measure data reporting requirement and policy for adding, removing, or replacing quality measures in the IOTA Model and intend to address a new or updated policy pursuant to future notice and comment rule making.

Comment: A commenter urged CMS to allow greater flexibility in the proposed survey and reporting timelines, as discussed in section III.C.5.e(2)(a) of this final rule, for IOTA participants and recommended that CMS allow IOTA participants to adjust data collection processes to align with clinical schedules and patient preference. They noted that by allowing for greater flexibility that this would enable them to collect patient data in alignment with clinical practice for pre- and post-transplant appointments and prevent potential operational challenges if or when a survey and reporting window misaligns.

Response: We appreciate the commenters' suggestion. As discussed in section III.C.5.e(2) of this final rule, we are not finalizing our proposed quality measure set. We intend to propose new quality measures for inclusion in the IOTA Model in future notice and comment rule making. As such, we will not be finalizing our proposed quality measure set survey and reporting requirements at § 512.428(b)(2)(ii), our proposed process for adding, removing or replacing a quality measure at § 512.428(b)(3) or the definition of survey and reporting windows at § 512.402 as described in the proposed rule. While we are not finalizing any of the provisions proposed in section III.C.5.e(2) of the proposed rule, we will take into consideration the commenter's recommendation to allow for greater flexibility during survey and reporting windows and continue to assess our quality measure data reporting requirement and policy for adding, removing, or replacing quality measures in the IOTA Model. We note that we will continue to assess our quality measure data reporting requirement and policy for adding, removing, or replacing quality measures in the IOTA Model and intend to address a new or updated policy pursuant to future notice and comment rule making.

Comment: A commenter noted that in the proposed rule we proposed that if performance on a quality measure among IOTA participants is so high and unvarying that meaningful distinctions and improvement in performance can no longer be made (''topped out'' measure), as defined in 42 CFR 412.140(g)(3)(i)(A) that CMS could remove or replace that quality measure (89 FR 43518). They requested that CMS provide further detail on the proposed CMS review process and timeline for evaluating if ''topping out'' or other criteria has occurred. They also felt that while case-by-case adjustments may be appropriate when specific concerns arise, an ad hoc evaluation process risks overlooking instances where quality measures fall short of the established criteria.

Response: We appreciate the commenters' suggestion. As discussed in section III.C.5.e(2) of this final rule, we are not finalizing our proposed quality measure set. We intend to propose new quality measures for inclusion in the IOTA Model in future notice and comment rule making. As such, we will not be finalizing any of the provisions proposed in section

III.C.5.e(2)(a) of the proposed rule. While we are not finalizing any of these proposed provisions, we will take into consideration the commenter's request to provide further specificity to our application of measure removal factors and continue to assess our quality measure data reporting requirement and policy for adding, removing, or replacing quality measures in the IOTA Model.

After consideration of the public comments we received, for the reasons set forth in this rule, we are not finalizing our policy for adding, removing, or replacing quality measures in the IOTA Model, as proposed at § 512.428(b)(2) of the proposed rule. Additionally, because we are not finalizing any of the quality measures we proposed, as described and finalized in section III.C.5.e(2) of this final rule, we are not finalizing our proposed provision requiring IOTA participants to report quality measure data to CMS at § 512.428(b)(2)(ii) or the definition of survey and reporting windows at § 512.402 as described in the proposed rule. While we are not finalizing any of these proposed provisions, we will continue to assess our quality measure data reporting requirement and policy for adding, removing, or replacing quality measures in the IOTA Model and address a new or updated policy pursuant to future notice and comment rule making.

(b) CollaboRATE Shared Decision-Making Score

In section III.C.5.e(2)(b) of the proposed rule, we stated that the CollaboRATE Shared Decision-Making Score is a patient-reported measure of shared decision-making. The measure provides a performance score representing the percentage of adults 18 years of age and older who experience a high degree of shared decision making. The CollaboRATE Shared Decision-Making Score is based on three questions that assess the degree to which effort was made to inform the patient of his or her health issues, to listen to the patient's priorities, and the extent to which the patient's priorities were included in determining next steps. The measure is generic and applies to all clinical encounters, irrespective of the condition or the patient group. We proposed that IOTA participants would be required to administer the CollaboRATE Shared Decision-Making Score to attributed patients once per PY, at minimum, and report quality measure data to CMS during survey and reporting windows, as defined in section III.C.5.e(2)(a) of the proposed rule, that would be established by CMS.

In section III.C.5.e(2)(b) of the proposed, we stated that we believed incentivizing shared decision-making is critical to ensuring the model centers the patient experience and treatment choice to meet the IOTA desired goals of improving equity, increasing the number of kidney transplants, and reducing kidney non-utilization. Patients needing a kidney transplant often face many challenges when making healthcare decisions, as they must first decide between treatment options (such as dialysis versus transplantation, living donor versus deceased-donor transplantation) and where they wish to be evaluated for transplantation. Research findings demonstrate the importance and impact of shared decision-making throughout the entire transplant process for patients because of the types of complex decisions they must make, and the dynamic factors involved in each patient's decision.[271] Research studies have found that shared decision-making shifts the patient-physician relationship past traditional practices and contributes to better health outcomes, increased quality of life, increased patient knowledge and medication adherence, and lower healthcare expenditures.[272] Furthermore, research findings support that shared decision-making with the patient could reduce kidney non-utilization, improve equity, and increase the number of kidney transplants.[273]

[271] Jones, E.L., Shakespeare, K., McLaughlin, L., & Noyes, J. (2023). Understanding people's decisions when choosing or declining a kidney transplant: a qualitative evidence synthesis. BMJ Open, 13(8), e071348. *https://doi.org/10.1136/bmjopen-2022-071348;* Stephenson, M.D., & Bradshaw, W. (2018). Shared decision making in chronic kidney disease. *Renal Society of Australasia Journal, 14*(1), 26. *https://www.proquest.com/scholarly-journals/shared-decision-making-chronic-kidney-disease/docview/2283078287/se-2;* Gordon, E.J., Butt, Z., Jensen, S.E., Lok-Ming Lehr, A., Franklin, J., Becker, Y., Sherman, L., Chon, W.J., Beauvais, N., Hanneman, J., Penrod, D., Ison, M.G., & Abecassis, M.M. (2013). Opportunities for Shared Decision Making in Kidney Transplantation. American Journal of Transplantation, 13(5), 1149–1158. *https://doi.org/10.1111/ajt.12195;* Salter, M.L., Babak Orandi, McAdams-DeMarco, M.A., Law, A., Meoni, L.A., Jaar, B.G., Sozio, S.M., Hong, W., Parekh, R.S., & Segev, D.L. (2014). Patient- and Provider-Reported Information about Transplantation and Subsequent Waitlisting. Journal of the American Society of Nephrology, 25(12), 2871–2877. *https://doi.org/10.1681/asn.2013121298;* Schold, J.D., Huml, A.M., Poggio, E.D., Reese, P.P., & Mohan, S. (2022). A tool for decision-making in kidney transplant candidates with poor prognosis to receive deceased donor transplantation in the United States. Kidney International. *https://doi.org/10.1016/j.kint.2022.05.025;* Schaffhausen, C.R., Bruin, M.J., McKinney, W.T., Snyder, J.J., Matas, A.J., Kasiske, B.L., & Israni, A.K. (2019). How patients choose kidney transplant centers: A qualitative study of patient experiences. 33(5), e13523–e13523. *https://doi.org/10.1111/ctr.13523;* Hart, A., Bruin, M., Chu, S., Matas, A., Partin, M.R., & Israni, A.K. (2019). Decision support needs of kidney transplant candidates regarding the deceased donor waiting list: A qualitative study and conceptual framework. Clinical Transplantation, 33(5), e13530. *https://doi.org/10.1111/ctr.13530;* S. Ali Husain, Brennan, C., Michelson, A., Tsapepas, D., Patzer, R.E., Schold, J.D., & Mohan, S. (2018). Patients prioritize waitlist over posttransplant outcomes when evaluating kidney transplant centers. 18(11), 2781–2790. *https://doi.org/10.1111/ajt.14985;* Patzer, R.E., McPherson, L., Basu, M., Mohan, S., Wolf, M., Chiles, M., Russell, A., Gander, J.C., Friedewald, J.J., Ladner, D., Larsen, C.P., Pearson, T., & Pastan, S. (2018). Effect of the iChoose Kidney decision aid in improving knowledge about treatment options among transplant candidates: A randomized controlled trial. American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 18(8), 1954–1965. *https://doi.org/10.1111/ajt.14693.*

[272] Stephenson, M. Stephenson, M. Stephenson, M. Stephenson, M.D., & Bradshaw, W. (2018). Shared decision making in chronic kidney disease. *Renal Society of Australasia Journal, 14*(1), 26. *https://www.proquest.com/scholarly-journals/shared-decision-making-chronic-kidney-disease/docview/2283078287/se-2;* Gordon, E. J., Butt, Z., Jensen, S.E., Lok-Ming Lehr, A., Franklin, J., Becker, Y., Sherman, L., Chon, W.J., Beauvais, N., Hanneman, J., Penrod, D., Ison, M.G., & Abecassis, M.M. (2013). Opportunities for Shared Decision Making in Kidney Transplantation. American Journal of Transplantation, 13(5), 1149–1158. *https://doi.org/10.1111/ajt.12195;* Schold, J.D., Huml, A.M., Poggio, E.D., Reese, P.P., & Mohan, S. (2022). A tool for decision-making in kidney transplant candidates with poor prognosis to receive deceased donor transplantation in the United States. Kidney International. *https://doi.org/10.1016/j.kint.2022.05.025;* Schaffhausen, C.R., Bruin, M.J., McKinney, W.T., Snyder, J.J., Matas, A.J., Kasiske, B.L., & Israni, A.K. (2019). How patients choose kidney transplant centers: A qualitative study of patient experiences. 33(5), e13523–e13523. *https://doi.org/10.1111/ctr.13523;* Hart, A., Bruin, M., Chu, S., Matas, A., Partin, M.R., & Israni, A.K. (2019). Decision support needs of kidney transplant candidates regarding the deceased donor waiting list: A qualitative study and conceptual framework. Clinical Transplantation, 33(5), e13530. *https://doi.org/10.1111/ctr.13530;* Patzer, R.E., McPherson, L., Basu, M., Mohan, S., Wolf, M., Chiles, M., Russell, A., Gander, J.C., Friedewald, J.J., Ladner, D., Larsen, C.P., Pearson, T., & Pastan, S. (2018). Effect of the iChoose Kidney decision aid in improving knowledge about treatment options among transplant candidates: A randomized controlled trial. American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 18(8), 1954–1965. *https://doi.org/10.1111/ajt.14693.*

[273] Kucirka, L.M., Grams, M.E., Balhara, K.S., Jaar, B.G., & Segev, D.L. (2011). Disparities in Provision of Transplant Information Affect Access to Kidney Transplantation. American Journal of Transplantation, 12(2), 351–357. *https://doi.org/10.1111/j.1600-6143.2011.03865.x;* Patzer, R.E., Retzloff, S., Buford, J., Gander, J., Browne, T., Jones, H., Ellis, M., Canavan, K., Berlin, A., Mulloy, L., Gibney, E., Sauls, L., Muench, D., Reeves-Daniel, A., Zayas, C., DuBay, D., Mutell, R., & Pastan, S.O. (2021). Community Engagement to Improve Equity in Kidney Transplantation from the Ground Up: the Southeastern Kidney Transplant Coalition. Current Transplantation Reports, 8(4), 324–332. *https://doi.org/10.1007/s40472-021-00346-x;* Schold, J.D., Huml, A.M., Poggio, E.D., Reese, P.P., & Mohan, S. (2022). A tool for decision-making in kidney transplant candidates with poor prognosis to

By pairing the CollaboRATE Shared Decision-Making Score measure with the proposed achievement domain number of kidney transplants metric, as described in section III.C.5.c. of the proposed rule, and the proposed quality domain post-transplant outcomes metrics, as described in section III.C.5.e.(1). of the proposed rule, we aimed to incentivize care delivery transformation and improvement activity across IOTA participants that would center attributed patients and their family and caregiver as a critical decision-maker in treatment choices that align with their preferences and values. This may include greater transparency on donor organ offers and reasons for non-acceptance, and increased education and support on the living donor process. We also believed that this would support attributed patients in receiving a kidney that may be at higher risk of non-use, but that may offer a survival and quality of life advantage over remaining on dialysis, dying while waitlisted, or being de-listed.[274]

In section III.C.5.e(2)(b) of the proposed rule, we acknowledged that the instrument used for the CollaboRATE Shared Decision-Making Score is generic; however, we were unable to identify alternative measures of shared decision-making that are specific to kidney transplant that have been endorsed by the CBE. Similarly, while there may be value in an instrument that measures shared decision-making regarding the types of kidney organ offers attributed patients are willing to accept, no such measure exists. We believed the CollaboRATE Shared Decision-Making Score would capture variation in the presence and quality of shared decision-making among IOTA participants and that the instrument need not be specific to kidney transplant to incentivize meaningful improvements in patient-centricity and the patient experience, equity, and reducing kidney non-use.

We sought comment on our proposal to include the CollaboRATE Shared Decision-Making Score as a quality measure for purposes of quality domain performance assessment.

The following is a summary of the comments received on our proposal to include the CollaboRATE Shared Decision-Making Score as a quality measure for purposes of quality domain performance assessment and our responses:

Comment: Commenters expressed concern over the proposed inclusion of CollaboRATE Shared Decision-Making Score as a quality measure within the quality measure set to assess IOTA participant performance in the quality domain. Many commenters noted its lack of validation for use with hospitals and data to support the use of this measure in this population. Many commenters expressed concerns that the CollaboRATE measure is for use in the outpatient setting and has not been designed for hospitals or transplant patients. Many commenters questioned the inclusion of CollaboRATE Shared Decision-Making Score because it does not require transplant-related discussions and its applicability for inclusion in the model is unclear. Some commenters were concerned that the CollaboRATE Shared Decision-Making Score might not impact the specific issues of organ offers when used to capture all kidney transplant care, but pilot work and a trail funded by the NIH are specifically studying shared decision making for kidney transplant organ offers with a focus on materials and interventions to support SDM in a specific decision or encounter. Several commenters expressed concern over whether survey responses would provide relevant data for care under the IOTA Model and suggested that responses might need to be adjusted to factor in patient demographic characteristics. A couple commenters noted that it was unclear when the survey would be completed, and questioned whether administering the survey once per year, as proposed, would result in each survey covering multiple visits, making it difficult to observe quality differences or determine how to intervene. Several commenters had concerns about the amount of burden placed on transplant hospitals to implement the CollaboRATE Shared Decision-Making Score. A couple commenters indicated that this would be especially burdensome for small transplant hospitals without access to electronic sampling methods and that a focus on high response rates may limit resources for SDM.

Response: In response to these comments, we will not be finalizing our proposal to include the CollaboRATE Shared Decision-Making Score as a quality measure for purposes of assessing performance within the quality domain, as described in section III.C.5.e(2) of this final rule. We believe incentivizing SDM is critical to centering the patient experience and treatment choices in the IOTA Model. This aligns with the model's goals of improving equity, increasing kidney transplants, and reducing non-utilization, as discussed in section III.C.5.e(2)(b) of the preamble in this final rule. While we are not finalizing this SDM measure, the IOTA Model promotes it through other policies, such as the transparency requirements as described and finalized in section III.C.8(a) of the preamble in this final rule.

Comment: A few commenters expressed support for CMS's proposal to include CollaboRATE Shared Decision-Making Score as a quality measure within the quality measure set to assess IOTA participant performance in the quality domain. A commenter indicated that the CollaboRATE Shared Decision-Making Score would capture how well providers engage with patients before and after surgery and help promote patient-centered care. A commenter also expressed belief that incorporating a SDM patient-reported measure requirement is critical for transplant patients. They also suggested that incentivizing SDM between patients and healthcare providers would foster patient-centered care and promote informed choices.

Response: We thank commenters for their support and for their comments in support of our proposal to include CollaboRATE Shared Decision-Making Score as a quality measure for purposes of assessing performance within the quality domain, as described in section III.C.5.e(2) of this final rule. However, in response to public comment, we will not be finalizing the CollaboRATE Shared Decision-Making Score as a quality measure, as described in section III.C.5.e(2) of this final rule. We still believe that incentivizing shared decision-making is critical to ensuring the model centers the patient experience and treatment choice to meet the IOTA desired goals of improving equity, increasing the number of kidney transplants, and reducing kidney non-utilization, as discussed in section III.C.5.e(2)(b) of this final rule. Although we are not finalizing this measure at this, we think that the IOTA Model promotes SDM through some of our other policies, such as the proposed

receive deceased donor transplantation in the United States. Kidney International. *https://doi.org/10.1016/j.kint.2022.05.025;* Patzer, R.E., McPherson, L., Basu, M., Mohan, S., Wolf, M., Chiles, M., Russell, A., Gander, J.C., Friedewald, J.J., Ladner, D., Larsen, C.P., Pearson, T., & Pastan, S. (2018). Effect of the iChoose Kidney decision aid in improving knowledge about treatment options among transplant candidates: A randomized controlled trial. American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 18(8), 1954–1965. *https://doi.org/10.1111/ajt.14693.*

[274] Massie, A.B., Luo, X., Chow, E.K.H., Alejo, J.L., Desai, N.M., & Segev, D.L. (2014). Survival benefit of primary deceased donor transplantation with high-KDPI kidneys. *American Journal of Transplantation, 14*(10), 2310–2316. *https://doi.org/10.1111/ajt.12830.*

transparency requirements as described and finalized in section III.C.8(a) of the preamble in this final rule.

After consideration of the public comments we received, for the reasons set forth in this rule, we are not finalizing our proposal to include the CollaboRATE Shared Decision-Making Score as a measure within the quality measure set to assess IOTA participant performance in the quality domain.

(c) Colorectal Cancer Screening

In section III.C.5.e(2)(C) of the proposed rule, we stated that the Colorectal Cancer Screening (COL) measure identifies the percentage of patients 50–75 years of age who had guideline concordant screening for colorectal cancer. Kidney transplant recipients are at higher risk for cancer than the general population, due in part to long-term immunosuppression.[275] Kidney transplant recipients have a higher incidence of colorectal cancer and advanced adenomas and may have worse prognoses than the general population, both of which support improved screening and prophylactic care for kidney transplant recipients.[276] [277] [278]

The COL measure is a Universal Foundation measure in the CMS Meaningful Measures 2.0 Wellness and Prevention Domain. By nature of its inclusion in the Universal Foundation measure set, the COL measure addresses a condition associated with significant morbidity and mortality and incentivizes action on high-value preventive care.[279] The COL measure is also aligned with the goals of the President's Cancer Moonshot to reduce the death rate from cancer by 50 percent over the next 25 years and improve the experience of people living with cancer and those who have survived it.[280]

As described in section III.C.5.e(2)(c) of the proposed rule, we proposed the COL measure for inclusion in our assessment of quality domain performance in the model because we believed it would provide a signal of the importance of ongoing post-transplant care and reduce variation in the screening and prophylactic care of kidney transplant recipients by transplant hospital. We proposed that IOTA participants would be required to administer the COL measure yearly to all attributed IOTA transplant patients who are Medicare beneficiaries. The COL measure would work in concert with the proposed composite graft survival metric to increase the likelihood that attributed patients in the IOTA Model would receive comprehensive post-transplant care that would account not only for the attributed patient and graft survival, but also complications and comorbidities associated with receiving a kidney transplant.

We sought comment on our proposal to include the COL measure as a quality measure for purposes of quality domain performance assessment.

The following is a summary of the comments received on our proposal to include the COL measure as a quality measure for purposes of quality domain performance assessment and our responses:

Comment: Many commenters expressed concerns about our proposal to include the COL measure as a quality measure for purposes of quality domain performance assessment. Specifically, some commenters noted that many transplant recipients return to community providers after their transplant, making it challenging for transplant hospitals to ensure appropriate post-transplant screenings after they are no longer responsible for overseeing their care. As described in section III.C.5.e.(2).(c). of this final rule, we proposed that IOTA participants would be required to administer the COL measure yearly to all attributed IOTA transplant patients who are Medicare beneficiaries. A couple commenters suggested that the COL measure, as proposed, would more accurately reflect the care provided by patients' primary care physicians, since many transplant hospitals transfer the patients' care back to their local primary care physicians. A few commenters noted that transplant hospitals are already required to administer the COL to patients prior to waitlisting; suggesting that its inclusion in the IOTA Model would be redundant and unnecessarily increase costs without improving patient care. Many commenters urged CMS to remove COL from inclusion in the IOTA Model; citing that this measure is unrelated to transplant outcomes, cancers other than colorectal cancer are much more common in transplant recipients, the measure was not designed to identify the quality of care, is not a transplant-specific quality measure and shifts primary care responsibilities to transplant hospitals as reasons for its removal. Some commenters felt that the inclusion of COL in the IOTA Model is redundant and not directly relevant to kidney transplant care and suggested removing COL or replacing it with quality measures more closely aligned to kidney transplant outcomes, such as a more comprehensive cancer screening protocol.

Response: We thank commenters for sharing their concerns. In response to these comments, we will not be finalizing our proposal to include the COL measure as a quality measure for purposes of assessing performance within the quality domain as described in section III.C.5.e.(2). of this final rule.

After consideration of the public comments we received, for the reasons set forth in this rule, we are not finalizing our proposal to include the COL as a measure within the quality measure set to assess IOTA participant performance in the quality domain, as discussed in section III.C.5.e.(2). of this final rule.

(d) 3-Item Care Transition Measure (CTM–3)

As described in section III.C.5.e.(2).(d). of the proposed rule, the 3-Item Care Transition Measure (CTM–3) is a hospital-level, patient-reported measure of readiness for self-care at time of discharge from an acute care hospital. The CTM–3 is based on data from a three-question instrument that assesses whether the patient and family's preferences were accounted for in the care plan; whether patients understood their role in self-management; and, whether appropriate medication education was provided. A higher score on the CTM–3 reflects a higher quality transition of care. We proposed that IOTA participants would be required to administer the CTM–3 to attributed patients once per PY, at minimum, and report quality measure data to CMS during survey and reporting windows, as defined and finalized in section III.C.5.e(2)(a) of this

[275] Rama, I., & Grinyó, J.M. (2010). Malignancy after renal transplantation: The role of immunosuppression. Nature Reviews Nephrology, 6(9), 511–519. *https://doi.org/10.1038/nrneph.2010.102.*

[276] Komaki, Y., Komaki, F., Micic, D., Ido, A., & Sakuraba, A. (2018). Risk of colorectal cancer in chronic kidney disease. Journal of Clinical Gastroenterology, 52(9), 796–804. *https://doi.org/10.1097/mcg.0000000000000880.*

[277] Privitera, F., Gioco, R., Civit, A.I., Corona, D., Cremona, S., Puzzo, L., Costa, S., Trama, G., Mauceri, F., Cardella, A., Sangiorgio, G., Nania, R., Veroux, P., & Veroux, M. (2021). Colorectal cancer after Kidney Transplantation: A screening colonoscopy case-control study. Biomedicines, 9(8), 937. *https://doi.org/10.3390/biomedicines9080937.*

[278] Farrugia, D., Mahboob, S., Cheshire, J., Begaj, I., Khosla, S., Ray, D., & Sharif, A. (2014). Malignancy-related mortality following kidney transplantation is common. Kidney International, 85(6), 1395–1403. *https://doi.org/10.1038/ki.2013.458.*

[279] Jacobs, D.B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L.A. (2023). Aligning quality measures across CMS—the Universal Foundation. New England Journal of Medicine, 388(9), 776–779. *https://doi.org/10.1056/nejmp2215539.*

[280] Cancer Moonshot. (n.d.). The White House. *https://www.whitehouse.gov/cancermoonshot/.*

final rule, that would be established by CMS.

Transitions of care after kidney transplant are common and indicate elements of modifiable transplant hospital quality. One study found that 30-day hospital readmissions after an organ transplant were significantly associated with graft loss and death.[281] Poor understanding of and adherence to immunosuppressive drugs were identified as key elements associated with an increased risk for early hospital readmission.[282] Mitigating readmission risk may be of special importance given that IOTA participants may choose to increase their number of transplants by transplanting more kidneys that may have clinical value to patients. Simultaneously, there may also be increased healthcare utilization needs due to delayed graft function (DGF), which could require longer hospital stays, readmissions, and more complex care coordination.[283] We have also heard from interested parties about the need for patient-reported measures to contribute to the assessment of post-transplant outcomes.

The CTM–3 is a patient-reported measure and would measure transplant hospital performance on an aspect of care that we understand to be important to the patient experience, modifiable by transplant hospitals, and that may not otherwise improve based on the financial incentives in the model targeted towards one- and three-year outcomes, but not directly at perioperative transitions of care and readmission risk. The CTM–3 is a domain of the HCAHPS (CBE ID: 0166). We believe that IOTA participants would have some familiarity with the HCAHPS survey and that the hospital systems of which IOTA participants would be a part would have an infrastructure in place for the administration of HCAHPS that could be leveraged to support administration of the CTM–3.

We sought comment on our proposal to include the CTM–3 measure as a quality measure as a quality measure for purposes of quality domain performance assessment.

The following is a summary of the comments received on our proposal to include the CTM–3 measure as a quality measure for purposes of quality domain performance assessment and our responses:

Comment: Many commenters urged CMS not to finalize CTM–3 as a quality measure within the quality measure set to assess IOTA participant performance in the quality domain, noting that it would add additional burden to patients and IOTA participants and unnecessary complexity, and cost to IOTA participants. A couple commenters urged CMS not to include the CTM–3 measure, indicating that the association between CTM–3 and readmissions is inconsistent in that it does not predict 30-day outcomes and only weakly predicts 3- and 12-month outcomes. Several commenters also noted that participants would be required to report the CTM–3 separately from their HCAHPS surveys, as this measure will soon be removed from the revised Inpatient Quality Reporting Program (IQR). A commenter also noted that collecting CTM–3 data could be redundant, as it will soon be removed from the hospital IQR in favor of an updated set of HCAHPS care coordination items. Finally, a commenter stated that they opposed the inclusion of CTM–3 as a quality measure within the quality measure set to assess IOTA participant performance in the quality domain.

Response: We thank the commenters for their comment and appreciate these commenters concerns to our proposal to include the CTM–3 measure as a quality measure for purposes of assessing performance in the quality domain. In response to these comments, we will not be finalizing our proposal to include the CTM–3 measure as a quality measure for purposes of assessing performance within the quality domain, as described in section III.C.5.e(2) of this final rule.

Comment: Some commenters recommended alternative measures that CMS should consider replacing the CTM–3 with. For example, several commenters suggested that CMS should replace the retired CTM–3 measure with the proposed ''Care Coordination'' Sub-Measure to align with the updates to the HCAHPS survey. A commenter suggested that CMS should consider only looking at readmission rates as a proxy for sound care transition planning or using HCAPS data instead of the CTM–3 measure.

Response: We thank the commenters for their comment and appreciate these commenters suggested alternatives to our proposal to include the CTM–3 measure as a quality measure for purposes of assessing performance in the quality domain. In response to the public comments we received, we will not be finalizing our proposal to include the CTM–3 measure as a quality measure for purposes of assessing performance within the quality domain as described in section III.C.5.e(2) of this final rule.

Comment: A couple commenters expressed support for the inclusion of CTM–3 as a quality measure within the quality measure set to assess IOTA participant performance in the quality domain. A commenter urged CMS to finalize this measure suggesting that it would encourage providers to actively engage patients before and after surgery to ensure they can make an informed decision about their treatment options and are prepared to manage their care afterwards.

Response: We thank commenters for their support and for their comments in support of our proposal to include the CTM–3 measure as a quality measure for purposes of quality domain performance assessment. We believe that transitions of care after kidney transplant are common and indicate elements of modifiable transplant hospital quality, as discussed in section III.C.5.e(2)(d) of this final rule. However, as described in comment responses noted previously, due to concerns raised by commenters we will not be finalizing CTM–3 as a quality measure, as described in section III.C.5.e(2) of this final rule. We will continue to evaluate the changing inventory of quality measures, considering public input, and intend to propose alternative quality measures through future notice and comment rulemaking

After considering public comments, for the reasons set forth in this rule, we are not finalizing our proposal to include the CTM–3 as a measure within the quality measure set to assess IOTA participant performance in the quality domain, as described and finalized in section III.C.5.e(2) of this final rule.

(e) Calculation of Points

In section III.C.5.e(2)(e) of the proposed rule, we proposed that the IOTA participant would receive up to 10 points for performance on our three proposed measures within the quality domain—the CollaboRATE Shared Decision-Making Score, COL, and CTM–3 measures. For purposes of quality measure set performance scoring, we proposed that IOTA participants may

[281] Covert, K.L., Fleming, J.N., Staino, C., Casale, J.P., Boyle, K.M., Pilch, N.A., Meadows, H.B., Mardis, C.R., McGillicuddy, J.W., Nadig, S., Bratton, C.F., Chavin, K.D., Baliga, P.K., & Taber, D.J. (2016). Predicting and preventing readmissions in Kidney Transplant Recipients. *Clinical Transplantation, 30*(7), 779–786. *https://doi.org/10.1111/ctr.12748.*

[282] Covert, K.L., Fleming, J.N., Staino, C., Casale, J.P., Boyle, K.M., Pilch, N.A., Meadows, H.B., Mardis, C.R., McGillicuddy, J.W., Nadig, S., Bratton, C.F., Chavin, K.D., Baliga, P.K., & Taber, D.J. (2016). Predicting and preventing readmissions in Kidney Transplant Recipients. *Clinical Transplantation, 30*(7), 779–786. *https://doi.org/10.1111/ctr.12748.*

[283] Jadlowiec, C.C., Frasco, P., Macdonough, E., Wagler, J., Das, D., Budhiraja, P., Mathur, A.K., Katariya, N., Reddy, K., Khamash, H., & Heilman, R. (2022). Association of DGF and early readmissions on outcomes following Kidney Transplantation. *Transplant International, 35. https://doi.org/10.3389/ti.2022.10849.*

receive up to 4 points for performance on the CollaboRATE Shared Decision-Making Score measure, up to 2 points on the COL measure, and up to 4 points on the CTM–3 measure. Lower weight in terms of scoring points were given to the COL measure because it is a claims-based measure that does not require reporting from IOTA participants. Because the CTM–3 and CollaboRATE are PRO–PMs we believed it was important to allot more points to them, to recognize the additional operational activities necessary for IOTA participants.

In section III.C.5.e(2)(e) of the proposed rule, we proposed to phase-in quality performance benchmarks for the three quality measures selected for the IOTA quality measure set, such that we would reward reporting for the first two years of the model performance period (''pay-for-reporting''), at minimum, before we reward performance against quality performance benchmarks for each measure (''pay-for-performance''). Thus, performance for each of these three quality measures would be measured against a ''response rate threshold'' applicable to our proposed ''pay-for-reporting'' method for PY 1—PY 2, while performance would be measured against quality performance benchmarks calculated by CMS applicable to our proposed ''pay-for-performance'' method for PY 3—PY 6. Table 10 illustrates our proposed pay-for-reporting and pay-for-performance timeline. We noted that we anticipated establishing a quality performance benchmarks and minimum attainment levels for quality measures in future rule making.

TABLE 10: MEASURE PAYMENT TYPE BY PERFORMANCE YEAR

Measure	PY 1	PY 2	PY 3	PY 4	PY 5	PY 6
CollaboRATE Shared Decision-Making Score	Pay for Reporting (P4R)	P4R	Pay for Performance (P4P)	P4P	P4P	P4P
Colorectal Cancer Screening (COL)	P4R	P4R	P4P	P4P	P4P	P4P
CTM-3	P4R	P4R	P4P	P4P	P4P	P4P

In section III.C.5.e(2)(e) of the proposed rule, we proposed that CMS would determine and share with IOTA participants the response rate threshold by the first day of each PY in a form and manner chosen by CMS. We stated that this approach to assessing IOTA participant quality performance would serve four key purposes. First, it would promote measure implementation, uptake, and data collection by IOTA participants through a rewards-only scoring system. Second, it would build experience over the first two model PYs, giving IOTA participants more time to prepare and build capacity to meet performance benchmarks. Third, it would allow CMS to collect data needed to develop measure benchmarks. Finally, it would focus model incentives on care delivery transformation and improvement activity directly aimed at meeting quality performance goals, as to ensure the patient is centered in this approach. Ultimately, we considered the pay-for-reporting approach to be a reasonable approach. We also believed that some IOTA participants may be familiar with this as it is similar to the format within the KCC Model. We recognized that these measures already exist, but, because they are used in a much broader population, there are no benchmarks that are applicable for the model.

In section III.C.5.e(2)(e) of the proposed rule, we proposed to define the ''response rate threshold'' as the level of complete and accurate reporting for each quality measure, within the quality measure set of the quality domain, that the IOTA participant must meet to earn points on the quality domain during a performance year as described in § 512.428(c) and (e) of the proposed rule. For the CTM–3 and CollaboRATE measures, we proposed that points be awarded based on response rate thresholds, as illustrated in Table 11, such that IOTA participants with a response rate threshold of—

- 90–100 percent of attributed patients would receive 4 points;
- 50–89 percent of attributed patients would receive 2 points; or
- Under 50 percent of attributed patients would receive 0 points.

In section III.C.5.e(2)(e) of the proposed rule, we proposed for the COL measure that a completion rate of 50 percent or greater would result in the IOTA participant receiving two points, and a completion rate of less than 50 percent would result in the IOTA participant receiving zero points, as illustrated in Table 11.

TABLE 11 — IOTA MODEL QUALITY MEASURE SET SCORING

Measure	Performance Relative to Target	Lower Bound Condition	Upper Bound Condition	Points Earned
CollaboRATE/CTM-3	90% Response Rate	Equals 90%	Greater than 90%	4
CollaboRATE / CTM-3	50% Response Rate	Equals 50%	Less than 90%	2
CollaboRATE / CTM-3	50% Response Rate	N/A	Less than 50%	0
COL	50% Response Rate	Equals 50%	Greater than 50%	2
COL	50% Response Rate	N/A	Less than 50%	0

As described in section III.C.5.e(2)(e) of the proposed rule, we recognized that the proposed response rate thresholds are high, but we want to make sure that we have enough data to set appropriate and meaningful benchmarks in PY 3 through PY 6. We considered setting a higher maximum measure completion rate; however, given that each IOTA participant may have different levels of engagement with kidney transplant waitlist patients, we felt a higher threshold may be difficult for IOTA participants to achieve. We also believed that a higher response rate

would incentivize IOTA participants to collect the data. We considered the following variations to the response rate threshold for each of the proposed quality measure:

- Response rate threshold of 100 percent would receive 10 points, if not 100 percent 0 points would be awarded.
- Response rate threshold of 80–100 percent would receive 10 points, 50–79 percent would receive 5 points, and 49–0 percent would receive 0 points.
- 50–100 percent would receive 10 points; under 50 percent would receive 0 points.

As described in section III.C.5.e(2)(e) of the proposed rule, we considered mirroring the point structure under which an IOTA participant would receive either all possible points, or, if data was not collected from all their attributed patients, none of the possible points. We thought that this could incentivize IOTA participants to administer the surveys associated with the proposed quality measures, which would allow us to create meaningful benchmarks for future model years. However, because there would be some additional burden placed onto IOTA participants to administer the surveys associated with the proposed quality measures, we believed this point structure would be difficult for some and wanted to provide more attainable response rate thresholds. We also considered lowering the response rate thresholds for the same reasons mentioned earlier, but, because there are currently no benchmarks for these measures in this specific population, we felt that the response rate threshold needed to be higher but still attainable.

We also considered achievement and improvement scoring for the proposed quality measures. However, because none of the measures included in the proposed quality measure set, as described in section III.C.5.e(2) of this final rule, currently have benchmarks, we did not believe it was appropriate to propose achievement and improvement scoring for the proposed quality measures at this time.

We sought comment on our proposed calculation of points for the quality measure set, as well as the proposal to reward IOTA participant reporting for the first two PYs (''pay-for-reporting''), before rewarding IOTA participant performance against quality performance benchmarks. We sought comment on the proposed response rate thresholds and point allocations for measures included in the proposed quality measure set within the quality domain.

The following is a summary of the comments received on our proposed calculation of points for the quality measure set, as well as the proposal to reward IOTA participant reporting for the first two PYs (''pay-for-reporting''), before rewarding IOTA participant performance against quality performance benchmarks and the proposed response rate thresholds, point allocations for measures included in the proposed quality measure set within the quality domain and our responses:

Comment: Some commenters expressed concern about the proposed response rate thresholds and point allocations and requested that CMS lower the proposed response rate threshold for the proposed quality measures. For example, a commenter expressed their belief that how well IOTA participants do getting their patients to respond to specific surveys is not an accurate reflection of quality. A few of commenters indicated that transplant hospitals currently struggle to achieve patient experience survey response rates above 30 percent. Given this challenge, they felt that the proposed 90 percent response rate threshold for quality measures is unrealistic. To achieve a 90 percent response rate for two new quality measures, a commenter suggested this would require that the surveys be administered in person; noting that this approach could create an administrative burden by requiring staff to distribute and collect the surveys, as well as necessitate patients making extra clinic visits solely for the purpose of completing the surveys. Several commenters urged CMS to adjust the response rate thresholds to mitigate this challenge. Specifically, a commenter recommended that CMS adopt a similar minimum response rate threshold like what is proposed for awarding domain points; suggesting 4 points awarded for response rate thresholds above 50 percent, 2 points awarded for response rate thresholds of 25 percent to 50 percent, and 0 points awarded for response rates below 25 percent.

Response: We thank these commenters for sharing their concerns. We acknowledge the concerns related to the high response rate thresholds proposed for the CollaboRATE Shared Decision-Making Score and CTM–3. As we stated in the proposed rule, we acknowledge that the proposed response rate thresholds are quite high and that these measures are already in use, though applied to a much wider population. As a result, there are no benchmarks that can be utilized for the IOTA Model, and we sought to ensure that we had enough data to set appropriate and meaningful quality performance benchmarks in PY 3 through PY 6.

We also thank the commenters for their recommendations to lower the response rate thresholds given the number of surveys requests and obligations transplant patients are already asked to complete and the additional burden that could be placed onto IOTA participants to administer the surveys associated with the proposed quality measures and lower the response rate thresholds. We also appreciate the commenters suggestion for an alternative scoring methodology. As we stated in the proposed rule, we did consider lowering the response rate thresholds for the same reasons mentioned earlier, but, because there are currently no benchmarks for these measures in this specific population, we felt that the response rate threshold needed to be higher but still attainable. We direct readers to section III.C.5.e.(2)(e) for further discussion on the alternative scoring methodologies that were considered for inclusion in the IOTA Model. We also note that we considered the added reporting burden on IOTA participants when evaluating potential quality measures for inclusion in the IOTA Model, and direct commenters to section III.C.5.e(2) of this final rule for further discussion.

Lastly, because we are not finalizing our proposed quality measure set, as described in section III.C.5.e(2) of this final rule, and in consideration on public comment received, we will not be finalizing our proposed quality measure set scoring methodology. In section III.C.5.e(e) of the proposed rule, we proposed that the IOTA participant would receive up to 10 points for performance on our three proposed measures within the quality domain while also noting in the proposed rule at 89 FR 43564, that if we finalize fewer measures, then we proposed to allocate the points accordingly within the remaining measures. Given that we are not finalizing any of the proposed measures within the quality measure set or quality measure set scoring methodology, the 10 points we proposed to award IOTA participants for performance on our three proposed measures within the quality domain will be allocated to the composite graft survival rate within the quality domain, as described and finalized in section III.C.5.e(1)(b) of this final rule.

Although we are not finalizing our quality measure set scoring methodology at this time, CMS will take into consideration the commenters concerns and suggestions and intends to propose an alternative or updated policy

proposal in future notice and comment rulemaking.

Comment: A couple commenters expressed support for the proposed response rate thresholds, but they felt that a 90% response rate would be extremely unlikely to be achieved.

Response: We thank commenters for their support and for their comments in support of our proposed response rate thresholds and concern over the achievability of a 90% response rate. As mentioned in comment responses noted previously, we acknowledge that the response rate thresholds we proposed were high. As discussed in the preamble of this final rule, we proposed the response rates for the proposed quality measures, as illustrated in Table 11 noted previously, to allow CMS to collect enough data to develop meaningful and appropriate measure benchmarks in PYs 3–6.

However, because we are not finalizing our proposed quality measure set, as described in section III.C.5.e(2) of this final rule, and based on public comment, we will not be finalizing our proposed quality measure set scoring methodology, as described in section III.C.5.e(2)(e) of this final rule, at this time, and intend to propose a new or updated policy in future notice and comment rulemaking that will address concerns with respect to response rate thresholds IOTA participants may have.

Comment: A couple commenters requested that CMS provide additional clarity about the proposed response rate thresholds and point allocations. For example, a commenter urged CMS to not only propose response rate thresholds, but also define what constitutes ''complete and accurate reporting'' and provide specifics on how the response rate threshold would be calculated for CollaboRATE; stating that until CMS did so, they could not support the inclusion of this measure in the IOTA Model. Another commenter cited that the Healthcare Effectiveness Data and Information Set (HEDIS) specifications for the COL measure indicate that COL is an administrative measure,[284] noting that CMS proposed response rate thresholds for it during the pay-for-reporting years of the model. This commenter asked CMS to clarify two key points: (1) How the response rate would be calculated for an administrative measure, and (2) How this calculation differs from the quality performance benchmarks that would need to be met once the measure transitions to pay-for-performance in future program years.

Response: We appreciate the commenters comments and clarifying questions. In the proposed rule at 89 FR 43658, we proposed to define response rate threshold as the level of complete and accurate reporting for each quality measure, within the quality measure set of the quality domain, that the IOTA participant must meet to earn points on the quality domain during a performance year as described in §§ 512.428(c) and 512.428(e). In response to the commenters request that CMS further explain how the response rate threshold would be calculated for CollaboRATE and COL, we clarify here that, based on our proposed definition and industry standards, the response rate for each of the proposed quality measures would be calculated as follows:

Equation 5: Response Rate Threshold

$$Response\ Rate\ = \frac{\#\ of\ complete\ and\ accurate\ responses\ submitted}{\#\ of\ eligible\ attributed\ patients\ surveyed} X100$$

For example, if in PY 1 of the model, an IOTA participant was required to administer the CollaboRATE to 30 of their attributed patients and submitted 28 complete and accurate responses, the response rate for that IOTA participant on the CollaboRATE would be 93% (28 complete and accurate responses submitted divided by 30 and then multiplied by 100). Based on our proposed quality measure set scoring methodology, as described in the preamble of this final rule, that IOTA participant would be awarded four points for their response rate threshold on the CollaboRATE.

In accordance with the Share Savings Program Final Rule as outlined in 76 FR 67873, we are clarifying that ''complete and accurate reporting'' signifies that that the quality data submitted to CMS is accurate, complete, and truthful. However, we disagree with the commenters' belief that CMS needs to define what is meant by ''complete and accurate reporting,'' as this is language that has been used in other models, such as the Shared Savings Program at 42 CFR 425.502. Regarding the commenters request that CMS clarify how our proposals for calculating response rate thresholds differs from calculating performance benchmarks in later PYs, we note that, as discussed in the proposed rule at 89 FR 43658, we anticipated establishing quality performance benchmarks and minimum attainment levels for quality measures in future rule making.

Finally, as mentioned in comment responses noted previously in this section, since we are not finalizing our proposed quality measure set, as described in section III.C.5.e(2) of this final rule, and based on public comment, we will not be finalizing our proposed quality measure set scoring methodology at this time and the 10 points we proposed to award IOTA participants for performance on our three proposed measures within the quality domain will be allocated to the composite graft survival rate within the quality domain, as described and finalized in section III.C.5.e(1)(b) of this final rule. We also note that we intend to propose a new or updated policy in future notice and comment rulemaking.

After consideration of the public comments we received, for the reasons set forth in this rule, we are not finalizing our proposed quality measure set scoring methodology, as described at § 512.428(e) of the proposed rule, or our proposed definition of response rate threshold, as described at § 512.402 of the proposed rule. Although we are not finalizing any of the measures that we proposed for inclusion in our proposed quality measure set, as described in section III.C.5.e(2) of this final rule, we intend to propose alternatives in future notice and comment rulemaking. Additionally, in section III.C.5.e(e) of the proposed rule, we proposed that the IOTA participant would receive up to 10 points for performance on our three proposed measures within the quality domain while also noting in the proposed rule at 89 FR 43564, that if we finalize fewer measures, then we proposed to allocate the points accordingly within the remaining measures. Given that we are not finalizing the proposed quality measure set within the quality domain or quality measure set scoring methodology, the 10

[284] National Committee for Quality Assurance. ''Colorectal Cancer Screening—NCQA.'' NCQA, 2024, *www.ncqa.org/hedis/measures/colorectal-cancer-screening/*.

points we proposed to award IOTA participants for performance on our three proposed measures within the quality domain will be allocated to the composite graft survival rate within the quality domain, as described and finalized in section III.C.5.e(1)(b) of this final rule. We will continue to assess our quality domain methodology and how to best balance incentives in the efficiency domain and quality domain and will address a new or updated policy pursuant to future notice and comment rulemaking.

■ 6. Payment

a. Purpose and Goals

We believe that risk-based payment arrangements in Innovation Center models drive healthcare innovation and transform the healthcare payment system by rewarding value over volume. Risk-based payment models hold participants financially accountable, as these payments are structured to incentivize value-based care that improves quality and reduces total cost of care for beneficiaries. Risk-based payment models may be upside-risk only, or have two-sided, upside and downside, risk. Under these risk-based arrangements, IOTA participants may receive a payment from CMS if performance goals are met or exceeded, and, if the model features downside risk, may owe a payment to CMS for failing to meet performance goals.[285]

For the IOTA Model, we proposed an alternative payment model (APM) structure that incorporates both upside and downside risk to existing Medicare fee-for-service (FFS) payments for kidney transplantations as described in section III.C.6.b. of the proposed rule.

The IOTA Model will test whether performance-based payments, including an upside risk payment and downside risk payment, to IOTA participants increases access to kidney transplants for attributed patients while preserving or enhancing quality of care and reducing kidney transplant hospital expenditures. As described in section III.C.5. of this final rule, IOTA participants will be assessed against proposed metrics to assess performance for each PY relative to specified targets, thresholds, or benchmarks proposed and determined by CMS. The final performance score, not to exceed a maximum of 100 points, will determine if and how upside and downside risk payments are applied, as described in section III.C.6.c. of this final rule. We believe this upside and downside risk approach will be a strong incentive to promote performance improvement.

We sought comment on our proposed two-sided risk payment design to incentivize model performance goals.

The following is a summary of the comments received on our proposed two-sided risk payment design and our responses:

Comment: We received multiple comments pointing out that kidney transplant hospitals do not make their decisions for transplants based on financial incentives and that it is inappropriate to incentivize IOTA participants to do more transplants through a pay-for-performance model.

Response: We understand that the decision to transplant a specific beneficiary is not made for financial reasons. However, we recognize that resource allocation decisions for a kidney transplant hospital are made at an administrative level that will allocate resources in part based on CMS reimbursement policies, which is why we are testing the IOTA Model using this framework.

Comment: We received a comment saying that CMS should consider the impact on private payer COE programs for transplant based on the incentives in the model.

Response: We recognize the importance of COE programs to kidney transplant hospitals and recognizes that being in a COE for a payer is a key source of revenue for many kidney transplant hospitals. The model was designed to align with many of the metrics used for a COE, which generally include a minimum volume requirement and some minimum level of performance on post-transplant outcomes. Though their metrics do not generally include a major requirement to increase volume like those of the IOTA Model, transplants represent a major source of potential savings on the plan side, just as it does for CMS. CMS is hopeful that with the finalization of the IOTA Model that other payers will more closely harmonize their measures to create a unified regulatory framework that reduces burden for kidney transplant hospitals and improves overall quality.

Comment: We received a comment saying that the model should not focus on accountability at the kidney transplant hospital level, but instead direct resources directly to the most vulnerable patients to assist them through the transplant process.

Response: We understand the comment, but ultimately disagree with the commenter. The IOTA Model is based on the idea that the kidney transplant hospital is the key locus for the transplant process, given the role of the kidney transplant hospital in getting candidates onto the waitlist, deciding which organs to accept, performing transplant surgeries, managing the living donor process, and overseeing post-transplant care. Given that role, we believe that the kidney transplant hospitals are closer to their patients and will be better able to determine their exact needs to help get them through the transplant process.

Comment: We received a comment saying that downside risk in the IOTA Model was inappropriate because organ supply is out of the control of kidney transplant hospitals.

Response: We recognize that kidney transplant hospitals are not the entities responsible for recovering organs. However, research has shown significant variance in organ-offer acceptance practices, even among kidney transplant hospitals that are geographically proximate, as discussed in the background section. Additionally, kidney transplant hospitals are in complete control of the living donor kidney process, which is not dependent upon the procurement process.

Comment: We received multiple comments saying that downside risk in the model was inappropriate because kidney transplant hospitals are new to value-based care.

Response: We understand the need for IOTA participants to ramp up their value-based care operations, which is why there is no downside risk for IOTA participants in PY 1. Additionally, in this final rule, we removed many requirements that may have been perceived as burdensome by kidney transplant hospitals, such as reporting on multiple quality measures and on declined organ offers and we believe that this will make it more achievable for IOTA participants to devote the necessary resources required to succeed in the IOTA Model. The IOTA Model also focuses on major functions and activities that kidney transplant hospitals are already doing, rather than changing the focus to a more population health perspective as is done in many other Innovation Center models. Given these circumstances, we then believe that downside risk can be fairly applied in PY 2 to help further incentivize performance in the model.

Comment: We received a comment saying that many kidney transplant hospitals face structural barriers that prevent them from increasing their numbers of transplants, making downside risk inappropriate for the model.

Response: We recognize that different kidney transplant hospitals face

[285] *https://www.cms.gov/priorities/innovation/key-concepts/risk-arrangements-health-care.*

different limitations in how they manage the transplant process. This is why the IOTA Model includes a flexible scoring system that gives IOTA participants different areas to focus on to achieve an upside risk payment under the model. Every IOTA participant can adjust their organ offer filters to be more efficient and remove offers that they are unlikely to use. Additionally, the model is not prescriptive on how IOTA participants can transplant more organs, meaning that IOTA participants could invest in their living donor program or could focus on using deceased donor organs that they may not have utilized in the baseline years. Finally, each IOTA participant is judged against scored based on their own historic number of transplants, or historic organ offer acceptance rate, for the achievement and efficiency domains. This approach demonstrates CMS's effort to recognize that kidney transplant hospitals are starting at different places before the IOTA Model and to provide an opportunity to fostering innovation by competing against their own historic performance.

Comment: We received a comment saying that many smaller or essential kidney transplant hospitals lack the resources to effectively participate in the IOTA Model and should have no downside risk.

Response: We understand that smaller kidney transplant hospitals may have fewer overall resources and we do not want any kidney transplant hospitals to stop offering kidney transplant services because of the IOTA Model. To address this issue, we proposed a low-volume threshold of 11 or more kidney transplants performed annually to exclude the kidney transplant hospitals with the lowest volumes, as described and finalized in section III.C.3.c of this final rule. Additionally, benchmarks for the achievement domain and efficiency domain in the IOTA Model are based on improvement relative to the IOTA participant's own historic number of transplants, or historic organ offer acceptance rate, meaning that for 80 of 100 possible points that an IOTA participant can earn for the model, they are evaluated against their own historic performance. Finally, the payment methodology for the IOTA Model is based on the number of transplants performed and includes asymmetrically less downside risk, minimizing the potential downside for smaller kidney transplant hospitals. We will monitor the effects of these different mechanisms within the IOTA Model to see if they are successful in helping smaller kidney transplant hospitals and will consider further efforts in future rulemaking based on the results of those monitoring efforts.

Comment: We received a comment supporting the two-sided risk structure for the IOTA Model, supporting the inclusion of downside risk in order to help change behavior of IOTA participants.

Response: We appreciate the feedback and believe that downside risk is ultimately necessary to help incentivize IOTA participants to achieve the goals of the IOTA Model.

Comment: A commenter questioned whether payment adjustments effectively drive physician behavior, and instead urged CMS to prioritize upstream investments as a means of promoting increased organ transplantation.

Response: We appreciate the feedback but disagree with the commenter. We recognize some of the limitations of payment adjustments to move physician behavior. However, we recognize that they have never been tried in this area. There is significant variation kidney transplant hospitals among their use of organ offer filters, organ offer acceptance rate, and investment in the living donation process, and the IOTA Model will test whether IOTA participants can learn from other IOTA participants that may be higher performing in these areas. We also recognize that organ transplant, as opposed to many other areas covered in other Innovation Center models, contains a cost-based reimbursement model for organ acquisition costs that provides a significant source of funding to support IOTA participants' investments in performance.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing this two-sided payment framework as originally designed. We believe that the two-sided framework best creates a clear incentive for improved performance by IOTA participants, with sufficient upside to reward IOTA participants for excellent performance. Furthermore, as described and finalized in section III.C.6.c(1) of this final rule, we are finalizing at § 512.430(b)(3)(i) that for PY 1, the IOTA participant does not owe a downside risk payment to CMS. We direct readers to sections III.C.6.C(2)(a-c) for a full discussion on our proposed upside risk payment, downside risk payment, and neutral zone provisions.

b. Alternative Payment Design Overview

There are two payment components in the current Medicare FFS program for organ transplantation. Under the Medicare Inpatient Prospective Payment System (IPPS), kidney transplant hospitals are paid a prospective payment system rate based on the MS–DRG for the organ transplant. Payment for organ acquisition costs as described at 42 CFR 413.402, which include costs associated with beneficiary and donor evaluation, is made on a reasonable cost basis. To remain active on the transplant waitlist, candidates must meet a variety of criteria, including annual screenings for cardiovascular diseases and cancers.

In the IOTA Model, CMS proposed two-sided performance-based payments for ''Medicare kidney transplants,'' defined as kidney transplants furnished to attributed patients whose primary or secondary insurance is Medicare FFS, as identified in Medicare FFS claims with MS–DRGs 008, 019, 650, 651 and 652, and as illustrated in Table 12. We stated that this APM design aligns with the Health Care Payment Learning & Action Network (LAN) Category 3 APM framework in which IOTA participants continue to be paid on the basis of Medicare FFS, but a retrospective annual attribution reconciliation and performance assessment after the end of each model PY is conducted to determine performance-based payments.[286] [287]

The IOTA Model's performance-based payments are linked to existing Medicare Part A and Part B services for kidney transplants, and align with other Innovation Center models' payment structure, including the ETC Model where upward and downward adjustments are made to certain Medicare payments under the ESRD Prospective Payment System and Physician Fee Schedule depending on an ETC Participant's performance at the aggregation group level under the model. The difference between ETC and the IOTA Model, for example, is how these retrospective adjustments would be paid or recouped by CMS. CMS did not propose to adjust existing Medicare IPPS payments for kidney transplants furnished to Medicare beneficiaries. Instead, CMS proposed to make performance-based payments to IOTA participants separate from claims-based payments.

[286] *https://hcp-lan.org/workproducts/apm-refresh-whitepaper-final.pdf.*

[287] *https://hcp-lan.org/workproducts/apm-refresh-whitepaper-final.pdf.*

TABLE 12: MS-DRGs PROPOSED FOR INCLUSION IN DEFINITION OF MEDICARE KIDNEY TRANSPLANTS

MS-DRG	Description
008	SIMULTANEOUS PANCREAS AND KIDNEY TRANSPLANT
019	SIMULTANEOUS PANCREAS AND KIDNEY TRANSPLANT WITH HEMODIALYSIS
650	KIDNEY TRANSPLANT WITH HEMODIALYSIS WITH MCC
651	KIDNEY TRANSPLANT WITH HEMODIALYSIS WITHOUT MCC
652	KIDNEY TRANSPLANT

We proposed to base performance-based payments on increasing the number of transplants and other metrics of efficiency and quality because we believe this approach: (1) would be a strong proxy for total cost; (2) directly aligns with the model's goal of increasing access to and the volume of kidney transplantations; (3) acknowledges kidney waitlist and transplant patients are high-cost and high-need, making performance based on total cost of care unfair for IOTA participants with lower volume and fewer capabilities and resources given the increased opportunity for outliers; and (4) may safeguard against unintended consequences introduced by defining value based on cost for an attributed patient population already at high-risk, such as inappropriate cost shifting and widening access to care disparities. We theorize that increasing the number of, and access to, kidney transplants alone would result in better quality. As indicated in our estimates presented in section IV of this final rule, it would also result in savings to Medicare.

While we proposed to assess model performance for each IOTA participant for all attributed patients regardless of payer type, as described in section III.C.6.c of this final rule, we proposed model performance-based payments that would only be based on kidney transplants furnished to attributed patients with Medicare FFS as their primary or secondary insurance.

As described in section III.C.6.b of the proposed rule, we considered also basing the model performance-based payments on kidney transplants furnished to attributed patients enrolled in Medicare Advantage (MA), as kidney transplants are a Medicare-covered service that MA plans must also cover. As these payments would be made to kidney transplant hospitals, a potential waiver of section 1851(i)(2) of the Act, which provides that only the MA plan shall be entitled to payments for services furnished to the beneficiary, may have been necessary to apply the payments to attributed patients enrolled in MA. Because further consideration was needed for the implications of such a potential waiver, we did not propose to apply model performance-based payments performed on attributed patients enrolled in MA.

We believed that the benefits of applying model performance-based payments to transplants furnished to attributed patients enrolled in MA would be recognizing the growth in MA enrollment relative to Medicare FFS enrollment, strengthening the model test through aligned payment incentives across payers, and protecting against unintended consequences of incentivizing inappropriate organ offer acceptance based on payer type. However, we did not propose to base payments on attributed patients enrolled in MA because of concerns about potentially waiving section 1851(i)(2) of the Act. This provision states that only the MA plan is entitled to payments for services provided to the beneficiary. We noted that waiving this requirement would be unprecedented and the effects are unknown. We recognized that the proposed incentives in the IOTA Model would have a larger effect if kidney transplant hospitals were receiving performance-based payments based on their entire panel of attributed beneficiaries who receive transplants, and not just based on transplants for attributed beneficiaries with Medicare FFS as their primary or secondary insurance. To that end, we proposed that the IOTA Model would encourage multi-payer alignment with the goal of aligning on goals, incentives, and quality. We noted in the proposed rule that CMS intended to engage with the payer community, including MA, Medicaid, and commercial payers, in future years to discuss opportunities and approaches for alignment.

We requested comment and feedback, especially from MA plans, on our decision not to calculate model performance-based payments to transplants furnished to attributed patients enrolled in MA. We were especially interested in comments that address how the Innovation Center should generally approach the growing MA population with the design of its models, which have traditionally been focused on the fee-for-service Medicare population.

While kidney transplant hospitals are subject to value-based payment programs, some IOTA participants may have limited APM experience, resources, and capacity to meet model goals. We considered an upside-risk payment only framework that would still base model payments on kidney transplant utilization and other metrics of efficiency and quality. However, we believed that two-sided risk payments would be stronger incentives to achieve the desired goals. We also recognized this in the model design by proposing a phased-in approach to two-sided risk, with only upside-risk applied to the first model PY. We also considered other APM frameworks that would link performance to quality, such as pay-for-reporting on the measures. We did not propose these frameworks, as they did not align with our goals of establishing two-sided risk accountability for IOTA participants. We recognized the benefits of a rewards-focused approach, particularly as it relates to quality performance, and we therefore did incorporate a rewards-focused performance scoring structure designed as pay-for-reporting and pay-for-performance within the quality domain performance assessment. (89 FR 43571).

Another alternative we considered was a flat positive adjustment to the Medicare FFS payment for a kidney transplant based on the number of completed kidney transplants that an IOTA participant performs. Increasing the amount paid for completed kidney transplants through a FFS adjustment is the simplest policy and aligns with the IOTA Model's focus on increasing the number of kidney transplants. Additionally, adjusting the FFS payment would directly incentivize an increase in the number of kidney transplants performed by IOTA participants. Under this approach, eligible claims would be identified utilizing Medicare claims data with Medicare Severity Diagnosis Related Groups (MS–DRGs) 008 (simultaneous pancreas-kidney transplant) and 652

(kidney transplant); and claims with ICD–10 procedure codes 0TY00Z0 (transplantation of right kidney, allogeneic, open approach), 0TY00Z1 (transplantation of right kidney, syngeneic, open approach), 0TY00Z2 (transplantation of right kidney, zooplastic, open approach) 0TY10Z0 (transplantation of left kidney, allogeneic, open approach), 0TY10Z1 (transplantation of left kidney, syngeneic, open approach), and 0TY10Z2 (transplantation of left kidney, zooplastic, open approach).

We did not propose a performance methodology based solely on adjusting the DRG payment for a kidney transplant, because this option would not encourage IOTA participants to focus on issues other than transplant volume, including equity, increased utilization of donor kidneys, quality of care, and patient outcomes, all of which are important parts of the transplant process where we believe performance is variable and can be improved. We further believe that the claims-only approach would not be as effective in incentivizing a continuous increase in transplants because IOTA participants that already have high kidney transplant volumes would be rewarded through increased reimbursements whether they improved year-over-year or not. Finally, we do not believe that this approach would provide any additional encouragement for IOTA participants to manage post-transplant care.

We also considered establishing a payment for transplant waitlist management to encourage additional investment in the transplant process, but decided to focus more on the outcomes described in section III.C.5 of the proposed rule. Additionally, given that IOTA participants are already reimbursed at cost for efforts to manage beneficiaries on the waitlist, we did not believe an explicit additional payment would be necessary in this area.

We sought feedback on our proposed alternative payment model design, data source to identify kidney transplants, and proposal to only apply model performance-based payments, both upside and downside, to Medicare FFS kidney transplants. We also sought feedback on alternative approaches considered, such as the alternative approach of including MA transplants. We welcomed input on how CMS may be able to work with multiple payers to ensure alignment with the IOTA Model.

The following is a summary of the comments we received regarding our proposed alternative payment model design, data source to identify kidney transplants, our proposal to apply model performance-based payments and our alternative approach of including MA transplants, and our responses:

Comment: We received over twenty comments urging CMS to apply the payment adjustments in the IOTA Model to transplants performed for beneficiaries with Medicare Advantage as a primary or secondary payer, and not just beneficiaries with Medicare FFS as a primary or secondary payer. Commenters pointed out the limited reach of the proposed incentives by focusing the incentives solely on a small portion of a kidney transplant hospital's overall patient panel. They were worried that the model may be ineffective without the incentive effects provided by applying the payment adjustments in the IOTA Model to more than just Medicare FFS transplants. Many commenters also pointed out that there is a rising number of beneficiaries enrolling in Medicare Advantage relative to Medicare FFS, which would decrease the effects of the model's proposed incentives over time. Commenters also pointed out that kidney transplant hospitals are paid directly through FFS Medicare for Organ Acquisition Costs for kidney transplants as defined in 42 CFR 413.402, even for beneficiaries with Medicare Advantage, due to their statutory exclusion in § 1853(k)(5) of the Act. Another commenter pointed out that in other Medicare APMs operated by the Innovation Center, when a beneficiary has transitioned from FFS Medicare to Medicare Advantage, it has made them become ineligible for payments from the APM and discouraged potential investment in those beneficiaries.

Response: We appreciate the feedback from commenters. However, we plan to finalize the policy as proposed as we do not believe that the additional incentive effects from including Medicare Advantage in the calculation for upside and downside payments are necessary at this point to provide sufficient incentive to test the model. We plan to further engage with Medicare Advantage plans to think about the incentives in the IOTA Model and those set up by Medicare Advantage plans. We also plan to monitor relative enrollment of beneficiaries who receive kidney transplants in Medicare FFS as opposed to Medicare Advantage to see if further policy changes will be necessary for future years of the IOTA Model.

Comment: Multiple commenters expressed concern that the proposed payment structure for the IOTA Model, which would make payments based only on Medicare FFS kidney transplants, could lead to IOTA participants preferring to transplant Medicare FFS patients at the expense of patients with Medicare Advantage.

Response: We appreciate the feedback from commenters as this is an outcome that we do not want. We recognize that the achievement domain is based on transplants performed across all payers and is worth the greatest number of points, which we believe will help to prevent this behavior. Additionally, we plan to monitor for potential shifts by payer as an unintended side effect of the model to ensure that this outcome does not occur, and we may consider taking additional action in future rulemaking if we see significant evidence that this is occurring.

Comment: A commenter supported our proposed policy to exclude payments for beneficiaries with Medicare Advantage from the positive and negative payment adjustments in the Model.

Response: We plan to monitor relative enrollment of beneficiaries who receive kidney transplants in Medicare FFS as opposed to Medicare Advantage to see if further policy changes will be necessary for future years of the IOTA Model.

Comment: We received a comment urging CMS to align the payments in the IOTA Model with those from Medicare Advantage plans.

Response: We recognize the importance of multi-payer alignment and has engaged in numerous conversations with Medicare Advantage plans about their transplant strategies. It is our understanding from discussions with MAOs that most MAOs use their COE programs to evaluate kidney transplant hospitals for network inclusion often provide them special contracting rates. Many plans use a variety of criteria to determine COE, including a minimum transplant volume, and minimum performance on certain outcomes metrics.[288] We believe that IOTA participants' quality improvement activities as a result of the model's performance metrics and payment methodology may help them reach and maintain COE status.

Comment: We received multiple comments urging CMS to include kidney transplants covered by other payers in the model's payment methodology, particularly the Medicaid program.

Response: Medicare is the dominant payer in the marketplace for transplants, accounting for 57 percent of adult transplants, relative to only 7 percent

[288] For instance, Aetna's criteria is here: *https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/Aetna-Institutes-of-Excellence.pdf.*

for patients with Medicaid. As such, we believe that testing the model payment incentives based on just those transplants for beneficiaries with Medicare will provide sufficient incentive to drive the increases in transplants that CMS is hoping will occur from the Model. Additionally, transplants provide additional savings for the Medicare program given that patients may become entitled to Medicare based on ESRD, and given that Medicare is the primary payer for services for the majority of patients with ESRD across the country.

However, we urge other payers, including private plans, to follow the lead of CMS and learn from the lessons we glean from this Model to evaluate how they pay kidney transplant hospitals to incentivize quality care and better outcomes.

As a result, we believe that applying these payments in the IOTA Model to all Medicare FFS transplants will apply a strong incentive for IOTA participants to increase access to kidney transplantation given Medicare's dominant role in the marketplace.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed definition of Medicare kidney transplants at § 512.402 without modification.

c. Performance-Based Payment Method

We proposed that the final performance score as described in section III.C.5. of this final rule would determine if and how an IOTA participant qualifies for an upside risk payment, falls in the neutral zone, or qualifies for a downside risk payment, proposed using a two-step process. First, we would determine if an IOTA participant's final performance score qualifies the IOTA participant for upside risk payments, downside risk payments, or the neutral zone, as described in section III.C.6.c.(1). of this final rule. Second, we would apply the proposed calculation formula for each of type of payment, as described in section III.C.6.c.(2). of this final rule. Ultimately, we proposed a performance-based payment method that prioritizes the following principles:

- Significant weight should be given to performance in the achievement domain, representing up to 60 points relative to a 100 maximum performance score, in alignment with the primary goals of the model to increase number of kidney transplants.
- The magnitude of performance-based payments should be tied to relative number of kidney transplants, given significant differentials across kidney transplant hospitals nationally.
- The largest performance-based payments amount in total dollars should go to IOTA participants that perform the most transplants because they are removing the most people from dialysis and creating the largest quality improvement and cost savings for the Medicare Trust Fund.
- The payments need to be calibrated to provide an incentive to IOTA participants, but still ensure net savings to Medicare based on the analysis performed by OACT in section IV of this final rule.
- The mechanisms should recognize that CMS has not previously offered kidney transplant hospitals a value-based care payment model around transplantation and should provide a transition to any form of downside risk to allow for an opportunity to become familiar with the value-based care process.
- Limit operational complexity for both IOTA participants and CMS to avoid any potential for errors.

(1) Determine Final Performance Score Range Category

We proposed to establish three final performance score range categories, as illustrated in Table 13, that dictate which type of performance-based payment would apply to an IOTA participant for a given PY.

We proposed at § 512.402 to define ''upside risk payment'' as a lump sum payment that CMS would make to an IOTA participant if the IOTA participant's final performance score for a PY falls within the payment range specified in section III.C.6.c(2)(a) of this final rule. As proposed and indicated in Table 13, if in PY 1–6, an IOTA participant's final performance score is greater than or equal to 60 points, the IOTA participant would qualify for an upside risk payment.

We proposed at § 512.402 to define ''neutral zone'' as the final performance score range in which the IOTA participant would not owe a downside risk payment to CMS or receive an upside-risk payment from CMS if the IOTA participant's final performance score falls within the ranges specified in section III.C.6.c.(2).(c). of this final rule. In the first year of the model, we proposed that the neutral zone would apply for final performance scores below 60. As such, only upside payments and the neutral zone would exist in PY 1. We also proposed that the neutral zone in PYs 2–6 would apply for final performance scores of 41–59 (inclusive). We believe that average performance should yield no upside or downside risk payment.

We proposed at § 512.402 to define ''downside risk payment'' as a lump sum payment the IOTA participant would be required to pay to CMS after a PY if the IOTA participant's final performance score falls within the ranges specified in section III.C.6.c.(2).(b). of this final rule. We proposed that there will be no downside risk payment in the PY 1. We proposed no downside risk payment in the first PY to allow IOTA participants time to implement changes to improve performance prior to facing downside risk. In PYs 2–6, we proposed to introduce downside risk payments. We proposed that an IOTA participant's final performance score of 40 or below in PYs 2–6, would result in a downside risk payment. We believe that below average performance should yield a downside risk payment.

The performance assessment scoring method, as described in section III.C.5. of this final rule, was designed such that IOTA participants with limited experience in APMs would still be likely to achieve a sufficient final performance score that would result in no downside risk payment. For example, it is expected that most IOTA participants would earn around 30 of 60 possible points in the achievement domain. We believe that average performance should be neither rewarded nor penalized. We also considered eliminating the neutral zone and only applying upside and downside performance payments, narrowing the neutral zone score range (that is, 44–55), or applying a wider-to-narrower phased-in approach over the model performance period. We believed these alternative options would be less flexible and more penalty-focused, with some IOTA participants more likely to be penalized due to varying degrees of capabilities and capacity that would limit their ability to achieve performance targets as they progress and evolve over the model performance period. Thus, we proposed a neutral zone that would allow for more opportunities and incentives to achieve improvements over time without a large probability of downside risk.

TABLE 13. PROPOSED PERFORMANCE-BASED PAYMENTS BY FINAL PERFORMANCE SCORE

Final Performance Score	PY 1	PY 2 – 6
60-100	Upside Risk Payment	Upside Risk Payment
41-59	Neutral Zone	Neutral Zone
0 - 40	Neutral Zone	Downside Risk Payment

We sought feedback on the use of the final performance scores to determine the upside risk payment, the downside risk payment, and the neutral zone.

The following is a summary of the comments received on our proposal to use the final performance scores to determine the upside risk payment, the downside risk payment, the neutral zone and our responses:

Comment: We received multiple comments urging a delay of downside payments until PY 3 or PY 4 of the model.

Response: We believe that downside risk is an important part of testing models. We recognize the importance of transition into the model, but our thought is that the six-month starting delay, along with no downside risk in PY 1 allows for times for IOTA Participants to invest and transition into the accountability of the model, while still allowing for increased accountability in future years of the model.

Comment: A commenter noted that IOTA participants would not receive their PY 1 results until PY 2, diminishing the impact of the initial year's lack of downside risk.

Response: We understand that IOTA participants will not receive final results until into PY 2, but we know that IOTA participants are able to track their number of transplants done and their post-transplant outcomes. To help IOTA participants to better project their potential results, CMS will also share interim data reports with IOTA participants.

Comment: We received comments urging that we lower the top of the neutral zone from 60 to 50 points.

Response: In designing the scoring system, CMS wanted to make sure that performance was evaluated symmetrically, such that it would take excellent performance or performance far below what was expected to be able to get a positive or negative payment adjustment. Additionally, given the breakdown of quality points for PY 1, we believe that reaching a positive payment adjustment will be more achievable for IOTA participants to be able to earn a positive payment adjustment.

Comment: We received multiple comments recommending that we lower the points required for a downside risk adjustment, including one recommending lowering the threshold to 20 points.

Response: We considered this recommendation but decided to keep it at 40 points to balance all the different goals on the model. Given that an IOTA participant performing as expected on the achievement and efficiency domains would receive 40 points, the proposed scoring methodology is our attempt to balance the goals of being fair to IOTA participants, while also attempting to incentivize improvement on the IOTA performance metrics.

After consideration of the public comments we received, we are finalizing our proposal to use the final performance scores to determine the upside risk payment, the downside risk payment, and the neutral zone as proposed without modification at § 512.430(a). Additionally, we are finalizing as proposed the definitions of upside risk payment, and neutral zone at § 512.402 without modification. Finally, we are finalizing as proposed the definition of downside risk payment § 512.402, with a minor technical correction to include the complete cross reference to § 512.430.

(2) Apply Payment Calculation Formula to Final Performance Score

In the proposed rule at § 512.430(a), we proposed that after determining if an IOTA participant's final performance score qualifies the IOTA participant for an upside risk payment, downside risk payment, or the neutral zone, as described in section III.C.6.c(1) of this final rule, we would apply a calculation formula unique to each PY to the final performance score, as specified in sections III.C.6.c(2)(a) through (c) of this final rule.

We are finalizing this provision without modification at § 512.430(a) and direct commenters to section III.C.6.c(1) of this final rule for discussion of the methodology for determining the final performance score and the use of the final performance scores to determine the upside risk payment, the downside risk payment, and the neutral zone.

(a) Upside Risk Payment

If, in PYs 1–6, an IOTA participant's final performance score is greater than or equal to 60 points, we proposed that the IOTA participant would qualify for an upside risk payment. If an IOTA participant's final performance score would qualify them for the upside risk payment, we proposed a methodology to calculate their upside risk payment using the formula in Equation 6 below, where:

- $8,000 is a fixed, risk-based payment amount within the calculation formula, estimated to be about 33 percent of the average Medicare FFS kidney transplant MS–DRG cost. We aimed to create a strong financial incentive with significant earning opportunity for IOTA participants that meet or exceed model performance expectations. We believe this amount or proportion of the MS–DRG to be a large financial incentive to promote behavior changes while maintaining expectations of net savings to Medicare. We calibrated this based on projection of the incentive effects that would encourage the necessary support and infrastructure investment needed to achieve high performance and produce overall model savings and have the effects that we are looking for.
- The final performance score is the sum of points earned from the achievement domain, efficiency domain, and quality domain in a PY, as described in section III.C.5 of this final rule.
- Medicare kidney transplants is the number of Medicare kidney transplants furnished by the IOTA participant in a PY.

Equation 6: Proposed Upside Risk Payment Calculation Formula

$$\textit{Upside Risk Payment} = \$8{,}000 * ((\textit{Final Performance Score} - 60)/40) * \textit{Medicare Kidney Transplants}$$

We also considered calculating the maximum positive multiplier per Medicare kidney transplant claim based on the Kidney Transplant Bonus in the KCC Model. In 2019, the Kidney Transplant Bonus for entities participating in the KCC Model was set to $15,000. Adjusted for inflation, this is roughly $18,000, which would be the

maximum allowable positive bonus payment per transplant. The Kidney Transplant Bonus was originally calculated based on the difference in spending between a beneficiary who went on to get a transplant and the average ESRD beneficiary cost. However, we believed that the maximum positive adjustment may be too large in relation to current Medicare payments for kidney transplants for the model to yield net savings.

We also considered using a system similar to the Hospital VBP Program under which CMS withholds 2 percent of participating's hospitals Medicare payments and uses the sum of these reductions to fund value-based incentive payments to hospitals based on their performance under the program. However, we wished to have the opportunity for both upside and downside across IOTA participants to most effectively incentivize performance in the model.

We also considered adjusting the maximum upside multiplier in PYs 2–6; however, we felt making that decision prior to the start of the model would be premature and wish to understand IOTA participant performance before making such a decision.

We sought comment on our proposed methodology to calculate the upside risk payment and alternatives considered.

The following is a summary of the comments received on our proposed methodology to calculate the upside risk payment, alternatives considered and our responses:

Comment: We received many comments saying that the proposed payment amount was not high enough to incentivize performance in the model. Commenters pointed out a concern that they lose money on kidney transplants, based on the difference between their cost and the Medicare FFS DRG payments and that an increased number of transplants would be more likely to come from using more complex organs, which would be more expensive for the IOTA participants. Many commenters also believed that the proposed maximum upside amount of $8,000 would not be sufficient to incentivize investment by hospital leadership, particularly given that the payment amount was only proposed to be applied to Medicare FFS kidney transplants.

Response: We appreciate the feedback from commenters and recognize the validity of the concerns expressed. The IOTA Model is designed to save money for CMS, improve care for beneficiaries, to save money for Medicare, and to increase payments to IOTA participants who do more transplants. To effectively accomplish those goals, the incentives must be effectively calibrated high enough to incentivize improved performance, while still ensuring sufficient savings for CMS. We believe that applying the payment adjustments to all Medicare kidney transplants, as discussed previously will help to increase the incentives in the model and account for the changing nature of the Medicare program. Additionally, the CMS Office of the Actuary conducted additional analyses and determined that CMS would still be able to see projected savings of $22 million if the maximum upward adjustment were raised to $15,000. We considered this alternative based on the Kidney Transplant Bonus in the KCC Model, which was designed to reflect the net savings to the Medicare Trust Fund from a patient who is transplanted. Our analyses also show an average cost in 2023 of approximately $40,000 for performing MS–DRG 650, which is billed for Kidney transplants that then require hemodialysis afterwards. We recognize that many of the kidney transplants that will be performed under the IOTA Model may be for more complex organs that require hemodialysis after being transplanted and wants to recognize the increased costs to the IOTA participants for the transplant surgery and recovery when that occurs. Given that costs will grow over the course of the model period until 2030, we believe that it is appropriate to take approximately ⅓ of those costs to calculate the maximum upward adjustment, as we did for the average payment in the proposed rule, to also come up with the $15,000 figure. We proposed to keep this figure flat over the course of the model, given that it already accounts for some level of cost growth over the six-year period of the model. We will also evaluate the effects of this maximum upward adjustment and consider updating the amount based on the incentive effects and CMS savings.

Comment: We received multiple comments arguing that higher risk candidates are more expensive and are the ones who are likely to receive transplants based on the incentives in the model. Commenters urged CMS to base payment amounts on DRGs for more complex transplant surgeries given this concern.

Response: We recognize this concern from commenters and, as described in comment responses in this section, are finalizing an increased maximum upside risk payment amount of $15,000, based on the increased costs of DRG–650, which CMS projects may be necessary to be billed for the use of more complex organs.

Comment: Multiple commenters suggested that CMS should base the upward risk payment amount on the Kidney Transplant Bonus from the Kidney Care Choices Model.

Response: We recognize the validity of these comments and adjusted the amount upwards to be similar to the amount that the Innovation Center paid out in the KCC Model.

Comment: We received a comment expressing concern that the maximum upward payment amounts would not be sufficient to support IOTA collaborators, given that they would only be used by IOTA participants.

Response: We recognize the commenter's concern and believe that the increased payment amounts and increased overall payments by accounting for all Medicare kidney transplants gives the opportunity for IOTA participants to earn enough upward payments through the model to be able to support collaboration with IOTA collaborators.

Comment: We received a comment from commenters that the maximum upward adjustment should increase over the years of the model.

Response: We recognize that costs have historically risen over time and CMS payments have gone up. As a result, the updated payment amount is based on a projected rise in costs from the 2023 costs of MS–DRG 650 of $40,151. We are taking slightly more than ⅓ of that amount and keeping it as a flat rate for all six years of the model to help account for a potential rise in costs in the future. We may also re-evaluate the effects of the maximum adjustment over time based on any potential future rise in payments and the effects on the Medicare Trust Fund.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed methodology to calculate the upside risk payment upside risk payment at § 512.430(b)(1), with slight modifications. Specifically, we are making a technical correction at § 512.430(b)(1)(i) to remove the following verbiage: from 100. In the proposed rule at 89 FR 43572, we proposed that the upside risk payment would be calculated by subtracting 60 from the IOTA participant's final performance score, as outlined in Equation 2 of section III.C.6.c(2)(a) of the proposed rule. As such, we are finalizing at § 512.430(b)(1)(i) that CMS subtracts 60 from the IOTA participant's final performance score. We are also modifying our regulation at § 512.430(b)(1)(iii) to reflect a maximum upside risk payment multiplier amount of $15,000 (see Equation 7).

Lastly, we are finalizing our proposed definition of Medicare kidney transplants at § 512.402 without modification, as described and finalized in section III.C.6(b) of this final rule.

Equation 7: Upside Risk Payment Calculation Formula

$$Upside\ Risk\ Payment = \$15{,}000 * \left(\frac{Final\ Performance\ Score - 60}{40}\right) * Medicare\ Kidney\ Transplants$$

(b) Downside Risk Payment

If an IOTA participant's final performance score is at or below 40 points in PYs 2–6, the IOTA participant would qualify for a downside risk payment. If an IOTA participant qualifies for a downside risk payment, we describe the methodology to calculate their downside risk payment risk using the formula in Equation 8:

Equation 8: Proposed Downside Risk Payment Calculation Formula

*Downside Risk Payment= $2,000 * ((40 − Final Performance Score)/40) * Medicare Kidney Transplants*

- $2,000 is a fixed, risk-based payment amount within the calculation formula, estimated to be about one-twelfth, or 8 percent, of the average Medicare FFS kidney transplant MS–DRG cost. We proposed a lower downside-risk value relative to the upside-risk value proposed for the upside risk payments (about one-fourth lower) because we wanted to maintain a greater rewards approach, while still holding IOTA participants accountable for poor performance. We also believe that this approach is more flexible and accommodating to IOTA participants with no, or limited, APM experience, or that are more limited in terms of resources and capabilities.
- The final performance score is the sum of points earned from the achievement domain, efficiency domain, and quality domain, as described in section III.C.5. of this final rule.
- Medicare kidney transplants is the count of furnished Medicare kidney transplants during the PY.

We also considered applying the same fixed amount to both the upside and downside risk payment ($8,000 or $2,000 in both) or having the downside risk payment be 50 percent of the fixed amount of the upside risk payment ($4,000) but opted against it to maintain lower levels of risk given the fact that this model would be mandatory for eligible kidney hospitals. As discussed in section III.C.6.b of this final rule, we considered an upside-risk only payment framework, thus eliminating the application of downside-risk payments. Recognizing the potential for volatility in performance year-over-year, we also considered requiring IOTA participants to owe downside-risk payments to CMS if their final performance score was at or below 40 for more than one PY, starting from PY 1, potentially giving IOTA participants a similar phased-in, or, rather, ramp-up, opportunity to adjust and improve before downside-risk payments kick in. We considered this option to be unnecessary and operationally complex, particularly as it would function in a similar way as our proposed approach from a phasing-in standpoint. We also considered adjusting the $2,000 fixed, risk-based payment amount for PYs 2–6; however, we believe a fixed amount would provide greater transparency to IOTA participants on financial risk and model implementation experience would better inform if this approach would be necessary.

We sought comment on our proposed downside risk payment calculation formula, and alternatives considered.

The following is a summary of the comments received on our proposed downside risk payment calculation formula, alternatives considered, and our responses:

Comment: A couple commenters suggested that we should increase the maximum downside risk payment. To encourage greater engagement from IOTA participants who are likely to struggle, a commenter recommended two changes: (1) Lowering the proposed final performance score threshold for the downside risk payment zone in PY 2 from less than 40 points to less than 20 points, and (2) Increasing the maximum downside risk payment amount to −$4000 per Medicare kidney transplant. The commenter believed that by decreasing the likelihood of failure but increasing its consequences, CMS would ensure that only IOTA participants who actively choose not to engage would face negative repercussions. Another commenter proposed increasing the maximum downside risk payment for each Medicare kidney transplant from the proposed $2,000 to $3,750. They believed the IOTA Model incentives must be substantial enough to capture the attention of transplant hospital and health system administrators, while the downside risk payment should be high enough to motivate IOTA participants to avoid incurring it entirely.

Another commenter pointed out that IOTA participants who abstain from participating risk termination from the model and may face penalties. Specifically, under the proposed rule, terminated IOTA participants could be liable for a penalty in the PY of their termination and may have to refund any upside risk payments from previous PYs. The commenter further noted that IOTA participants could view the penalty as a low-cost way to avoid accountability in the model through 2031. The commenter also pointed out that the shrinking pool of Medicare FFS patients, has the same effect of reducing both upside risk payments and downside risk payments. Based on these concerns, the commenter urged CMS to reconsider how it calculates downside risk payments, and at minimum, to apply the same $8,000 fixed amount used in the upside risk payment calculation to the downside risk payment calculation.

Response: We thank the commenters for their suggestions. In putting downside risk in the model, we are attempting to incentivize improved performance on the IOTA metrics, while also attempting to not make the model too punitive for IOTA participants. As such, we will be finalizing the maximum downside risk payment as proposed. We will evaluate the effects of our payment methodology and may propose raising the maximum downside risk payment if we are not seeing the level of change that we are hoping for in future notice and comment rule making

Comment: A commenter urged that CMS make the proposed maximum downside risk payment proportional to the proposed maximum upside risk payment.

Response: The model was designed with asymmetric upside and downside risk in recognition of the benefits provided by transplant to the Medicare Trust Fund and the desire of CMS to not be overly punitive in a mandatory model. We plan to test out the effects of a $2,000 maximum downside risk payment to assess its effects on the metrics in the IOTA Model. Based on the results, we may consider increasing the maximum downward amount in future notice and comment rule making.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing the proposed provision for calculating the downside risk payment at § 512.430(b)(3), without modification.. We also note that we are finalizing, as proposed, the definition of Medicare kidney transplants at § 512.402 without modification, as described and finalized in section III.C.6(b) of this final rule.

(c) Neutral Zone

If, in PY 1, an IOTA participant's final performance score was below 60 points, or if, in PYs 2–6, an IOTA participant's final performance score was between 41 and 59 (inclusive), we proposed that the final performance score, as described in section III.C.6.c.(1). of this final rule, would qualify the IOTA participant for the neutral zone, where no upside risk payment or downside risk payment would apply. As such, in a PY where an IOTA participant's final performance score falls in the neutral zone, no money would be paid to the IOTA participant by CMS, nor would money be owed by the IOTA participant to CMS.

We sought comment on our proposed neutral zone.

Comment: Multiple comments urge constricting the neutral zone to make it more likely that an IOTA participant would receive a positive or negative payment adjustment.

Response: To begin the model, we plan to keep the neutral zone as designed. Our goal is to recognize both excellent performers and those that fall far below expectations and ensure that only those IOTA participants receive a positive or negative payment adjustment. We will evaluate how many IOTA participants fall into the neutral zone and consider constriction in the future.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing the neutral zone provisions at § 512.430(b)(2) as proposed without modification.

(3) Payments Operations and Timelines

After the end of each PY, CMS would assess each IOTA participant's performance in accordance with section III.C.5. of this final rule and calculate performance-based payments in accordance with the methodology specified in section III.C.6.c. of this final rule. We proposed to define this process as ''preliminary performance assessment and payment calculations.''

We proposed that CMS would conduct and calculate preliminary performance assessment and payment calculations at least 3 to 6 months after the end of each PY to allow for sufficient Medicare kidney transplant claims runout. We proposed that CMS would notify IOTA participants of their preliminary model performance assessment, including the IOTA participant's score for each metric within the achievement domain, efficiency domain, and quality domain and the final performance score, and payment calculations with respect to any applicable upside risk payment or downside risk payment, at least 5 to 9 months after the end of each PY, allowing for a two-to-three month period for CMS to conduct calculations after the claims runout period. We proposed that a 30-day notification period between preliminary and final calculations would apply, giving IOTA participants 30 days to review preliminary data and calculations and request targeted reviews, as described in section III.C.6.c.(4). of this final rule. This 30-day notification period would also be intended to provide IOTA participants with advance notice of forthcoming performance-based payments before upside risk payments or demand letters for downside risk payments would be issued by CMS. We also proposed that CMS would notify IOTA participants of their model performance assessment and payment calculations in a form and manner determined by CMS, such as letters, email, or model dashboard. We proposed that CMS would notify the IOTA participant of their final performance score and any associated upside risk payment or downside risk payment at least 30 days after notifying the IOTA participant of their preliminary model performance assessment and payment calculations.

We proposed that after CMS notifies the IOTA participant of their final performance score and any associated upside risk payment and by a date determined by CMS, CMS would issue the upside risk payment to the tax identification number (TIN) on file for the IOTA participant in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS).

We proposed that after CMS notifies the IOTA participant of their final performance score and any associated downside risk payment and by a date determined by CMS, CMS would issue a demand letter to the TIN on file in PECOS for the IOTA participant for downside risk payments owed to CMS, with a payment due date of at least 60 days after the date on which the demand letter is issued. We proposed that the demand letter would include details on model performance, the downside risk payment, and how payments would be made to CMS.

Rather than the proposed lump-sum payment and demand letter approach, we also considered making the upside risk payments and downside risk payments to IOTA participants in the form of Medicare FFS claim adjustments. The benefit of this approach would be that upside risk payments and downside risk payments, which are retrospective, would be applied prospectively and spread out over a 12-month period, so that a transplant hospital would not need to pay back to CMS a large sum of monies owed all at once. However, we believe that this approach would delay model payments and collection of monies owed to CMS. We also consider this approach to be disruptive to standard claims processing systems and operationally complex, with more opportunities for error and less flexibility to correct errors in a timely manner.

We sought comment on our proposed payment operations and timeline and alternative considered.

The following is a summary of the comments received on our proposed payment operations and timeline, alternative considered and our responses:

Comment: We received a comment approving of the payment operations timeline process.

Response: We appreciate that comment and plan to finalize as proposed.

Comment: We received a comment urging an alternative methodology for potential repayments that would allow an IOTA participant to mitigate the downside risk payments owed to CMS through an agreed upon strategy of process and performance improvement across various metrics.

Response: We see this as an interesting idea, but ultimately decided to go with the proposed strategy of repayment to recognize the large

behavioral incentives of wanting to avoid writing a check to repay CMS. We also see that this process is inherently present in the model, given that performance on model measures resets each year. We also recognize that there is no downside risk in PY 1, and we hope that any IOTA participants with a final performance score below 40 who would otherwise have had to pay downside risk payments to CMS can use that as an opportunity for process improvement to avoid having to make downside risk payments for PY 2.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing these provisions without modification at § 512.430(d). We are also finalizing the definition of preliminary performance assessment and payment calculations at § 512.402, without modification.

(4) Targeted Review

We believe that CMS calculation errors are possible, and therefore IOTA participants should be able to dispute the results of calculations.

Thus, upon receipt of CMS issued notifications of preliminary performance assessment and payment calculations, as described in section III.C.6.c(3) of this final rule, we proposed at § 512.434 that IOTA participants may appeal via a ''targeted review process,'' defined as the process in which an IOTA participant could dispute performance assessment and payment calculations made, and issued, by CMS.

We proposed at § 512.434(a) that an IOTA participant would be able to request a targeted review for one or more calculations made and issued by CMS within the preliminary performance assessment and payment calculations. We proposed at §§ 512.434(a)(1) and (2) that an IOTA participant would be able to request a targeted review for CMS consideration if—

- The IOTA participant believes an error occurred in calculations due to data quality or other issues; or
- The IOTA participant believes an error occurred in calculations due to misapplication of methodology.

We proposed at § 512.434(b)(1) that an IOTA participant would be required to submit a targeted review request within 30 days, or another time period as specified by CMS, of receiving its preliminary performance assessment and payment calculations from CMS. We also proposed at § 512.434(b)(2) that the request would require supporting information from the IOTA participant, in a form and manner specified by CMS. The 30-day window to appeal generally aligns with the length of time we have finalized for submitting appeals in other CMS models, such as the ETC Model, as well as under the Hospital VBP Program, and we believed would allow ample time for IOTA participants to separately review CMS calculations.

We proposed at § 512.434(c) that the targeted review process would not provide IOTA participants the ability to dispute policy and methodology, as it would be limited to the dispute of calculations. Specifically, we proposed at § 512.434(c)(1) that CMS would not consider targeted review requests regarding, without limitation, the following:

- The selection of the kidney transplant hospital to be an IOTA participant.
- The attribution of IOTA waitlist patients and the attribution of IOTA transplant patients to the IOTA participant, or to any other kidney transplant hospital selected for participation in the IOTA Model, or to any kidney transplant hospital not selected for participation in the IOTA Model.
- The methodology used for determining the achievement domain, efficiency domain, and quality domain.
- The methodology used for calculating and assigning points for each metric within the achievement domain, efficiency domain, and quality domain.
- The methodology used for calculating the payment amount per Medicare kidney transplant paid to an IOTA participant.

We proposed § 512.434(c)(2) that a targeted review request that includes one or more of the exclusions under § 512.434(c)(1) could still be reviewed by CMS, given that all remaining considerations of the request meet all other criteria for consideration by CMS.

Upon receipt of a targeted review request from an IOTA participant, we proposed at § 512.434(d)(1) that CMS would conduct an initial assessment and final assessment of the targeted review. We believed that this proposal would be in line with other CMS models.

The CMS targeted review initial assessment would determine if the targeted review request met the targeted review requirements and contained sufficient information to substantiate the request. If the request was not compliant with the requirements or required additional information, CMS would follow up with IOTA participants to request additional information in a form and manner determined by CMS. Any additional information that CMS requests from an IOTA participant would be due to CMS within 30 days of CMS's request, also in a form and manner determined by CMS. An IOTA participant's non-responsiveness to the request for additional information from CMS could result in the closure of the targeted review request.

In a final assessment, CMS would determine whether it erred in a calculation, as disputed by the IOTA participant.

CMS's correction of an error may delay the date of payment of an IOTA participant's upside risk payments or downside risk payments.

We stated in the proposed rule that were a calculation error to be found as a result of an IOTA participant's targeted review request, we would notify the IOTA participant within 30 days of any findings in a form and manner determined by CMS and resolve and correct the error and discrepancy in the amount of the upside risk payment or downside risk payment in a time and manner as determined by CMS.

We proposed at § 512.434(d)(2) that targeted review decisions made by CMS would be final, unless submitted by the IOTA participant or CMS for a CMS Administrator review. We also proposed to include the reconsideration determination process as outlined in proposed § 512.190 in the IOTA Model.

We noted that if an IOTA participant has regular Medicare FFS claims issues or decisions that it wishes to appeal (that is, issues during the model performance period with Medicare FFS that are unrelated to the model performance and payment calculations and payments), then the IOTA participant should continue to use the standard CMS procedures. Section 1869 of the Act provides for a process for Medicare beneficiaries, providers, and suppliers to appeal certain claims and decisions made by CMS.

We sought comment on our proposals regarding the process by which an IOTA participant could request a targeted review of CMS calculations.

The following is a summary of the comments received on our proposals regarding the process by which an IOTA participant could request a targeted review of CMS calculations and our responses:

Comment: We received a comment approving of the proposed targeted review process.

Response: We that the commenter for their support and plan to finalize these provisions as proposed.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing the provisions for the proposed targeted review process at 512.434(d) without

modification. We are also finalizing the definition of targeted review process at § 512.402, with a minor technical correction to update the cross reference.

(5) Extreme and Uncontrollable Circumstances

As we stated in the proposed rule, events may occur outside the purview and control of the IOTA participant that may affect their performance in the model (89 FR 43518). In the event of extreme and uncontrollable circumstances, such as a public health emergency, we proposed that CMS may reduce the downside risk payment, if any, prior to recoupment by an amount determined by multiplying the downside risk payment by the percentage of total months during the PY affected by an extreme and uncontrollable circumstance, by the percentage of attributed patients who reside in an area affected by the extreme and uncontrollable circumstance. We proposed to address only the downside risk payment under this policy, as we wish to mitigate the harm to entities due to extreme and uncontrollable circumstances. We considered applying this policy to upside risk payments and final performance scores in the neutral zone, but we believe that IOTA participants that have been able to achieve model success do not need to be made whole by this policy.

We proposed at § 512.436(a)(1) to apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred, and the affected areas, during the PY. We chose the Quality Payment Program to align across Innovation Center models and CMS policy. We proposed at § 512.436(a)(2) that CMS has the sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred and the percentage of attributed patients residing in affected areas for the IOTA participant.

We requested comment on our extreme and uncontrollable circumstances policy and whether the determinations by the Quality Payment Program that an extreme and uncontrollable circumstance have occurred should apply to IOTA participants.

We did not receive any comments on this policy and therefore are finalizing these provisions without modification at § 512.436.

7. Data Sharing

a. General

As discussed in the proposed rule, we expect that IOTA participants would work toward independently identifying and producing their own data, through electronic health records, health information exchanges, or other means that they believe are necessary to best evaluate the health needs of their patients, improve health outcomes, and produce efficiencies in the provision and use of services.

To assist IOTA participants in this process, we proposed to provide IOTA participants with certain beneficiary-identifiable data for their Medicare beneficiaries who are attributed patients, upon request. We anticipated that IOTA participants would use this data to better assess transplant readiness and post-transplant outcomes. We also proposed to provide certain aggregate data that has been de-identified in accordance with the HIPAA Privacy Rule, 45 CFR 164.514(b), as discussed later in this section, for the purposes of helping IOTA participants understand their progress towards the model's performance metrics.

Specifically, subject to the limitations discussed in this final rule, and in accordance with applicable law, including the HIPAA Privacy Rule, we proposed that CMS may offer an IOTA participant an opportunity to request certain Medicare beneficiary-identifiable data and reports as discussed in section III.C.7.b of this final rule. We proposed that CMS would share this beneficiary-identifiable data with IOTA participants on the condition that the IOTA participants, their IOTA collaborators, and other individuals or entities performing functions or services related to the IOTA participant's activities observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information, and comply with the terms of the data sharing agreement described in this section of the final rule.

We proposed that the beneficiary-identifiable claims data described in section III.C.7.b of this final rule would omit individually identifiable data for Medicare beneficiaries who have opted out of data sharing with the IOTA participant, as described in section III.C.7.c of this final rule. We also noted that, for the beneficiary-identifiable claims data, we would exclude information that is subject to the regulations governing the confidentiality of substance use disorder patient records (42 CFR part 2) from the data shared with an IOTA participant.

b. Beneficiary-Identifiable Data

(1) Legal Authority To Share Beneficiary-Identifiable Data

As discussed in the proposed rule, we believe that an IOTA participant may need access to certain Medicare beneficiary-identifiable data for the purposes of evaluating its performance, conducting quality assessment and improvement activities, conducting population-based activities relating to improving health or reducing health care costs, or conducting other health care operations listed in the first or second paragraph of the definition of ''health care operations'' under the HIPAA Privacy Rule, 45 CFR 164.501.

We proposed that, subject to providing the beneficiary with the opportunity to decline data sharing as described in section III.C.10.a of this final rule, and subject to having a valid data sharing agreement in place, an IOTA participant may request from CMS certain beneficiary identifiable claims for attributed patients who are Medicare beneficiaries.

As stated in section III.C.7(b)(1) of the proposed rule, we recognized there are sensitivities surrounding the disclosure of individually identifiable (beneficiary-specific) health information, and several laws place constraints on the sharing of individually identifiable health information. For example, section 1106 of the Act generally bars the disclosure of information collected under the Act unless a law (statute or regulation) permits the disclosure. Here, we noted that, in this circumstance, the HIPAA Privacy Rule would allow for the proposed disclosure of individually identifiable health information by CMS.

We noted in the proposed rule that under the HIPAA Privacy Rule, covered entities (defined in 45 CFR 160.103 as health care plans, health care providers that submit certain transactions electronically, and health care clearinghouses) are barred from using or disclosing individually identifiable health information (called ''protected health information'' or PHI) in a manner that is not explicitly permitted or required under the HIPAA Privacy Rule, without the individual's authorization (89 FR 43518). The Medicare FFS program, a ''health plan'' function of the Department, is subject to the HIPAA Privacy Rule limitations on the disclosure of PHI without an individual's authorization. IOTA participants are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they or their agents electronically engage in one or more HIPAA standard transactions, such as for claims,

eligibility or enrollment transactions. In light of these relationships, as discussed in the proposed rule, we believe that the proposed disclosure of the beneficiary-identifiable data under the IOTA Model would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for ''health care operations'' purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations purposes if both covered entities have or had a relationship with the subject of the PHI to be disclosed, the PHI pertains to that relationship, and the recipient will use the PHI for a ''health care operations'' function that falls within the first two paragraphs of the definition of ''health care operations'' in the HIPAA Privacy Rule (45 CFR 164.506(c)(4)).

The first paragraph of the definition of health care operations includes ''conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines,'' and ''population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination.'' The second paragraph of the definition of health care operations includes ''evaluating practitioner and provider performance'' (45 CFR 164.501).

Under our proposal, IOTA participants would be using the data on their patients to evaluate the performance of the IOTA participant and other providers and suppliers that furnished services to the patient, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health for their patients. When done by or on behalf of a covered entity, these are covered functions and activities that would qualify as ''health care operations'' under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. Hence, as discussed in the proposed rule, we believe that this provision is extensive enough to cover the uses we would expect an IOTA participant to make of the beneficiary-identifiable data and would be permissible under the HIPAA Privacy Rule. Moreover, our proposed disclosures would be made only to HIPAA covered entities that have (or had) a relationship with the subject of the information, the information we would disclose would pertain to such relationship, and those disclosures would be for purposes listed in the first two paragraphs of the definition of ''health care operations.'' Finally, the proposed disclosures would be limited to beneficiary-identifiable data that we believe would meet HIPAA requirements in 45 CFR 164.502(b) to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when Federal agencies maintain systems of records by which information about an individual is retrieved by use of one of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act generally prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply (5 U.S.C. 552a(b)).

As described in the proposed rule, ''routine uses'' are an exception to this general principle (89 FR 43576). A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. As we stated in the proposed rule, we believe that the proposed data disclosures are consistent with the purposes for which the data discussed in this rule was collected, and, thus, would not run afoul of the Privacy Act, provided we ensure that an appropriate Privacy Act system of records ''routine use'' is in place prior to making any disclosures. The systems of records from which CMS would share data are the Medicare Integrated Data Repository (IDR) and the Health Resources and Services Administration (HRSA) Organ Procurement and Transplantation Network (OPTN)/Scientific Registry of Transplant Recipients (SRTR) Data System. We stated in the proposed rule that we believe that the proposed data disclosures are consistent with the purposes for which the data were collected and may be disclosed in accordance with the routine uses applicable to those records.

We proposed that CMS would share the following beneficiary-identifiable lists and data with IOTA participants that have submitted a formal request for the data. Under our proposal, the request must be submitted on an annual basis in a manner and form and by a date specified by CMS. The request also would need to identify the data being requested and include an attestation that (A) the IOTA participant is requesting this beneficiary-identifiable data as a HIPAA covered entity or as a business associate, as those terms are defined at 45 CFR 160.103, to the IOTA participant's providers and suppliers who are HIPAA covered entities; and (B) the IOTA participant's request reflects the minimum data necessary for the IOTA participant to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501. In addition, we proposed that IOTA participants who request this data must have a valid and signed data sharing agreement in place, as described in more detail later in this section. We proposed that we would make available beneficiary-identifiable data as described in section III.C.8.b. of this final rule for IOTA participants to request for purposes of conducting health care operations that fall within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of their attributed patients who are Medicare beneficiaries. We explained that we believe that access to beneficiary-identifiable claims data would improve care coordination between IOTA participants and other health care providers. Patients can spend months in between their visits to the kidney transplant hospital at which they are listed, and the post-transplant period is critical to transplant success. We stated that we believe that improved care coordination would improve outcomes and keep patients engaged in their care.

We also proposed that IOTA participants limit the request for beneficiary-identifiable claims data to Medicare beneficiaries whose name appears on the quarterly attribution list who have been notified in compliance with section III.C.10.a. of the proposed rule, and who did not decline having their claims data shared with the IOTA participant, as proposed in section III.C.7.d. of the proposed rule. Finally, we proposed that CMS would share beneficiary identifiable data with an IOTA participant on the condition that the IOTA participant, its IOTA collaborators, and other individuals or entities performing functions or services related to the IOTA participant's activities, observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and comply with the terms of the data sharing agreement described in section III.C.7.f. of the proposed rule.

The following is a summary of the public comments we received on the proposal to share certain beneficiary-

identifiable data with IOTA participants and our responses:

Comment: A couple of commenters expressed support for the proposal to share certain beneficiary-identifiable data with IOTA participants. The commenters indicated that these data would enable IOTA participants to identify their patient populations, plan and improve care, and gauge the quality of post-acute care providers.

Response: We thank the commenters for their support for the proposal to share certain beneficiary-identifiable data under this model and concur with the stated benefits for IOTA participants in receiving such data.

After consideration of the comments received, we are finalizing at § 512.440 our proposals to share certain beneficiary-identifiable claims data with IOTA participants as proposed with minor technical corrections. Specifically, we made a minor technical correction at § 512.440(a) to clarify that, as stated in this section and in the proposed rule, CMS shares certain beneficiary-identifiable data as described in § 512.440(b) and certain aggregate data as described in § 512.440(c) with IOTA participants regarding attributed patients who are Medicare beneficiaries and performance under the model. We also made a minor technical correction at § 512.440(b)(3) to correct a grammatical error.

(2) Quarterly Attribution Lists

We proposed that this beneficiary-identifiable data would include, for the relevant PY, a beneficiary attribution report, shared quarterly, that would include a list of attributed patients and patients who have been de-attributed from the IOTA participant. We proposed that the report would include at least the following information for each attributed patient: the attribution year the attributed patient became attributed to the IOTA participant; the effective date of the attributed patient's attribution to the IOTA participant; the effective date of the patient's de-attribution from the IOTA participant and the reason for such removal (if applicable); and the attributed patient's data sharing preferences made pursuant to section III.C.7.d. of this final rule. We proposed that CMS may include additional information at its discretion in any of the quarterly attribution reports as data becomes available. Such data may include information from the SRTR or OPTN on waitlist status or transplant status.

We requested comment on whether such additional information would be beneficial to IOTA participants or whether this information is best accessed by the IOTA participant through other means.

We received no public comments on these proposals and therefore are finalizing this provision as proposed to provide quarterly attribution lists to IOTA participants at § 512.440(b)(5)(i), without modification.

(3) Beneficiary-Identifiable Claims Data

In section III.C.7(b)(3) of the proposed rule, we proposed to offer certain beneficiary-identifiable claims data to IOTA participants no later than one month after the start of each PY, in a form and manner specified by CMS. We proposed that IOTA participants may retrieve this data at any point during the relevant PY and that it would include, at a minimum—

- Three years of historical Parts A, B, and D claims data files for attributed patients who are Medicare beneficiaries for 36 months immediately preceding the effective date of the Medicare beneficiary's attribution to the IOTA participant;
- Monthly Parts A, B, and D claims data files specified for attributed patients who are Medicare beneficiaries; and
- Monthly Parts A, B, and D claims data files for Medicare beneficiaries who have been de-attributed from the IOTA participant for claims with a date of service prior to the date the Medicare beneficiary was removed from attribution to the IOTA participant.

We proposed that CMS would omit from the beneficiary-identifiable claims data any substance use disorder patient records subject to 42 U.S.C. 290dd–2 and the implementing regulations at 42 CFR part 2.

We stated that we believe these data elements would consist of the minimum data element necessary for IOTA participants to effectively manage the care of Medicare beneficiaries who are attributed patients. Specifically, this data would allow IOTA participants to coordinate care across the continuum as Medicare beneficiaries who are attributed patients transition from IOTA waitlist patients to IOTA transplant patients.

We requested comments on this proposal to share beneficiary-identifiable claims data with IOTA participants at § 512.440(b)(5)(ii).

The following is a summary of the public comments we received on the proposal to share beneficiary-identifiable claims data with IOTA participants and our responses:

Comment: A few commenters expressed support for the proposal to share certain beneficiary-identifiable claims data with IOTA participants. A commenter indicated that more data delivered more frequently to ensure timely opportunity to influence performance would be more beneficial.

Response: We thank the commenters for their support for the proposal to share certain beneficiary-level data under this model and will strive to deliver data to IOTA participants in a timely manner to assist in their performance under the model. We have committed to a minimum data set and this specific frequency to allow for potential operational challenges or delays.

After consideration of the comments received, we are finalizing our regulation at § 512.440 (b)(5)(ii) to share certain beneficiary-identifiable claims data with IOTA participants, without modification.

c. Minimum Necessary Data

We proposed IOTA participants must limit their beneficiary-identifiable data requests to the minimum necessary to accomplish a permitted use of the data. We proposed the minimum necessary Parts A and B data elements may include, but are not limited to, the following data elements:

- Medicare beneficiary identifier (ID).
- Procedure code.
- Gender.
- Diagnosis code.
- Claim ID.
- The from and through dates of service.
- The provider or supplier ID.
- The claim payment type.
- Date of birth and death, if applicable.
- Tax Identification Number (TIN).
- National Provider Identification (NPI).

We proposed the minimum necessary Part D data elements may include, but are not limited to, the following data elements:

- Beneficiary ID.
- Prescriber ID.
- Drug service date.
- Drug product service ID.
- Quantity dispensed.
- Days supplied.
- Brand name.
- Generic name.
- Drug strength.
- TIN.
- NPI.
- Indication if on formulary.
- Gross drug cost.

We requested comment and feedback on the minimum beneficiary-identifiable claims data necessary for IOTA participants to request for purposes of conducting permissible health care operations purposes under this model.

We received no public comments on our proposed provisions regarding the minimum beneficiary-identifiable claims data necessary for IOTA participants to request for purposes of conducting permissible health care operations under this model. Thus, we are finalizing the proposed provisions at § 512.440(b)(ii)(6), without modification.

d. Medicare Beneficiary Opportunity To Decline Data Sharing

As described in section III.C.10.a. of this final rule, we proposed that Medicare beneficiaries must receive notification about the IOTA Model. We also proposed that Medicare beneficiaries must be given the opportunity to decline claims data sharing, and instructions on how to inform CMS directly of their preference.

We proposed that Medicare beneficiaries would be notified about the opportunity to decline claims data sharing through the proposed notifications discussed in section III.C.10.a. of this final rule. We proposed that these notifications must state that the IOTA participant may have requested beneficiary identifiable claims data about the Medicare beneficiary for purposes of its care coordination and quality improvement work and/or population-based activities relating to improving health or reducing health care costs, and inform the Medicare beneficiary how to decline having his or her claims information shared with the IOTA participant in the form and manner specified by CMS. We proposed that Medicare beneficiary requests to decline claims data sharing would remain in effect unless and until a beneficiary subsequently contacts CMS to amend that request to permit claims data sharing with IOTA participants.

As discussed in the proposed rule (89 FR 43577), we proposed that Medicare beneficiaries may not decline to have the aggregate, de-identified data proposed in section III.C.7.f. of the proposed rule shared with IOTA participants. We also proposed that Medicare beneficiaries may not decline to have the initial attribution lists, quarterly attribution lists, or annual attribution reconciliation list as proposed in section III.C.4.b.(2)., b.(3). and b.(4). of this final rule shared with IOTA participants. We noted that, in accordance with 42 U.S.C. 290dd–2 and its implementing regulations at 42 CFR part 2, CMS would not share beneficiary identifiable claims data relating to the diagnosis and treatment of substance use disorders under this model.

In section III.C.7(d) of the proposed rule, we noted that the proposed opt out provisions discussed in this section would relate only to the proposed sharing of beneficiary-identifiable data between the Medicare program and the IOTA participant under the IOTA Model, and were in no way intended to impede existing or future data sharing under other authorities or models.

We requested comment and feedback on our proposed policies to enable Medicare beneficiaries to decline data sharing under the model.

We received no comments on this proposal and therefore are finalizing the proposed provisions to allow Medicare beneficiaries to decline data sharing at § 512.440(b)(ii)(7), without modification.

e. Data Sharing Agreement

(1) General

As noted in section III.C.7.a. of this final rule, we proposed that, prior to receiving any beneficiary-identifiable data, IOTA participants would be required to first complete, sign, and submit—and thereby agree to the terms of—a data sharing agreement with CMS. We proposed that under the data sharing agreement, the IOTA participant would be required to comply with the limitations on use and disclosure that are imposed by HIPAA, the applicable data sharing agreement, and the statutory and regulatory requirements of the IOTA Model. We also proposed that the data sharing agreement would include certain protections and limitations on the IOTA participant's use and further disclosure of the beneficiary-identifiable data and would be provided in a form and manner specified by CMS. Additionally, we proposed that an IOTA participant that wishes to retrieve the beneficiary identifiable-data would be required to complete, sign, and submit to CMS a signed data sharing agreement at least annually. We stated that we believe that it is important for the IOTA participant to complete and submit a signed data sharing agreement at least annually so that CMS has up-to-date information that the IOTA participant wishes to retrieve the beneficiary-identifiable data and information on the designated data custodian(s). As described in greater detail later in this section, we proposed that a designated data custodian would be the individual(s) that an IOTA participant would identify as responsible for ensuring compliance with all privacy and security requirements and for notifying CMS of any incidents relating to unauthorized disclosures of beneficiary-identifiable data.

As described in section III.C.7.e(1) of the proposed rule, CMS believes it is important for the IOTA participant to first complete and submit a signed data sharing agreement before it retrieves any beneficiary-identifiable data to help protect the privacy and security of any beneficiary-identifiable data shared by CMS with the IOTA participant. We noted that there are important sensitivities surrounding the sharing of this type of individually identifiable health information, and CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with IOTA participants would be further protected in an appropriate fashion.

We solicited public comment on our proposal to require that the IOTA participant agree to comply with all applicable laws and terms of the data sharing agreement as a condition of retrieving beneficiary-identifiable data, and on our proposal that the IOTA participant would need to submit the signed data sharing agreement at least annually if the IOTA participant wishes to retrieve the beneficiary-identifiable data.

The following is a summary of the public comments we received on the proposals to define the IOTA data sharing agreement, to require compliance with the terms of the IOTA data sharing agreement as a condition of retrieving the beneficiary-identifiable data, and to require submission of the IOTA data sharing agreement at least annually, and our responses to these comments:

Comment: A couple commenters expressed support and appreciation for the proposed protections surrounding the sharing of beneficiary-identifiable data with IOTA participants. A commenter reiterated that any data sharing should be conducted in a manner that protects patient privacy and allows all points of care to maximize lessons learned and implement quality improvement activities. A commenter expressed concern with prohibiting disclosures to an individual practitioner in a treatment relationship with the attributed patient who is a Medicare beneficiary, or that practitioner's business associates.

Response: We thank the commenters for their support and agree that appropriate protections must be ensured in the sharing of beneficiary-identifiable data. We are finalizing that the data sharing agreement will include a provision prohibiting any further disclosure, not otherwise required by law, of the beneficiary-identifiable data to anyone who is not a HIPAA covered entity or business associate, as defined

in 45 CFR 160.103, or who is not an individual practitioner in a treatment relationship with the attributed patient who is a Medicare beneficiary, or that practitioner's business associates. Therefore, this provision would not prohibit data sharing with a covered entity or its business associate for treatment purposes. Such a prohibition would be similar to that imposed by CMS in other models tested under section 1115A of the Act, such as the KCC Model, in which CMS shares certain beneficiary-identifiable data with model participants for their health care operations.

CMS will include this prohibition in the data sharing agreement because there exist important legal and policy limitations on the sharing of the beneficiary-identifiable data and must carefully consider the ways in which and reasons for which CMS would provide access to this data for purposes of the IOTA Model.

After consideration of the comments received, for the reasons set forth in this rule, we are finalizing at § 512.440(b)(8) the provisions of the data sharing agreement as an agreement entered into between the IOTA participant and CMS that includes the terms and conditions for any beneficiary-identifiable data shared with the IOTA participant under § 512.440, without modification. In addition, we are finalizing at § 512.440(b)(8)(i) the proposal that the IOTA participant would need to submit the signed IOTA data sharing agreement at least annually if the IOTA participant wishes to retrieve the beneficiary-identifiable data from CMS.

We are also finalizing at § 512.440(b)(8)(ii) the proposed requirement that the IOTA participant agree to comply with all applicable laws and the terms of the IOTA data sharing agreement as a condition of retrieving the beneficiary-identifiable data.

(2) Content of the Data Sharing Agreement

We proposed that CMS would share the following beneficiary-identifiable data with IOTA participants that have requested the data and have a valid data sharing agreement in place, as described in more detail later in this section. We proposed that an IOTA participant that wishes to receive beneficiary-identifiable data for its attributed patients who are Medicare beneficiaries must also agree to certain terms, namely: (1) to comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations at 45 CFR part 160 and part 164, subparts A and E, and the requirements of the proposed IOTA Model; (2) to comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the data sharing agreement; (3) to contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the IOTA participant, including all IOTA collaborators, to the same terms and conditions with the IOTA participant is itself bound in its data sharing agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data retrieved by the IOTA participant under the IOTA Model; and (4) that if the IOTA participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may: (A) deem the IOTA participant ineligible to retrieve the beneficiary-identifiable data under paragraph (b) of this section for any amount of time; (B) terminate the IOTA participant's participation in the IOTA Model under § 512.466; and (C) subject the IOTA participant to additional sanctions and penalties available under the law.

We stated in the proposed rule that CMS believes these proposed terms for sharing beneficiary-identifiable data with IOTA participants are appropriate and important, as CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with IOTA participants would be further protected by the IOTA participant, and any business associates of the IOTA participant, in an appropriate fashion.

CMS sought public comment on the additional privacy, security, breach notification, and other requirements that we would include in the data sharing agreement. CMS has these types of agreements in place as part of the governing documents of other models tested under section 1115A of the Act and in the Medicare Shared Savings Program. In these agreements, CMS typically requires the identification of data custodian(s) and imposes certain requirements related to administrative, physical, and technical safeguards relating to data storage and transmission; limitations on further use and disclosure of the data; procedures for responding to data incidents and breaches; and data destruction and retention. These provisions would be imposed in addition to any restrictions required by law, such as those provided in the HIPAA privacy, security, and breach notification regulations. We noted that these data sharing agreement provisions would not prohibit the IOTA participant from making any disclosures of the data otherwise required by law.

CMS also sought public comment on what specific disclosures of the beneficiary identifiable data might be appropriate to permit or prohibit under the data sharing agreement. For example, we stated that CMS was considering prohibiting, in the data sharing agreement, any further disclosure, not otherwise required by law, of the beneficiary-identifiable data to anyone who is not a HIPAA covered entity or business associate, as defined in 45 CFR 160.103, or to an individual practitioner in a treatment relationship with the attributed patient who is a Medicare beneficiary, or that practitioner's business associates. Such a prohibition would be similar to that imposed by CMS in other models tested under section 1115A of the Act in which CMS shares certain beneficiary-identifiable data with model participants for their health care operations.

We noted in the proposed rule that CMS is considering these possibilities because there exist important legal and policy limitations on the sharing of the beneficiary-identifiable data and CMS must carefully consider the ways in which and reasons for which we would provide access to this data for purposes of the IOTA Model. We stated that CMS believes that some IOTA participants may require the assistance of business associates, such as contractors, to perform data analytics or other functions using this beneficiary-identifiable data to support the IOTA participant's review of their care management and coordination, quality improvement activities, or clinical treatment of IOTA beneficiaries. CMS also believes that this beneficiary-identifiable data may be helpful for any HIPAA covered entities who are in a treatment relationship with the IOTA beneficiary.

We sought public comment on how an IOTA participant might need to, and want to, disclose the beneficiary-identifiable data to other individuals and entities to accomplish the goals of the IOTA Model, in accordance with applicable law.

Under our proposal, the data sharing agreement would include other provisions, including requirements regarding data security, retention, destruction, and breach notification. For example, as stated in section III.C.7 of the proposed rule, we were considering including, in the data sharing agreement, a requirement that the IOTA

participant designate one or more data custodians who would be responsible for ensuring compliance with the privacy, security and breach notification requirements for the data set forth in the data sharing agreement; various security requirements like those found in participation agreements for other models tested under section 1115A of the Act, but no less restrictive than those provided in the relevant Privacy Act system of records notices; how and when beneficiary-identifiable data could be retained by the IOTA participant or its downstream recipients of the beneficiary-identifiable data; procedures for notifying CMS of any breach or other incident relating to the unauthorized disclosure of beneficiary-identifiable data; and provisions relating to destruction of the data. We stated that these are only examples and are not the only terms CMS would potentially include in the data sharing agreement.

We solicited public comment on this proposal to impose certain additional requirements in the IOTA data sharing agreement related to privacy, security, data retention, breach notification, and data destruction.

We received no comments on this proposal and therefore are finalizing these proposed provisions at § 512.440(b)(8), without modification.

f. Aggregate Data

We proposed that CMS would share certain aggregate performance data with IOTA participants in a form and manner to be specified by CMS. This aggregate data would be de-identified in accordance with HIPAA requirements at 45 CFR 164.514(b) and would include, when available, transplant target data.

We proposed that, for the relevant PY, CMS would provide aggregate data to the IOTA participant detailing the IOTA participant's performance against the transplant target, as described in section III.C.5.c.(2). of this final rule.

We sought comment and feedback on our proposal to share aggregate data with IOTA participants.

We received no comments on this proposal and therefore are finalizing the proposed provisions at § 512.440(c) without modification.

8. Other Requirements

a. Transparency Requirements

(1) Publication of Patient Selection Criteria for Kidney Transplant Evaluations

Transplant hospitals are currently required to use written patient selection criteria in determining a patient's suitability for placement on the waitlist or a patient's suitability for transplantation per the CoP (see 42 CFR 482.90). If the transplant hospital performs living donor transplants, the transplant hospital must use written donor selection criteria to determine the suitability of candidates for donation.[289] The patient selection criteria must ensure fair and non-discriminatory distribution of organs, and the program must document in the patient's medical record the patient selection criteria used.[290] Prior to placement on the transplant hospital's waitlist, a prospective transplant candidate must receive a psychosocial evaluation, if possible.[291] Before a transplant hospital places a transplant candidate on its waitlist, the candidate's medical record must contain documentation that the candidate's blood type has been determined.[292] In addition, when a patient is placed on a hospital's waitlist or is selected to receive a transplant, the transplant hospital must document in the patient's medical record the patient selection criteria used.[293] Currently, the transplant hospital must also provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by the patient or a dialysis facility. For living donor selection, the transplant hospital's living donor selection criteria must be consistent with the general principles of medical ethics.[294] [295] Transplant hospitals must also ensure that a prospective living donor receives a medical and psychosocial evaluation, document in the living donor's medical records the living donor's suitability for donation, and document that the living donor has given informed consent.[296]

Available data and studies demonstrate that disparities exist for patients in underserved communities who seek or are referred for, or are evaluated for a transplant and who eventually are placed on a transplant waitlist and receive an organ transplant (89 FR 43579).[297] For instance, the data has shown that White patients are more likely than Black patients to be referred for organ transplant, while Black patients are less likely than White patients to be referred for transplant evaluation.[298] Racial disparities also exist in transplant wait listing, even after correcting for SDOH.[299] In addition, there are sex and gender disparities in access to the kidney transplant waitlist, with men more likely to have access compared to women.[300] Finally, a recent article in the Journal of the American Medical Association considers how transplant programs factor patient financial resources into waitlist decisions.[301] The authors' review of several studies suggested that socioeconomically deprived patients were proportionally less likely to be selected for placement on a waitlist for an organ transplant. They suggested, based on the strong and consistent associations between race and poverty, that ''withholding transplants from those with inadequate financial resources equates to an example of structural racism in the health care system.'' We refer readers to the numerous additional studies regarding disparities in organ transplantation and organ donation that are cited throughout the final rule.

In section III.C.8.a(1) of the proposed rule, to improve transparency for those looking to gain access to a transplant waitlist in the transplant program evaluation processes, we proposed to require IOTA participants to publicly post, on a website, their patient selection criteria for evaluating patients for addition to their kidney transplant waitlist by the end of PY 1. We proposed to finalize this requirement only if it is not redundant with other

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[289] *https://www.ecfr.gov/current/title-42/section-482.90.*

[290] Ibid.

[291] Ibid.

[292] Ibid.

[293] Ibid.

[294] OPTN. (n.d.). *OPTN Policies—Living Donation, Chapter 14. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.*

[295] AMA Council on Ethical and Judicial Affairs. (2019). AMA Code of Medical Ethics' Opinions on Organ Transplantation. *AMA Journal of Ethics, 14*(3), 204–214. *https://doi.org/10.1001/virtualmentor.2012.14.3.coet1-1203.*

[296] *https://www.ecfr.gov/current/title-42/section-482.90.*

[297] Park, C., Jones, M.-M., Kaplan, S., Koller, F.L., Wilder, J.M., Boulware, L.E., & McElroy, L.M. (2022). A scoping review of inequities in access to organ transplant in the United States. International Journal for Equity in Health, 21(1). *https://doi.org/10.1186/s12939-021-01616-x.*

[298] Epstein, A.M., Ayanian, J.Z., Keogh, J.H., Noonan, S.J., Armistead, N., Cleary, P.D., Weissman, J.S., David-Kasdan, J.A., Carlson, D., Fuller, J., Marsh, D., & Conti, R.M. (2000). Racial Disparities in Access to Renal Transplantation—Clinically Appropriate or Due to Underuse or Overuse? *New England Journal of Medicine, 343*(21), 1537–1544. *https://doi.org/10.1056/nejm200011233432106.*

[299] Ng, Y.-H., Pankratz, V.S., Leyva, Y., Ford, C.G., Pleis, J.R., Kendall, K., Croswell, E., Dew, M.A., Shapiro, R., Switzer, G.E., Unruh, M.L., & Myaskovsky, L. (2019). Does Racial Disparity in Kidney Transplant Wait-listing Persist After Accounting for Social Determinants of Health? *Transplantation,* 1. *https://doi.org/10.1097/tp.0000000000003002.*

[300] Ahern, Patrick et al. Sex Disparity in Deceased-Donor Kidney Transplant Access by Cause of Kidney Disease. 2021. *Clinical Journal of the American Society of Nephrology.* 16 (2) 241–250, *https://cjasn.asnjournals.org/content/16/2/241.*

[301] Wadhwani, S.I., Lai, J.C., & Gottlieb, L.M. (2022). Medical Need, Financial Resources, and Transplant Accessibility. *JAMA, 327*(15), 1445. *https://doi.org/10.1001/jama.2022.5283.*

HHS guidance. We also considered requiring that IOTA participants update their selection criteria at a certain frequency to ensure that attributed patients have the most up to date information. However, we are unsure what cadence of update would be most appropriate.

We solicited public comments on this proposal and on how often the selection criteria should be updated by the IOTA participant.

The following is a summary of the comments received on our proposal to require IOTA participants to publicly post their patient selection criteria for kidney transplant waitlist candidates on a website and the frequency at which updating this information should occur and our responses:

Comment: Many commenters stated they support the publication of patient selection criteria for kidney transplant evaluations. A commenter specified that it could help reduce distrust around organ transplant decisions.

Response: We thank the commenters for their support. We agree that posting patient selection criteria for evaluating patients for addition to a waitlist will help reduce distrust about organ transplant decisions.

Comment: A commenter suggested that patient selection criteria should be posted in common languages of the local community and that any written materials be delivered in patients' preferred language.

Response: We thank the commenter for their suggestion. We agree that public facing patient selection criteria for evaluating patients for addition to a waitlist should be made available in local languages and should be compliant with regulations requiring patients to have written information in their preferred language.

Comment: Numerous commenters were concerned about the impact of publicly posted patient selection criteria on their patients. A commenter was concerned that overwhelming patients with selection criteria published on a public-facing website is not patient-centered, does not promote autonomy and impacts the patient-provider relationship. Similarly, a commenter conveyed their concern that there is a significant risk of misinterpretation of the selection criteria by referring providers in the community and patients, which may decrease referrals. Additionally, a commenter was concerned that public disclosure of waitlist selection criteria that only applies to IOTA participants, does not help patients who may live in a region with access to more than one kidney transplant hospital.

Response: We thank the commenters for their responses and concerns. We believe that providing patient selection criteria for evaluating patients for addition to a waitlist publicly creates transparency for both patients and for their referring nephrologists. Referring nephrologists have more patient contact than a transplant nephrologist at time of referral, and therefore are key in referring patients for kidney transplant evaluation and in having the ability to guide the patient to the kidney transplant hospital that may be most ideal for the patient. With the overwhelming amount of information that a kidney transplant patient learns during their multi-hour initial transplant evaluation, we believe that resources to encourage early transplant discussions between a referring nephrologist and patient can create opportunities for a more fruitful evaluation experience for the patient. This may also open communication between transplant nephrologists and referring nephrologists. We agree that potential transplant candidates and selection criteria can be extremely complex and vary on a case-by-case basis; however, we believe that providing general expectations for kidney transplant candidacy is by no means unreasonable and can make the evaluation process more efficient. For example, if a kidney transplant hospital will definitively not transplant a patient with a certain co-morbidity, whereas another kidney transplant hospital may, this can be extremely helpful for a patient to know before taking off from work or a dialysis session and organizing transportation or both for a kidney transplant hospital that is hundreds of miles away. Sometimes it may take months to schedule specialist visits or preventative health screenings, needed for transplant waitlisting. Listing selection waitlist criteria can help patients anticipate what appointments they may need to schedule. We understand there are ''gray'' areas of candidacy and subsequently have not created prescriptive requirements for patient selection lists.

Public-facing patient selection criteria for evaluating patients for addition to a waitlist allows patients to understand general expectations earlier in their transplant evaluation journey, ensures keeping criteria up to date, and provides greater access and autonomy to patients. While non-participants of the IOTA Model are not mandated by this requirement, we suggest that other kidney transplant hospitals follow suit.

Comment: A commenter was concerned that public posting of kidney transplant waitlist selection criteria policy is redundant since it is already available publicly through groups such as CMS, HRSA, UNOS and OPTN.

Response: We thank the commenter for their concern. While 42 CFR 482.90 already requires documentation of selection criteria within the patient's medical record upon placement on the waiting list, it does not specify the need for publicly posting patient selection criteria decisions.[302] Currently, there is not a centralized site listing all transplant programs' selection criteria. Patients have access to their medical records through patient portals or can alternatively access a hard copy of their records by request. We believe it is also important that the patient has access to this information before the visit. We also believe that public facing listing criteria provides greater access to patients who may not be able to easily access their patient portal, reducing disparities.

Comment: A commenter suggested that CMS would need to closely monitor this transparency requirement and penalize IOTA participants that do not comply.

Response: Thank you for your responses regarding monitoring for compliance. We agree that long term there will need to be monitoring and auditing to ensure that IOTA participants are compliant with listing their selection criteria. We are hopeful to receive further feedback throughout and after PY 1 to modify this requirement to be as specific as is reasonable to ensure compliance. Additionally, we are hopeful that there is opportunity to have a collective site, which would feature all IOTA participants' selection criteria on one website.

Comment: A couple of commenters were concerned by the differences in self-reported listing criteria versus characteristics of patients that are ultimately listed. One of these commenters recommended that CMS focus on the data of waitlist patients. A commenter stated that CMS should also consider the differences in the criteria for accepting a referral, evaluating the patient, and listing the patient.

Response: We thank the commenters for their feedback. We recognize there are limitations in mandating public posting of selection criteria and that there is discordance between self-reported kidney transplant hospital listing criteria and the actual characteristics of their listed patients for transplant. While we acknowledge that

[302] *https://www.ecfr.gov/current/title-42/section-482.90.*

it may be challenging to package numerous patient co-morbidities into an easily digestible and reasonable list of selection criteria, we believe that exercising a requirement to bring transparency to selection criteria will also assist kidney transplant hospitals in tailoring those criteria and be as specific as possible. To avoid deterring referrals of possible transplants, we have not considered posting referral requirements at this time and will not do so without further consideration and input from the transplant community. We do, however, believe it would be greatly beneficial for kidney transplant hospitals to outline the difference between referral, evaluation and listing on their website and additionally review this information during every patient's transplant evaluation visit.

Comment: A couple of commenters included their support for the development of a centralized, standardized way to present information about transparency requirements such as selection criteria and bypass filters. A commenter further recommended that patient education surrounding this transparency information should be created by a centralized group (such as OPTN or SRTR) to reduce kidney transplant hospital burdens.

Response: We agree that a centralized location for waitlist selection criteria and organ offer acceptance criteria would be ideal and are hopeful that the transplant community can move toward a database that is accessible to patients and providers or both that will provide this information; however, we do not believe that this is necessary for PY 1 for IOTA participants. We believe it is reasonable and not overly burdensome to request IOTA participants to post their selection criteria on their website. We intend to continue discussions about a centralized database for patient waitlist selection criteria and will consider this for future rulemaking,

Comment: A commenter suggested that IOTA participants should be required to conduct targeted outreach to non-citizens and other underserved communities to provide clarifications and education on transplant.

Response: We appreciate the commenter's feedback. We believe it is in the purview of individual IOTA participants to have outreach events to serve their community. Currently the IOTA Model does not outline the topic of educational outreach; however, we will take this comment into consideration for future rulemaking since patient education is extremely important throughout the continuum of kidney care and is needed to expand equal access to transplant. Additionally, please note that community outreach would be a potential opportunity for IOTA participant to consider as part of the voluntary health equity plans in the IOTA Model, as reviewed in section III.C.8.c of this final rule.

Comment: A commenter requested that CMS provide flexibility regarding the frequency of updating waitlist selection criteria. A couple of commenters were concerned with balancing accurate information with resource burden.

Response: We appreciate the commenter's response regarding frequency of waitlist criteria updates and type of information included. Beyond requirements previously outlined in 42 CFR 482.90, we have not provided specific requirements that IOTA participants must include regarding listing practices.[303] We do, however, expect and trust that IOTA participants are acting in good faith to provide accurate waitlisting criteria and specific details, when possible. While we did not propose a specific cadence as to how frequently IOTA participants should be required to update their selection criteria after PY 1, we will take these comments into consideration during future rulemaking. We do not believe that requesting a public online posting about patient waitlist selection criteria by the end of PY 1, is overly burdensome to IOTA participants, as IOTA participants are already expected to provide these criteria in patient waitlist documentation. We are finalizing this requirement as originally proposed in section III.C.8.a(1) of the proposed rule, for PY 1, without modification.

Comment: A commenter suggested that waitlist selection criteria should include specific details such as absolute contraindications of IOTA participants (for example, BMI limits), whether there are financial reserve requirements, and if other factors such as psychiatric or psychosocial factors impact listing.

Response: We thank the commenters for their recommendations. Beyond requirements previously outlined in 42 CFR 482.90, CMS has not provided specific requirements that IOTA participants must include regarding listing practices.[304] We do believe, though, that if IOTA participants have a list of absolute versus relative contraindications for their patients, it would be beneficial to make patients and referring nephrologists aware of these concerns.

While we agree that it could be helpful for patients to understand specific psychosocial and psychiatric requirements, we believe that this could be challenging given the multidimensional evaluation that is completed during transplant evaluation and the complexity of understanding each individual's situation. Additionally, psychiatric and psychosocial diagnoses can be fluid, and we would not want to discourage patients from transplant evaluation, particularly since they may learn about helpful resources during the evaluation. A goal of the IOTA Model is to reduce disparities in kidney transplant, and we believe that listing granular psychosocial or psychiatric requirements could be contradictory to these goals.

Listing specific financial requirements could be helpful if transplant programs have absolute cutoffs for transplant recipients; however, if patients do not initially meet financial requirements, transplant program resources (financial counselor, social workers) may be able to help that patient create a financial plan to meet that requirement. We will take this comment into consideration for future iterations of the IOTA Model and encourage additional feedback from kidney transplant hospitals during PY 1.

Comment: A commenter suggested it may be easier if CMS created a list of criteria that each IOTA participant needs to address in the selection criteria.

Response: We thank you for your comment. As previously mentioned in section III.C.8.a.(1) of this final rule, 42 CFR part 428.90 does outlines basic requirements for kidney transplant evaluation.[305] Currently, we believe that being prescriptive beyond these requirements prevents kidney transplant providers and kidney transplant hospitals from creating selection criteria applicable to risk level they believe is appropriate based on their resources and their community. We believe that including referring nephrologists in conversations regarding specific listing criteria could be helpful, however, we are not mandating this.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing the requirement that IOTA participants must publicly post their patient selection waitlist criteria on a website by the end of PY 1 at § 512.442(a), without modification. We intend to use

[303] *https://www.ecfr.gov/current/title-42/section-482.90.*

[304] *https://www.ecfr.gov/current/title-42/section-482.90.*

[305] *https://www.ecfr.gov/current/title-42/section-482.90.*

future rulemaking to determine the cadence of updating this website and patient selection criteria. For IOTA participants who choose to post their patient selection criteria for evaluating patients for addition to their kidney transplant waitlist early in the PY 1, we also encourage them to update their criteria again, should it change throughout the year.

(2) Transparency Into Kidney Transplant Organ Offers

As discussed in section III.C.8.a(2) of the proposed rule, those active on a kidney transplant waitlist may receive organ offers at any time. However, there is currently no requirement for providers to discuss organ offers with their patients. A provider may decline an organ offer for any number of reasons; however, declining without disclosing the rationale with the patient may miss an important opportunity for shared decision-making.

In section III.C.8.a(2) of the proposed rule, we proposed to add requirements to increase transparency for IOTA waitlist patients who are Medicare beneficiaries regarding the volume of organ offers received on their behalf while on the waitlist. Specifically, we proposed that for each month an organ is offered for an IOTA waitlist patient who is a Medicare beneficiary, an IOTA participant must inform the Medicare beneficiary, on a monthly basis, of the number of times an organ is declined on the Medicare beneficiary's behalf and the reason(s) for the decline. We are not proposing to prescribe the method of this notification but would require that the medical record reflect that the patient received this information and the method by which it was delivered (for example, mail, email, medical appointment, internet portal/dashboard, etc.). We proposed that this information must be shared with the IOTA waitlist patient who is a Medicare beneficiary, and should be shared, where deemed appropriate, with their nephrologist or nephrology professional, to provide the opportunity for questions and clarification of information.

Organ offer filters are a tool that transplant programs can use to bypass organ offers they would not accept. Offer filters were tested during two pilot programs and released nationally in January 2022.[306] In section III.C.8.a(2) of the proposed rule, we proposed that IOTA participants would be required to review transplant acceptance criteria and organ offer filters with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist. We proposed that this review may be done on an individual basis in a patient visit, via phone, email, or mail. We believed that sharing this information with the patient would offer an opportunity for shared decision-making between the patient and IOTA participants and may increase the patient's quality of care. We proposed that Medicare beneficiaries would be able to decline this review with the IOTA participant, as some may not wish to have this information. We anticipated that the Medicare beneficiary may decline this review during their next provider visit or over the phone.

We solicited public comment on whether an alternative frequency of sharing of organ offers with the Medicare beneficiary is more appropriate. We also solicited comment on whether there is a more suitable timeframe and frequency for addressing acceptance criteria with attributed patients. Per 42 CFR 482.94(c), and 482.102(a) and (c), kidney transplant hospitals currently review these criteria with patients upon patient request. Our goal was to provide a balance of transparency and patient engagement in this process without being overly prescriptive or burdensome. We also recognized that there are beneficiaries on the waitlist who may not be eligible to receive an organ offer for multiple years, so we sought feedback on whether this requirement should be limited to beneficiaries who have received or are likely to receive an organ offer in the next year.

The following is a summary of comments we received on our proposal to (1) require monthly notifications to Medicare beneficiaries receiving organ offers who are IOTA waitlist patients about number of organs declined and the rationale for the decline and to (2) require review of transplant acceptance criteria and organ offer filters with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist and our responses:

Comment: Commenters expressed concern about the proposed transparency into kidney transplant organ offers provision, which would require IOTA participants to inform, on a monthly basis, IOTA waitlist patients who are Medicare beneficiaries of the number of times an organ is declined on the patient's behalf and the reason(s) for the decline. Specifically, commenters felt this would impose a significant administrative burden on IOTA participants. Some of these commenters were concerned that notifying waitlisted Medicare patients of organ offer declines and the reasons for those declines would be burdensome, costly, and of questionable value. This was seen as at odds with the IOTA Model's quality and efficiency domain goals and was seen as disproportionately burdensome to smaller transplant hospitals. Commenters also noted that the provision does not account for the clinical and administrative resources needed to review the high volume of organ declines across all waitlisted individuals. This could divert resources away from patient care. Furthermore, a commenter stated that patient care groups are more interested in data on time-to-transplant and likelihood of receiving a transplant, which are already publicly available.

Response: We thank the commenters for their concerns. Due to the many concerns received, we recognize that monthly notification to Medicare beneficiaries regarding volume and reason for organ decline could be very burdensome to IOTA participants and their staff in PY 1 since this is a new initiative and there is not current infrastructure or database resources to aid in minimizing burden on IOTA participants. We believe we need more time to better identify how we can increase transparency of the organ offer process for transplant recipients with the help of the transplant community. Minimizing administrative burden for kidney transplant hospitals while maximizing meaningful communication with beneficiaries will be key in these discussions as the transplant community participates in this dialogue. Subsequently, we will not be finalizing our regulation at proposed § 512.442(b), which required that Medicare beneficiaries on the IOTA participant's waitlist be notified monthly about organ offers. We look forward to engaging in conversation with transplant stakeholders to understand additional transparency opportunities to mutually meet patient and provider goals, prior to potentially revisiting this in future rulemaking.

Comment: A commenter expressed concern that discussions about organ offer filters, while allowing patients to influence decisions, may not provide providers with enough data to fully inform and engage patients. For example, providers may lack information on how these filters impact wait times. The commenter suggested this could prevent patients from believeing they can meaningfully contribute to shared decision-making.

[306] *Optimizing Usage of Kidney Offer Filters—OPTN.* (n.d.). *Optn.transplant.hrsa.gov.* Retrieved March 11, 2023, from *https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/optimizing-usage-of-kidney-offer-filters/.*

Response: We appreciate the commenter's feedback and subsequently recognize that our proposal to require IOTA participants to review transplant acceptance criteria and organ offer filters with their IOTA waitlist patients who are Medicare beneficiaries requires clarification. We also acknowledge that explaining the organ offer filter itself may not promote the same outcome as sharing the impact of organ offer acceptance criteria. In light of this, we are finalizing our review of selection criteria and organ offer filters provisions with slight modifications. Specifically, we are finalizing at § 512.442(c) that IOTA participants must review transplant organ offer acceptance criteria (rather than acceptance criteria and organ offer filters) with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist. Additionally, we are removing all references to organ offer filters.

Regarding the commenter's concern that they may not have enough information to share with patients regarding organ offer filters, we believe that generally discussing organ offer acceptance criteria is a first step in increasing patient's awareness about why certain organs may or may not be accepted at a particular transplant program. As IOTA participants may choose to analyze data to better understand ideal organ offer filters, these findings can be used as supporting evidence when explaining to beneficiaries why their transplant program for example, may not accept kidney transplant with a particular cold ischemic time.

Comment: A commenter agreed that organ offer filters should be reviewed with patients at least every 6 months to strengthen their original education.

Response: We thank the commenter for their support. We recognize that explaining the organ offer filter itself may not promote the same outcome as sharing the organ offer acceptance criteria. Subsequently, we are finalizing and clarifying that reviewing organ offer acceptance criteria (rather than the filter itself), with IOTA waitlist patients who are Medicare beneficiaries at least every 6 months, will meet this requirement. We suspect that IOTA participants will have more frequent changes in their organ offer filters during the first few years of the IOTA Model as kidney transplant hospitals optimize their practices.

Comment: A commenter expressed support for reviewing transplant organ offer acceptance criteria with IOTA waitlist patients who are Medicare beneficiaries every six months.

Response: We thank the commenter for their support.

Comment: A commenter argued that operationalizing the proposed transparency into kidney transplant organ offers would be more efficiently achieved by directing the OPTN to develop a patient portal. This portal would allow patients to view their own organ offer filters and organ decline statistics online, rather than requiring each IOTA participant to develop their own reporting system. The commenter emphasized that this approach would promote patient engagement, education, and accountability at kidney transplant hospitals, as patients would be able to access the information themselves. Overall, the commenter felt this would be both more efficient and more effective in achieving the desired result of increased transparency.

Response: We thank the commenter for their valuable suggestions. We recognize the importance of delivering consistent messages about patient education and matters such as organ offer filters, organ offer acceptance criteria, and declined organ offers. As we continue our collaborative work with OTAG, we will carefully consider these recommendations. Additionally, we encourage IOTA participants to discuss this proposal within the IOTA Model learning system. We direct readers to section III.C.15 of this final rule for a full discussion on the IOTA Model learning system.

Comment: A few commenters suggested reviewing acceptance criteria and declined organ offers during key timeframes, such as transplant evaluation, annual waitlist visits, or when first listed on the waiting list. For example, a commenter, while supporting transparency, encouraged upfront communication with patients about organ offer practices during evaluation and annual visits. As an alternative, this commenter recommended that IOTA participants be required to educate patients on the organ offer process, declines, and patients' right to information—with IOTA participants providing specific details upon patient request.

Another commenter expressed support for sharing organ offer filters and transplant acceptance criteria with patients. However, the commenter recommended IOTA participants review these details with patients when they are first listed on the waiting list, and update patients if any changes are made. For patients who want information about declined offers, the commenter suggested discussing their transplant acceptance criteria periodically as they receive that information. For patients who opt out of declined offer details or do not discuss them with the IOTA participant, the commenter recommended an annual review of their organ offer filters and transplant acceptance criteria (or at the time of re-evaluation, whichever comes first). Additionally, the commenter supported CMS's proposal to allow patients to decline this review altogether. Lastly, a commenter suggested that IOTA participants review organ offers received with their waitlisted patients during annual or biannual waitlist visits. The commenter asserted that this would give patients the chance to discuss any changes to their organ offer acceptance criteria and ask their provider questions directly.

Response: We appreciate the valuable feedback from commenters. Although many kidney transplant hospitals see their waitlisted patients at least annually, this practice is inconsistent. Waitlist patient visit frequency can also vary depending on the patient's active or inactive waitlist status. To better inform patients about organ offers and the reasons for declining them, beyond the initial evaluation and waitlist clinic visits, we proposed more frequent patient notifications, as described in section III.C.8.a(2) of this final rule. In light of the comments received, we recognize that successfully implementing an organ offer notification process will require more extensive planning. Therefore, we will not be finalizing the transparency into kidney transplant organ offer provisions at proposed § 512.442(b). However, we remain committed to increasing communication and engagement with patients on the kidney transplant waitlist.

Regarding the proposed review of acceptance criteria and organ offer filters transparency requirement, as described in section III.C.8.a(2) of this final rule, we believe it is important to finalize this provision for several key reasons: (1) it should not create a significant administrative burden; (2) it provides the building blocks of education for IOTA waitlist patients; and (3) due to other themes of the IOTA Model that may impact organ offer filter use, we believe reviewing organ offer acceptance criteria with patients every 6 months is appropriate. As mentioned in comment responses in this section, we also recognize that explaining organ offer filters with waitlisted patients may not promote the same outcome as reviewing organ offer acceptance criteria. As such, we will be finalizing our proposed review of acceptance

criteria provision at § 512.442(c) with minor technical corrections. Specifically, we added ''organ offer'' to transplant acceptance criteria that must be disclosed and removed all references to ''organ offer filters''. Additionally, we will provide further sub-regulatory guidance on how IOTA waitlist patients who are Medicare beneficiaries can choose to decline the review of their transplant organ offer acceptance criteria.

Comment: Several commenters recommended organ offer inclusion or exclusion criteria for the proposed transparency into kidney transplant organ offer provision. The commenters believed the proposed notification requirement should be limited to minimize administrative burden. Their suggested inclusion criteria were: (1) if the patient is the primary recipient, or (2) if the kidney offer is declined by one hospital but used by another. Their suggested exclusion criteria included: (1) kidneys outside a 250-mile radius, (2) discarded kidneys, (3) kidney organ offers that were declined by all kidney transplant hospitals on the match run, or (4) patients removed from a waitlist before a monthly reporting period concluded. Several commenters replied about the inclusions and exclusions from notification requirements.

Response: We appreciate the commenters' feedback. We reiterate that, as mentioned in comment responses in this section, we are not finalizing the proposed transparency organ offer notification provision at proposed § 512.442(b). We aim to engage with the transplant community to identify conditions that should be captured in exclusion criteria, to inform future rulemaking pertaining to transparency into kidney transplant organ offers.

Comment: Some commenters expressed concerns about the proposed transparency into kidney organ offers provision. In particular, they worried it may require IOTA participants to carefully manage how information is shared. The commenters also mentioned that additional security controls may be needed to prevent donor information from being shared with recipients. Another commenter stated the transparency into kidney transplant organ offers provision should include specific details on donor kidney offers, to protect patient privacy and prevent increased use of suboptimal kidneys. Additionally, a commenter cited safeguarding patients' legal and ethical rights to informed consent and autonomy as paramount. Lastly, a couple commenters suggested alternatives, such as only discussing declined organ offer review at the programmatic level among transplant program providers, or using a collaborative model with some privacy walls while sharing select information with patients or the public.

Response: We thank the commenters for sharing their concerns and suggestions about patient privacy. We agree that patient privacy of donors and potential recipients is paramount and believe that safeguarding patients' rights to informed consent and autonomy is imperative. However, in response to the comments we received, as mentioned in comment responses in this section, we are not finalizing the proposed transparency into kidney transplant organ offers provision, requiring IOTA participants to inform IOTA waitlist patients who are Medicare beneficiaries of the number of times an organ is declined on the patient's behalf, at proposed § 512.442(b).

Comment: A few commenters expressed concerns that the transparency into kidney transplant organ offers provisions are overly complex and unnecessary. Moreover, a commenter felt these requirements are redundant, as transplant programs must already provide patients access to SRTR data resources that publicly disclose information about their organ offer acceptance rates.

Response: We thank the commenters for expressing their concerns. While we acknowledge that the new processes needed to meet the proposed transparency into kidney transplant organ offer provisions (89 FR 43580) would initially be labor-intensive or technologically challenging, we maintain that these requirements are important and increase patient awareness.

Additionally, we disagree that the proposed transparency into kidney transplant organ offers requirements are redundant programmatic requirements of providing SRTR data; providing generalized organ offer acceptance rate ratio data is very different from providing direct notification to a patient about an organ offer that was declined on their behalf. However, based on commenter feedback, we recognize the complexities of notifying patients about declined organ offers. While we are not finalizing the proposed transparency into kidney transplant organ offers provisions at proposed § 512.442(b), we remain interested in exploring alternative ways to promote transparency for kidney transplant waitlist patients.

Comment: A couple commenters urged CMS to consider how the proposed transparency into kidney transplant organ offers provision could inadvertently impact the behavior of kidney transplant hospitals. For example, a commenter noted that the proposed organ offers notification requirement emphasizes the importance of discussing organ offer declines with patients, which is crucial for informed decision-making. However, the commenter expressed concern that the focus on organ offer declines could deter the use of higher-risk organs, ultimately reducing the number of viable transplants, or kidney transplant hospitals might potentially offer the organ despite it not being the best fit for the recipient.

Response: We appreciate the commenters concerns regarding the proposed transparency into kidney transplant organ offers provision, as outlined at § 512.442(b) in the proposed rule. We agree that this provision may impact provider and staff awareness of consistent kidney transplant offers that are being declined, which could affect filtering practices. Increasing patient-staff conversations not only creates opportunities for patients to stay better informed about their care, but also allows transplant staff to stay up to date on a patient's waitlist status and recent medical changes. We view more frequent patient interactions as a positive behavioral change. As previously discussed in comment responses in this section, we are not finalizing the transparency into kidney transplant organ offers provision at proposed § 512.442(b), however, we continue to be committed to working with the transplant community to identify alternative transparency opportunities for kidney transplant waitlist patients.

Comment: A couple of commenters stated that CMS should consider alternate ways to promote transparency, including incorporating the voices of consumers, including patients in community councils, inviting community members to serve on boards and equipping patients with data about kidney transplant hospitals so they can make informed decisions.

Response: We appreciate the commenters' feedback. We believe direct dialogue and advocacy between patients and kidney transplant hospitals can enhance communication, helping these hospitals better understand areas needing improvement, such as information gaps and lack of transparency. HHS intends to make organ offer information more easily accessible for patients who are on the waiting list, to minimize administrative burden. While these concepts are not incorporated into the IOTA Model, we believe they are concepts that kidney

transplant hospitals should further consider.

Comment: A commenter expressed concern that the proposed organ offer notification requirement would create disparities, as it would only apply to Medicare patients and IOTA participants.

Response: We thank the commenter for sharing their concern that the transparency into kidney transplant organ offers provision, as proposed, would create disparities because only Medicare patients and IOTA patients would be subject to the requirement. The Innovation Center's authority in this proposed rule only extends to Medicare beneficiaries, which is why we only proposed that it apply to IOTA waitlist patients who are Medicare beneficiaries. However, as mentioned in comment responses in this section, we are not finalizing the proposed transparency into kidney transplant organ offers provision, requiring IOTA participants to inform IOTA waitlist patients who are Medicare beneficiaries of the number of times an organ is declined on the patient's behalf, at proposed § 512.442(b).

Comment: A few commenters urged CMS to reduce the administrative burden on IOTA participants imposed by the proposed transparency requirements. Suggestions included leveraging existing technology and data, evaluating the administrative and financial impacts, and providing IOTA participants with the necessary resources to successfully implement the proposed transparency requirements. Several commenters supported a centralized process to achieve transparency, facilitated by CMS or UNOS/OPTN, which could include standardized patient-specific reports using existing OPTN information, an application programming interface, or a patient portal.

Response: We agree that a future centralized online resource could improve patient access and reduce administrative burdens for kidney transplant hospitals by providing patient organ offer notifications. HHS intends to make organ offer information more easily accessible in the future, to minimize administrative burden for transplant programs. As previously mentioned in this section, we will not be finalizing the proposed transparency into kidney transplant organ offers provision at proposed § 512.442(b). We aim to examine the administrative and financial challenges involved in notifying patients of organ offers, and explore how technology can be used to reduce this administrative burden.

Comment: A commenter expressed support for informing patients on the transplant waitlist, if a patient is active on the transplant waiting list and eligible to receive organ offers, when those organ offers have been declined on their behalf. The commenter argued that transparency should not be compromised for these patients. Additionally, the commenter urged CMS to hold IOTA participants accountable for communicating a patient's waitlisting status when: (1) a patient becomes inactive, including explaining the reasons why and possible solutions to regaining active status, if feasible; and, (2) a patient regains active waitlisting status after being inactivated.

Response: We thank the commenter for their support of the proposed transparency into kidney transplant organ offers provision. However, as mentioned in comment responses in this section, we will not be finalizing this provision at this time. We still believe that it is important to increase transparency for kidney transplant waitlist patients regarding the volume of organ offers received and declined on their behalf while on the waiting list. We also value the commenter's recommendation to hold IOTA participants accountable for communicating a patient's waitlisting status. We acknowledge the importance of patient awareness regarding their waitlist status, an aspect that is often overlooked. Additionally, we recognize the significant number of inactive patients on the waiting list, many of whom may be unaware of their inactive status or the reasons behind it. This aligns with our goal of promoting transparency and SDM between the patient and IOTA participants. We will consider the commenter's suggestion along with the public comments on the proposed transparency requirements and may make future proposals during the course of the model test.

Comment: A commenter asserted that CMS could achieve the goals of the proposed transparency into kidney transplant organ offers requirements without significantly increasing the administrative burden on participating kidney transplant hospitals. Instead of the proposed requirements, the commenter recommended that CMS mandate a discussion about offer screening during the patient consent process. Additionally, the commenter suggested that participating kidney transplant hospitals be required to document these discussions, include them in their records, or address them with patients during evaluations or once they are placed on the waitlist.

Response: We thank the commenters for their suggestions. However, we are concerned that organ offer discussions at the time of initial evaluation for transplant candidacy, while a good start, is insufficient for patient education. Patients often feel overwhelmed by the extensive transplant education they receive when first considering a kidney transplant. This can be especially challenging for those who have recently been diagnosed with kidney disease, making the prospect of transplant seem particularly daunting. While comprehensive education at the time of evaluation and waitlist is important, we believe patients would benefit from more frequent, ongoing guidance about organ offers, acceptance criteria, and deferral tendencies throughout the listing process. As previously mentioned in comment responses in this section, we will not be finalizing the transparency into kidney transplant organ offers provisions at proposed § 512.442(b) at this time due to the aforementioned concerns. We are committed to exploring new ways to increase transparency in collaboration with the transplant community.

Comment: A commenter highlighted that they previously urged CMS to mandate greater transparency about the risk aversion of transplant hospitals and surgeons. This transparency, the commenter argued, would allow patients to find a transplant hospital that aligns with their personal risk tolerance. While the commenter welcomed the IOTA Model's proposal to include two such transparency policies, they strongly disagreed with the policies being part of a demonstration rather than a nationwide requirement.

Response: We thank the commenter for their support. The Innovation Center is limited in exercising authority specific to Medicare beneficiaries and is unable to create nationwide mandates for patients with all types of insurance coverage. However, successful Innovation Center models are often reviewed and discussed as opportunities to expand to the nation through other policies. While we are not finalizing the proposed transparency into kidney transplant organ offers requirements at § 512.442(b) of the proposed rule, we hope that transplant hospitals who are not selected to participate in the IOTA Model will consider integrating IOTA Model concepts into their kidney transplant hospital.

Comment: A few commenters mentioned that modifications to the transparency requirements were needed or that the transparency into kidney transplant offers provision should be

eliminated entirely but did not provide further suggestions or justification.

Response: We thank the commenters for the feedback. We are interested in understanding the commenters' specific modification suggestions and invite them to provide further details in the future.

Comment: Several commenters supported the provision requiring transparency into kidney transplant organ offers, with some of them specifying that providing Medicare beneficiaries the option to be informed about organs that were declined on their behalf supports increased communication and shared decision making between patients and providers. One of these commenters also believed that increasing transparency would hold kidney transplant hospitals accountable, drive ongoing improvements across the transplant system and help eliminate health disparities.

Response: We greatly appreciate the commenters' words of support; however, we are not finalizing this provision. We look forward to future feedback as we work to create transparency requirements that are not unduly burdensome. We remain invested in evaluating alternative transparency opportunities with the transplant community.

Comment: A couple of commenters conveyed concerns with barriers to patient receipt of transparency notifications, stating that IOTA participants may use automated notifications in place of the meaningful communication that would be required to provide quality care. A commenter was specifically concerned by technical barriers reaching patients, such as outdated contact information.

Response: We agree these are valid challenges with all types of patient communications. While automated notifications may be preferred by some patients, it may further worsen disparities in already vulnerable populations. We recognize that disparities in access to technology can limit certain patients, making phone calls or other methods of contact necessary. Patient portals may provide a source of quick, easy access to information; however, this can prevent real-time discussions. This concern is one of the reasons that we will not be finalizing the proposed transparency into kidney transplant organ offers provision as proposed at § 512.442(b). We look forward to engaging with kidney transplant hospitals to identify and share efficient yet appropriate methods for equitably notifying and making patients aware of declined kidney transplant organ offers, without creating disparities for those who may not have access to technology.

Comment: Several commenters suggested CMS modify the transparency into kidney transplant organ offers provision, which would require IOTA participants to inform, on a monthly basis, IOTA waitlist patients who are Medicare beneficiaries of the number of times an organ is declined on the patient's behalf and the reason(s) for the decline. Specifically, they suggested that organ offer declines should be shared only to a certain sequence number in the match run, keeping the information to a manageable amount and focusing on organs that the patient had a reasonable likelihood of receiving. Suggested notification thresholds included the top 5, 100, 150, or 200 matches of the match run, or only when the organ was used for a transplant candidate positioned further down on the waiting list. For example, a commenter suggested that since a quarter of organ offers are accepted at or after having been offered to 73 transplant candidates, organ offer declines should be shared with transplant candidates up to match run sequence 150, which is about 73 doubled. Alternatively, the commenter suggested that CMS could mirror the SRTR definition of a hard-to-place kidney (100) and cap sharing the organ offer decline information at transplant candidates who were lower than 100 in the match run sequence.

Response: We thank the commenters for their suggestion to only share organ offer declines to a certain sequence number in the match run and modify the provision requiring transparency into kidney transplant organ offers. Since we are not currently finalizing this provision, as mentioned in comment responses in this section, we will keep this feedback in mind as we consider alternatives in future rulemaking.

Comment: Many commenters requested clarification on the proposed transparency into kidney transplant organ offer provision requiring IOTA participants, for months in which an organ offer is made, to inform IOTA waitlist patients who are Medicare beneficiaries of the number of times an organ is declined on the patient's behalf. For example, a commenter wanted to know what deliverable(s) CMS expects in order to validate compliance with this requirement. Another commenter asked CMS to clarify what constitutes an organ offer decline. The commenter stated that due to the complexity of the organ offer system and variability in OPO behavior, a transplant hospital may receive an organ offer before many transplant hospitals ahead of them have reviewed and declined it. As a result, the commenter was concerned that a transplant hospital may review an offer when they do not actually have the opportunity to transplant the organ, as they are not the ''primary'' recipient. The commenter also noted a recent significant increase in expedited organ placement, where an OPO can send an organ to a hospital that is not next in line. Additionally, the commenter pointed out that an IOTA waitlist patient may have a declined offer but then be removed from the waitlist due to transplant or other reasons before the monthly report period ends; potentially creating uncertainty for IOTA participants on whether to notify the IOTA waitlist patient in such scenarios. Furthermore, the commenter suggested that different IOTA participants may define the required reporting differently, and that some declined offers may be more relevant to IOTA waitlist patients than others.

A few commenters sought clarity on which organ offers and declines would be included in this requirement. For instance, a commenter asked if the requirement would cover only primary offers, which occur sporadically, or all offers regardless of match quality—potentially numbering in the hundreds per month. This same commenter also raised questions about whether hospital representatives or physicians (who may be unaffiliated private practitioners) should have discussions about organ offers with IOTA waitlist patients, and how IOTA participants could effectively communicate complex clinical information to non-clinical patients without causing strife or animosity, as patients and families often misunderstand or underestimate the risks of poorly matched organs and recipients.

Response: We thank the commenters for their questions and feedback. As mentioned in comment responses in this section, we are not finalizing the proposed transparency into kidney transplant organ offers provision, requiring IOTA participants to inform IOTA waitlist patients who are Medicare beneficiaries of the number of times an organ is declined on the patient's behalf. However, as we continue to consider ways to increase transparency, we will consider this feedback in future rulemaking.

Comment: A few commenters expressed concerns that the new transparency requirements into kidney transplant organ offers may have unintended consequences. They worried the requirements could encourage IOTA participants to accept

lower-quality kidneys, offer kidneys that are not the best fit for recipients, or deter the use of higher-risk organs. Additionally, a commenter noted that monthly reporting on declined kidney offers does not account for the increasing reliance on out-of-sequence allocation for high-risk kidneys that may otherwise be discarded.

Many commenters emphasized the importance of allowing transplant surgeons, who are knowledgeable about each patient's unique circumstances, to exercise discretion in making clinical decisions without facing pressure to accept suboptimal organs or penalties for denying them. They warned that restricting this discretion could undermine trust between the transplant program and patients. One of these commenters also expressed concern that transplant programs are worried about patient dissatisfaction and potential legal actions due to declinations. This is because patients might falsely be given the sense that they would have had the option of accepting a kidney that is not clinically acceptable.

Response: We thank the commenters for their feedback. The proposed provisions for transparency into declined kidney transplant offers is not intended to question a provider's medical judgment or expertise. Rather, it aims to better inform patients about whether they are receiving offers and the reasons behind any declines. For instance, if a size mismatch between the recipient and donor kidney prompts deferring the transplant to an alternative recipient, the transparency requirement should not impact that clinical decision. However, we proposed that IOTA waitlist patients who are Medicare beneficiaries be made aware of any declined offers and the rationale, allowing them the opportunity to ask questions and understand the process. The goal of this proposed transparency requirement is to facilitate more open patient-provider discussions about the kidney transplant process before undergoing the major, life-altering procedure—not to erode trust or encourage litigation. Although we are not finalizing the proposed transparency into kidney transplant organ offers provisions at proposed § 512.442(b), we continue to support increasing transparency for patients on the waiting list and will consider alternative pathways with the transplant community to fulfill this important need.

Comment: Numerous commenters voiced concerns about the transparency into kidney transplant organ offers requirements. Specifically, they worried that notifying patients about declined organ offers could undermine patient trust, evoke strong emotions, and negatively impact mental health. Commenters also expressed concern that patients and families may not fully grasp complex medical factors like organ quality and suitability, potentially leading to confusion over the clinical decisions made.

Response: We appreciate the commenters' feedback and agree that monthly notifications of declined organ offers may not be the right option for every patient. We believe this is an important topic to consider as we evaluate future opportunities for transparency requirements. At this time, we will not be finalizing the proposed transparency into kidney transplant organ offers provisions; however, we will take this feedback into consideration for future notice and comment rulemaking.

Comment: Several commenters mentioned that patient-centered and secure reporting is important stating that CMS should consider beneficiaries' preferences to ensure that the transparency requirements are practical for IOTA participants to implement and meaningful to kidney transplant patients and should ensure that data reported is meaningful. A commenter specified the information should be culturally and linguistically appropriate. Several commenters stated that information should be processed in a way that safeguards patients and their families, and authentication measures should be implemented to verify that patients' contact information. Commenters added that mechanisms for sharing information should be developed carefully and with input from the donation and transplant community. Some of these commenters also felt patients should be able to opt in and out of receiving notifications.

Response: We appreciate the commenters' feedback. We agree that organ offer notifications in addition to organ offer acceptance criteria need to be practical and consider linguistic and cultural modifications. Although we are not finalizing the proposed transparency into kidney transplant organ offers provisions, as mentioned in comment responses in this section, we will consider these important patient-centered provision details in future notice and comment rulemaking.

Comment: A commenter recommended that rather than report monthly on kidney transplant offers, CMS should require IOTA participants to report their quartile rank for their organ offer acceptance rate ratio to all wait-listed patients on a semiannual or annual basis.

Response: Thank you for your recommendation. As described in section III.C.5.d of this final rule, we are finalizing the inclusion of the organ offer acceptance rate ratio performance measure in the efficiency domain. Section 1115A(b)(4)(B) of the Act requires CMS to the public, and we plan to do so annually. This report would include the organ offer acceptance rate ratio results. Despite making organ offer acceptance rate ratio results available to patients, we believe that this does not negate the need for other transparency requirements as one data point focuses on kidney transplant hospital level data while the other focuses on patient level data. Although we are not finalizing the proposed transparency into kidney transplant organ offers provisions, as mentioned in comment responses in this section, this remains an important topic requiring ongoing discussion.

Comment: A couple of commenters recommended that organ offer declines be shared with both the patient and their referring nephrologist.

Response: We appreciate the commenters' feedback and agree that referring nephrologists are an important individual in the care continuum for patients with kidney disease. As described in comment responses in this section, we are not finalizing our proposed transparency into kidney transplant organ offers provisions at this time. However, we believe this is an important consideration and will take this comment into consideration in future notice and rulemaking. After consideration of public comment, for the reasons set forth in this rule, we are not finalizing our proposed provision for transparency into kidney transplant organ offers at § 512.442(b).

We are, however, finalizing the provisions as proposed at § 512.442(c), with minor technical corrections. Specifically, we added ''organ offer'' to transplant acceptance criteria that must be disclosed and removed all references to ''organ offer filter'' from the provision at § 512.442(c). Additionally, at § 512.442(c) we replaced ''selection criteria'' to now say ''acceptance criteria''. These changes were made in order to clarify the specific provisions regarding the review of transplant organ offer acceptance criteria, as described in section III.C.8(a)(2) of the preamble in this final rule. We will provide further sub-regulatory guidance on the specifics of how IOTA waitlist patients who are Medicare beneficiaries can decline reviewing their transplant organ offer acceptance criteria.

(3) Publication of IOTA Participant Results

In the Specialty Care Models final rule (85 FR 61114), CMS established certain general provisions in 42 CFR part 512 subpart A that apply to all Innovation Center models. One such general provision pertains to rights in data. Specifically, in the Specialty Care Models final rule, we stated that to enable CMS to evaluate the Innovation Center models as required by section 1115A(b)(4) of the Act and to monitor the Innovation Center models pursuant to § 512.150, in § 512.140(a) we would use any data obtained in accordance with § 512.130 and 512.135 to evaluate and monitor the Innovation Center models (85 FR 61124). We also stated that, consistent with section 1115A(b)(4)(B) of the Act, CMS would disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. We stated that the data to be disseminated would include, but would not be limited to, patient de-identified results of patient experience of care and quality of life surveys, as well as patient de-identified measure results calculated based upon claims, medical records, and other data sources. We finalized these policies in 42 CFR part 512.140(a).

Consistent with these provisions, we proposed in section III. C.8.a(3) of the proposed rule, to publish results from all PYs of the IOTA Model. Specifically, for each PY, we intend to post performance across the achievement domain, efficiency domain, and quality domain for each IOTA participant. We would also identify each IOTA participant for the PY. The results would be published on the IOTA Model website. Given that we have proposed that the IOTA Model would include a process for IOTA participants to request a targeted review of the calculation of performance score which is calculated based on the various rates we intend to publish, CMS anticipates that it would publish these rates only after they have been finalized and CMS has resolved any targeted review requests timely received from IOTA participants under section II.E. of this final rule. We believed that the release of this information would inform the public about the cost and quality of care and about IOTA participants' performance in the IOTA Model. This would supplement, not replace, the annual evaluation reports that CMS is required to conduct and release to the public under section 1115A(b)(4) of the Act.

In section III.C.8.a(3) of the proposed rule, we considered requiring IOTA participants to publish their performance results on their own websites as well to increase transparency; however, we did not want to place additional reporting burden on IOTA participants, particularly because we proposed that CMS would publish the performance results, which should be adequate.

We sought comment on our intent to post this information to our website, as well as the information we intend to post and the manner and timing of the posting.

The following is a summary of comments received on our intent to publish this information to our website, as well as the information we intend to post and the manner and timing of the posting and our responses:

Comment: A commenter urged CMS to ensure that any data shared on the CMS website is easily understandable for the public.

Response: We thank the commenter for their feedback. We agree that it is important for patients to have information that is presented in a format that is easily reviewed and understood. We will review the results to be published and further consider how to best present information to both the public and kidney transplant hospitals in a meaningful manner, while abiding by the requirements of section 1115A(b)(4) of the Act.

Comment: A commenter stated that sharing results during the test phase should be limited to enrolled IOTA participants to avoid confusion and inequities.

Response: We thank the commenter for their recommendation and sharing their concerns, however, section 1115A(b)(4)(B) of the Act requires that model evaluation results be made available to the public. We believe it is important for patients to have model information available to them as they review IOTA participants. Additionally, access to these reports by all patients invites further research and evaluation by the transplant community to identify model requirements that should be applied to all kidney transplant hospitals and to identify areas of necessary changes in future iterations of the IOTA Model and transplant policy.

Comment: A commenter suggested that CMS should develop charts or other tools that track and communicate performance to IOTA participants in real-time. The commenter also suggested that performance-related information should be made available to providers in addition to IOTA participants so they can better identify areas for improvement and change behaviors as necessary before each performance year ends.

Response: We appreciate the commenter's feedback. We suggest referring to section III.C.7 of this final rule, on data sharing, for more detailed comment and will consider this request for timely performance reports as we develop implementation methodology for data collection and data reporting to IOTA participants.

Comment: A few commenters relayed their support for the publication of IOTA participant results. A commenter stated that they are eager to evaluate the model after its conclusion to determine whether the three domains were effective and whether the IOTA Model goals have been achieved, but also want to reevaluate further future improvements, encouraging CMS to publish annual interim reporting to assess the model's progress.

Response: We thank the commenters for their support and we reiterate the importance of transparency of performance results of IOTA participants to understand the pros and cons of the IOTA Model, what to modify in future iterations of the IOTA Model, and what components should be part of routine care for all kidney transplant hospitals in the future. Additionally, these performance results give patients, the transplant community and IOTA participants the opportunity to compare kidney transplant hospitals and identify where there is room for improvement year over year.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing our proposals to publish results from all PYs of the IOTA Model, without modification, as outlined in section III.C.8.a(3) of this final rule. Specifically, for each PY, we intend to identify each IOTA participant for the PY and to post performance across the achievement domain, efficiency domain, and quality domain for each IOTA participant on the IOTA Model website annually, as they become available. Not only does this meet CMS requirements, as previously discussed, but also demonstrates transparency for the transplant community. We will further consider the frequency and availability of interim performance results in future rulemaking. We direct readers to section III.C.7 of this final rule, for further details on data sharing.

b. Health Equity Data Reporting

(1) Demographic Data Reporting

As previously discussed in section III.B. of this final rule, and throughout this final rule, disparities exist

throughout the transplant process. These circumstances highlight the importance of data collection and analysis that includes race, ethnicity, language, disability, sexual orientation, gender identity, and sex characteristics or other demographics by health care facilities. Such data are necessary for integration of health equity in quality programs, because the data permits stratification by patient subpopulation.[307] [308] Stratified data can produce meaningful measures that can be used to expose health disparities, develop focused interventions to reduce them, and monitor performance to ensure interventions to improve care do not have unintended consequences for certain patients.[309] Furthermore, quality programs are carried out with well-known and widely used standardized procedures, including but not limited to, root cause analysis, plan-do-study-act (PDSA) cycles, health care failure mode effects analysis, and fish bone diagrams. These are common approaches in the health care industry to uncover the causes of problems, show the potential causes of a specific event, test a change that is being implemented, prevent failure by correcting a process proactively, and identify possible causes of a problem and sort ideas into useful categories, respectively.[310] [311] [312] [313] Adding a health equity prompt to these standardized procedures integrates a health equity lens within the quality structure and cues considerations of the patient subpopulations who receive care and services from a transplant hospital.[314]

To align with other Innovation Center efforts, we considered proposing that, beginning with the first PY and each PY thereafter, each IOTA participant would be required to collect and report to CMS demographic and SDOH data pursuant to 42 CFR part 403.1110(b) for the purposes of monitoring and evaluating the model. We considered proposing that, in conducting the collection required under this section, the IOTA participant would make a reasonable effort to collect demographic and social determinants of health data from all attributed patients but, in the case the IOTA participant attributed patient elects not to provide such data to the IOTA participant, the IOTA participant would indicate such election by the attributed patient in its report to CMS.

We decided not to propose the collection of demographic data as this data is already collected by OPOs and the SRTR, thereby making such a requirement for purposes of this model potentially duplicative and unnecessarily burdensome. We wish to minimize reporting burden on IOTA participants where possible to ensure sufficient time and effort is spent adjusting to the requirements of a mandatory model.

We solicited public comment on the decision not to propose the collection of this data and potential applications.

The following is a summary of the comments received and our responses:

Comment: A few commenters agreed with CMS' decision not to propose the collection of demographic data as this data is already collected, thereby making such a requirement for purposes of this model potentially duplicative and unnecessarily burdensome.

Response: We thank commenters for their support in our decision to not include demographic data reporting in the IOTA Model.

After consideration of the public comments we received, we are not finalizing any requirements to include demographic data reporting in the IOTA Model.

(2) Health Related Social Needs (HRSN) Data Reporting

The Innovation Center is charged with testing innovations that improve quality and reduce the cost of health care. There is strong evidence that non-clinical drivers of health are the largest contributor to health outcomes and are associated with increased health care utilization and costs.[315] [316] These individual-level, adverse social conditions that negatively impact a person's health or healthcare are referred to as ''health-related social needs'' or HRSNs.[317] CMS aims to expand the collection, reporting, and analysis of standardized HRSNs data in its efforts to drive quality improvement, reduce health disparities, and better understand and address the unmet social needs of patients. Standardizing HRSN Screening and Referral as a practice can inform larger, community-wide efforts to ensure the availability of and access to community services that are responsive to the needs of Medicare beneficiaries.

HRSN screening is becoming increasingly common nationally, but implementation is not uniform across geography or health care setting. A literature review of national surveys measuring prevalence of social screening found that almost half of State Medicaid agencies have established managed care contracting requirements for HRSN screening in Medicaid.[318] It also found that health care payers and delivery organizations or both reported a screening prevalence of 55–77 percent, with ''the highest estimate reported among American Hospital Association member hospitals.'' [319] Despite screening proliferation and generally positive views toward screening among both patients and health care providers, implementation of screening and referral policies for beneficiaries of CMS programs with similar health—and even demographic—profiles may be inconsistent, potentially exacerbating

[307] IOM (Institute of Medicine). 2009. *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement* (p.287). The National Academies Press *https://www.ahrq.gov/sites/default/files/publications/files/iomracereport.pdf.*

[308] Sivashanker, K., & Gandhi, T.K. (2020). Advancing Safety and Equity Together. *New England Journal of Medicine, 382*(4), 301–303. *https://doi.org/10.1056/nejmp1911700.*

[309] Weinick, R.M., & Hasnain-Wynia, R. (2011). Quality Improvement Efforts Under Health Reform: How To Ensure That They Help Reduce Disparities—Not Increase Them. *Health Affairs, 30*(10), 1837–1843. *https://doi.org/10.1377/hlthaff.2011.0617.*

[310] American Society for Quality. (2019). *What is root cause analysis (RCA)? Asq.org. https://asq.org/quality-resources/root-cause-analysis.*

[311] Agency for Healthcare Research and Quality. (2020). *Plan-Do-Study-Act (PDSA) directions and examples. www.ahrq.gov. https://www.ahrq.gov/health-literacy/improve/precautions/tool2b.html.*

[312] *Failure Modes and Effects Analysis (FMEA) Tool | IHI—Institute for Healthcare Improvement.* (2017). *www.ihi.org. https://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx.*

[313] Kane, R. (2014). *How to Use the Fishbone Tool for Root Cause Analysis. https://www.cms.gov/medicare/provider-enrollment-and-certification/qapi/downloads/fishbonerevised.pdf.*

[314] Sivashanker, K., & Gandhi, T.K. (2020). Advancing Safety and Equity Together. *New England Journal of Medicine, 382*(4), 301–303. *https://doi.org/10.1056/nejmp1911700.*

[315] Booske, B.C., Athens, J.K., Kindig, D.A., Park, H., & Remington, P.L. (2010). *County Health Rankings* (Working Paper). *https://www.countyhealthrankings.org/sites/default/files/differentPerspectivesForAssigningWeightsToDeterminantsOfHealth.pdf.*

[316] *ROI Calculator for Partnerships to Address the Social Determinants of Health Review of Evidence for Health-Related Social Needs Interventions.* (2019). *https://www.commonwealthfund.org/sites/default/files/2019-07/COMBINED-ROI-EVIDENCE-REVIEW-7-1-19.pdf.*

[317] Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End- Stage Renal Disease Treatment Choices model NPRM (citing A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool) 87 FR 38554 (Jun. 28, 2022).

[318] De Marchis, E., Brown, E., Aceves, B., Loomba, V., Molina, M., Cartier, Y., Wing, H., Ma, L., & Gottlieb. (n.d.). *State of the Science of Screening in Healthcare Settings siren State of the Science on Social Screening in Healthcare Settings Summer 2022. https://sirenetwork.ucsf.edu/sites/default/files/2022-06/final%20SCREEN%20State-of-Science-Report%5B55%5D.pdf.*

[319] Ibid.

disparities in the comprehensiveness and quality of care.

One of the goals stated in the Innovation Center Strategy Refresh for advancing system transformation is to require all new models to collect and report demographic and SDOH data. Thus, in addition to the proposed health equity requirements in section III.C.8.b. of this final rule, we considered proposing a requirement that IOTA participants conduct HRSN screening for at least four core areas—food security, housing, transportation, and utilities. We recognize these areas as some of the most common barriers to kidney transplantation and the most pertinent for the IOTA participant patient population. However, given the need for a psychosocial evaluation prior to addition to the waitlist, we understand that such a requirement may be redundant given current clinical practices, we have refrained from making such a proposal.

We sought comment on whether we should include a requirement for IOTA participants to conduct HRSN screening and report HRSN data in a form and manner specified by CMS each PY for their attributed patients. We sought input on following the questions in this section, and comment on any aspect of the psychosocial evaluation of waitlisted patients and how this compares to HRSN screenings for the four domains—food security, housing, transportation, and utilities. Even if CMS were to adopt an HRSN screening and reporting requirement in the final rule, CMS might consider delaying the implementation of such a requirement.

- When evaluating a patient for potential addition to the kidney transplant waitlist, what questions are asked as part of the psychosocial evaluation?
- How might a psychosocial evaluation compare to an HRSN screening? What HRSNs are identified as part of a psychosocial evaluation?
- What data is collected from the psychosocial evaluation on HRSNs?
- If HRSNs are identified as part of the evaluation process, what, if any, steps are taken to assist the patient in addressing these needs and improving their transplant readiness?
- If HRSNs are identified of a patient already on the transplant waitlist, how might this affect their status on the transplant waitlist? Could a patient be removed from the transplant waitlist if HRSNs are identified that may impact transplant readiness?
- What, if any, follow-up is conducted with waitlist patients that have identified HRSNs?
- Are there any concerns with HRSN screening and data collection requirements?

We received 33 submissions on this RFI. We thank commenters for their comments. While we will not be responding to specific comments submitted in response to this RFI, we have shared all the comments received with the appropriate agencies and offices for consideration in subsequent rulemaking for the inclusion of demographic data reporting.

c. Health Equity Plans

To further align with other Innovation Center models and promote health equity across the transplant process, we proposed that, for PY 2 through PY 6, each IOTA participant must submit to CMS, in a form and manner and by the date(s) specified by CMS, a health equity plan. Given that this would be a mandatory model, we proposed that the health equity plan be voluntary in the first PY of the model to allow IOTA participants time to adjust to model requirements. We proposed that the health equity plan must:

- Identify target health disparities. We proposed to define ''target health disparities'' as health disparities experienced by one or more communities within the IOTA participant's population of attributed patients that the IOTA participant would aim to reduce.
- Identify the data sources used to inform the identification of target health disparities.
- Describe the health equity plan intervention. We proposed to define ''health equity plan intervention'' as the initiative(s) the IOTA participant would create and implement to reduce target health disparities.
- Include a resource gap analysis. We proposed to define ''resource gap analysis'' as the resources needed to implement the health equity plan interventions and identifies any gaps in the IOTA participant's current resources and the additional resources that would be needed.
- Include a health equity project plan. We proposed to define ''health equity project plan'' as the timeline for the IOTA participant to implement the IOTA participant's the health equity plan.
- Identify health equity plan performance measure(s). We proposed to define ''health equity performance plan measure(s)'' as one or more quantitative metrics that the IOTA participant would use to measure the reductions in target health disparities arising from the health equity plan interventions.
- Identify health equity goals and describes how the IOTA participant would use the health equity goals to monitor and evaluate progress in reducing targeted health disparities. We proposed to define ''health equity goals'' as targeted outcomes relative to the health equity plan performance measures for the first PY and all subsequent PYs.

In the proposed rule, we proposed that once an IOTA participant submits their health equity plan to CMS, CMS would use reasonable efforts to approve or reject the health equity plan within 60 business days (89 FR 43582). We proposed that if CMS approves the IOTA participant's health equity plan, the IOTA participant must engage in activities related to the execution of the IOTA participant's health equity plan, including implementing health equity plan interventions and monitoring and evaluating progress in reducing target health disparities. Discrimination on the basis of race, ethnicity, national origin, religion, or gender in activities related to the execution of the IOTA participant's health equity plan would be prohibited.

Should CMS determine that the IOTA participant's health equity plan does not satisfy the proposed requirements and is inconsistent with the applicable CMS Health Equity Plan guidance, does not provide sufficient evidence or documentation to demonstrate that the health equity plan is likely to accomplish the IOTA participant's intended health equity goals, or is likely to result in program integrity concerns or negatively impact beneficiaries' access to quality care, we proposed that CMS may reject the health equity plan or require amendment of the health equity plan at any time, including after its initial submission and approval (89 FR 43582).

We proposed that if CMS rejects the IOTA participant's health equity plan, in whole or in part, the IOTA participant must not, and must require its IOTA collaborators to not, conduct health equity activities identified in the health equity plan that have been rejected by CMS (89 FR 43582).

We proposed that in PY 3, and each subsequent PY, in a form and manner and by the date(s) specified by CMS, each IOTA participant would be required to submit to CMS an update on its progress in implementing its health equity plan (89 FR 43582). We stated that this update would be required to include all of the following:

- Updated outcomes data for the health equity plan performance measure(s).

- Updates to the resource gap analysis.
- Updates to the health equity project plan.

We proposed that if an IOTA participant fails to meet the requirements of the heath equity plan described in this section of the proposed rule, the IOTA participant would be subject to remedial action as specified in section III.C.16. of this final rule. Such remedial actions could include requesting a corrective action plan, recoupment of any upside risk payments; or termination from the model (89 FR 43582).

We solicited feedback on these proposals. We also solicited comment on the potential impact of creation of a health equity plan, whether such plans should be voluntary, and whether health equity plans should only be a requirement in later PYs of the IOTA Model.

The following is a summary of the comments received on our proposed health equity plan provisions, whether such plans should be voluntary, and whether health equity plans should be a requirement in later PYs of the IOTA Model and our responses:

Comment: Several commenters applauded CMS' proposed requirement to integrate health equity plans into the model framework. Commenters expressed support stating the health equity plans provide a context-specific system-level approach to addressing the social determinants of health and the health equity plan provision will encourage IOTA participants to identify health equity gaps and to develop and implement targeted strategies to address those gaps.

Response: We appreciate the commenters' support of the IOTA health equity plan. We acknowledge commenters' support for CMS' and the IOTA model's goal to promote health equity across the transplant process.

Comment: A few commenters suggested that CMS should not pursue the health equity plan provision. Several commenters supported the proposed requirements to delay the submission of the heath equity plans until performance year two, however, other commenters recommended CMS reconsider requiring each IOTA participant to submit to CMS an update on its progress in implementing its health equity plan (in PY 3, and each subsequent PY). Some commenters expressed the health equity plan requirement would be burdensome and inhibit IOTA participants resources and their ability to successfully implement and operationalize the model requirements. For example, commenters stated the health equity plans would be an unfair requirement and burdensome for transplant hospitals that have a larger low-income patient population and would penalize model participants' efforts to address health equity issues. Other commenters suggested that to reduce burden, CMS should provide clarity on the health equity plan criteria. For example, commenters stated CMS should consider providing IOTA participants examples of a comprehensive health equity plan that describes the health equity plan inclusion criteria, and clear and measurable endpoints on which CMS would deem suitable for approval.

Response: We thank the commenters for their feedback. However, we disagree with the suggestion to remove the health equity plan provision from the model. We believe health equity plans are vital to incentivize meaningful changes and promote health equity across the transplant process. However, we recognize that the IOTA health equity plan requirement may be burdensome for some model participants, and CMS solicited comment on whether such plans should be voluntary. With respect to comments received, we are modifying our proposal to allow health equity plans to be a voluntary provision for all performance years.

Comment: Several commenters recommended that CMS provide upfront investment funding to support the development and implementation of the IOTA participants' health equity plans. Several commenters stated the health equity plan requirements would be burdensome to model participants and would require significant resources and investments involving administrative, human and operational capital from model participants to be successful. In addition, some commenters stated that the health equity plan requirement fails to consider or address patients' barriers such as high out-of-pocket costs, or patients living in rural areas.

Other commenters expressed their support of the health equity plan policy but expressed concerns that the lack of upfront investments of resources and the design rigor would make the health equity plan requirements unlikely to yield meaningful results for patients. For example, these commenters suggested CMS should include upfront financial support to help empower participating hospitals to fully engage in the IOTA Model without compromising their financial stability or the quality of care they provide to their communities and patients. A commenter stated that tasking transplant hospitals to address patient's social risk factors and the social determinants of health via the health equity plan is beyond the purview or expertise of transplant hospitals. The commenter stated that the social determinants of health issues among transplant hospital patients are generally managed by social workers (and/or non-clinical staff) within the patients' communities, and therefore, supplemental funding would be needed to hire appropriate staff and support the resources needed to design and implement the IOTA health equity plan. Other commenters suggested CMS should consider issuing waivers to allow for broader financial assistance programs for underserved communities who may be facing additional barriers and social risk factors such as food insecurity, housing insecurity, inaccessible transportation and high childcare costs. A commenter suggested CMS should include additional incentives or supplemental funding for local healthcare providers and dialysis units to screen patients for social determinants of health metrics and link patients to community-based services.

Response: We appreciate the commenters' suggestions for CMS to include supplemental funding for the health equity plan provision. We believe it is important that IOTA participants receive the necessary support to successfully implement their health equity plan. We sought comment on the potential impact of creation of a health equity plan, and we will consider including health equity plan supplemental funding opportunities in future rulemaking.

Comment: Some commenters expressed concern that the health equity plan provision may promote discriminatory practices on the basis of race. Specifically, commenters stated the health equity plan requirement incentivizes model participants to prioritize certain group(s) over others in a discriminatory manner. A commenter suggested that the IOTA health equity plan ''target health disparities'' requirement should be defined in race-neutral terms, and CMS should prohibit IOTA participants' health equity plans from being implemented in a discriminatory manner.

Response: We acknowledge the commenters concerns. Our proposal states that ''discrimination on the basis of race, ethnicity, national origin, religion, or gender in activities related to the execution of the IOTA participant's health equity plan would be prohibited.'' We believe there are significant safeguards in place to assure health equity plans will not be designed or implemented in a discriminatory manner.

Comment: Some commenters recommended CMS implement the IOTA health equity plans through the CMS Hospital Inpatient Quality Reporting (IQR) Program. For example, commenters stated they do not agree that the IOTA model is an appropriate venue to promote health equity and the health equity plan provision would be better served within the IQR program given transplant hospitals already participant in IQR. Commenters suggested the IOTA health equity plan requirements would be duplicative, create additional administrative burden, and be confusing for hospitals given CMS has already introduced the Hospital Commitment to Health Equity via the IQR program. Other commenters suggested CMS should implement the model's health equity plans through The Joint Commission instead of an IOTA-specific plan. Another commenter recommended dialysis centers would be a more suited environment to implement health equity plans rather than via transplant hospitals.

Response: We disagree with implanting IOTA health equity plans within other CMS or hospital programs. The IOTA Model structure is designed to promote improvement activities across selected transplant hospitals, including the social determinants of health, and health equity. The IOTA health equity plans are designed specifically for the selected transplant hospital participants.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed provisions on health equity plans at § 512.444(a)(1–7) with slight modifications. Specifically, we are redesignating what was proposed at § 512.444 to be § 512.446. Additionally, we proposed at § 512.444(a) that the health equity plan be voluntary for IOTA participants for PY 1 and mandatory for PY 2 through PY 6. We are instead finalizing at § 512.446(a) that a health equity plan shall be voluntarily submitted by an IOTA participant for all performance years (PY 1 through PY 6) in a form and manner and by the date(s) specified by CMS. We are also finalizing that a health equity plan voluntarily submitted by an IOTA participant must include all elements as proposed at § 512.446(a)(1–7), without modification.

Additionally, we are finalizing as proposed without modification the definitions of target health disparities, health equity plan intervention, resource gap analysis, health equity project plan, health equity performance plan measure(s) and health equity goals at § 512.402. We also note that we are finalizing the proposed definition of health equity performance plan measure(s) with a slight modification to correct the defined term to read as follows: health equity plan performance measure(s). In the proposed rule at 89 FR 43582, we proposed to define health equity performance plan measure(s) as one or more quantitative metrics that the IOTA participant would use to measure the reductions in target health disparities arising from the health equity plan interventions. However, in the proposed rule at 89 FR 43582, we proposed that health equity plans must identify health equity plan performance measure(s). Additionally, in the proposed rule at 89 FR 43582, we proposed to define health equity goals as targeted outcomes relative to the health equity plan performance measures for the first PY and all subsequent PYs. As such, we are finalizing the definition of health equity plan performance measure(s) at § 512.402 as one or more quantitative metrics that the IOTA participant would uses to measure the reductions in target health disparities arising from the health equity plan interventions.

9. Overlap With Other Innovation Center Models, CMS Programs, and Federal Initiatives

a. Other Innovation Center Models and CMS Programs

We proposed that IOTA participants would be allowed to simultaneously participate in IOTA and other CMS programs and models. The IOTA Model would overlap with several other CMS programs and models and Departmental regulatory efforts, and we sought comment on our proposals to account for overlap.

KCC Model—The KCC Model is a voluntary Innovation Center model for nephrologists, dialysis facilities, transplant providers, and other providers and suppliers that are focused on beneficiaries with CKD and beneficiaries with ESRD. The KCC Model performance period began on January 1, 2022, and is scheduled to end December 31, 2026. As such, the KCC Model would run concurrently for 2 years with the IOTA Model, which would have a proposed start date of January 1, 2025. The KCC Model includes a payment incentive called the Kidney Transplant Bonus (KTB). KCC participants are eligible for up to $15,000 for every aligned beneficiary with CKD or ESRD who receives a kidney transplant, whether from a living or deceased donor, provided the transplant remains successful. Kidney Contracting Entities (KCEs) participating in the KCC Model are also required to include a transplant provider, defined as a transplant program that provides kidney transplants, a transplant hospital that provides kidney transplants, a transplant surgeon who provides kidney transplants, a transplant nephrologist, a transplant nephrology practice, an OPO, or another Medicare-enrolled provider or supplier that provides kidney transplant related covered services to Medicare beneficiaries.

Though transplant hospitals are one of the types of health care provider eligible to serve as a transplant provider, CMS has found relatively low participation by transplant hospitals in the KCC Model. Across the 100 KCEs participating in the model in 2023, there were only 10 kidney transplant hospitals participating in the model and serving as the transplant provider for the relevant KCE. In discussions with participants and with kidney transplant hospitals, CMS heard a few reasons for this relatively low rate of participation. CMS heard that it was difficult administratively for kidney transplant hospitals to participate as they are part of corporate entities that may have a larger organizational focus on broader shared savings efforts, rather than just for the kidney population.

We proposed that any providers or suppliers participating in the KCC Model that meet the proposed IOTA participant eligibility requirements would still be required to participate in the IOTA Model. We believed that granting an exemption to the IOTA Model for these providers or suppliers could disrupt the patterns of care being tested in the KCC Model. We also believed that a prohibition on dual participation could prevent enough KCEs from having a transplant provider and meeting model requirements, which could undermine participation in the KCC model.

We considered proposing that any transplant hospitals participating in the IOTA Model would not be able to participate in the KCC Model and be able to receive any portion of a Kidney Transplant Bonus payment. However, we did not believe that this was necessary given that there are currently only 10 transplant hospitals participating in the KCC Model, meaning that dual participation should not substantially affect the evaluation of either model. We also considered proposing that any kidney transplant for an aligned beneficiary that results in a Kidney Transplant Bonus being paid out in the KCC Model would not be counted for calculating an upside risk payment or downside risk payment in the IOTA Model. We decided not to propose this policy because of potential disruption to

the KCC Model, which would be in its fourth performance year when the proposed IOTA Model would likely begin in 2025. Additionally, the Kidney Transplant Bonus payment in the KCC Model serves multiple functions within that model, as it also incentivizes post-transplant care for up to three years post-transplant.

We believed that it is important to test both the IOTA Model and the KCC Model, to test the effectiveness of payment incentives for kidney transplants at different points of the care coordination process. The IOTA Model would test the effect of upside and downside risk payments for kidney transplant hospitals, while the KCC Model tests how nephrologists and other providers and suppliers can support transplantation in the overall care coordination process. Upside risk payment and downside risk payment from the IOTA Model would not be counted as expenditures for purposes of the KCC Model, as they would not be adjustments to claims for individual beneficiaries, but would be paid out in a lump sum based on aggregate performance directly tied to individual beneficiary level claims. Additionally, we do not want to potentially hurt KCC participants that have beneficiaries who could benefit from the KCC participant's potential high performance in the IOTA Model.

Both the KCC Model and the IOTA Model would include explicit incentives for participants when aligned beneficiaries receive kidney transplants; and a transplant hospital participating in both models would be eligible to receive a portion of a Kidney Transplant Bonus from a KCE under the KCC Model and an upside risk payment or downside risk payment under the IOTA Model. Kidney transplants represent the most desired and cost-effective treatment for most beneficiaries with ESRD, but providers and suppliers may currently have insufficient financial incentives to assist beneficiaries through the transplant process because dialysis generally results in higher reimbursement over a more extended period of time than a transplant. As a result, CMS believed it would be appropriate to allow a transplant hospital to receive both an upside risk payment or downside risk payment from the IOTA Model and portion of a Kidney Transplant Bonus from the KCC Model and the IOTA Model simultaneously to assess their effects on the transplant rate.

ETC Model—The ETC Model is a mandatory Innovation Center model that includes as participants certain clinicians who manage dialysis patients (referred to as Managing Clinicians) and ESRD facilities and provides incentives for increasing rates of home dialysis, transplant waitlisting, and living donor transplantation. The ETC Model began on January 1, 2021, and the model performance period is scheduled to end December 31, 2025, and it would have one year of overlap with the proposed model performance period of the IOTA Model beginning January 1, 2025. The ETC Model includes an upward or downward payment adjustment called the Performance Payment Adjustment (PPA) that is calculated in part based on the rates of transplant waitlisting and living donor transplants for the population of beneficiaries aligned to a participating Managing Clinician or ESRD facility.

We believed that the goals of the ETC Model and the goals of the proposed IOTA Model are aligned. As CMS described in the 2020 rule finalizing the ETC Model (85 FR 61114), ''[t]he ETC Model [is] a mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants.'' We believe that the IOTA Model would then test a corresponding incentive on the transplant hospital side to further assist beneficiaries in moving through the transplant process to get a transplant. CMS believed it is appropriate to test both models as the ETC Model does not include direct incentives for transplant hospitals and we believe that transplant hospitals play a very important role in the transplant process.

We note for the ETC Model, participants are selected based on their location in a Selected Geographic Area, which are randomly selected Hospital Referral Regions (HRR), stratified by census region, representing approximately one third of the country, as well as HRRs predominately comprised of ZIP codes in Maryland. This is a different randomization strategy than is being proposed for the IOTA Model. It is our intent to look at the effects of each model and its randomization strategy on the transplant rate as part of our model evaluation, which is discussed in section III.C.12 of this final rule.

Additionally, we note that the ETC Model includes the ETC Learning Collaborative as part of its model test. This is further discussed in section III.C.13. of this final rule, where we sought feedback about the experience of kidney transplant hospitals, OPOs, ETC Participants, and other interested parties engaged in the ETC Learning Collaborative, as we consider how to best promote shared learning in the IOTA Model.

Other Medicare Alternative Payment Models (APMs)—For the Medicare Shared Savings Program (the Shared Savings Program) and the ACO Realizing Equity, Access, and Community Health (ACO REACH) Model, which focus on total cost of care, payment adjustments made under the IOTA Model would not be counted as program expenditures. The Medicare Shared Savings Program regulations address payments under a model, demonstration, or other time-limited program when defining program expenditures. Specifically, when calculating Shared Savings and Shared Losses for an ACO in the Shared Savings Program, CMS considers only ''individually beneficiary identifiable final payments made under a demonstration, pilot, or time limited program'' to be a part of the ACO's Medicare Parts A and B fee-for-service expenditures (see, for example, 42 CFR 425.605(a)(5)(ii)). Similarly, in the ACO REACH Model, an ACO's performance year expenditure is defined to include the total payment that has been made by Medicare fee-for-service for services furnished to REACH Beneficiaries (see ACO REACH Model First Amended and Restated Participation Agreement (Dec. 1, 2023)). Payments under the IOTA Model are not directly tied to any specific beneficiary. Instead, they are made on a lump sum basis based on aggregate performance across transplant patients seen by the center during the performance year. IOTA Model payments, therefore, would not be considered by the Shared Savings Program as an amount included in Part A or B fee-for-service expenditures or by the ACO REACH Model as an amount included in payment for REACH Beneficiaries' Medicare fee-for-service services.

Hospital VBP Program—CMS adjusts payments to hospitals under the Inpatient Prospective Payment System (IPPS) based on their performance under the Hospital VBP Program. However, the Hospital VBP Program does not currently include any measures related to transplant services. In addition, transplant services are only offered by a subset of hospitals. Given the different focuses between the Hospital VBP Program and the IOTA Model, we are not proposing any changes to the Hospital VBP Program and believe it is appropriate to test the IOTA Model alongside the existing Hospital VBP Program.

b. Overlap With Departmental Regulatory Efforts

December 2020 OPO Conditions for Coverage—In December 2020, CMS

issued a final rule titled ''Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final Rule'' (85 FR 77898). The final rule revised the OPO CfCs and was intended to increase donation rates and organ transplantation rates by replacing the previous outcome measures. In general, the new outcome measures improve on the prior measures by using objective, transparent, and reliable data, rather than OPO self-reported data, to establish the donor potential in the OPO's DSA. The rule also permits CMS to begin decertifying underperforming OPOs beginning in 2026.

We believed that the proposed IOTA Model supports the policies set out in that final rule. We noted that we have received feedback from OPOs and other interested parties that OPOs are required to procure more organs, while there is not a corresponding incentive on the transplant hospital side to transplant more organs into beneficiaries. We also noted that the number of discarded organs has risen from 21 percent to 25 percent from 2018 to 2022.[320] Though there have been other changes during that time, including the updated organ allocation system and the effects of the COVID–19 pandemic, this rise in discarded organs is highly concerning, and we believed that the IOTA Model can help to mitigate this troubling rise by giving transplant hospitals an incentive to accept more offers that they may not have accepted without that incentive.

In September 2019, CMS finalized a rule titled ''Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51732). This rule was in part motivated by a commitment across CMS and HHS to ''the vision of creating an environment where agencies incorporate and integrate the ongoing retrospective review of regulations into Department operations to achieve a more streamlined and effective regulatory framework.''

One of the major provisions finalized in this rule was the removal of data submission, clinical experience, and outcomes requirements for Medicare re-approval that were previously required of transplant hospitals participating in the Medicare program. As described in the rule, CMS had put in place additional CoPs in the March 2007 final rule (72 FR 15198) in an effort to increase the quality of care by specifying minimal health and safety standards for transplant hospitals. In addition, outcome metrics (1 year graft and patient survival) were included in the regulation and mirrored the OPTN outcomes metrics as calculated by the SRTR.

CMS removed the outcomes requirements for a few key reasons. First, the concern was that transplant centers were also subject to OPTN policies, so parallel regulation on the CMS side was duplicative. Additionally, the concern was that ''increased emphasis on organ and patient survival rates, as key metrics of transplant performance, created incentives for transplant programs to select organs most likely to survive after transplant without rejection, and to select recipients most likely to survive after the transplant.'' This focus had the effect of creating ''performance standards that focused only on organ and patient survival rates for those who received a transplant, not on survival rates of patients awaiting transplant.'' [321]

In December 2021, CMS published an RFI titled ''Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities'' (86 FR 68594).[322] In this RFI, CMS asked questions about the overall transplant ecosystem, with goal of helping ''to inform potential changes that would create system-wide improvements, which would further lead to improved organ donation, organ transplantation, quality of care in dialysis facilities, and improved access to dialysis services.''

We noted that we were seeking ways to harmonize policies across the primary HHS agencies (CMS, HRSA, and the Food and Drug Administration (FDA)) that are involved in regulating stakeholders in the transplant ecosystem so that our requirements are not duplicative, conflicting, or overly burdensome. We asked if there any current requirements for transplant programs, ESRD facilities, or OPOs that are unnecessarily duplicative of, or in conflict with, OPTN policies or policies that are covered by other government agencies. We also asked about the impacts of these duplicative requirements on organ utilization and transplant program/ESRD facility/OPO quality and efficiency (86 FR 68596).

Given the concerns described in these past efforts, the OPTN has been in part responsive to concerns from interested parties about their metrics and effects and has expanded which metrics they are evaluating transplant centers for their performance. In December 2021, the OPTN approved four new risk-adjusted metrics to be used to monitor transplant program performance, including 90-day graft survival hazard ratio, 1-year conditional graft survival hazard ratio, pre-transplant mortality rate ratio, and offer acceptance ratio.[323] This added two new metrics for areas beyond simply looking at transplant survival, and looked at a more holistic view of patient care for beneficiaries on the transplant list. There is a critical role for both the Department and the OPTN with regard to the transplant ecosystem. The final rule governing the operation of the OPTN from 1996 (63 FR 16296) stated the following:

The Department believes that the transplantation network must be operated by professionals in the transplant community, and that both allocation and other policies of the OPTN should be developed by transplant professionals, in an open environment that includes the public, particularly transplant patients and donor families. It is not the desire or intention of the Department to interfere in the practice of medicine. This rule does not alter the role of the OPTN to use its judgment regarding appropriate medical criteria for organ allocation nor is it intended to circumscribe the discretion afforded to doctors who must make the difficult judgments that affect individual patients. At the same time, the Department has an important and constructive role to play, particularly on behalf of patients. Human organs that are given to save lives are a public resource and a public trust.

We believed that the proposed IOTA Model recognizes the goals of the Department on behalf of the public and the medical judgment exhibited by the OPTN. We believed that constructing

[320] Sumit Mohan, Miko Yu, Kristen L. King, S. Ali Husain, Increasing Discards as an Unintended Consequence of Recent Changes in United States Kidney Allocation Policy, Kidney International Reports, Volume 8, Issue 5, 2023, Pages 1109–1111, ISSN 2468–0249, *https://doi.org/10.1016/j.ekir.2023.02.1081.*

[321] *https://www.federalregister.gov/d/2019-20736/p-87.*

[322] Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities. *https://www.federalregister.gov/documents/2021/12/03/2021-26146/request-for-information-health-and-safety-requirements-for-transplant-programs-organ-procurement.*

[323] *OPTN Board adopts new transplant program performance metrics—OPTN.* (2021, December 16). Optn.*transplant.hrsa.gov.* Retrieved May 30, 2023, from *https://optn.transplant.hrsa.gov/news/optn-board-adopts-new-transplant-program-performance-metrics/.*

this as a model test would enable the Department to test out a different approach to incentivize certain behavior for transplant centers, while also acknowledging the role of the OPTN and transplant professionals in this area.

We noted the concern put forward by kidney transplant hospitals that they would not be able to increase their number of transplants without potentially affecting their performance 90 day and 1-year graft survival rate metrics used by the MPSC. However, we believed that there are several different ways that IOTA participants would ultimately be able to succeed under the IOTA Model and OPTN policies:

- The MPSC standard represents a standard far below the national average of performance that should be able to be met by member transplant centers. The MPSC describes this as meaning that to be identified for outcomes review in a document describing their Performance Reviews,[324] ''[t]he adult criteria is based on the likelihood that the program's performance was at least 75 percent worse than an average program, accounting for differences in the types of recipients and donor organs transplanted. The pediatric criterion is based on the likelihood that the program's performance was at least 60 percent worse than an average program, accounting for differences in the types of recipients and donor organs transplanted. Even if a program meets one or both of the criteria for graft survival, the MPSC may not send the program an inquiry based on various situations, such as recent release from review for outcomes or program membership status.'' This represents a minimum standard of care and only a small percentage were flagged for not meeting those standards.
- The IOTA Model incentivizes investment in both living and deceased donor transplants. Living donor transplantation has rates that have been relatively flat for 20 years and has recipients of those organs with better post-transplant outcomes.
- MPSC outcomes metrics are risk adjusted based on organ quality and can account for the use of organs that are currently being discarded.
- Many organs currently being discarded are quality organs. Though the median KDRI of discarded kidneys was higher for discarded kidneys than transplanted kidneys, there is a large overlap in the quality of discarded and transplanted kidneys.[325]
- Per 42 CFR 121.10(c)(1), the reviews conducted by the OPTN result in an advisory opinion to the Secretary of a recommended course of action. The Secretary then has the option under 42 CFR 121.10(c)(2) of requesting additional information, declining to accept the recommendation, accepting the recommendation, or taking such other action as the Secretary deems necessary. Given the enforcement discretion given to the Secretary, the Secretary may take into account performance on the metrics evaluated in the IOTA Model as part of a holistic evaluation of transplant hospital performance.

Additionally, CMS also considered, but did not propose, a limited waiver of section 1138(a)(1)(B) of the Act as part of the IOTA Model, which requires that a hospital be a member and abide by the rules and requirements of the OPTN. We considered retaining transplant hospitals' membership obligations to the OPTN with the exception of their required responsiveness to MPSC transplant hospital performance reviews and the potential for adverse actions that may risk a transplant hospital's operations and reimbursement by Federal health insurance programs. However, we do not believe that this waiver is necessary for testing the model, and that a transplant hospital can perform on both the metrics put forward by the MPSC and demonstrate successful performance in the IOTA Model.

We invited public comments on our proposals to account for overlaps with other CMS programs and models.

The following is a summary of the comments received on our proposals to account for overlaps with other CMS programs and models and our responses:

Comment: We received multiple comments about the OPTN Modernization and concerns that the OPTN Modernization process is happening right now, as the IOTA Model is being implemented, which would potentially be too disruptive to the transplant system. We also received comments concerned about the solicitation for a new OPTN contractor and concerns that any potential transition that could happen from a new contract could lead to disruption that could impact ability to perform in the IOTA Model.

Response: We disagree with the commenters as we believe that the OPTN Modernization process will improve the system overall and includes a series of improvements in technology, governance, and organ tracking that will benefit IOTA participants as they participate in this model. At a high level, the IOTA Model was proposed and developed in coordination with CMS and HRSA in an effort to create a series of coordinated initiatives across the transplant ecosystem, using a variety of different levers to improve performance and equity in the United States transplant system. Through the OTAG, CMS and HRSA have collaborated and produced the IOTA Model, the OPTN Modernization Process, and further efforts to come including around the HIV Organ Policy Equity Act in an effort to increase accountability in the transplant system and improve it for patients.

Additionally, HRSA and the OPTN are committed that the Modernization Process will not disrupt existing procurement and allocation practices. HHS also believes that this modernization process will improve accountability and performance for the OPTN and accelerate progress in technology, data transparency and analytics, governance, operations, and quality improvement and innovation. Some key steps that have already been taken include in August 2024 separating the OPTN Board of Directors from the OPTN contractor so it may better serve the interests of patients and their families, which HHS believes will strengthen governance and prevent conflicts of interest within the Network. Other major steps include issuing a Request for Proposals for a multi-vendor contract solicitation for critical OPTN functions and a transition to an upgraded IT system that leverages industry-leading standards. The net result of these efforts will be a more functional and accountable system that will better be able to get and share data than in the status quo. We also believe that the delayed start date for model accountability to July 1, 2025, will enable the OPTN Modernization to progress further and allow for the awarding of these contracts and onboarding of new contractors before accountability begins. We also note that the randomized design of the model means that major national changes, like this OPTN Modernization effort, will apply equally to both the selected IOTA DSAs and the DSAs that are not selected and are in the comparison group, meaning that CMS will still be able to fully evaluate the impacts of the interventions in the IOTA Model.

Comment: We received multiple comments about the OPTN's

[324] *https://optn.transplant.hrsa.gov/media/5j5dov5s/what_to_expect_performance_reviews.pdf.*

[325] Mohan, S., Chiles, M.C., Patzer, R.E., Pastan, S.O., Husain, S.A., Carpenter, D.J., Dube, G.K., Crew, R.J., Ratner, L.E., & Cohen, D.J. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney International, 94*(1), 187–198. *https://doi.org/10.1016/j.kint.2018.02.016.*

Expeditious Task Force, with some concerns about the implications of overlapping initiatives both designed to increase number of transplants. A commenter specifically pointed out that a part of the Expeditious effort includes a proposed allocation variance to allow for the study of out-of-sequence allocation.

Response: We appreciate the comments and believe that overall, there is a great deal of synergy between the efforts being promoted as part of the Expeditious Task Force and the IOTA Model, starting with their initial aim of greatly increasing the number of transplants completed across the country. The Expeditious efforts include many different components, many of which will help selected IOTA participants perform better in the model. This includes efforts like analyzing patterns of non-use of kidneys, conducting data analysis to improve organ offer filters, and working on how to best secure commitments from hospital leadership to secure investment for the IOTA participant to be able to build up infrastructure to support a growth in kidney transplants. We believe that these efforts are incredibly helpful and will support improved performance in the achievement and efficiency domains in the IOTA Model.

We saw multiple comments about out-of-sequence allocation and the proposed limited trials being proposed by the Expeditious Task Force that are designed to test a proposed variance to the allocation methodology for certain OPOs. We note that these proposed trials are meant to last for only a few months and are meant to be limited in scope and do not believe that they would impact the ability to evaluate the IOTA Model. We also note that we described in the monitoring section of this rule that we plan to monitor out-of-sequence allocation in the context of the IOTA Model to see if that is a strategy used by IOTA participants to utilize more kidneys.

Comment: We received a comment saying that this model is being proposed to be implemented amidst too many other initiatives, including the proposed new OPTN data collection initiative.

Response: HHS believes that collecting the proposed data from OPOs and kidney transplant hospitals will be beneficial for patients, improve the overall transplant process, and help IOTA participants succeed in the IOTA Model. The transplant hospital forms will help to track sources of waitlist referral, the results of referrals, and the results of transplant evaluations to see who makes it onto the transplant waiting list. We believe that this data driven approach will help transplant hospitals better understand their sources of referral and potential areas of improvement in the waitlisting process that may allow for better waitlist management. The organ procurement forms will require OPOs to track how effective they are at responding to referrals from donor hospitals and how effective they are at procuring organs from potential donor candidates. We believe that this data driven approach will help OPOs with quality improvement to understand their success at different stages in the procurement process and will therefore help to increase the supply of organs for IOTA participants.

At the same time, HHS understands this potential criticism and will work to coordinate once the waitlist referral and evaluation forms are established, recognizing that it would be the same staff at transplant hospitals who would be likely to fill these out as those who would be working to increase the number of transplants under the IOTA Model. We also note that the proposed forms for transplant hospitals and OPOs will undergo a thorough public review process that began via **Federal Register** Notice on November 4, 2024.[326]

Comment: We received multiple comments about the metrics used by the MPSC, some pointing out the duplicative nature with the metrics that are a part of the IOTA Model and some worried that their performance on MPSC metrics may be hurt by their performance under the IOTA Model.

Response: As discussed previously in this section, we anticipated this concern and believe that there are several different ways that IOTA participants would ultimately be able to succeed under the IOTA Model and OPTN policies. Given the relatively low bar for the different metrics for the MPSC, the risk adjusted nature of their metrics, and the potential for increasing transplants with the quality organs that are currently going unused and the opportunity to increase living donation rates, we see many ways that participants will be able to be successful under both sets of metrics. Additionally, we constructed the IOTA Model in the context of the regulatory efforts through the OPTN and the CMS Transplant Center CfCs, recognizing that CMS is incentivizing more transplants for patients, but that we want to make sure they are done in a way that still ensures an appropriate level of patient safety.

Comment: We received a comment about the potential that OPTN will move to continuous allocation for kidneys, which could disrupt their operations.

Response: HHS recognizes that the OPTN is considering further adjustments to the organ allocation system. We believe that the randomly selection methodology in the IOTA Model will help to account for any changes to the allocation system, given the national focus of any of these changes. We also believe that the focus on organ offer acceptance rate in the model will encourage participating kidney transplant hospitals to carefully consider their organ offer filters, which will help to limit potential disruption to transplant operations.

We also received comments about the potential overlap between initiatives and regulations elsewhere within CMS and the IOTA Model.

Comment: We received multiple comments worried about implementation of the 2020 update to the OPO CfCs and their potential impact on OPO decertification, with worries about the potential effects of new OPOs coming in on organ allocation. We also received comments about the OPO CfC methodology that were out of scope.

Response: We recognize that implementation of accountability in the IOTA Model will intersect with the recertification period for OPOs in 2026. However, we believe that though there is a hypothetical potential for some disruption as a new OPO takes over a DSA, we believe that the interaction between the IOTA Model and the updated CfCs will ultimately be positive for both OPOs and transplant hospitals and will better allow both to perform better on their respective metrics. Since the updated CfCs were finalized in 2020, OPOs have been procuring more organs and have complained that there was not a corresponding incentive on the transplant hospital side to use more of the organs that are procured. Additionally, the number of organ offers and turndowns has grown since the updated CfCs and allocation system were finalized. We believe that the incentives in the IOTA Model will help to better ensure more judicious use of organ offer filters to better reflect potential for utilization, which will make it easier for OPOs to place the organs that they procure. CMS also commits to recognizing the potential for disruption with the decertification of

[326] U.S. Department of Health and Human Services. (2024, November 4). *Agency information collection activities; proposed collection; public comment request* [Docket No. HHS–2024–25522]. **Federal Register**. *https://www.federalregister.gov/documents/2024/11/04/2024-25522/agency-information-collection-activities-proposed-collection-public-comment-request-information.*

any OPO and will work to make this process as smooth as possible.

Comment: We received a comment asking CMS to prioritize waiver requests from hospitals seeking to work with a different OPO before taking action on creating a new transplant model.

Response: We appreciate this commenters suggestion and the importance of this issue; however, this comment is beyond the scope of this rule.

Comment: We received a comment from a hospital pointing out that they are already subject to the CMS Survey and Certification process, making the IOTA Model unnecessary.

Response: As discussed previously, in 2019, CMS removed any outcomes requirements from its Survey and Certification requirements. The IOTA Model focuses on increasing numbers of transplants and improving organ offer acceptance rate, neither of which were addressed in the previous version of the Survey and Certification requirements and includes financial incentives for performance that are not included in the CMS Survey and Certification process. We believe that this model test can complement existing Survey and Certification requirements as those will help to ensure a baseline level of patient care in the transplant process, while still enabling CMS to test out a new method to pay for care, without compromising care for patients.

Comment: We received some concern about the potential implications on the IOTA Model if CMS implements some previously proposed changes to the way that organ acquisition costs are calculated.

Response: In the FY 2022 IPPS Final Rule (CMS 1752–FC3), We decided not to finalize a proposed change to the way that Medicare's share of organ acquisition costs are calculated for centers. Based on the consideration of concerns received from commenters, CMS decided not to finalize the proposed policy with respect to counting organs at this time, but stated that we may consider it in future rulemaking.

We also received comments from the public about interaction with multiple efforts at the Innovation Center.

Comment: We received a comment from a dialysis company pointing out the potential for cooperation between selected IOTA transplant hospitals and participants in the existing ETC and KCC Models.

Response: We appreciate the comment, as these models were designed to fit together. Participating entities in the KCC Model have the opportunity to partner with selected IOTA participants and to even add them to their participant lists for an upcoming performance year. CMS encourages greater collaboration throughout the entire spectrum of transplant care and believes that alignment for patients from the first detection of CKD, through the need for dialysis, and all the way through the delivery of a transplant results in the best outcomes for most beneficiaries.

Comment: We received a comment from a hospital association urging that transplant hospitals participating in any Innovation Center Advanced APM model be able to opt out of the proposed IOTA Model.

Response: We disagree with the comment as CMS decided to make the model mandatory for reasons discussed previously in the relevant section. We recognize that many kidney transplant hospitals have made decisions to be involved in many other different value-based purchasing programs like the Shared Savings Program or another Innovation Center Model and allowing those involved in those other models to opt out could hurt the ability to evaluate the IOTA Model. We also recognize that none of these models, outside of the KCC Model which has seen a relatively low level of participation from kidney transplant hospitals, are particularly focused on transplantation, which we believe helps to show the need for a transplant-focused value-based care model.

Comment: We received a comment from one hospital expressing concern about being opted into both the IOTA Model and the TEAM Model, recently finalized by the Innovation Center, and were concerned about their ability to conduct change management at their hospital if they are selected into both models.

Response: The TEAM Model was finalized in the 2025 IPPS Rule in July 2024 (CMS–1808–F). We recognize the potential complications as CMS and particularly the Innovation Center tests multiple models at the same time. However, we believe that this model has very different goals than the TEAM Model, which is focused on surgical bundles for five procedures and post-acute care spending, rather than the transplant process. We also note that both models include a period of time before implementation, creating an opportunity for hospitals that are required to participate in both models' time to enact necessary changes in practice.

After consideration of the public comments we received, we are finalizing the overlaps policy in the model as proposed. The Innovation Center will continue to monitor developments in the transplant ecosystem to see if changes are needed to the model for unintended consequences. The Innovation Center is committed to continuing to work and coordinate with other components of CMS and HRSA as they continue to implement the updated OPO CfCs and the OPTN Modernization process in order to see if any actions do end up affecting the ability of selected IOTA transplant hospitals to perform in the model. These coordination efforts through the Organ Transplant Affinity Group are part of a larger HHS effort to ensure policy coordination and ensure input across HHS as we consider and implement reforms to the transplant system.

10. Beneficiary Protections

a. Beneficiary Notifications

At § 512.450 of the proposed rule, we proposed to require IOTA participants to provide notice to attributed patients that the IOTA participant is participating in the IOTA Model. We believed it would be important for IOTA participants to provide attributed patients with a standardized, CMS-developed, beneficiary notice to limit the potential for fraud and abuse, including patient steering. We intended to provide a notification template that IOTA participants would be required to use. This template would, at minimum, indicate content that the IOTA participant would not be permitted to change and would indicate where the IOTA participant could insert its own content. It would also include information regarding the attributed patient's ability to opt-out of data sharing with IOTA participants and how they may opt out if they choose to do so (89 FR 43518).

At § 512.450 of the proposed rule, we proposed requiring IOTA participants to display a notice containing these rights and protections prominently at each office or facility location where an attributed patient may receive treatment, in a clear manner on its public facing website, and to each attributed patient in a paper format. This would increase the probability that the attributed patients would receive and take note of this information.

We sought comment on the proposed requirements for beneficiary notifications.

The following is a summary of the public comments received on these proposals and our response:

Comment: Several commenters expressed support for requiring hospitals and providers to notify

patients about their participation in the IOTA Model.

Response: We thank the commenters for their support.

Comment: A commenter expressed concern that CMS should provide more information about the required notice of attribution, including expectations for hospitals and patients.

Response: We thank the commenter for its feedback. We will provide a template for the beneficiary notification that will have additional information concerning the notice of attribution. We will take the commenter's feedback into consideration as we draft the template.

Comment: Several commenters suggested that the beneficiary notifications should require an IOTA participant to notify patients of participation in IOTA in multiple languages and that CMS limit the requirement for beneficiary notifications to be provided only upon patient request and only at the main transplant hospital.

Response: We thank the commenters for their feedback. Although the IOTA Model does not require IOTA participants to provide beneficiary notifications in multiple languages, other federal laws and regulations that apply to language services will still apply to IOTA participants. Accordingly, we decline to include such requirements in the IOTA Model regulations at this time.

We also disagree with the suggestion that the notice only be required upon patient request. Many patients may not be aware of their rights and not know that such a request should be made. Additionally, we disagree with the suggestion that the notice only be required at the main location of the IOTA participant. It is possible that a beneficiary would not be seen at the main location of the IOTA participant and therefore not be properly informed.

After consideration of the public comments received, for the reasons set forth in this rule, we are finalizing our proposed provision to require IOTA participants to provide notice to attributed patients that the IOTA participant is participating in the IOTA Model, including the requirement to display a notice containing these rights and protections prominently at each office or facility location, at § 512.450, with minor technical corrections to update the spacing in the regulation and provide clarification, including the removal of duplicative text, at § 512.450(a)(3)(ii).

b. Availability of Services and Beneficiary Freedom of Choice

In section II.B of the proposed rule, we proposed the Standard Provisions for Innovation Center Models relating to availability of services and beneficiary freedom of choice would apply to the IOTA Model. These provisions were originally finalized as general provisions in the Code of Federal Regulations (42 CFR part 512 subpart A) that applied to specific Innovation Center models, but are finalized separately in section II.B of this final rule for expansion to all mandatory Innovation Center Models with performance periods that begin on or after January 1, 2025. Consistent with this final rule, IOTA participants will need to preserve beneficiary freedom of choice and continue to make medically necessary covered services available to beneficiaries to the extent required by applicable law.

We received no comments on these proposals and therefore are finalizing these proposals without modification.

11. Financial Arrangements and Attributed Patient Engagement Incentives

a. Background

We believe it is necessary to provide IOTA participants with flexibilities that could support their performance in the IOTA Model and allow for greater support for the needs of attributed patients. These flexibilities are outlined in this section and include the ability to engage in financial arrangements to share IOTA upside risk payments and responsibility for paying Medicare for IOTA downside risk payments with providers and suppliers making contributions to the IOTA participants' performance against model metrics, and the availability of the provision of attributed patient engagement incentives. Such flexibilities would allow IOTA participants to share all or some of the payments they may be eligible to receive from CMS and to share the responsibility for the funds needed to pay CMS providers and suppliers engaged in caring for attributed patients, if those providers and suppliers have a role in the IOTA participant's spending or quality performance. Additionally, we believe that IOTA participants caring for attributed patients may want to offer attributed patient engagement incentives to encourage adherence to recommended treatment and active patient engagement in recovery. These incentives may help an IOTA participant reach their quality and efficiency goals for the model, while also benefitting beneficiaries' health and the Medicare Trust Fund if the IOTA participant improves the quality and efficiency of care that results in the Medicare beneficiary's reductions in hospital readmissions, complications, days in acute care, and mortality, while recovery continues uninterrupted or accelerates.

b. Overview of IOTA Model Financial Arrangements

We believe that IOTA participants may wish to enter into financial arrangements with providers and suppliers caring for attributed patients to share model upside risk payments or downside risk payments, to align the financial incentives of those providers and suppliers with the IOTA Model goals of increasing the number of kidney transplants furnished to attributed patients to lower costs and to improve their quality of life. To do so, we expect that IOTA participants would identify key providers and suppliers caring for attributed patients in their communities and DSAs. The IOTA participants could establish partnerships with these providers and suppliers to promote accountability for the quality, cost, and overall care for attributed patients, including managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigning care processes for high quality and efficient service delivery; and carrying out other obligations or duties under the IOTA Model. These providers and suppliers may invest substantial time and other resources in these activities, yet they would neither be the direct recipients of any model upside risk payments from Medicare, nor directly responsible for paying to CMS any downside risk payments incurred. Therefore, we believe it is possible that an IOTA participant that may receive an upside risk payment from Medicare or may need to pay a downside risk payment to Medicare may want to enter into financial arrangements with other providers or suppliers to share these performance adjustments with the IOTA participant.

We require that all financial relationships established between IOTA participants and providers or suppliers for purposes of the IOTA Model would only be those permitted under applicable law and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements. As discussed in section III.C.3 of this final rule, CMS determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)(1)) is available to

protect the financial arrangements proposed in this section when arrangements with eligible providers and suppliers are in compliance with this policy and the conditions for use of the Federal anti-kickback statute safe harbor set out at § 1001.952(ii)(1).

We recognize that there are numerous arrangements that IOTA participants may wish to enter other than the financial arrangements described in the proposed regulations for which safe harbor protection may be extended that could be beneficial to the IOTA participants. For example, IOTA participants may choose to engage with organizations that are neither providers nor suppliers to assist with matters such as data analysis; local provider and supplier engagement; care redesign planning and implementation; beneficiary outreach; beneficiary care coordination and management; monitoring IOTA participants' compliance with the model's terms and conditions; or other model-related activities. Such organizations may play important roles in an IOTA participant's plans to implement the model based on the experience these organizations may bring, such as prior experience with living donation initiatives, care coordination expertise, familiarity with a particular local community, or knowledge of SRTR data. We require that all relationships established between IOTA participants and these organizations for purposes of the model would be those permitted only under existing law and regulation, including any relationships that would include the IOTA participant's sharing of model upside risk payments or downside risk payments with such organizations., and must comply with all applicable laws and regulations We require these relationships to be solely based on the level of engagement of the organization's resources to directly support the participants' model implementation.

c. IOTA Collaborators

Given the financial incentives of the IOTA performance-based payments, as described in section III.C.6.c of this final rule, an IOTA participant may want to engage in financial arrangements with providers and suppliers making contributions to the IOTA participant's performance across the achievement domain, efficiency domain, and quality domain. Such arrangements would allow the IOTA participant to share monies earned from the upside risk payments. Likewise, such arrangements could allow the IOTA participant to share the responsibility for the funds needed to repay CMS the downside risk payments. We proposed to use the term ''IOTA collaborator'' to refer to these providers and suppliers.

Because attributed patients include both those on the kidney transplant waitlist and those who have received a kidney transplant, as described in section III.C.4.a of this final rule, many providers and suppliers other than the IOTA participant would furnish related services to attributed patients during the model performance period. As such, for purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)), we proposed that the following types of providers and suppliers that are Medicare-enrolled and eligible to participate in Medicare may be IOTA collaborators:

- Nephrologist.
- ESRD Facility.
- Skilled Nursing Facility (SNF).
- Home Health Agency (HHA).
- Long-Term Care Hospital (LTCH).
- Inpatient Rehabilitation Facility (IRF).
- Physician.
- Nonphysician practitioner.
- Therapist in a private practice.
- Comprehensive Outpatient Rehabilitation Facility (CORF).
- Provider or supplier of outpatient therapy services.
- Physician Group Practice (PGP).
- Hospital.
- Critical Access Hospital (CAH).
- Non-physician provider group practice (NPPGP).
- Therapy Group Practice (TGP).

We sought comment on the proposed definition of IOTA collaborators and any additional Medicare-enrolled providers or suppliers that should be included in this definition.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Several commenters supported the inclusion of IOTA collaborators in the model and encouraged expanding the types of entities allowed as IOTA collaborators to include other provider types.

Commenters recommended including in the list of IOTA collaborators: audiologists, registered dietitian nutritionists (RDNs), and rural emergency hospitals.

Response: We thank commenters for their recommendations and support of this initiative. We appreciate your insights on expanding the types of entities allowed as IOTA collaborators. We will take them into consideration in future rulemaking.

After consideration of the public comments received, for the reasons set forth in this rule, we are finalizing the proposal for the model definition of IOTA collaborators as proposed at § 512.402. We are also finalizing as proposed the definitions for the types of IOTA collaborator Medicare-enrolled providers or suppliers at § 512.402 with minor technical corrections to update cross references. Specifically, we are finalizing our proposed definition of nonphysician practitioner at § 512.402 with a minor technical correction to include the full cross reference. Additionally, we are finalizing our proposed definition of therapist at § 512.402 with a minor technical correction to include the correct cross reference to the regulatory definition for that term. Lastly, we are finalizing our proposed definition of hospital at § 512.402 with a technical correction to specify that hospital has the meaning set forth in § 1861(e) of the Act.[327]

d. Sharing Arrangements

(1) General

Similar to the Comprehensive Care for Joint Replacement Payment Model (CJR) (42 CFR part 510), we proposed that certain financial arrangements between an IOTA participant and an IOTA collaborator be termed ''sharing arrangements.'' For purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)), we proposed that a sharing arrangement would be a financial arrangement to share only—(1) the upside risk payment; and (2) the downside risk payment.

Where a payment from an IOTA participant to an IOTA collaborator is made pursuant to a sharing arrangement, we proposed to define that payment as a ''gainsharing payment,'' which is discussed in section III.C.11.d.(3). of this final rule. Where a payment from an IOTA collaborator to an IOTA participant is made pursuant to a sharing arrangement, we proposed to define that payment as an ''alignment payment,'' which is discussed in section III.C.11.d.(3). of this final rule.

We sought comment about all provisions described in the preceding discussion.

We received no comments on these proposals and therefore are finalizing these proposals as proposed in our regulation at § 512.452. We are also finalizing without modification the proposed definitions of sharing

[327] Subsequent to the publication of the proposed rule, we found that the proposed definition of ''hospital'' included an incorrect citation to the Social Security Act. Section 1861(u) of the Act defines ''provider of services,'' which includes more than just hospitals. We clarify that, for the purposes of the IOTA Model, the term ''hospital'' has the meaning set forth in § 1861(e) of the Act.

arrangements, gainsharing payment, and alignment payment at § 512.402.

(2) Requirements

We proposed several requirements for sharing arrangements to help ensure that their sole purpose is to create financial alignment between IOTA participants and IOTA collaborators toward the goals of the model while maintaining adequate program integrity safeguards. An IOTA participant must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement. We proposed that a sharing arrangement must comply with the provisions of § 512.452 and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

We proposed that the IOTA participant must develop, maintain, and use a set of written policies for selecting providers and suppliers to be IOTA collaborators. To safeguard against potentially fraudulent or abusive practices, we proposed that the selection criteria must include the quality of care delivered by the potential IOTA collaborator. We also proposed that the selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between, or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent. Additionally, we proposed that IOTA participants must consider the selection of IOTA collaborators based on criteria related to, and inclusive of, the anticipated contribution to the performance of the IOTA participant across the achievement domain, efficiency domain, and quality domain by the potential IOTA collaborator to ensure that the selection of IOTA collaborators takes into consideration the likelihood of their future performance.

It is necessary that IOTA participants have adequate oversight over sharing arrangements to ensure that all arrangements meet the requirements of the model. Therefore, we proposed that the board or other governing body of the IOTA participant have responsibility for overseeing the IOTA participant's participation in the model, including, but not limited to, its arrangements with IOTA collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives (as discussed in III.C.11.g of this final rule).

Finally, we proposed that if an IOTA participant enters a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the model. Requiring oversight of sharing arrangements to be included in the compliance program provides a program integrity safeguard.

We sought comment about all provisions described in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

We proposed that the sharing arrangement must be in writing, signed by the parties, and entered into before care is furnished to attributed patients during the PY under the sharing arrangement. In addition, participation in the sharing arrangement must require the IOTA collaborator to comply with the requirements of this model, as those pertain to their actions and obligations. Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation. It is important that providers and suppliers rendering items and services to attributed patients during the model performance period have the freedom to provide medically necessary items and services to attributed patients without any requirement that they participate in a sharing arrangement to safeguard beneficiary freedom of choice, access to care, and quality of care. The sharing arrangement must set out the mutually agreeable terms for the financial arrangement between the parties to guide and reward model care redesign for future performance across the achievement domain, efficiency domain, and quality domain, rather than reflect the results of model PYs that have already occurred and where the financial outcome of the sharing arrangement terms would be known before signing.

We proposed that the sharing arrangement must require the IOTA collaborator and its employees, contractors (including collaboration agents), and subcontractors to comply with certain requirements that are important for program integrity under the arrangement. We note that the terms contractors and subcontractors, respectively, include collaboration agents as defined later in this section. The sharing arrangement must require all of the individuals and entities in this group to comply with the applicable provisions of §§ 512.450–512.466 of this final rule, including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees, because these individuals and entities all would play a role in model care redesign and be part of financial arrangements under the model. The sharing arrangement must also require all individuals and entities in the group to comply with the applicable Medicare provider enrollment requirements at § 424.500 *et seq.,* including having a valid and active TIN or NPI, during the term of the sharing arrangement. This is to ensure that these individuals and entities have the required enrollment relationship with CMS under the Medicare program, although we note that they are not responsible for complying with requirements that do not apply to them. Finally, the sharing arrangement must require these individuals and entities to comply with all other applicable laws and regulations.

We proposed that the sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care so that financial relationships between IOTA participants and IOTA collaborators do not negatively impact beneficiary protections under the model. The sharing arrangement must require the IOTA collaborator to have, or be covered by, a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the IOTA Model that apply to its role as an IOTA collaborator, including any distribution arrangements, just as we require IOTA participants to have a compliance program that covers oversight of the sharing arrangement for this purpose as a program integrity safeguard. We sought comment on the anticipated effect of the proposed compliance program requirement for IOTA collaborators, particularly with regard to individual physicians and nonphysician practitioners, small PGPs, NPPGPs, and TGPs and whether alternative compliance program requirements for all or a subset of IOTA collaborators should be adopted to mitigate any effect of the proposal that could make participation as an IOTA collaborator infeasible for any provider, supplier, or other entity on the proposed list of types of IOTA collaborators.

For purposes of sharing arrangements under the model, we proposed to define activities related to promoting accountability for the quality, cost, and overall care for attributed patients and performance across the achievement domain, efficiency domain, and quality domain, including managing and

coordinating care; encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; the provision of items and services pre- or post-transplant in a manner that reduces costs and improves quality; or carrying out any other obligation or duty under the model as ''IOTA activities.'' In addition to the quality of episodes of care, we believe the activities that would fall under this proposed definition could encompass the totality of activities upon which it would be appropriate for sharing arrangements to value the contributions of collaborators and collaboration agents toward meeting the performance goals of the model. We sought comment on the proposed definition of IOTA activities as an inclusive and comprehensive framework for capturing direct care and care redesign that contribute to performance across the achievement domain, efficiency domain, and quality domain.

We proposed that the written sharing arrangement agreement must specify the following parameters of the arrangement:

- The purpose and scope of the sharing arrangement.
- The identities and obligations of the parties, including specified IOTA activities and other services to be performed by the parties under the sharing arrangement.
- The date of the sharing arrangement.
- Management and staffing information, including type of personnel or contractors that would be primarily responsible for carrying out IOTA activities.
- The financial or economic terms for payment, including all of the following:

++ Eligibility criteria for a gainsharing payment.

++ Eligibility criteria for an alignment payment.

++ Frequency of gainsharing or alignment payment.

++ Methodology and accounting formula for determining the amount of a gainsharing payment that is substantially based on performance across the achievement domain, efficiency domain and quality domain, and the provision of IOTA Model activities.

++ Methodology and accounting formula for determining the amount of an alignment payment.

Finally, we proposed to require that the terms of the sharing arrangement must not induce the IOTA participant, IOTA collaborator, or any employees, contractors, or subcontractors of the IOTA participant or IOTA collaborator to reduce or limit medically necessary services to any attributed patient or restrict the ability of an IOTA collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments. These requirements are to ensure that the quality of care for attributed patients is not negatively affected by sharing arrangements under the model.

The proposals for the requirements for sharing arrangements under the model are included in § 512.452.

We sought comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

We received no comments on these proposals and therefore are finalizing these proposals as proposed in our regulation at § 512.452 with slight modifications. Specifically, we are redesignating what was proposed at §§ 512.452(b)(5), (6), (7), and (8) to be §§ 512.452(b)(6), (7), (8), and (9). We are also finalizing without modification the proposed definition of IOTA activities at § 512.402.

(3) Gainsharing Payments and Alignment Payments

We proposed several conditions and limitations for gainsharing payments and alignment payments as program integrity protections for the payments to and from IOTA collaborators. We proposed to require that gainsharing payments be derived solely from upside risk payments; that they be distributed on an annual basis, not more than once per performance year; that they not be a loan, advance payment, or payment for referrals or other business; and that they be clearly identified as a gainsharing payment at the time they are paid.

We believe that gainsharing payment eligibility for IOTA collaborators should be conditioned on two requirements—(1) contributing to performance across the achievement domain, efficiency domain or quality domain; and (2) rendering items and services to attributed patients during the model performance period—as safeguards to ensure that eligibility for gainsharing payments is solely based on aligning financial incentives for IOTA collaborators with the performance metrics of the model. With respect to the first requirement, we proposed that to be eligible to receive a gainsharing payment, an IOTA collaborator must contribute to the performance of the IOTA participant across the achievement domain, efficiency domain or quality domain during the PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment. We also proposed that the contribution to performance across the achievement domain, efficiency domain, or quality domain criteria must be established by the IOTA participant and directly related to the care of attributed patients. With regard to the second requirement, to be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an IOTA collaborator other than a PGP, NPPGP, or TGP must have directly furnished a billable item or service to an attributed patient that occurred during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment. For purposes of this requirement, we consider a hospital, CAH or post-acute care provider to have ''directly furnished'' a billable service if one of these entities billed for an item or service for an attributed patient in the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment. The phrase ''PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment'' does not mean the year in which the gainsharing payment was made. These requirements ensure that there is a required relationship between eligibility for a gainsharing payment and the direct care for attributed patients during the PY for these IOTA collaborators. We believe the provision of direct care is essential to the implementation of effective care redesign, and the requirement provides a safeguard against payments to IOTA collaborators other than a PGP, NPPGP, or TGP that are unrelated to direct care for attributed patients during the model performance period.

We proposed to establish similar requirements for IOTA collaborators that are PGPs, NPPGPs and TGPs that vary because these entities do not themselves directly furnish billable services. To be eligible to receive a gainsharing payment or required to make an alignment payment, a PGP, NPPGP or TGP must have billed for an item or service that was rendered by one or more members of the PGP, NPPGP or TGP to an attributed patient that occurred during the same PY for which the IOTA participant earned an upside risk payment that comprises the gainsharing payment or incurred a

downside risk payment. Like the proposal for IOTA collaborators that are not PGPs, NPPGPs or TGPs, these proposals also require a link between the IOTA collaborator that is the PGP, NPPGP or TGP and the provision of items and services to attributed patients during the PY by PGP, NPPGP or TGP members.

Moreover, we further proposed that, because PGPs, NPPGPs and TGPs do not directly furnish items and services to patients, to be eligible to receive a gainsharing payment or be required to make an alignment payment, the PGP, NPPGP or TGP must have contributed to IOTA activities and been clinically involved in the care of attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment. For example, a PGP, NPPGP, or TGP could have contributed to IOTA activities and been clinically involved in the care of attributed patients if they—

- Provided care coordination services to attributed patients during and after inpatient admission;
- Engaged with an IOTA participant in care redesign strategies, and performed a role in the implementation of such strategies, that were designed to improve the quality of care for attributed patients; or
- In coordination with other providers and suppliers (such as PGP members, NPPGP members, or TGP members; the IOTA participant; and post-acute care providers), implemented strategies designed to address and manage the comorbidities of attributed patients.

We proposed to limit the total amount of gainsharing payments for a PY to IOTA collaborators that are physicians, nonphysician practitioners, PGPs, NPPGPs or TGPs. For IOTA collaborators that are physicians or nonphysician practitioners, that limit is 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by that physician or nonphysician practitioner to the IOTA participant's attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being made. For IOTA collaborators that are PGPs, NPPGPs or TGPs that limit is 50 percent of the Medicare-approved amounts under the PFS for items and services billed by the PGP, NPPGP or TGP and furnished to the IOTA participant's attributed patients by members of the PGP, NPPGP or TGP during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being made. These limits are consistent with those in the CJR model.

We proposed that the amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on contribution to performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA activities. The methodology may take into account the amount of such IOTA activities provided by an IOTA collaborator relative to other IOTA collaborators. While we emphasize that financial arrangements may not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent so that their sole purpose is to align the financial incentives of the IOTA participant and IOTA collaborators toward the model, we believe that accounting for the relative amount of IOTA activities by IOTA collaborators in the determination of gainsharing payments does not undermine this objective. Rather, the proposed requirement allows flexibility in the determination of gainsharing payments where the amount of an IOTA collaborator's provision of IOTA activities (including direct care) to attributed patients during the model performance period may contribute to the IOTA participant's upside risk payment that may be available for making a gainsharing payment. Greater contributions of IOTA activities by one IOTA collaborator versus those that result in greater differences in the funds available for gainsharing payments may be appropriately valued in the methodology used to make gainsharing payments to those IOTA collaborators to reflect these differences in IOTA activities among them. For example, a physician who is an IOTA collaborator who treats 20 attributed patients during the PY that result in high quality, less costly care could receive a larger gainsharing payment than a physician who is an IOTA collaborator who treats 10 attributed patients during episodes that similarly result in high quality, less costly care.

However, we do not believe it would be appropriate to allow the selection of IOTA collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment to take into account the amount of IOTA activities provided by a potential or actual IOTA collaborator relative to other potential or actual IOTA collaborators because these financial relationships are not to be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between, or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent. Specifically, with respect to the selection of IOTA collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment, we do not believe that the amount of model activities provided by a potential or actual IOTA collaborator relative to other potential or actual IOTA collaborators could be taken into consideration by the IOTA participant without a significant risk that the financial arrangement in those instances could be based directly or indirectly on the volume or value of referrals or business generated by, between or among the parties. Similarly, if the methodology for determining alignment payments was allowed to take into account the amount of IOTA activities provided by an IOTA collaborator relative to other IOTA collaborators, there would be a significant risk that the financial arrangement could directly account for the volume or value of referrals or business generated by, between, or among the parties and, therefore, we proposed that the methodology for determining alignment payments may not directly take into account the volume or value of referrals or business generated by, between or among the parties.

We sought comment on this proposal for gainsharing payments, where the methodology could take into account the amount of IOTA activities provided by an IOTA collaborator relative to other IOTA collaborators. We also sought comments about whether this standard would provide sufficient additional flexibility in the gainsharing payment methodology to allow the financial reward of IOTA collaborators commensurate with their level of effort that achieves model goals. In addition, we requested comment on whether additional safeguards or a different standard is needed to allow for greater flexibility to provide certain performance-based payments consistent with the goals of program integrity, protecting against abuse and ensuring the goals of the model are met.

We proposed that for each PY, the aggregate amount of all gainsharing payments that are derived from an upside risk payment must not exceed the amount of the upside risk payment

paid by CMS. In accordance with the prior discussion, no entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments, directly or indirectly, on the volume or value of referrals or business otherwise generated by, between, or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent. We proposed that an IOTA participant must not make a gainsharing payment to an IOTA collaborator that is subject to any action for noncompliance with this 42 CFR part 512 or the fraud and abuse laws, or for the provision of substandard care to attributed patients or other integrity problems. Finally, the sharing arrangement must require the IOTA participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on an upside risk payment or was based on the submission of false or fraudulent data. These requirements provide program integrity safeguards for gainsharing under sharing arrangements.

With respect to alignment payments, we proposed that alignment payments from an IOTA collaborator to an IOTA participant may be made at any interval that is agreed upon by both parties. We proposed that alignment payments must not be issued, distributed, or paid prior to the calculation by CMS of a payment amount reflected in a notification of the downside risk payment; loans, advance payments, or payments for referrals or other business; or assessed by an IOTA participant if the IOTA participant does not owe a downside risk payment. The IOTA participant must not receive any amounts under a sharing arrangement from an IOTA collaborator that are not alignment payments.

We also proposed certain limitations on alignment payments that are consistent with the CJR Model. For a PY, the aggregate amount of all alignment payments received by the IOTA participant must not exceed 50 percent of the IOTA participant's downside risk payment. Given that the IOTA participant would be responsible for developing and coordinating care redesign strategies in response to its IOTA participation, we believe it is important that the IOTA participant retain a significant portion of its responsibility for payment to CMS. For example, upon receipt of a notification indicating that the IOTA participant owes a downside risk payment of $100 to CMS, the IOTA participant would be permitted to receive no more than $50 in alignment payments, in the aggregate, from its IOTA collaborators. In addition, the aggregate amount of all alignment payments from a single IOTA collaborator to the IOTA participant may not be greater than 25 percent of the IOTA participant's downside risk payment over the course of a single PY for an IOTA collaborator. We sought comment on our proposed aggregate and individual IOTA collaborator limitations on alignment payments.

We proposed that all gainsharing payments and any alignment payments must be administered by the IOTA participant in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book). Additionally, we proposed that all gainsharing payments and alignment payments must be made by check, electronic funds transfer (EFT), or another traceable cash transaction. We sought comment on the effect of this proposal.

The proposals for the conditions and restrictions on gainsharing payments and alignment payments under the model are included in § 512.452.

We sought comment about all of the conditions and restrictions set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters supported CMS' proposal to allow gainsharing in IOTA but expressed concern regarding the proposed 50 percent cap on shared losses. The commenters recommended that CMS remove the 50 percent cap on shared losses in order to reduce administrative burden for providers, strengthen integration between kidney transplant hospitals and specialists, and maintain consistency with prior models like CJR and BPCI Advanced.

Response: We thank the commenters for their suggestions regarding the proposed 50 percent cap on shared losses. We believe, however, that given that the IOTA participant would be responsible for achieving model goals, it is important that the IOTA participant retain a significant portion of its responsibility for repayment amounts. With that said, we also believe that the 50 percent cap on shared losses supports CMS' goal. However, we will consider this recommendation in future notice and comment rulemaking.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed provisions for gainsharing payment and alignment payment conditions and limitations in our regulation at § 512.452 with a slight modification. As described and finalized in section III.C.1.a of this final rule, we are finalizing an alternative model start date of July 1, 2025. As such, we are also finalizing a slight modification to the definition of performance year (PY) to mean a 12-month period beginning on July 1 and ending on June 30 of each year during the model performance period, as described and finalized in section III.C.1.a of this final rule. Accordingly, we are modifying the regulation at § 512.452(c)(1)(ii) to remove reference to a calendar year and specify that gainsharing payments and alignment payments must be distributed on an annual basis (not more than once per performance year).

(4) Documentation Requirements

To ensure the integrity of the sharing arrangements, we proposed that IOTA participants must meet a variety of documentation requirements for these arrangements. Specifically, the IOTA participant must—

- Document the sharing arrangement contemporaneously with the establishment of the arrangement;
- Maintain accurate current and historical lists of all IOTA collaborators, including IOTA collaborator names and addresses. Specifically, the IOTA participant must—

++ Update such lists on at least a quarterly basis; and

++ Publicly report the current and historical lists of IOTA collaborators and any written policies for selecting individuals and entities to be IOTA collaborators required by the IOTA participant on a web page on the IOTA participant's website; and

- Maintain and require each IOTA collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum the—

++ Nature of the payment (gainsharing payment or alignment payment);

++ Identity of the parties making and receiving the payment;

++ Date of the payment;

++ Amount of the payment;

++ Date and amount of any recoupment of all or a portion of an IOTA collaborator's gainsharing payment; and

++ Explanation for each recoupment, such as whether the IOTA collaborator received a gainsharing payment that contained funds derived from a CMS overpayment of an upside risk payment, or was based on the submission of false or fraudulent data.

In addition, we proposed that the IOTA participant must keep records for all of the following:

- Its process for determining and verifying its potential and current IOTA collaborators' eligibility to participate in Medicare;
- A description of current health information technology, including systems to track upside risk payments and downside risk payments; and
- Its plan to track gainsharing payments and alignment payments.

Finally, we proposed that the IOTA participant must retain and provide access to, and must require each IOTA collaborator to retain and provide access to, the required documentation in accordance with § 512.460 and § 1001.952(ii).

The proposals for the requirements for documentation of sharing arrangements under the model are included in § 512.452(d).

We sought comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

We received no comments on these proposals and therefore are finalizing these proposals as proposed in our regulation at § 512.452.

e. Distribution Arrangements

(1) General

Similar to the CJR Model, we proposed that certain financial arrangements between IOTA collaborators and other individuals or entities called ''collaboration agents'' be termed ''distribution arrangements.'' For purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)), we proposed to define ''distribution arrangement'' as a financial arrangement between an IOTA collaborator that is a PGP, NPPGP or TGP and a collaboration agent for the sole purpose of sharing a gainsharing payment received by the PGP, NPPGP or TGP. We proposed to define ''collaboration agent'' as an individual or entity that is not an IOTA collaborator and that is a member of a PGP, NPPGP, or TGP that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is an IOTA collaborator. Where a payment from an IOTA collaborator that is an PGP, NPPGP, or TGP is made to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments, we proposed to define that payment as a ''distribution payment.'' We proposed that a collaboration agent could only make a distribution payment in accordance with a distribution arrangement that complies with the provisions of § 512.454 and all other applicable laws and regulations, including the fraud and abuse laws.

The proposals for the general provisions for distribution arrangements under the model are included in § 512.454.

We sought comment about all of the provisions set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

We received no comments on these proposals and therefore are finalizing these proposals as proposed in our regulation at § 512.454. We are also finalizing without modification the proposed definitions of distribution arrangement, collaboration agent, and distribution payment at § 512.402.

(2) Requirements

We proposed a number of specific requirements for distribution arrangements as a program integrity safeguard to help ensure that their sole purpose is to create financial alignment between IOTA collaborators and collaboration agents and performance across the achievement domain, efficiency domain, and quality domain. These requirements largely parallel those proposed in § 512.452 for sharing arrangements and gainsharing payments based on similar reasoning for these two types of arrangements and payments. We proposed that all distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to attributed patients under the distribution arrangement. Furthermore, we proposed that participation must be voluntary and without penalty for nonparticipation, and the distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

Like our proposal for gainsharing payments, we proposed that the opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent. We proposed more flexible standards for the determination of the amount of distribution payments from PGPs, NPPGPs and TGPs for the same reasons we proposed this standard for the determination of gainsharing payments.

We note that for distribution payments made by a PGP to PGP members, by NPPGPs to NPPGP members, or by TGPs to TGP members, the requirement that the amount of any distribution payments must be determined in accordance with a methodology that is substantially based on performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA activities may be more limiting in how a PGP pays its members than is allowed under existing law. Therefore, to retain existing flexibility for distribution payments by a PGP to PGP members, we proposed that the amount of the distribution payment from a PGP to PGP members must be determined in a manner that complies with § 411.352(g) or in accordance with a methodology that is substantially based on contribution to performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA activities and that may take into account the amount of such IOTA activities provided by a collaboration agent relative to other collaboration agents. The former option may allow a PGP to provide its members a financial benefit through the model without consideration of the PGP member's individual contribution to performance across the achievement domain, efficiency domain and quality domain, and PGP members that are not collaboration agents (including those who furnished no services to attributed patients) would be able to receive a share of the profits from their PGP that includes the monies contained in a gainsharing payment. We believe this is an appropriate exception to the general standard for determining the amount of a distribution payment under the model from a PGP to a PGP member, because CMS has determined under the physician self-referral law that payments from a group practice as defined under § 411.352 to its members that comply with § 411.352(g) are appropriate.

We sought comment on this proposal and specifically on whether there are additional safeguards or a different

standard is needed to allow for greater flexibility in calculating the amount of distribution payments that would avoid program integrity risks and whether additional or different safeguards are reasonable, necessary, or appropriate for the amount of distribution payments from a PGP to its members, a NPPGP to its members or a TGP to its members.

Similar to our proposed requirements for sharing arrangements for those IOTA collaborators that furnish or bill for items and services, except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g), we proposed that a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to an attributed patient during the same PY for which the IOTA participant earned the upside risk payment. We note that all individuals and entities that fall within our proposed definition of collaboration agent may either directly furnish or bill for items and services rendered to attributed patients. This proposal ensures that, absent the alternative safeguards afforded by a PGP's distribution payments in compliance with § 411.352(g), there is the same required relationship between direct care for attributed patients during the PY and distribution payment eligibility that we require for gainsharing payment eligibility. We believe this requirement provides a safeguard against payments to collaboration agents that are unrelated to direct care for attributed patients during the PY when the amount of the distribution payment is not determined in a manner that complies with § 411.352(g).

Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g), we proposed the same limitations on the total amount of distribution payments to physicians, nonphysician practitioners, PGPs, NPPGPs and TGPs as we proposed for gainsharing payments. In the case of a collaboration agent that is a physician or nonphysician practitioner, we proposed to limit the total amount of distribution payments paid for a PY to the collaboration agent to 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the collaboration agent to the IOTA participant's attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being distributed. In the case of a collaboration agent that is a group practice, we proposed that the limit would be 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by the group practice for items and services furnished by members of the group practice to the IOTA participant's attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being distributed. We believe that, absent the alternative safeguards afforded by a group practice's distribution payments in compliance with § 411.352(g), these proposed limitations on distribution payments, which are the same as those for gainsharing payments to physicians, nonphysician practitioners, and group practices, are necessary to eliminate any financial incentives for these individuals or entities to engage in a financial arrangement as an IOTA collaborator versus as a collaboration agent. Furthermore, we believe that group practices should be able to choose whether to engage in financial arrangements directly with IOTA participants as IOTA collaborators without having a different limit on their maximum financial gain from one arrangement versus another.

We further proposed that with respect to the distribution of any gainsharing payment received by a PGP, NPPGP or TGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the IOTA collaborator from the IOTA participant. Like gainsharing and alignment payments, we proposed that all distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments. Finally, the distribution arrangement must not induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

We proposed that the IOTA collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.454, including—

- The relevant written agreements;
- The date and amount of any distribution payment(s);
- The identity of each collaboration agent that received a distribution payment; and
- A description of the methodology and accounting formula for determining the amount of any distribution payment.

We proposed that the IOTA collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same IOTA participant. This proposal ensures that the proposed separate limitations on the total amount of gainsharing payment and distribution payment to PGPs, NPPGPs, TGPs, physicians, and nonphysician practitioners that are substantially based on performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA activities are not exceeded in absolute dollars by a PGP, NPPGP, TGP, physician, or nonphysician practitioner's participation in both a sharing arrangement and distribution arrangement for the care of the same IOTA beneficiaries during the PY. Allowing both types of arrangements for the same individual or entity for care of the same attributed patients during the PY could also allow for duplicate counting of the individual or entity's same contribution to the achievement domain, efficiency domain, and quality domain and provision of IOTA Model activities in the methodologies for both gainsharing and distribution payments, leading to financial gain that is disproportionate to the contribution to the achievement domain, efficiency domain and quality domain and provision of IOTA Model activities by that individual or entity. Finally, we proposed that the IOTA collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.460.

The proposals for requirements for distribution arrangements under the model are included in § 512.454.

We sought comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met. In addition, we sought comment on how the regulation of the financial arrangements under this proposal may interact with how these or similar financial arrangements are regulated under the Medicare Shared Savings Program.

The following is a summary of the public comments received on these proposals and our responses:

Comment: A commenter expressed support for the proposal that the Federal anti-kickback statute safe harbor be made available to IOTA participants and their IOTA collaborators.

Response: We thank the commenter for their support.

After consideration of the public comment we received, we are finalizing our proposals regarding the requirements for distribution arrangements without modification in our regulation at § 512.454.

f. Enforcement Authority

OIG authority is not limited or restricted by the provisions of the model, including the authority to audit, evaluate, investigate, or inspect the IOTA participant, IOTA collaborators, collaboration agents, or any other person or entity or their records, data, or information, without limitations. Additionally, no model provisions limit or restrict the authority of any other Government Agency to do the same. The proposals for enforcement authority under the model are included in § 512.455.

We sought comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

We received no comments on these proposals. These proposals are finalized at § 512.455 with slight modification to remove a stray reference to the CJR Model at § 512.455(b).

g. Attributed Patient Engagement Incentives

We believed it was necessary and appropriate to provide additional flexibilities to IOTA participants for purposes of testing the IOTA Model to give IOTA participants additional access to the tools necessary to improve attributed patients' access to kidney transplants and ensure attributed patients receive comprehensive and patient-centered post-transplant care. As discussed in section III.C.11.i. of this final rule, CMS made a determination that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives is available to protect Part B and Part D immunosuppressive drug cost sharing support and attributed patient engagement incentives finalized in this section when the incentives are offered in compliance with this policy, specifically the conditions for use of the Federal anti-kickback statute safe harbor set out at § 1001.952(ii)(2).

(1) Part B and Part D Immunosuppressive Drug Cost Sharing Support

The cost of immunosuppressive drugs is a financial burden for many transplant recipients, particularly those without sufficient health insurance coverage.[328] A person's ability to pay for immunosuppressive drugs, among other services needed in the perioperative and postoperative periods, is a factor used by transplant hospitals to assess suitability for the transplant waitlist.[329] Studies have found that low income status decreases the likelihood of waitlisting.[330] One survey of transplant programs found that 67.3 percent of programs surveyed reported frequent or occasional failure to list patients due to concerns regarding ability to pay for immunosuppressive medications.[331] In assessing the financial implications of extending Medicare coverage of immunosuppressive drugs for the lifetime of the patient, the Assistant Secretary for Planning and Evaluation (ASPE) assumed a non-adherence graft failure rate of 10.7 percent and assessed that factors outside of affordability had minimal impact on non-adherence to immunosuppressive drugs.[332]

Between 2016 and 2019, immunosuppressive drugs represented the greatest proportion of drug expenditures in the year following kidney transplant in Medicare Parts B and D.[333] Between 2016 and 2019, the Per-Patient-Per-Year expenditure in the year following transplant in Medicare Parts B and D was $6,947.[334] Medicare beneficiaries whose immunosuppressive drugs are covered by Part B are responsible for 20 percent of these costs. The cost sharing obligation of Medicare beneficiaries whose immunosuppressive drugs are covered by Part D can vary depending on the benefit structure of the Part D plan.

At § 512.456 of the proposed rule, we proposed to allow IOTA participants to subsidize, in whole or in part, the cost sharing associated with immunosuppressive drugs covered by Part B, the Part B Immunosuppressive Drug (Part B ID) benefit, and Part D (''Part B and Part D immunosuppressive drug cost sharing support'') incurred by attributed patients. As discussed in section III.C.11.i. of this final rule, CMS has made a determination that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect the subsidy of cost sharing obligations that are made in compliance with this policy and the conditions for use of the Federal anti-kickback statute safe harbor set out at § 1001.952(ii)(2).

As stated in the proposed rule, we expect that a large proportion of an IOTA participant's attributed patient population would be Medicare ESRD beneficiaries, covered either by traditional Medicare or by MA (89 FR 43518). Most ESRD beneficiaries covered by traditional Medicare receive immunosuppressive drug coverage through Part B. A proportion of ESRD beneficiaries who are not eligible for Part A at the time of the kidney transplant or who receive a kidney transplant in a non-Medicare approved facility receive immunosuppressive drugs through Medicare Part D. ESRD beneficiaries covered by MA receive Part B immunosuppressive drugs through the plan in which the beneficiary is enrolled.

To be eligible for Part B and Part D immunosuppressive drug cost sharing support, at § 512.402 of the proposed rule, we proposed to define eligible attributed patient as an attributed patient that receives immunosuppressive drug coverage through Part B or Part D but that does not have secondary insurance that could provide cost sharing support. An IOTA participant's attributed patient population could include several subsets of eligible attributed patients. One subset of eligible attributed patients could be ESRD beneficiaries who are not able to purchase secondary insurance due to State laws that do not require insurers to sell Medigap plans to Medicare Beneficiaries under the age of 65. Another subset of eligible attributed patients could, under certain conditions, be ESRD beneficiaries whose eligibility for Medicare only due to ESRD ends 36 months following a kidney transplant. Attributed patients whose eligibility for Medicare due to ESRD ends 36 months following a

[328] James, A., & Mannon, R.B. (2015). The Cost of Transplant Immunosuppressant Therapy: Is This Sustainable? *Current Transplantation Reports, 2*(2), 113–121. *https://doi.org/10.1007/s40472-015-0052-y.*

[329] *The kidney transplant waitlist.* (n.d.). Transplant Living. *https://transplantliving.org/kidney/the-kidney-transplant-waitlist/.*

[330] Park, C., Jones, M.-M., Kaplan, S., Koller, F.L., Wilder, J.M., Boulware, L.E., & McElroy, L.M. (2022). A scoping review of inequities in access to organ transplant in the United States. *International Journal for Equity in Health, 21*(1). *https://doi.org/10.1186/s12939-021-01616-x.*

[331] Evans, R.W., Applegate, W.H., Briscoe, D.M., Cohen, D.J., Rorick, C.C., Murphy, B.T., & Madsen, J.C. (2010). Cost-related immunosuppressive medication nonadherence among kidney transplant recipients. *Clinical Journal of the American Society of Nephrology, 5*(12), 2323–2328. *https://doi.org/10.2215/cjn.04220510.*

[332] *Assessing the Costs and Benefits of Extending Coverage of Immunosuppressive Drugs under Medicare.* (n.d.). ASPE. *https://aspe.hhs.gov/reports/assessing-costs-benefits-extending-coverage-immunosuppressive-drugs-under-medicare.*

[333] United States Renal Data System. (2022). 2022 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD. *https://usrds-adr.niddk.nih.gov/2022.*

[334] Ibid.

kidney transplant may be eligible for the Part B–ID benefit depending on the availability of other health coverage options such as Medicaid, plans purchased via a State health exchange, or the TRICARE for Life program. Other attributed patients whose Medicare eligibility due to ESRD concludes 36 months following a transplant could choose to return to work and receive immunosuppressive drug coverage through an Employer Group Health Plan (EGHP), enroll in a Qualified health plan (QHP) under the Affordable Care Act as defined by 45 CFR 155.20, or receive coverage through Medicaid. These attributed patients would not be eligible for Part B and Part D immunosuppressive drug cost sharing support. We believed that Part B and Part D immunosuppressive drug cost sharing support would have special value for attributed patients whose Medicare eligibility due only to ESRD ends after 36 months and who are eligible for Medicare Savings Programs (MSPs) but who live in States that have not expanded Medicaid eligibility for adults to include certain individuals with incomes up to 138 percent of the Federal Poverty Level (FPL). These individuals may have incomes that are too high to qualify for Medicaid, but too low to qualify for advance premium tax credits (APTCs) or cost-sharing reductions (CSRs) that would allow them to purchase a QHP. We did not propose that Part B and Part D immunosuppressive drug cost sharing support would count towards an eligible attributed patients' Part D True Out-of-Pocket (TrOOP). Part B and Part D immunosuppressive drug cost sharing support would be reported on the Prescription Drug Event (PDE) record as Patient Liability Reduction due to Other Payer Amount (PLRO) (89 FR 43518).

At § 512.456(a) of the proposed rule, we proposed to allow IOTA participants to subsidize, in whole or in part, the cost sharing associated with immunosuppressive drugs covered by Part B, the Part B–ID benefit, and Part D because we believed cost sharing associated with medically necessary immunosuppressive drugs would represent a significant out-of-pocket cost burden to attributed patients who receive immunosuppressive drug coverage through Part B, the Part B–ID benefit, or Part D, and because we believed an IOTA participant's attributed patient population would include beneficiaries whose immunosuppressive drugs are covered through each of these avenues (that is, Part B, the Part B–ID benefit, and Part D).

At § 512.456(a) of the proposed rule, we proposed several safeguards for the proposed Part B and Part D immunosuppressive drug cost sharing support policy. First, an attributed patient must be eligible to receive cost sharing support under the Part B and Part D cost sharing support policy. IOTA participants must provide a written policy for Part B and Part D immunosuppressive drug cost sharing support in a form and manner determined by CMS that is approved by CMS prior to the PY in which the cost sharing support would be available and prior to offering attributed patients the incentive. An IOTA participant would be required to revalidate the written policy with CMS in a form and manner determined by CMS prior to each PY in which Part B and Part D immunosuppressive drug cost sharing support would be offered subsequently. The initial written policy and the policy that would be revalidated by CMS must establish and justify the criteria that qualify an eligible attributed patient to receive Part B and Part D immunosuppressive drug cost sharing support. In providing the written policy and the revalidation of the written policy for Part B and Part D immunosuppressive drug cost sharing support, the IOTA participant must attest that the IOTA participant will not, in providing Part B and Part D immunosuppressive drug cost sharing support, take into consideration the type, cost, generic status, or manufacturer of the immunosuppressive drug(s) or limit an eligible attributed patient's choice of pharmacy. We believed these policies were necessary to ensure that an IOTA participant would have a sound basis for determining eligibility requirements for Part B and Part D immunosuppressive drug cost sharing support.

At § 512.456(b) of the proposed rule, we proposed safeguards to protect against an IOTA participant preferentially providing cost sharing support for certain immunosuppressive drugs. An IOTA participant must not take into consideration the type, cost, generic status, or manufacturer of the immunosuppressive drug(s) or limit an eligible attributed patients' choice of pharmacy when providing Part B and Part D immunosuppressive drug cost sharing support. In addition, an IOTA participant must not accept financial or operational support for the Part B and Part D immunosuppressive drug cost sharing support from pharmacies and pharmaceutical manufacturers. Immunosuppressive drug regimens are adjusted to an individual's unique clinical characteristics to achieve a balance between preserving the health of the transplanted organ and reducing morbidity associated with long-term immunosuppression. We did not believe that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives should be used to protect arrangements that could limit or influence attributed patients' access to the most clinically appropriate immunosuppressive drugs. Finally, to facilitate compliance monitoring, we proposed that IOTA participants must maintain documentation regarding this beneficiary incentive. At minimum, the IOTA participant must maintain contemporaneous documentation that includes the identity of the eligible attributed patient to whom Part B and Part D immunosuppressive drug cost sharing support was provided, the date or dates on which Part B and Part D immunosuppressive drug cost sharing support was provided, and the amount or amounts of Part B and Part D immunosuppressive drug cost sharing support that was provided. IOTA participants must retain and provide access to the required documentation consistent with section III.C.12 and § 1001.952(ii)(2).

We considered alternative safeguards for the Part B and Part D immunosuppressive drug cost sharing support policy (89 FR 43518). We considered requiring that an IOTA participant that wishes to offer Part B and Part D immunosuppressive drug cost sharing support must offer it to every attributed patient whose immunosuppressive drugs are covered by Part B or Part D and who does not have secondary insurance (89 FR 43518). Ultimately, we believed such a policy would run counter to our intention to offer IOTA participants flexibility to meet the needs of their attributed patient populations.

We also considered alternatives to the entirety of the proposed Part B and Part D immunosuppressive drug cost sharing support policy (89 FR 43594). We considered waiving Medicare payment requirements such that CMS would pay the full amount of the Part B or Part B–ID coinsurance for immunosuppressive drugs that are medically necessary for preventing or treating the rejection of a transplanted organ or tissue. If we were to pay 100 percent of the cost of immunosuppressive drugs for attributed patients who are Medicare beneficiaries whose immunosuppressive drugs are covered by Part B and attributed patients whose immunosuppressive drugs are covered by the Part B–ID benefit, such attributed patients would have no cost sharing obligation.

However, we believed that this policy would represent too large an impact to the IOTA Model savings estimates, and thus would potentially jeopardize our ability to continue to test the IOTA Model, if such a policy were finalized.

We also considered waiving the premium for the Part B–ID benefit (89 FR 43595). Under section 402(d) of the CAA and the implementing regulations at 42 CFR 408.20(f), the Secretary determines and promulgates a monthly premium rate for individuals enrolled in the Part B–ID benefit that is 15 percent of the monthly actuarial rate for beneficiaries who are age 65 and older. The Part B premium for 2024 for individuals enrolled in the Part B–ID benefit who file individual or joint tax returns with a modified adjusted gross income of less than or equal to $103,000 or $206,000 respectively, is $103.00. The Part B–ID premium is subject to income-related adjustments based on modified adjusted gross income. We believed the Part B–ID benefit monthly premium may represent a substantial out-of-pocket expenditure for individuals enrolled in the benefit given that it is prudent for the individual to acquire additional health insurance to cover other necessary health care services outside of immunosuppressive drugs. A premium waiver for the Part B–ID benefit is authorized by section 1115A(d)(1) of the Act, under which the Secretary may waive provisions of Title XVIII of the Act, including provisions of section 1836(b) of the Act, as may be necessary solely for purposes of carrying out section 1115A of the Act. We believed, however, that waiving the premium for the Part B–ID benefit would have too significant an impact on the IOTA Model savings estimates; therefore, we are not proposing to waive it for purposes of the IOTA Model.

We sought feedback on the proposal to allow an IOTA participant to subsidize the 20 percent coinsurance on immunosuppressive drugs covered by Part B or the Part B–ID benefit and the cost sharing associated with immunosuppressive drugs covered by Part D, when an attributed patient is eligible, meaning the attributed patient does not have secondary insurance and meets the eligibility criteria defined by the IOTA participant and approved by CMS prior to the PY in which the cost sharing support is provided. We also solicited input from interested parties on additional patient-centered safeguards that we may consider protecting cost sharing subsidies made under the proposed Part B and Part D immunosuppressive drug cost sharing support policy, if finalized.

The following is a summary of the public comments received on these proposals and our responses:

Comment: Several commenters expressed support to provide cost sharing for immunosuppressive drugs covered under Part B and Part D to ensure long term success of kidney transplants.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern with the Part B and Part D drug cost-sharing provision, as it could incentivize patient choice of kidney transplant hospital, disadvantage patients with other insurance, create logistical challenges, and create significant financial burden for IOTA participants.

Response: We thank the commenters for their feedback. We understand the concerns about possible incentivization of patient choice of kidney transplant hospital but believe patient choice is adequately protected in the provision to be finalized. First, and most importantly, we note that providers and suppliers are still required to provide all medically necessary services to beneficiaries, and that this model does not change beneficiary access to services, providers, or suppliers. Second, we note that there are already policies in other models that include similar incentives. We also understand the possible disadvantage to patients with other insurance. We expect that a large portion of the IOTA participant's attributed patient population would be Medicare ESRD beneficiaries, covered by traditional Medicare, so any possible impact would be mitigated as there would be only a small number of patients with other insurance. We also believe that the safeguards that we have put into place, such as the written policy requirements, will limit these concerns as we will be monitoring the provision of any incentives.

We also understand the concerns about the potential burdens these incentives may place on IOTA participants. IOTA participants can choose whether to offer the Part B and Part D drug cost-sharing provision. As such, if the logistical challenges and financial burden for transplant hospitals exceeds the benefits for the IOTA participants, then the benefit does not need to be provided. Our goal is to ensure that beneficiary incentives effectively support patient care without imposing unnecessary burdens on IOTA participants. We are finalizing this policy as proposed. However, we appreciate these insights and will take them into account in future rulemaking cycles.

Comment: Several commenters suggested the cost-sharing provision should include additional metrics such as allowing the Part B copay to count towards out-of-pocket maximum, allowing IOTA participants to have the cost sharing total be offset in part or whole, and track the effectiveness of cost sharing on patient care.

Response: We thank the commenters for their suggestion. We did not propose that Part B and Part D immunosuppressive drug cost sharing support would count towards an eligible attributed patients' Part D True Out-of-Pocket (TrOOP). Part B and Part D immunosuppressive drug cost sharing support would be reported on the Prescription Drug Event (PDE) record as Patient Liability Reduction due to Other Payer Amount (PLRO). We believe that as these costs are not being expended by the attributed patients themselves but rather by the IOTA participant, that it would contravene the purposes behind the TrOOP.

Neither allowing IOTA participants to have the cost sharing total to be offset nor tracking the effectiveness of cost sharing on patient care were included in the proposed rule, and we therefore are not finalizing this expansion suggested by the commenters in this final rule. We will take the commenters' feedback into consideration as we consider potential future changes to the model design.

Comment: A few commenters suggested CMS should provide full cost coverage for Part B and Part D immunosuppressive drugs for all patients included on the low-income list.

Response: We thank the commenters for their suggestion. We considered waiving Medicare payment requirements such that we would pay the full amount of the Part B or Part D coinsurance for immunosuppressive drugs that are medically necessary for preventing or treating the rejection of a transplanted organ or tissue. We believe that covering the cost even for the subset of patients who qualify as low-income would represent too large an impact to the IOTA Model savings estimates, and thus would potentially jeopardize our ability to continue to test the IOTA Model. As such, we determined that a cost support subsidy rather than a reduction would meet the objectives of this model.

Comment: A few commenters suggested the provision should include other related services, such as anti-viral, blood pressure and diabetes medications, blood and urine testing, and office visits.

Response: We thank the commenters for their suggestion. The suggested

expansion of other related services, such as anti-viral, blood pressure and diabetes medications, blood and urine testing, and office visits, was not included in the proposed rule, and we therefore are not finalizing this expansion suggested by the commenters in this final rule. We will take the commenters' feedback into consideration as we consider potential future changes to the model design.

After consideration of the public comments we received, we are finalizing our proposed provision for the Part B and Part D immunosuppressive drug cost sharing support beneficiary incentive as proposed, with a minor technical correction to update the section numbering in our regulation at § 512.456. We are finalizing the proposed definition of eligible attributed patient at § 512.402 with a minor technical correction to address a typographical error by inserting the word ''drug'' in ''immunosuppressive drug coverage.'' We are also finalizing the proposed definition of Part B and Part D immunosuppressive drug cost sharing support at § 512.402 with a minor technical correction to update the cross reference. Specifically, we are removing the cross reference to § 512.458 and replacing it to reflect § 512.456.

(2) Attributed Patient Engagement Incentives

We believed that providing additional flexibilities under the IOTA Model would allow IOTA participants to support attributed patients in overcoming challenges associated with remaining active on the kidney transplant waitlist and adhering to comprehensive post-transplant care. Thus, at § 512.458(a) of the proposed rule, we proposed that IOTA participants may offer the following attributed patient engagement incentives under certain circumstances:

- Communication devices and related communication services directly pertaining to communication with an IOTA participant or IOTA collaborator to improve communication between an attributed patient and an IOTA participant or IOTA collaborator;
- Transportation to and from a transplant hospital that is an IOTA participant and between other providers and suppliers involved in the provision of ESRD care;
- Mental health services to address an attributed patient's behavioral health symptoms pre- and post-transplant; and
- In-home care to support the health of the attributed patient or the kidney transplant in the post-transplant period.

For the purposes of the proposed attributed patient engagement incentives, at § 512.402 of the proposed rule, we defined post-transplant period to mean the 90-day period following an attributed patient's receipt of a kidney transplant. We proposed a 90-day post-transplant period because it may take up to 3 months for many individuals to fully recover from a kidney transplant.[335] At § 512.458(b) of the proposed rule, we proposed that attributed patient engagement incentives that are communication devices and related communication services, transportation to and from an IOTA participant and between other providers and suppliers involved in the provision of ESRD care, and mental health services to address an attributed patient's behavioral health symptoms could, under certain circumstances described in this section, be offered while an attributed patient is on a waitlist, after an attributed patient receives a transplant, or both. In-home care to support the health of the attributed patient or the kidney transplant may only be offered in the post-transplant period.

A mixed methods study of transplant providers' assessment of barriers to accessing a kidney transplant found that transportation was the most reported impediment to transplant (89 FR 43518).[336] Interested parties have informed us that transportation to medical appointments pre- and post-transplant, as well as to and from the dialysis center for treatments pre-transplant, is an important factor in maintaining active status on the list and the health of an individual and the graft after the transplant. Interested parties have also communicated with us about the importance of communication with waitlisted patients. We understood it can be common for an individual to not receive important information about the kidney transplant process when transplant hospitals and dialysis facilities do not communicate with one another about a patient's status. We believed we may be able to overcome this challenge by providing IOTA participants with greater flexibility to communicate directly with attributed patients about their status in the kidney transplant process.[337] [338] We understood that attributed patients who face communication and transportation barriers while on the kidney transplant waitlist may be inactivated, meaning that the attributed patient cannot receive organ offers (89 FR 43518). An attributed patient that cannot receive organ offers is misaligned with the IOTA Model's proposed performance assessment methodology, which would encourage an IOTA participant to increase its number of transplants. An attributed patient that cannot receive organ offers represents a missed opportunity for transplant, which is inconsistent with the goals of the proposed IOTA Model. Accordingly, we were interested in providing a framework under which an IOTA participant would be able to offer attributed patient engagement incentives in the form of communication devices and related communication services may increase the number of attributed patients who achieve and maintain active status on the kidney transplant waitlist. We believed the availability of transportation to and from an IOTA participant and between other providers and suppliers involved in the provision of ESRD care and mental health services to address an attributed patient's behavioral health symptom may also act in service of assisting more attributed patients in overcoming barriers to achieving or maintaining active status on a waitlist, among other challenges in the kidney transplant process prior to and after receiving a kidney transplant.

For example, we were also interested in providing greater flexibility to IOTA participants to support improved adherence to processes of care pre- and post-transplant that may support the ability of an attributed patient to accept an organ offer and the outcomes of the attributed patient and the graft after receiving a kidney transplant. Anxiety and depression may increase as attributed patients spend time on the kidney transplant waitlist.[339] Prevalence of depression is reported to decrease after kidney transplant, but may still

[335] *Recovery after transplant surgery | American Kidney Fund.* (2021, December 14). *www.kidneyfund.org. https://www.kidneyfund.org/kidney-donation-and-transplant/life-after-transplant-rejection-prevention-and-healthy-tips/recovery-after-transplant-surgery.*

[336] Browne, T., McPherson, L., Retzloff, S., Darius, A., Wilk, A.S., Cruz, A., Wright, S., Pastan, S.O., Gander, J.C., Berlin, A.A., & Patzer, R.E. (2021). Improving access to kidney transplantation: Perspectives from Dialysis and Transplant Staff in the Southeastern United States. Kidney Medicine, 3(5). *https://doi.org/10.1016/j.xkme.2021.04.017.*

[337] *Ibid.*

[338] Gillespie, A. (2021). Communication breakdown: Improving communication between transplant centers and dialysis facilities to improve access to kidney transplantation. Kidney Medicine, 3(5), 696–698. *https://doi.org/10.1016/j.xkme.2021.08.003.*

[339] Corruble, E., Durrbach, A., Charpentier, B., Lang, P., Amidi, S., Dezamis, A., Barry, C., & Falissard, B. (2010). Progressive increase of anxiety and depression in patients waiting for a kidney transplantation. Behavioral Medicine, 36(1), 32–36. *https://doi.org/10.1080/08964280903521339.*

exceed 20 percent.[340] Interested parties have reported that behavioral health symptoms interfere with adherence to care recommendations, including activities that support remaining active on the transplant waitlist and behaviors that support positive clinical outcomes for the patient and the graft after the kidney transplant procedure. Interested parties have also informed us of the importance of a transplant recipient having the support of another person in the home for a short period in the post-transplant period to enhance recovery.

We also believed providing the option for flexibility to offer attributed patient engagement incentives under the auspices of the IOTA Model would allow IOTA participants to provide attributed patients with tools to overcome barriers in the process of receiving a kidney transplant, thereby increasing adherence to the kidney transplant process, improving post-transplant outcomes, and supporting patient-centricity in the IOTA Model. As stated in section III.C.11.i. of this final rule, we made the determination that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect the attributed patient engagement incentives proposed in this section when the incentives are offered or given to the attributed patient solely when the remuneration is exchanged between an IOTA participant and an attributed patient in compliance with the requirements of § 512.459 and the conditions of the safe harbor for CMS-sponsored model patient incentives.

At § 512.458(b) of the proposed rule, we proposed programmatic requirements for the attributed patient engagement incentives. First, an IOTA participant must provide a written policy in a form and manner determined by CMS for the provision of attributed patient engagement incentives. The IOTA participant's written policy must be approved by CMS before the PY in which an attributed patient engagement incentive is first made available, and must be revalidated by CMS, in a form and manner specified by CMS, prior to each PY in which an IOTA participant wishes to offer an attributed patient engagement incentive subsequently. The IOTA participant's written policy must describe the items or services the IOTA participant plans to provide, an explanation of how each item or service that would be an attributed patient engagement incentive has a reasonable connection to, at minimum, one of the following: (1) achieving or maintaining active status on a kidney transplant waitlist; (2) accessing the kidney transplant procedure; or (3) the health of the attributed patient or the kidney transplant in the post-transplant period, and a justification for the need for the attributed patient engagement incentives that is specific to the IOTA participant's attributed patient population. The IOTA participant's written policy must also include an attestation that items that are attributed patient engagement incentives would be provided directly to an attributed patient, meaning that third parties would be precluded from providing an item that is an attributed patient engagement incentive to an attributed patient. We are not requiring an IOTA participant to provide any such attestation pertaining to services that are attributed patient engagement incentives because we acknowledge that services such as communication services, mental health services and in-home care services are generally provided by third parties. The IOTA participant would, however, be required to attest in its written policy that the IOTA participant would pay the service provider directly for services. Finally, the IOTA participant's written policy must also include an attestation that any items or services acquired by the IOTA participant that would be furnished as attributed patient engagement incentives would be acquired for the minimum amount necessary for an attributed patient to achieve or maintain active status on the kidney transplant waitlist, access the kidney transplant procedure, or support the health of the attributed patient or the kidney transplant in the post-transplant period.

At § 512.458(c) of the proposed rule, we proposed the following restrictions on the provision of attributed patient engagement incentives. An IOTA participant must provide items that are attributed patient engagement incentives must be provided directly to an attributed patient and an IOTA participant must pay a service provider directly for any services that are offered as attributed patient engagement incentives. An IOTA participant must not offer attributed patient engagement incentives that are tied to the receipt of items of services from a particular provider or supplier or advertise or promote items or services that are attributed patient engagement incentives, except to make an attributed patient aware of the availability of the items or services at the time an attributed patient could reasonably benefit from them. An IOTA participant must not receive donations directly or indirectly to purchase attributed patient engagement incentives. Finally, items that are attributed patient engagement incentives must be retrieved from the attributed patient when the attributed patient is no longer eligible for that item or at the conclusion of the IOTA Model, whichever is earlier. Documented, diligent, good faith attempts to retrieve items that are attributed patient engagement incentives are deemed to meet the retrieval requirement.

At § 512.458(c) of the proposed rule, we proposed the following, additional restrictions pertaining to attributed patient engagement incentives that are communication devices, because we believe that such items may be especially susceptible to abuse. An IOTA participant's purchase of items that are communication devices must not exceed $1000 in retail value for any one attributed patient in any one PY. Items that are communication devices must remain the property of the IOTA participant. An IOTA participant must retrieve the item that is a communication device either when the attributed patient is no longer eligible for the communication device or at the conclusion of the IOTA Model, whichever is earlier. Items that are communication devices must be retrieved from an attributed patient before another communication device may be provided to the same attributed patient. This restriction applies across PYs. In other words, an IOTA participant may not offer another communication device to the same attributed patient across all IOTA Model years until the first communication device has been retrieved. We believed these additional restrictions on communication devices that are offered under the attributed patient engagement incentive policy are necessary to ensure that IOTA participants are not providing communication devices for purposes that are not aligned with the goals of the IOTA Model.

At § 512.458(d) of the proposed rule, we also proposed documentation requirements that pertain to the provision of attributed patient engagement incentives. The IOTA participant must maintain contemporaneous documentation of items and services furnished as attributed patient engagement incentives that includes, at minimum, the date an attributed patient engagement incentive is provided and the identity of the attributed patient to

[340] Szeifert, L., Molnar, M.Z., Ambrus, C., Koczy, A.B., Kovacs, A.Z., Vamos, E.P., Keszei, A., Mucsi, I., & Novak, M. (2010). Symptoms of depression in kidney transplant recipients: A cross-sectional study. American Journal of Kidney Diseases, 55(1), 132–140. *https://doi.org/10.1053/j.ajkd.2009.09.022*.

whom the item or service was provided. In accordance with the retrieval requirements for items that attributed patient engagement incentives, IOTA participants must document all retrieval attempts of items that are attributed patient engagement incentives, including the ultimate date of retrieval. IOTA participants must retain all records pertaining to the furnishing of attributed patient engagement incentives and make those records available to the Federal Government in accordance with section III.C.12. of this final rule.

Taken together, we believed the safeguards described in this section are necessary to ensure that attributed patient engagement incentives offered by an IOTA participant are provided in compliance with the intent of the proposed policy and, if met, the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect these attributed patient engagement incentives.

We considered not allowing IOTA participants to offer attributed patient engagement incentives for attributed patients in the IOTA Model, which would simplify the IOTA Model (89 FR 43518). Further, having no attributed patient engagement incentive policy would allow IOTA participants to direct available resources to the proposed Part B and Part D immunosuppressive drug cost sharing support policy described in section III.C.11.g(1) of this final rule. We took these considerations into account; however, we believed allowing for the maximum amount of flexibility possible for IOTA participants to meet the needs of attributed patients that relate to accessing a kidney transplant is consistent with the model's goals. In addition, we were unable to find any literature to suggest that one type of item or service, for example, cost sharing subsidies under Part B and Part D immunosuppressive drug cost sharing support, is of greater value to an individual waiting for a kidney transplant or having received a kidney transplant than another, for example, an attributed patient engagement incentive. We also considered including dental services as a service that may be offered as an attributed patient engagement incentive (89 FR 43518). Sources of oral infection must be resolved before an individual can receive a kidney transplant because post-transplant immunosuppression puts a kidney transplant recipient at greater risk for oral infections that can spread to the rest of the body.[341] We did not include dental services as an allowable attributed patient engagement incentive because we understand that sources of oral infection must be resolved before an individual can be waitlisted for a kidney transplant; in other words, prior to the ability of an individual to be attributed to the IOTA Model. We were interested in receiving comments on the extent to which dental issues emerge once an individual has been listed for a kidney transplant and whether we should consider dental services as an attributed patient engagement incentive under the auspices of the IOTA Model.

We solicited feedback on our proposal to allow IOTA participants to offer attributed patient engagement incentives in a manner that complies with the restrictions and safeguards in this section. We further solicited feedback on other barriers to remaining active on the kidney transplant waitlist, receiving organ offers, and adhering to pre- and post-transplant care that we may be able to address by expanding the attributed patient engagement incentives available to attributed patients through future rulemaking.

The following is a summary of the comments received on our proposed provisions for attributed patient engagement incentives, and our responses:

Comment: A few commenters expressed concern about the patient engagement incentives, as they would require significant planning and resources, and suggested that CMS should clarify whether coverage of dental services is included in the provision.

Response: We thank the commenters for their feedback. We understand the concerns about the potential burdens these incentives may place on IOTA participants. IOTA participants can choose whether to offer these patient engagement incentives. As such, if the logistical challenges and financial burden for IOTA participants exceeds the benefits for the IOTA participants, then the benefit does not need to be provided. Our goal is to ensure that beneficiary incentives effectively support patient care without imposing unnecessary burdens on IOTA participants.

We considered but did not ultimately include dental services as an allowable attributed patient engagement incentive because sources of oral infection must be resolved before an individual can be waitlisted for a kidney transplant; in other words, prior to the ability of an individual to be attributed to the IOTA Model.

We are finalizing this policy as proposed. However, we appreciate these insights and will take them into account in future rulemaking cycles.

Comment: Several commenters suggested the provision should also address health-related social needs (HRSNs) for patients on the waitlist and provide full living donor cost reimbursement including costs not covered by other payers, include mechanisms to help offset the cost of providing these incentives, and provide more flexibility.

Response: We thank the commenters for their suggestion. As described and finalized in § 512.446(a) of this final rule, IOTA participants may voluntarily submit a health equity for all PYs of the IOTA Model. We direct readers to section III.C.8.c of this final rule for further discussion on health equity plans in the IOTA Model. We believe that these health equity plans address HRSNs for patients on the waitlist. If in the future CMS requires the collection of HRSN data from Medicare provider and suppliers more widely and strengthens the availability of HRSN data, we will consider if there is sufficient and high-quality HRSN data available in future baseline years as we consider potential future changes to the model design.

Regarding living donor cost reimbursement, we note that Medicare or the kidney recipient's private insurance will generally cover the medical costs of testing and surgery for a living kidney donor. We understand, however, that there are often costs that are not reimbursed, such as meals, lodging, and transportation costs. As discussed later in this section, we are not issuing any fraud and abuse waivers in this final rule. A model provision protecting such reimbursement could be susceptible to abuse by potentially impermissibly steering beneficiaries in their selection of kidney transplant hospitals so as to mitigate costs for their donors, disadvantaging smaller kidney transplant hospitals without resources to provide this remuneration, and incentivizing donation decisions.

Comment: Several commenters suggested that CMS change the attributed patient engagement incentives to include additional services such as Medical Nutrition Therapy, dental coverage, and home phlebotomy and infusion services.

Response: We thank the commenters for their suggestion. The suggested expansion of Medical Nutrition

[341] Kwak, E.J., Kim, D.J., Choi, Y., Joo, D.J., & Park, W. (2020). Importance of oral health and dental treatment in organ transplant recipients. International Dental Journal, 70(6), 477–481. *https://doi.org/10.1111/idj.12585.*

Therapy, home phlebotomy and infusion services was not included in the proposed rule, and we therefore are not finalizing these expansions suggested by the commenters in this final rule. We did not include dental services as an allowable attributed patient engagement incentive because we understand that sources of oral infection must be resolved before an individual can be waitlisted for a kidney transplant; in other words, prior to the ability of an individual to be attributed to the IOTA Model.

We are finalizing this policy as proposed with one exception. The reference to section III.C.g(2) for the Part B and Part D immunosuppressive drug cost sharing support was incorrect. We clarify that the Part B and Part D immunosuppressive drug cost sharing support is described in section III.C.11.g(1) of this final rule.

After consideration of the public comments received, we are finalizing our proposed provision for attributed patient engagement incentives, with a minor technical correction to update the section numbering in our regulation at § 512.458.

h. General Payment Waivers [342]

We stated in the proposed rule that we would need to waive certain Medicare program regulations in order to make the upside risk payments and downside risk payments discussed in the proposed rule and in sections III.C.6.c.(2)(a) and III.C.6.c.(2)(b) of this final rule, respectively.

Therefore, in accordance with the authority granted to the Secretary in section 1115A(d)(1) of the Act to waive certain requirements as may be necessary solely for purposes of testing models, and consistent with other mandatory models such as the ETC Model and the CJR Model, we proposed at 89 FR 43597 to waive requirements of section 1881(b) of the Act only to the extent necessary to make the upside risk payments and downside risk payments under the IOTA model. Section 1881(b) of the Act determines how Medicare FFS pays for services such as dialysis, transplantation, and home dialysis support services for individuals with ESRD. Waiving requirements of section 1881(b) of the Act is necessary for the upside risk payments and downside risk payments to be made to or collected from the IOTA Participants. These model payments will be made in addition to, and not in lieu of, the Medicare FFS payments provided under section 1881(b) of the Act.

We proposed to waive this requirement under section 1881(b) of the Act because these statutory provisions establish the current Medicare FFS payment methodology, which does not include the upside risk payments and downside risk payments. Without waiving these specific provisions of the Act to permit the upside risk payments and downside risk payments, we would not be able to implement and test whether the payment methodology of the model was effective at reducing program expenditures while preserving or enhancing the quality of care.

We also proposed at 89 FR 43597 to waive sections 1833(a) and 1833(b) of the Act to the extent necessary to make payments under the IOTA Model. The purpose of this proposed waiver was to ensure that the upside risk payments and downside risk payments, as described in sections III.C.6.c.(2)(a) and III.C.6.c.(2)(b), respectively, in this final rule, would not alter the beneficiary cost-sharing requirements for the related Part B services received by IOTA participants. We did not propose to alter the existing Medicare beneficiary cost sharing structure, and this waiver would maintain that existing structure while enabling the upside risk payments and downside risk payments under the IOTA model.

Therefore, we proposed to waive the requirements of sections 1881(b), 1833(a), and 1833(b) of the Act to the extent necessary to make the payments we proposed under the IOTA Model (89 FR 43597). We sought comment on our proposed waivers of Medicare payment requirements related to the upside risk payment and downside risk payment and beneficiary cost sharing.

We received no public comments on these proposed waivers. As such, we are finalizing our proposal to waive sections 1881(b), 1833(a) and 1833(b) of the Act only to the extent necessary to make payments under the IOTA Model at § 512.470 without modification.

i. Fraud and Abuse Waiver and OIG Safe Harbor Authority

Under section 1115A(d)(1) of the Act, the Secretary may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii) of the Act, and certain provisions of section 1934 of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act.

For this model and consistent with the authority under section 1115A(d)(1) of the Act, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act. No fraud or abuse waivers are being issued in this document; fraud and abuse waivers, if any, would be set forth in separately issued documentation. Any such waiver would apply solely to the IOTA Model and could differ in scope or design from waivers granted for other programs or models. Thus, notwithstanding any provision of this final rule, IOTA participants and IOTA collaborators must comply with all applicable laws and regulations, except as explicitly provided in any such separately documented waiver issued pursuant to section 1115A(d)(1) of the Act specifically for the IOTA Model.

In addition to or in lieu of a waiver of certain fraud and abuse provisions in sections 1128A and 1128B of the Act, at § 512.470 of the proposed rule, CMS proposed to waive sections 1881(b) and 1833(a) and 1833(b) of the Act only to the extent necessary to make certain payments under the IOTA Model. These waivers, while originally included in this section of the proposed rule, are general payment waivers and not fraud and abuse waivers. As such, this discussion has been moved to section III.C.11.h of this final rule.

CMS has made a determination, in this final rule, that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§ 1001.952(ii)(1) and (2)) is available to protect remuneration exchanged pursuant to certain financial arrangements and patient incentives that may be permitted under the final rule. Specifically, we determined that the CMS-sponsored models safe harbor would be available to protect the following financial arrangements and incentives: the IOTA Model Sharing Arrangement's gainsharing payments and alignment payments, the Distribution Arrangement's distribution payments, the Part B and Part D immunosuppressive drug cost sharing support policy and attributed patient engagement incentives.

We considered not allowing use of the safe harbor provisions (89 FR 43518). However, we determined that use of the safe harbor would encourage the goals of the model. We believed that a successful model requires integration

[342] Section III.C.11.h did not appear in the notice of proposed rulemaking, and the general payment waivers were instead discussed in section III.C.11.i, which also addressed fraud and abuse waivers and OIG safe harbor authority. This section III.C.11.h has been added here to address the general payment waivers separately, as they are distinct from the fraud and abuse waivers. As we stated in the proposed rule, the general payment waivers are necessary to make the upside risk payments and downside risk payments under the IOTA model. The proposed regulatory text regarding the general payment waivers at § 512.470 is not changed.

and coordination among IOTA participants and other health care providers and suppliers. We believed the use of the safe harbor would encourage and improve beneficiary experience of care and coordination of care among providers and suppliers. We also believed the safe harbor offers flexibility for innovation and customization. The safe harbor allows for emerging arrangements that reflect up-to-date understandings in medicine, science, and technology.

We sought comment on this proposal, including that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)) be available to IOTA participants and IOTA collaborators.

The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters expressed support for the fraud and abuse provision, stating that the IOTA participants needed protections in place to form financial arrangements necessary for the model.

Response: We thank the commenters for their support.

After consideration of the public comments received, we are finalizing our proposed provision for application of the CMS-sponsored model arrangements and patient incentives safe harbor at § 512.459.

12. Audit Rights and Record Retention

By virtue of their participation in an Innovation Center model, IOTA participants and IOTA collaborators may receive model-specific payments, access to Medicare payment waivers, or some other model-specific flexibility, such as the ability to provide cost sharing support to eligible attributed patients for the proposed Part B and Part D immunosuppressive drug cost sharing support policy. It is therefore necessary and appropriate for CMS to audit, inspect, investigate, and evaluate records and other materials related to participation in the IOTA Model. CMS must be able to audit, inspect, investigate, and evaluate records and materials related to participation in the IOTA Model to allow us to ensure that IOTA participants are in no way denying or limiting the coverage or provision of benefits for beneficiaries as part of their participation in the IOTA Model. We proposed to define ''model-specific payment'' to mean a payment made by CMS only to IOTA participants, or a payment adjustment made only to payments made to IOTA participants, under the terms of the IOTA Model that is not applicable to any other providers or suppliers; the term ''model-specific payment'' would include, unless otherwise specified, the model upside risk payment and downside risk payment, described in section III.C.6 of this final rule. It is necessary to propose this definition to distinguish payments and payment adjustments applicable to IOTA participants as part of their participation in the IOTA Model, from payments and payment adjustments applicable to IOTA participants as well as other providers and suppliers, as certain provisions of proposed part 512 would apply only to the former category of payments and payment adjustments.

There are audit and record retention requirements under the Medicare Shared Savings Program (see 42 CFR 425.314) and in other models being tested under section 1115A of the Act (see, for example, 42 CFR 510.110 and § 512.135).

We proposed to adopt audit and record retention requirements for the IOTA Model. Specifically, as a result of our proposal to revise the scope of the general provisions of 42 CFR part 512 Subpart A to include the IOTA Model, see proposed 42 CFR 512.100, we proposed to apply § 512.135(a) through (c) to each IOTA participant and its IOTA collaborators. In applying § 512.135(a) to the IOTA Model, the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, would have a right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of an Innovation Center model. In applying existing § 512.135(b) and (c) to the IOTA Model, an IOTA participant and its IOTA collaborators would be required to:

- Maintain and give the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, access to all documents (including books, contracts, and records) and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the IOTA Model, including, without limitation, documents and other evidence regarding all of the following:

++ Compliance by the IOTA participant and its IOTA collaborators with the terms of the IOTA Model, including proposed new subpart A of proposed part 512.

++ The accuracy of model-specific payments made under the IOTA Model.

++ The IOTA participant's downside risk payments owed to CMS under the IOTA Model.

++ Quality measure information and the quality of services performed under the terms of the IOTA Model, including proposed new subpart A of proposed part 512.

++ Utilization of items and services furnished under the IOTA Model.

++ The ability of the IOTA participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

++ Where cost sharing support is furnished under the Part B and Part D immunosuppressive drug cost sharing support policy, the IOTA participant must maintain contemporaneous documentation that includes the identity of the eligible attributed patient to whom Part B and Part D immunosuppressive drug cost sharing support was provided, the date or dates on which Part B and Part D immunosuppressive drug cost sharing support was provided, and the amount or amounts of Part B and Part D immunosuppressive drug cost sharing support that was provided.

++ Contemporaneous documentation of items and services furnished as attributed patient engagement incentives in accordance with § 512.458 that includes, at minimum, the date the attributed patient engagement incentive is provided and the identity of the attributed patient to whom the item or service was provided.

++ Patient safety.

++ Any other program integrity issues.

- Maintain the documents and other evidence for a period of 6 years from the last payment determination for the IOTA participant under the IOTA Model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

++ CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the IOTA participant at least 30 days before the normal disposition date; or

++ There has been a termination, dispute, or allegation of fraud or similar fault against the IOTA participant or its IOTA collaborators, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

If CMS notifies the IOTA participant of a special need to retain a record or group of records at least 30 days before the normal disposition date, the IOTA participant would be required to maintain the records for such period of time determined by CMS. If CMS notifies the IOTA participant of a special need to retain records or there has been a termination, dispute, or

allegation of fraud or similar fault against the IOTA participant or its IOTA collaborators, the IOTA participant would be required to notify its IOTA collaborators of the need to retain records for the additional period specified by CMS. This provision would ensure that the government has access to the records.

We note that we previously adopted a rule at 42 CFR 512.110 defining the term ''days,'' as used in 42 CFR 512.135, to mean calendar days.

We solicited public comment on these proposals regarding audits and record retention.

The following is a summary of the comments received on our proposed provisions for auditing and record retention, and our responses:

Comment: CMS received a comment asking to use HIPAA documentation retention standards.

Response: We thank the commenter for this feedback. By applying § 512.135(a) through (c), CMS ensures that IOTA participants are in no way denying or limiting the coverage or provision of benefits for beneficiaries as part of their participation in the IOTA Model. We believe that the current document retention time is reasonable.

After consideration of the public comment we received, we are finalizing our proposal for Audit Rights and Record Retention as proposed at § 512.460. We are also finalizing without modification the proposed definition of model-specific payment at § 512.402.

13. Compliance and Monitoring

a. General

We proposed in § 512.462 of the proposed rule that CMS, or its approved designees, would conduct compliance monitoring activities, to ensure compliance by the IOTA participant and IOTA collaborators with the terms of the IOTA Model, including to understand IOTA participants' use of model-specific payments and to promote the safety of attributed patients and the integrity of the IOTA Model. Such monitoring activities would include, but not be limited to—

- Documentation requests sent to the IOTA participant and its IOTA collaborators, including surveys and questionnaires;
- Audits of claims data, quality measures, medical records, and other data from the IOTA participant and its IOTA collaborators;
- Interviews with the IOTA participant, including leadership personnel, medical staff, other associates, and its IOTA collaborators;
- Interviews with attributed patients and their caregivers;
- Site visits to the IOTA participant and its IOTA collaborators, which would be performed in accordance with § 512.462(c), described in section III.C.13.b of this final rule;
- Monitoring quality outcomes and attributed patient data;
- Tracking beneficiary complaints and appeals;
- Monitoring the definition of and justification for the subpopulation of the IOTA participant's eligible attributed patients that may receive Part B and Part D immunosuppressive drug cost sharing support in accordance with § 512.456; and
- Monitoring the provision of attributed patient engagement incentives provided in accordance with § 512.458.

Additionally, CMS is concerned about IOTA participants bypassing the match run, as defined in section III.C.5.d(1)(a) of this final rule, the rank order list of transplant candidates to be offered an organ. This practice, known as ''list diving,'' can improve efficiency in placing organs, but may undermine the mechanisms promoting fairness in rationing this scarce resource, if overused. We proposed that CMS would monitor out of sequence allocation of kidneys by assessing how often top-ranked attributed patients receive the organ that was offered to them and if they did not receive it, what the reason for that was.

We believe these specific monitoring activities, which align with those currently used in other models being tested by the Innovation Center, are necessary to ensure compliance with the terms of the IOTA Model and can protect attributed patients from potential harm that may result from the activities of the IOTA participant or its IOTA collaborators, such as attempts to reduce access to or the provision of medically necessary covered services.

We proposed at § 512.462 of the proposed rule that when CMS is conducting compliance monitoring and oversight activities, CMS or its designees would be authorized to use any relevant data or information, including without limitation Medicare claims submitted for items or services furnished to attributed patients who are Medicare beneficiaries. We believe that it is necessary to have all relevant information available to CMS during compliance monitoring and oversight activities, including any information already available to CMS through the Medicare program.

IOTA participants would remain subject to all existing requirements and conditions for Medicare participation as set out in Federal statutes and regulations and provider and supplier agreements, unless waived under the authority of section 1115A(d)(1) of the Act solely for purposes of testing the IOTA Model.

b. Site Visits

In § 512.462(c) of the proposed rule, we proposed that IOTA participants would be required to cooperate in periodic site visits conducted by CMS or its designee. Such site visits would be conducted to facilitate the model evaluation performed pursuant to section 1115A(b)(4) of the Act and to monitor compliance with the IOTA Model requirements. We further proposed that CMS or its designee would provide the IOTA participant with no less than 15 days advance notice of a site visit, to the extent practicable. Furthermore, we proposed that, to the extent practicable, CMS would attempt to accommodate a request that a site visit be conducted on a particular date, but that the IOTA participant would be prohibited from requesting a date that was more than 60 days after the date of the initial site visit notice from CMS. We believe the 60-day period would reasonably accommodate IOTA participant schedules while not interfering with the operation of the IOTA Model. Further, in § 512.462 of the proposed rule, we proposed to require the IOTA participant to ensure that personnel with the appropriate responsibilities and knowledge pertaining to the purpose of the site visit be available during any and all site visits. We believe this proposal is necessary to ensure an effective site visit and prevent the need for unnecessary follow-up site visits.

Further, we proposed in § 512.462 of the proposed rule that nothing in the previous sections would limit CMS from performing other site visits as allowed or required by applicable law. We believe that CMS must retain the ability to timely investigate concerns related to the health or safety of attributed patients or program integrity issues, and to perform functions required or authorized by law. In particular, we believe that it is necessary for CMS to monitor, and for IOTA participants to be compliant with our monitoring efforts, to ensure that they are not denying or limiting the coverage or provision of medically necessary covered services to attributed patients in an attempt to change model results or their model-specific payments, including discrimination in the provision of services to at-risk patients (for example,

due to eligibility for Medicare based on disability).

In the alternative, we considered allowing unannounced site visits for any reason. However, we determined that giving advanced notice for site visits for routine monitoring would allow the IOTA participant to ensure that the personnel with the applicable knowledge is available and would allow the IOTA participant the flexibility to arrange these site visits around their operations. However, we proposed in § 512.462 of the proposed rule that if there is a concern regarding issues that may pose risks to the health or safety of attributed patients or to the integrity of the IOTA Model, unannounced site visits would be warranted. We believe this would allow us to address any potential concerns in a timely manner without a delay that may increase those potential risks.

We direct readers to section III.C.13.c of this final rule for a summary of the comments received on our proposals regarding site visits and our responses.

c. Reopening of Payment Determinations

To protect the financial integrity of the IOTA Model, we proposed in § 512.462(d) that if CMS discovers that it has made or receives a request from the IOTA participant about an incorrect model payment, CMS may make payment to, or demand payment from, the IOTA participant.

CMS' interests include ensuring the integrity and sustainability of the IOTA Model and the underlying Medicare program, from both a financial and policy perspective, as well as protecting the rights and interests of Medicare beneficiaries. For these reasons, CMS or its designee needs the ability to monitor IOTA participants to assess compliance with model terms and with other applicable Medicare program laws and policies. We believe our monitoring efforts help ensure that IOTA participants are furnishing medically necessary covered services and are not falsifying data, increasing program costs, or taking other actions that compromise the integrity of the IOTA Model or are not in the best interests of the IOTA Model, the Medicare program, or Medicare beneficiaries.

We invited public comment on these proposed provisions regarding monitoring of the IOTA Model and alternatives considered.

The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters expressed support for the monitoring measures proposed to ensure that IOTA participants comply with the model requirements and the program is improving patient care.

Response: We thank the commenters for their support of this proposed policy.

Comment: A few commenters indicated concern that the compliance monitoring provision will negatively impact smaller transplant programs, cause interruptions in the quality and continuity of patient care and create significant administrative burdens.

Response: We understand the concerns facing smaller transplant programs; however, we disagree that the compliance monitoring provision will negatively impact smaller transplant programs. The IOTA Model's compliance monitoring activities align with those currently used in other models being tested by the Innovation Center as well as those any hospital would have under Medicare. Ensuring the integrity and sustainability of the IOTA Model as well as promoting the safety and protection of attributed patients is the purpose of the compliance monitoring provision regardless of the size of the transplant hospital.

Comment: We received a comment suggesting that the IOTA Model should establish a robust feedback mechanism that allows transplant hospitals and other stakeholders to provide ongoing input on the implementation and impact of the IOTA Model. The commenter believes that feedback would be crucial for adapting the model to real-world challenges and achieving its intended outcomes.

Response: We appreciate the comment and plan to have transparent and ongoing communications with all the participants as the model progresses to achieve the intended outcomes.

Comment: A commenter asked CMS to provide greater notice than 15 days prior to a site visit.

Response: We appreciate the commenters' feedback and support. As noted in the proposed rule, we believe that providing at least 15 days of notice before a site visit is sufficient. Furthermore, we proposed that, to the extent practicable, CMS would attempt to accommodate a request that a site visit be conducted on a particular date, but that the IOTA participant would be prohibited from requesting a date that was more than 60 days after the date of the initial site visit notice from CMS. We believe the 60-day period would reasonably accommodate IOTA participant schedules while not interfering with the operation of the IOTA Model.

After consideration of the public comment we received, we are finalizing the proposed monitoring practices, compliance with laws, site visits, and reopening of payments policies at § 512.462 with minor technical corrections to update cross references. Specifically, at § 512.462(d)(1) we are removing the cross reference to § 512.462 and replacing it to reflect § 405.986 of this chapter. At § 512.462(d)(1), we are also removing the cross reference to § 512.464 and replacing it to reflect § 405.902 of this chapter.

14. Evaluation

Section 1115A(b)(4) of the Act requires the Secretary to evaluate each model tested under the authority of section 1115A of the Act and to publicly report the evaluation results in a timely manner. The evaluation must include an analysis of the quality of care furnished under the model and the changes in program spending that occurred due to the model. Models tested by the Innovation Center are rigorously evaluated. For example, when evaluating models tested under section 1115A of the Act, we require the production of information that is representative of a wide and diverse group of model participants and includes data regarding potential unintended or undesirable effects. The Secretary must take the evaluation into account if making any determinations regarding the expansion of a model under section 1115A(c) of the Act. In addition to model evaluations, the Innovation Center regularly monitors model participants for compliance with model requirements.

For the reasons described in section III.C.13 of this final rule, these compliance monitoring activities are an important and necessary part of the model test. Therefore, we note that IOTA participants and their IOTA collaborators must comply with the requirements of 42 CFR 403.1110(b) (regarding the obligation of entities participating in the testing of a model under section 1115A of the Act to report information necessary to monitor and evaluate the model), and must otherwise cooperate with CMS' model evaluation and monitoring activities as may be necessary to enable CMS to evaluate the Innovation Center model in accordance with section 1115A(b)(4) of the Act. This participation in the evaluation may include, but is not limited to, responding to surveys and participating in focus groups. Subsequent to the publication of the proposed rule, we wish to clarify that the evaluation

activities may also include site visits and case studies.

We received no comments on the proposed evaluation approach and therefore are finalizing this provision without modification.

15. Learning

In the Specialty Care Models final rule (85 FR 61114), we established the voluntary ETC Learning Collaborative (ETCLC). The goals of the ETCLC are to increase the supply and use of deceased donor kidneys by convening OPOs, transplant hospitals, donor hospitals, and patients and families to reduce the variation in OPO and transplant hospital performance and reduce kidney non-use.[343] The ETCLC is addressing three national aims over a 5-year period: (1) achieve a 28 percent absolute increase in the number of deceased donor kidneys with a KDPI greater than or equal to 60 recovered for transplant from the 2021 OPTN/SRTR baseline of 11,284; (2) decrease the current national non-use rate of all procured kidneys with a KDPI ≥ 60 by 20 percent; and (3) decrease the current national discard rate of all procured kidneys with a KDPI < 60 by 4 percent. The ETCLC has developed Quality Improvement (QI) Teams that are identifying and implementing best practices based on the ETCLC Kidney Donation and Utilization Change Package. As of June 2023, 54 OPOs and 181 transplant hospitals were enrolled in ETCLC.[344]

While we considered continuing the ETCLC under the auspices of the IOTA Model in section III.C.15 of the proposed rule, we proposed to conclude the ETCLC at the end of the ETC Model test and implement a learning system specific to the IOTA Model. An IOTA Model learning system would deal only with issues specific to the IOTA Model and would have neither national aims nor include other providers in the transplant ecosystem such as OPOs or donor hospitals as regular participants. The advantages of this approach are that CMS could provide a forum for IOTA participants to discuss elements of the model, share experiences implementing IOTA Model provisions, and solicit support from peers in overcoming challenges that may arise. Since most transplant hospitals have less experience with Innovation Center models than other provider types, we believe an independent learning system would provide unique value to IOTA participants.

In section III.C.15 of the proposed rule, we also considered continuing ETCLC under the aegis of the IOTA Model. We believed many IOTA participants would already be enrolled in the ETCLC and dedicating staff and time to participating in QI Teams and engaging with the Kidney Donation and Utilization Change Package. We also believed that there may be overlap between the QI work being undertaken by ETCLC participants and the issues that would be of interest to IOTA participants. We further considered whether the ETCLC needed more time to achieve its national aims that could be provided by continuing the ETCLC under the IOTA Model.

We solicited feedback on our proposal to conclude the ETCLC with the ETC Model and implement a new learning system specific to the IOTA Model. We sought feedback on the following questions:

- What are specific examples of how ETCLC is supporting transplant hospital QI to increase access to kidney transplant?
- What features of a new learning system would be important for IOTA participants?
- Could the ETCLC meet IOTA participants' need for QI support to succeed in the model?

The following is a summary of the comments received on our proposed learning system for the IOTA Model, our proposal to end the ETCLC at the completion of the ETC Model, feedback on the questions we posed in the proposed rule at 89 FR 43600, and our responses:

Comment: A commenter was in favor of supporting the CMS proposal to develop an IOTA-specific learning system, instead of relying on the methods used by the ETCLC in the ETC Model. Additionally, a commenter supported finalizing the ETCLC with the ETC Model.

Response: We appreciate the feedback and support for a learning system specific to the IOTA Model. We agree it is important to provide specialized support due to the importance of the subject matter and due to prior limited interaction transplant programs may have had with other Innovation Center models or alternative payment models.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing a voluntary learning system focused on increasing kidney transplant access, as described in section III.C.15 of this final rule. This learning system will be independent of the ETCLC, which will conclude at the end of the ETC Model test. We intend for the learning system to support IOTA participants and IOTA collaborators throughout the model performance period. While we did not specifically include IOTA collaborators in the proposed rule, we believe it is important to allow IOTA collaborators to participate if they would like to due to their close relationship with and their contributions to IOTA participants and their performance.

Additionally, we note that we did not receive any public comments regarding the questions we sought feedback on in the proposed rule at 89 FR 43600.

16. Remedial Action and Termination

a. Remedial Action

At § 512.464 of the proposed rule, we proposed the Standard Provisions for Innovation Center Models relating to remedial actions, originally finalized as general provisions in the Code of Federal Regulations (42 CFR part 512 subpart A) that applied to specific Innovation Center models but that we proposed for expansion to all Innovation Center Models with model performance periods that begin on or after January 1, 2025, in section II.B. of this final rule would apply to the IOTA Model. We proposed that CMS could impose one or more remedial actions on the IOTA participant if CMS determines that—

- The IOTA participant has failed to furnish 11 or more transplants during the PY or any baseline years;
- The IOTA participant or its IOTA collaborator has failed to comply with any of the terms of the IOTA Model;
- The IOTA participant has failed to comply with transparency requirements as listed in section III.C.8.a. of this final rule;
- The IOTA participant or its IOTA collaborator has failed to comply with any applicable Medicare program requirement, rule, or regulation;
- The IOTA participant or its IOTA collaborator has taken any action that threatens the health or safety of an attributed patient;
- The IOTA participant or its IOTA collaborator has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model;
- The IOTA participant or its IOTA collaborator has undergone a change in control, as described in section III.C.17.b of this final rule, that presents a program integrity risk;
- The IOTA participant or its IOTA collaborator is subject to any sanctions

[343] *End Stage Renal Disease Treatment Choices Learning Collaborative—End Stage Renal Disease Treatment Choices Learning Collaborative—QualityNet Confluence.* (n.d.). Qnetconfluence.cms.gov. Retrieved May 30, 2023, from *https://qnetconfluence.cms.gov/display/ETCLC/End+Stage+Renal+Disease+Treatment+Choices+Learning+Collaborative.*

[344] Ibid.

of an accrediting organization or a Federal, State, or local government agency;

- The IOTA participant or its IOTA collaborator is subject to investigation or action by HHS (including the HHS–OIG or CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint or filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the Federal Government has intervened, or similar action;
- The IOTA participant or its IOTA collaborator has failed to demonstrate improved performance following any remedial action imposed by CMS; or
- The IOTA participant has misused or disclosed beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the applicable data sharing agreement.

At § 512.464 of the proposed rule, we proposed that CMS may take one or more of the following remedial actions if CMS determines that one or more of the grounds for remedial action described in section III.C.16.a. of this final rule has taken place:

- Notify the IOTA participant and, if appropriate, require the IOTA participant to notify its IOTA collaborators of the violation;
- Require the IOTA participant to provide additional information to CMS or its designees;
- Subject the IOTA participant to additional monitoring, auditing, or both;
- Prohibit the IOTA participant from distributing model-specific payments, as applicable;
- Require the IOTA participant to terminate, immediately or by a deadline specified by CMS, its sharing arrangement with an IOTA collaborator with respect to the IOTA Model;
- Terminate the IOTA participant from the IOTA Model;
- Suspend or terminate the ability of the IOTA participant to provide Part B and Part D immunosuppressive drug cost sharing support, or attributed patient engagement incentives in accordance with sections III.C.11.g(1) and (2) of this final rule.
- Require the IOTA participant to submit a corrective action plan (CAP) in a form and manner and by a deadline specified by CMS;
- Discontinue the provision of data sharing and reports to the IOTA participant;
- Recoup model-specific payments;
- Reduce or eliminate a model-specific payment otherwise owed to the IOTA participant, as applicable; or
- Such other action as may be permitted under the terms of the IOTA Model.

As part of the Innovation Center's monitoring and assessment of the impact of models tested under the authority of section 1115A of the Act, CMS has a special interest in ensuring that these model tests do not interfere with the program integrity interests of the Medicare program. For this reason, CMS monitors actions of IOTA participants for compliance with model terms, as well as other Medicare program rules. When CMS becomes aware of noncompliance with these requirements, it is necessary for CMS to have the ability to impose certain administrative remedial actions on a noncompliant model participant.

In the alternative, we considered a policy where the IOTA participant would remain in the IOTA Model regardless of any noncompliance. However, if there are circumstances in which the IOTA participant has engaged, or is engaged in, egregious actions, we proposed that CMS may terminate the IOTA participant, as further described in section III.C.16.b. of this final rule. In addition, we considered allowing IOTA participants access to their data and reports regardless of their compliance with the requirements of the IOTA Model, however, we proposed to discontinue data sharing and reports as a potential remedial action if there are grounds for doing so.

We sought comment on these proposed provisions regarding the proposed grounds for remedial actions, remedial actions generally, and whether additional types of remedial action would be appropriate.

The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters expressed support for the IOTA Model grounds for remedial action and types of remedial action.

Response: We thank commenters for their feedback and support.

Comment: A commenter suggested that modest penalties for opting out of the IOTA Model could be bypassed in an economically rational way and ultimately threaten efforts to accurately assess the model.

Response: Participation in the IOTA Model is mandatory, so a participant cannot opt out. If a participant does not comply with the participation requirements of the IOTA Model, there will be remedial actions, which could include reducing or eliminating model specific payments or discontinuing data sharing and reports.

Comment: A commenter suggested that CMS should remove the risk that a program failing to meet the HEP requirements are subject to remedial action.

Response: We are no longer requiring health equity plans so participants will not be subject to remedial action for not submitting a plan.

After consideration of the public comments, for the reasons set forth in this final rule, we are finalizing our proposal on remedial actions as proposed at § 512.464 with a slight modification to update language to accurately reflect what we proposed at 89 FR 43618. Specifically, we are modifying the regulatory text at § 512.464(a)(1) to specify that CMS may impose remedial actions if CMS determines that the IOTA participant has failed to furnish 11 or more kidney transplants for patients aged 18 years or older, regardless of payer, during a PY or any baseline years.

b. Termination of IOTA participant From the IOTA Model by CMS

At proposed § 512.466(a), we proposed that CMS may immediately or with advance notice terminate an IOTA participant from participation in the IOTA Model if:

- CMS determines that it no longer has the funds to support the IOTA Model;
- CMS modifies or terminates the model pursuant to section 1115A(b)(3)(B) of the Act;
- CMS determines that the IOTA participant—

++ Has failed to comply with any model requirement or any other Medicare program requirement, rule, or regulation;

++ Has failed to comply with a monitoring or auditing plan or both;

++ Has failed to submit, obtain approval for, implement or fully comply with the terms of a CAP;

++Has failed to demonstrate improved performance following any remedial action;

++ Has taken any action that threatens the health or safety of a Medicare beneficiary or other patient;

++Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model;

++ Has undergone a change in control; [345] or

[345] At § 512.468(b)(2), we proposed that CMS may terminate an IOTA participant from the IOTA Model if the IOTA participant undergoes a change

++ Assigns or purports to assign any of the rights or obligations under the model, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS.

• Poses significant program integrity risks, including but not limited to:

++ Is subject to sanctions or other actions of an accrediting organization or a Federal, State, or local government agency; or

++ Is subject to investigation or action by HHS (including OIG or CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

We requested comment and feedback on the proposal for termination of an IOTA participant from participating in the IOTA Model.

The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters expressed concern that the termination provision may allow transplant programs not interested in the model to simply accept a fine and exit the model and offers no downside to enrolled participants.

Response: Participation in the IOTA Model is mandatory, so a participant cannot exit the model. There are downside consequences if a participant does not comply with the requirements of the IOTA Model, such as remedial actions, which could include reducing or eliminating model specific payments or discontinuing data sharing and reports. The participant would not be able to accept a fine and exit the model, but rather negative financial consequences would be imposed, and continue to be imposed in subsequent Performance Years, on the participant. The participant would also be required to continue its participation in the IOTA Model.

After considering public comments, for the reasons set forth in this rule, we are finalizing our policy for termination of an IOTA participant from the IOTA Model by CMS as proposed in our regulation at § 512.466(a), with slight modifications. Specifically, we are redesignating what was proposed at § 512.466(a)(3)(vii) to be § 512.466(a)(3)(viii). We are also redesignating what was proposed at § 512.466(a)(3)(viii) to be § 512.466(a)(3)(ix). Lastly, at § 512.468(b)(2), we proposed that CMS may terminate an IOTA participant from the IOTA Model if the IOTA participant undergoes a change of control. As such, we have added a corresponding provision at § 512.466(a)(3)(vii), which allows for termination for a change in control consistent with § 512.468(b)(2).

c. Termination of Model Participation by IOTA Participant

Given the mandatory nature of this model, we proposed at § 512.466(b) of the proposed rule that an IOTA participant would not be able to terminate its own participation in the model. Maintaining a cohort of participants as close to 50 percent of eligible kidney transplant hospitals across the country is critical to evaluation of the IOTA Model. As such, while we proposed CMS may terminate an IOTA participant for reasons such as failure to meet eligibility criteria or change in kidney transplant hospital status, as described in section III.C.16.b. of this final rule, we did not propose voluntary termination by the IOTA participant.

We considered allowing an IOTA participant to voluntarily terminate their participation in the model; however, we felt this went against the mandatory nature of the model and jeopardized our ability to evaluate model success and savings.

We solicited comment and feedback on our proposal not to allow IOTA participants to terminate their participation in the IOTA Model.

The following is a summary of the public comments received on these proposals and our responses:

Comment: A commenter shared their support for not allowing participants to terminate themselves from the model.

Response: We appreciate your feedback and support.

After considering public comments, we are finalizing our policy for termination of model participation by IOTA participant as proposed in our regulation at § 512.466(b).

d. Financial Settlement Upon Termination

In section III.C.16.d of the proposed rule, we proposed that if CMS terminates the IOTA participant's participation in the IOTA Model or CMS terminates the IOTA Model, CMS would calculate the final performance score and any upside risk payment or downside risk payment, if applicable, for the entire PY in which the IOTA participant's participation in the model or the IOTA Model was terminated.

We proposed that if CMS terminates an IOTA participant for any reason listed in section III.C.16.b of this final rule, CMS shall not make any payments of upside risk payment for the PY in which the IOTA participant was terminated, and the IOTA participant shall remain liable for payment of any downside risk payment up to and including the PY in which termination becomes effective (89 FR 43602). We proposed that CMS would determine the IOTA participant's effective date of termination.

We considered that in the event of termination, CMS would not pay any upside risk payments for the year in which the IOTA participant was terminated, but also only keep the IOTA participant liable for paying CMS any downside risk payments for completed PYs and not the year in which the IOTA participant is terminated (89 FR 43602). However, to deter poor or non-compliant performance, we believe it necessary to also keep the IOTA participant liable for paying to CMS any downside risk payment for the PY in which the IOTA participant is terminated.

We solicited comment on this proposal and alternative considered.

We received no comments on our proposed financial settlement upon termination policies and therefore are finalizing these proposals at § 512.466(c) without modification.

e. Termination of the IOTA Model

In the proposed rule, we proposed that the general provisions relating to termination of the model by CMS in 42 CFR 512.165 would apply to the IOTA Model (89 FR 43602). Consistent with these provisions, in the event we terminate the IOTA Model, we would provide written notice to IOTA participants specifying the grounds for termination and the effective date of such termination. As provided by section 1115A(d)(2) of the Act and *§ 512.170(e),* termination of the model under section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review. We proposed that in the event of termination of the model, financial settlement terms would be the same as those set forth in section III.C.16.d. of this final rule.

We solicited public comment on these proposals regarding termination of the IOTA Model.

We received no comments on the proposed policies for termination of the IOTA Model, and therefore are finalizing these proposals with slight modification at § 512.466(d) to clarify

of control. For consistency, in this final rule, we have added a corresponding provision at § 512.466(a)(3)(vii).

that, as stated in this section and in the proposed rule at 89 FR 43602, termination of the IOTA Model under section 1115A(b)(3)(B) of the Act is not subject to administrative or judicial review.

17. Miscellaneous Provisions on Bankruptcy and Other Notifications

a. Notice of Bankruptcy

In the proposed rule, we proposed that if an IOTA participant has filed a bankruptcy petition, whether voluntary or involuntary, the IOTA participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the IOTA participant under the terms of each model tested under section 1115A of the Act in which the IOTA participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved (89 FR 43602). We proposed the notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number), and a list of all models tested under section 1115A of the Act in which the IOTA participant is participating or has participated. This list would not need to identify a model tested under section 1115A of the Act in which the IOTA participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the IOTA participant and CMS have been fully and finally resolved with respect to that model. The notice to CMS would be addressed to the CMS Office of Financial Management, Mailstop C3–01–24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified on the CMS website for purposes of receiving such notices.

We received no comments on these proposals and therefore are finalizing these provisions at § 512.468(a), without modification.

b. Change in Control

We proposed that CMS could terminate an IOTA participant from the model if the IOTA participant undergoes a change in control. We proposed that the IOTA participant shall provide written notice to CMS at least 90 days before the effective date of any change in control. For purposes of this rule, we proposed a ''change in control'' would mean at least one of the following: (1) the acquisition by any ''person'' (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the IOTA participant representing more than 50 percent of the IOTA participant's outstanding voting securities or rights to acquire such securities; (2) the acquisition of the IOTA participant by any individual or entity; (3) any merger, division, dissolution, or expansion of the IOTA participant (4) the sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the IOTA participant; or (5) the approval and completion of a plan of liquidation of the IOTA participant, or an agreement for the sale or liquidation of the IOTA participant.

We received no comments on these proposals and therefore are finalizing these provisions at § 512.468(b) as proposed, with a slight modification to include a cross-reference to § 512.466 at § 512.468(b)(2). We are also finalizing without modification the proposed definition of change in control at § 512.402.

c. Prohibition on Assignment

We proposed that except with the prior written consent of CMS, an IOTA participant shall not transfer, including by merger (whether the IOTA participant is the surviving or disappearing entity), consolidation, dissolution, or otherwise: (1) any discretion granted it under the model; (2) any right that it has to satisfy a condition under the model; (3) any remedy that it has under the model; or (4) any obligation imposed on it under the model. We proposed that the IOTA participant provide CMS 90 days advance written notice of any such proposed transfer. We proposed this obligation remains in effect after the expiration or termination of the model or the IOTA participant's participation in the model and until final payment by the IOTA participant under the model has been made. We proposed CMS may condition its consent to such transfer on full or partial reconciliation of upside risk payments and downside risk payments. We proposed that any purported transfer in violation of this requirement is voidable at the discretion of CMS.

We received no comments on these proposals and therefore we are finalizing these provisions, as proposed without modification, at § 512.468(c).

D. Requests for Information (RFIs) on Topics Relevant to the IOTA Model

In the proposed rule (89 FR 43603), we sought input on several requests for information (RFIs).

1. Patient-Reported Outcome Performance Measures (PRO–PM)

In the proposed rule (89 FR 43603), we sought comment on the potential use of patient-reported outcome performance measures in the IOTA Model. Specifically, we sought feedback on the following questions:

- For a meaningful evaluation of transplant program outcomes from the recipient point of view, are there currently any validated PROMs of quality of life that are appropriate for use in the IOTA Model?
- Are there specific aspects of quality of life (QOL) that are particularly important to include for these populations? Why are these aspect(s) of QOL a high priority for inclusion in a survey? What should these metrics be (that is, measurement tools, instruments, concepts)? How should they be measured?
- For kidney transplant recipients: What other topic area(s) should be included in a new patient-reported outcome measure or performance measure assessing quality of life?
- For kidney transplant recipients: What domains of HRQOL can be influenced or improved by actions taken by transplant hospital and thus may be appropriate for performance measurement?

In addition, we sought input on the questions later in this section on existing PROMs and quality measures that are currently being used by transplant hospitals.

- Which patient-reported outcomes measure(s) that assess quality of life in kidney transplant recipients are currently being used?

++ What information is collected in these PROMs? How well do these surveys perform? What are the strengths of the survey(s) currently in use?

++ What content area(s) are missing from these survey(s) that are currently in use?

++ Which content area(s) are low priority or not useful in these currently used survey(s)? Why are they not useful?

++ How are the results and findings of these current survey(s) used to evaluate and improve quality of life/care? Are the results and findings of these current survey(s) used for other purposes?

• Are there any other PROMs or PRO–PMs that CMS should consider using to measure a transplant program's performance?
• Are there any other quality measures in general that CMS should consider using to measure a transplant program's performance?
• For transplant hospitals: Can PROs be effectively used to assess performance?
• For transplant hospitals: Does a reporting requirement effectively incentivize a transplant hospital to improve patient quality of life without tying payment to performance?
• When is the appropriate time to measure HRQOL post-transplantation?
• For transplant hospitals: What, if any, challenge(s) are there to collecting information about patient quality of life?
• For kidney transplant recipients: What, if any, challenge(s) are there to reporting information about patient quality of life?
• For transplant hospitals: What actions or approaches by transplant hospitals would facilitate the collection of quality-of-life information?
++ What data collection approach(es) would be most likely to promote participation by transplant recipients to a survey (for example, web-based, paper-and-pencil, etc.)?
++ How much time would transplant hospitals need to build processes to collect and use data in a meaningful way?
• For transplant hospitals: How could CMS support transplant hospitals in introducing a measure like this into the model?

While we are not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform any future quality measure efforts.

2. Access to Waitlist Measure

In the proposed rule (89 FR 43604), we sought comment on the potential use of an access to waitlist measure in the IOTA Model. Specifically, we sought feedback on the following questions:
• For kidney transplant hospitals: What existing measures are currently being used to measure access to the waitlist?
++ What are the strengths and weaknesses of those measures?
++ What are the domains of those measures?
• For kidney transplant recipients and dialysis and ESRD patients: Why is a quality measure that looks at access to waitlist important to include?
• When measuring access to waitlist, what components should be analyzed (for example, time from referral to waitlist, time from waitlist to transplant)?
• What data would be necessary to create a measure on those specified components? How could that data be transmitted to CMS that minimizes additional burden to transplant hospitals?
• What data would be necessary to create a measure of time to referral to waitlist, time from referral to waitlist and time from waitlist to transplant? How could that data be transmitted to CMS that reduces burden to transplant hospitals?

While we are not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform any future quality measure efforts.

3. Interoperability

In the proposed rule (89 FR 43605), we sought comment on interoperability requirements in the IOTA Model. Specifically, we sought comment on how CMS can promote interoperability in the proposed IOTA Model; in particular, we sought comment on the extent to which participants are planning on participating in the Trusted Exchange Framework and Common Agreement (TEFCA) in the next 1–2 years, as well as other means by which interoperability may support care coordination in the IOTA Model. We noted that any further proposals related to interoperability in the IOTA Model would be proposed through future notice and comment rulemaking.

We received no comments on this RFI.

IV. Collection of Information Requirements

The Standard Provisions for Innovation Center Models and the Increasing Organ Transplant Access (IOTA) Model would be implemented and tested under the authority of the CMS Innovation Center. Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this final rule would need not be reviewed by the Office of Management and Budget.

V. Regulatory Impact Analysis

A. Statement of Need

The best treatment for most patients with kidney failure is transplantation. Kidney transplants provide improved survival and quality of life relative to dialysis and generates savings to the Medicare Trust Fund over 10 years, but only 30 percent of patients with end-stage renal disease (ESRD) are living with one.[346] The underutilization of kidney transplantation is particularly prominent among structurally disadvantaged populations. The kidney transplant process involves silos of care, gaps in accountability, disparities, and misaligned financial incentives that we believe value-based care incentives are well positioned to target.[347]

The IOTA Model will be a mandatory payment model, beginning on July 1, 2025, and ending June 30, 2031, that tests whether upside and downside performance-based payments (''upside risk payments'' and ''downside risk payments'') increase the number of kidney transplants performed by select IOTA participants (that is, transplant hospitals). Performance would be measured across three domains: (1) Achievement; (2) Efficiency; and (3) Quality. The achievement domain would assess each selected IOTA participant on the overall number of kidney transplants performed relative to a participant-specific target. The efficiency domain would assess the kidney organ offer acceptance rates of each selected IOTA participant relative to a national rate. The quality domain would assess the quality of care provided by the selected IOTA participant based on the composite graft survival rate. Each selected IOTA participant's performance score across these three domains would determine the amount of the performance-based payment that CMS would pay to the selected IOTA participant, or that the selected IOTA participant would pay to CMS. The upside risk payment would be a lump sum payment paid by CMS to the selected IOTA participants with

[346] Organ Procurement and Transplantation Network. Kidney Donor Profile Index (KDPI) Guide for Clinicians. *https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/kidney-donor-profile-index-kdpi-guide-for-clinicians/;* United States Renal Data System. 2022. USRDS Annual Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 9: Healthcare Expenditures for Persons with ESRD. Figure 9.11.

[347] King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. Journal of the American Society of Nephrology, 31(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335.*

high final performance scores. Conversely, the downside risk payment would be a lump sum payment paid to CMS by the selected IOTA participants with low final performance scores.

1. Analytic Baseline

Historical data for the analytic baseline are from the Organ Procurement and Transplant Network/Scientific Registry of Transplant Recipients (OPTN/SRTR).[348] There were 24,667 total adult kidney transplants in the United States in 2021, with a growth rate of 7.3 percent from 2020 to 2021. Similarly, the 5-year compound annual growth rate (CAGR) for the pre-pandemic years of 2015–2019 was 7.1 percent. The majority, 86.7 percent, of adult kidney transplants were from deceased donors in 2021. The trend in growth for deceased donor kidney transplants has been steadily increasing since the revision of the kidney allocation system in 2014, while the trend in growth for living donor kidney transplants has been relatively stable. The number of adult deceased donor kidney transplants increased 5.7 percent from 2020 to 2021, a slowdown from the 2015–2019 CAGR of 7.8 percent.

Among the 18,931 adult deceased donor kidney transplant recipients in 2021, 64.7 percent reported Medicare as their primary payer (stable from 64.8 percent in 2020) and 24.0 percent reported private insurance as their primary payer (down from 25.7 percent in 2020). Deceased donor kidney transplant recipients had 2015–2019 CAGR of 6.9 percent for Medicare as their primary payer and 11.6 percent for private insurance as their primary payer. The age distribution of the 18,931 adult deceased donor kidney transplant recipients in 2021 showed that the majority of recipients are younger than the aged Medicare population. Specifically, 11.5 percent of recipients were ages 18–34 years, 26.1 percent were ages 35–49 years, 40.5 percent were ages 50–64 years, and 21.9 percent were at least 65 years of age at the time of transplant. The 2015–2019 CAGR was greatest for the two latter age categories, at 9.3 percent and 14.4 percent for ages 50–64 years and 65+ years, respectively.

The supply of donated kidneys has not grown with the demand from kidney transplant recipient candidates. There were a total of 96,130 adult kidney transplant candidates on the transplant waitlist at the end of the year in 2021, which included 41,765 newly added candidates. The number of newly added adult candidates to the waitlist increased 11.7 percent from 2020 to 2021, recovering from the pandemic-related decline in the prior year, and exceeding the 2015 to 2019 CAGR of 9.2 percent.

For the model, we assumed an average of $40,000 in savings to Medicare over a 10-year period for each additional kidney transplant furnished to a Medicare beneficiary compared to remaining on dialysis. For the 50 percent of IOTA participants proposed to be randomly selected to participate in the model, we assume that the total number of kidney transplants from all payers over the 6-year model performance period would have a CAGR of 6.6 percent in the absence of the model (for example, if the rule is not finalized). We also assume that the 6-year model performance period CAGR for the total number of kidney transplants furnished to beneficiaries with Medicare as the primary payer would be 7.0 percent. The baseline share of deceased donor kidneys that are currently discarded is roughly 20 percent. If the IOTA Model were not implemented, then IOTA participants would not have the performance-based upside and downside risk payments to increase their organ offer acceptance rate. Therefore, pre-pandemic growth rates for deceased donor kidney transplants would be expected to continue during the projection period. The living donor kidney transplant growth rate is also expected to continue close to pre-pandemic rates in the absence of the model.

One initiative and one recent reform have the potential to impact the IOTA study population, even in the absence of the model. First, the OPTN Modernization Initiative that HRSA announced in March 2023 includes several actions to strengthen accountability, transparency, equity, and performance in the OPTN.[349] Some of the proposed OPTN Modernization Initiative actions that are relevant to the IOTA Model's target population include data dashboards detailing individual transplant center and organ procurement organization data on organ retrieval, waitlist outcomes, and transplants, and demographic data on organ donation and transplant will be made available to patients. In the absence of the IOTA Model, the OPTN Modernization Initiative has the potential to incentivize IOTA participants to improve upon some of the IOTA Model's incentive domains, such as improving the organ offer acceptance rate and post-transplant outcomes.

Second, the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act (H.R. 5534; also known as the Immuno Bill) passed in November 2020, which stipulates lifelong coverage for immunosuppressive drugs for kidney transplant recipients, has the potential to improve patient survival.[350] Beginning January 1, 2023, the Medicare Part B Immunosuppressive Drug benefit covers immunosuppressive drugs beyond 36 months for eligible kidney transplant recipients that do not have other health coverage for immunosuppressive drugs. The most current statistics of post-transplant patient survival are reported by Hariharan et al.[351] The authors used data from the OPTN/SRTR and found that post-deceased donor kidney transplant patient survival rates at years 1 and 3 are 97.1 percent and 93.3 percent, respectively, for transplantation taking place during 2016–2019. Post-living donor kidney transplant patient survival rates are 99.1 percent and 96.5 percent during the same period. These rates decrease over the longer term. For kidney transplantation during 2008–2011, patient survival rates at 10 years are 66.9 percent for deceased donor kidney transplants and 81.3 percent for living donor kidney transplants. The authors project that survival rates will continue to improve, explaining that the decline in survival starting 3 years after transplantation has been attributed to, and coincides with, the discontinuation of insurance coverage for long-term immunosuppressive medications.

B. Overall Impact

We have examined the impacts of this rule under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 titled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory

[348] Organ Procurement and Transplant Network/Scientific Registry of Transplant (OPTN/SRTR). ''OPTN/SRTR YYYY Annual Data Report: Kidney. Supplemental Data Tables.'' Where YYYY is for report years 2015, 2018, 2019, 2020, and 2021. *https://www.srtr.org/reports/optnsrtr-annual-data-report/.*

[349] HHS. 2023. ''HRSA Announces Organ Procurement and Transplantation Network Modernization Initiative.'' *https://www.hhs.gov/about/news/2023/03/22/hrsa-announces-organ-procurement-transplantation-network-modernization-initiative.html.*

[350] CMS. 2022. ''Medicare Program; Implementing Certain Provisions of the Consolidated Appropriations Act, 2021 and Other Revisions to Medicare Enrollment and Eligibility Rules. Final Rule.'' **Federal Register** 87 FR 66454: 66454–66511.

[351] Hariharan S, Irani AK, Danovitch G (2023). ''Long-Term Survival after Kidney Transplantation.'' *New England Journal of Medicine.* 385:729–43. *https://www.nejm.org/doi/full/10.1056/NEJMra2014530.*

Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 titled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OMB's Office of Information and Regulatory Affairs (OIRA) in each case.

We have prepared a regulatory impact analysis (RIA) for major rules with significant regulatory action/s and/or that are significant under section 3(f)(1) of Executive order 12866 ($200 million or more in any 1 year). Based on our estimates from the CMS Office of the Actuary, OMB's OIRA has determined that this rulemaking is not significant per section 3(f)(1). We have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking. In accordance with the Congressional Review Act), OMB's OIRA has also determined that this rule does not meet the criteria set forth in 5 U.S.C. 804(2). We solicited comment on the RIA and provide our responses to each comment later in the RIA.

C. Detailed Economic Analysis

Several important factors have been identified that lead to the discard of donated kidneys, including significant increased cost to hospitals for transplanting organs from older donors and/or donors with comorbidities. Value-based payments that reward hospitals for increasing the number of transplants as well as related quality and process measures may improve the acceptance of offered organs and outcomes for patients.[352] A stochastic model was constructed to estimate the financial impact of the IOTA Model. When possible, assumptions were informed by historical data. Transplant hospital adult transplant counts by donor type and recipients' primary source of payment were obtained from the SRTR dashboard.[353] Organ offer acceptance ratios [354] and the composite graft survival rate [355] were analyzed from SRTR's program-specific statistics and transplant hospital-level data on kidney transplants. The SRTR data source includes data on all transplant donors, candidates, and recipients in the U.S.

IOTA participants would receive upside or downside risk payments based on their performance across three domains: achievement, efficiency, and quality. The three domains would measure certain metrics and award points as shown in the following Table I:

TABLE I: IOTA PERFORMANCE DOMAINS

Domain	Metrics Description	Points
Achievement	The number of transplants performed relative to an IOTA participant-specific target. Rolling baseline.	60
Efficiency	Organ offer acceptance rate**,** which is a ratio of observed versus expected organ offer acceptances.	20
Quality	Composite graft survival rate.	20
Total Possible		100

The upside risk payment would be a lump sum payment paid by CMS to the IOTA participants that achieve high final performance scores. Conversely, the downside risk payment would be a lump sum payment paid to CMS by the IOTA participants with low final performance scores. The performance-based payments would be based on the following thresholds. Total scores of 60 and above would result in a maximum upside risk payment of $15,000, as shown in equation 7. Scores below 60 would fall into the neutral zone with no upside or downside risk payment in PY 1. After the first PY, scores from 41 to 59 would fall in the neutral zone, and scores of 40 and below would receive a downside risk payment. The maximum downside risk payment in the model would be $2,000, as shown in equation 8. This performance-based payment would then be multiplied by the total number of kidney transplants furnished by the IOTA participant to attributed patients for which model payments apply during the PY.

Equation 7: IOTA Upside Risk Payment for Scores of 60 and Above

[352] Cooper, M. et. al. (2018). Report of the National Kidney Foundation Consensus Conference to Decrease Kidney Discards. *Journal of Clinical Transplantation and Translational Research, https://doi.org/10.1111/ctr.13419.*

[353] Scientific Registry of Transplant Recipients. Adult Recipient Transplants By Donor Type, Center: U.S. Transplants Performed: January 1, 1988–September 30, 2024; For Organ = Kidney; Include: Transplant Year & Recipient Primary Source of Payment. *https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/.* Accessed October 22, 2024.

[354] Scientific Registry of Transplant Recipients. National Center Level Data by Organ: Kidney CSRS Final Tables, Table B11 & Figures B10–B14. *https://www.srtr.org/reports/program-specific-reports/.* Accessed May 25, 2023.

[355] Scientific Registry of Transplant Recipients. National Center Level Data by Organ: Kidney CSRS Final Tables, Tables C5–C12 Figures C1–C20. *https://www.srtr.org/reports/program-specific-reports/.* Accessed May 25, 2023.

$$IOTA\ Lump\ Sum\ Payment = \$15{,}000 * \left(\frac{Final\ Performance\ Score - 60}{40}\right) * Medicare\ Kidney\ Transplants$$

Equation 8: IOTA Downside Risk Payment for Scores of 40 and Below

$$IOTA\ Performance\ Payment = \$2{,}000 * \left(\frac{40 - Final\ Performance\ Score}{40}\right) * Medicare\ Kidney\ Tranplants$$

We randomly selected half of all DSAs in the country and all eligible IOTA participants within those DSAs and applied assumptions for transplant growth and performance on other domains affecting the incentive formula for purposes of estimating impacts in this portion of the rule. Random variables accounted for variation in transplant growth and transplant hospital-level performance on other measures. A pivotal uncertainty relates to the potential growth in transplants as a result of upside and downside risk payments presented by the model. The current share of deceased donated kidneys that are discarded is roughly 20 percent.[356] [357] Such growth was assumed to phase in over a 2- to 5-year period using a skewed distribution, with a gradual phase-in of 5 years being the most likely outcome.

Comment: A few commenters provided justification for a revised payment methodology. A commenter recommended that CMS increase the maximum upside risk payment from $8,000 to $15,125 and the maximum downside risk payment from $2,000 to $3,750 and to apply these proposed payments for performance scores based on the national growth rate instead of to the IOTA participant's own past peak performance. The commenter expected that these modifications would likely yield significantly more savings. A few commenters additionally urged CMS to revise potential financial incentives for IOTA participants upward in congruence with the potential new savings assumption but did not offer any specific alternative payment amounts. A few commenters recommended that the transplant target should be based on the arithmetic mean of volume for the 3-year baseline period instead of the peak performance during the baseline period. The commenter stated that the proposed targets are likely to result in the imposition of significant penalties on high-performing participants.

Response: The maximum upside risk payment was increased from $8,000 in the proposed rule to $15,000 in the final rule (refer to section III.C.6. of this final rule (Payment) for the rationale behind the increase in the maximum risk payment amount). The maximum downside risk payment remained at $2,000. For clarification, in the proposed rule, the transplant target was equal to the highest number of deceased or living donor kidney transplants performed during the three-year baseline period trended forward by the national growth rate. In the final rule, the transplant target was updated to equal to the average number of transplants performed during baseline years trended forward by the national growth rate. Changing the transplant target to be the average of the baseline years instead of the highest number should set the base within reach for IOTA participants to achieve their targets.

For IOTA participants randomized into the model, assumptions were also made for gradual improvement over baseline kidney acceptance rates, with individual IOTA participants assumed to have, in year 1, up to a 10-percent chance (up to a 20-percent chance by year 2, etc.) of increasing their acceptance ratio by between 20 to 80 percentage points and maintaining such simulated improvement in ensuing model years. The share of IOTA participants receiving passing confidence intervals for the 1-year post transplant composite graft survival ratio was assumed to be roughly 95 percent in year 1, gradually improving by about half of a percentage point per year. Please see section III.C.5.e.(1). of this rule for the discussion on post-transplant outcomes.

Tables II, III, and IV show the possible point allocations for performance relative to target for the Achievement Domain, Efficiency Domain, and Quality Domain, respectively. For the Achievement Domain (Table II), the transplant target is the average number of transplants performed during baseline years trended forward by the national growth rate. For the Efficiency Domain (Table III), in recognition that all IOTA participants may not be able to achieve the highest national rank, but still may be performing beyond their previous standards, this domain will be scored in two ways: achievement scoring and improvement scoring (not displayed in Table III). IOTA participants will be awarded points based on the scoring system that yields the highest allocation. In Table III, organ-offer acceptance will be calculated as a rate ratio of observed organ offer acceptances versus expected organ offer acceptances. Performance will be assessed across all centers

[356] Li MT, King KL, Husain SA, et al. 2021. ''Deceased Donor Kidneys Utilization and Discard Rates During COVID–19 Pandemic in the United States.'' *Kidney Int Rep;* 6(9): 2463–2467. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8419126/.*

[357] Robinson A, Booker S, Gauntt K, UNOS Research Department. 2022. ''Eliminate Use of DSA and Region from Kidney Allocation One Year Post-Implementation Monitoring Report.'' *OPTN Kidney Transplantation Descriptive Data Report. https://optn.transplant.hrsa.gov/media/p2oc3ada/data_report_kidney_full_20220624_1.pdf.*

nationally. In the Quality Domain (Table IV), the composite graft survival rate is equal to the total number of functioning grafts divided by the total number of completed kidney transplants.

TABLE II: ACHIEVEMENT DOMAIN – SCORING FOR TRANSPLANT TARGET

Performance Relative to Target	Points Earned
≥ 125%	60
120% ≤ x < 125%	55
115% ≤ x < 120%	50
105% ≤ x < 115%	40
95% ≤ x < 105%	30
85% ≤ x < 95%	20
75% ≤ x < 85%	10
< 75%	0

TABLE III: EFFICIENCY DOMAIN - ACHIEVEMENT SCORING FOR ORGAN OFFER ACCEPTANCE RATE

Performance Relative to Target	Points Earned
≥ 80th Percentile	20
60th ≤ x < 80th Percentile	15
40th ≤ x < 60th Percentile	10
20th ≤ x < 40th Percentile	6
0 ≤ x < 20th Percentile	0

TABLE IV: QUALITY DOMAIN - SCORING FOR COMPOSITE GRAFT SURVIVAL RATE

Performance Relative to Target	Points Earned
≥ 80th Percentile	20
60th ≤ x < 80th Percentile	18
40th ≤ x < 60th Percentile	16
20th ≤ x < 40th Percentile	14
10th ≤ x < 20th Percentile	12
0 ≤ x < 10th Percentile	10

Table V later in this section shows the projected impacts for upside and downside risk payments, transplants, and Federal spending. Although transplant recipients with any type of insurance may benefit from a transplant hospital's participation in the model, model payments will be based on the number of transplant recipients who are beneficiaries with Medicare fee-for-service (FFS) coverage including beneficiaries enrolled in Medicare as a secondary payer. Just over one-third of IOTA participants are projected to receive upside risk payments in the first year, rising to about 43 percent over the succeeding 5 model years, with only a small fraction of participants projected to owe downside risk payments in any of years 2 through 6 (ranging from 16 to 18 percent). The magnitude of the average downside risk payment is relatively small, and the cumulative projected upside risk payments to IOTA participants, amounting to $117 million, are over 100 times the magnitude of a cumulative $1 million in projected receipts from downside risk payments from IOTA participants to CMS. The amount of projected savings from new transplants was greater than the net cost of payments in about 58 percent of simulation trials. The mean 3,683 added transplants over the 6-year model performance period is an increase from the proposed rule for the following reasons: (1) a more effective response in terms of added transplants was assumed in the final rule due to the larger maximum per-transplant incentive; and (2) more hospitals were estimated to receive a positive incentive any given year because the scoring thresholds were made more gradual and the surrounding quality scoring methodology would make higher scores more attainable. Overall, mean net savings totaled $28 million over 6 years, ranging from a savings of $152 million to a cost of $77 million at the 10th and 90th percentiles.

TABLE V: PROJECTED IMPACT OF UPSIDE/DOWNSIDE RISK PAYMENTS, KIDNEY TRANSPLANTS, AND NET FEDERAL SPENDING

							6-Year Totals		
	7/1/25-6/30/26	7/1/26-6/30/27	7/1/27-6/30/28	7/1/28-6/30/29	7/1/29-6/30/30	7/1/30-6/30/31	Mean	10th Percentile	90th Percentile
Upside Risk Payments	$15	$17	$20	$21	$21	$23	$117	$90	$144
Downside Risk Payments	$0	$0	$0	$0	$0	$0	-$1	-$2	-$1
Total Net Payments	**$15**	**$17**	**$19**	**$21**	**$21**	**$23**	**$116**	**$89**	**$142**
Added Transplants	161	343	546	761	913	959	3,683	1,372	6,261
Impact on FFS Spending	**-$5**	**-$12**	**-$20**	**-$-29**	**-$37**	**-$40**	**-$144**	**-$152**	**-$37**
Mean Net Savings	**$9**	**$5**	**-$1**	**-$8**	**-$15**	**-$18**	**-$28**	**-$152**	**$77**

(Projected savings allocated to year of transplant; dollars in millions)

In Table V, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase in Medicare spending. The mean net savings results were generated from the average of 10,000 individual simulation trials and the results for the percentiles are from the top 10th and 90th percentiles of the 10,000 individual simulations. The outcomes in each row do not necessarily flow from the same trial in the model at the 10th and 90th percentiles. For example, the 90th percentile for added transplants more likely corresponds to the trial that produced the 10th percentile in impact on FFS spending from those transplants (because spending is reduced when transplants grow).

There is a wide range of potential changes in Federal spending for each new transplant. Savings on avoided dialysis may in many cases be exceeded when transplants are especially complex and post-transplant complications are more likely, for example when deceased organs have a high kidney donor profile index and/or recipients are of advanced age.[358] But even in such cases Federal savings can be substantial if Medicare is not primary payer at time of transplant or the beneficiary eventually returns to private insurance post-transplant. We relied on the savings per transplant estimate published in the ESRD Treatment Choices (ETC) Model final rule [359] to account for different primary payer scenarios at the time of transplant, as well as the likelihood that the beneficiary would have remained on Medicare after transplantation. For the ETC Model, OACT produced a 10-year savings to Medicare of approximately $32,000 per beneficiary for a deceased donor kidney transplant with a high-kidney donor profile index. For the proposed IOTA Model, we assumed the average Federal spending impact could range from a cautious $20,000 increase to optimistically at most a $100,000 savings per additional transplant (mean assumption being a $40,000 savings).

The mean assumption of $40,000 in savings is marginally higher than the ETC Model's 10-year estimated savings to Medicare of approximately $32,000 per beneficiary for a deceased donor kidney transplant with a high-kidney donor profile index because it includes at least some potential for an increase in other types of transplants. The 10-year estimated savings to Medicare of approximately $32,000 per beneficiary used in the ETC Model based on deceased donor, high-kidney donor profile transplants was assumed because of the relatively limited focus that model appeared to have on improving the number of transplants and outcomes for transplants. By comparison, the estimate for the IOTA Model still focused on deceased donor kidneys, but this model warranted a marginally higher savings per transplant estimate, allowing for the mean assumption of $40,000 in savings. To determine the outer bounds of the assumption, we identified individual points in our organ-type/payer matrix that ranged from a $100,000 increase in costs to $200,000 (or wider) in savings, so the bounds we chose for the estimate were based on realizing new transplants were going to be mixed across the matrix and not all congregated at an extreme end on one side or the other (keeping in mind that they will likely come mostly from decedent donor kidneys). We assumed that kidney transplant savings would accumulate in the year of the transplant even though the cost of the transplant would, in practice, lead to higher spending in the first year (unless Medicare was not the primary payer). It would likely take longer than the 6 model years for the cumulative net savings projected in Table III to ultimately materialize. The timing of when savings would accumulate could not be estimated with more precision for the following reasons. Savings could range from being virtually immediate if new transplants occur when a beneficiary is not Medicare primary payer status, to being backloaded if the beneficiary receives the transplant when Medicare is primary payer, to being a net cost if the beneficiary transplant fails within a short period after transplant. Given those uncertainties, and the underlying uncertainties about where the new transplants will materialize from (by donor and recipient), we were not able to imply more precision than we were able to model from the evidence.

Comment: Some commenters recommended that CMS increase the proposed estimate of $40,000 in savings to Medicare over a 10-year period for each additional kidney transplant furnished to a Medicare beneficiary compared to remaining on dialysis. The commenters expressed that the estimate understates Medicare savings resulting from kidney transplantation and a few commenters noted it is inconsistent with estimates calculated by commenters using United States Renal Data System (USRDS) data to compare costs for patients receiving a kidney transplant to those on dialysis. A few commenters cited published literature that also used USRDS data to support their concern that the savings to Medicare estimate may be in error. These commenters also noted that the published study used as an input for the savings assumption did not account for costs of death on the waiting list.

[358] Axelrod DA, Schnitzler MA, Xiao H, et al. 2018. ''An Economic Assessment of Contemporary Kidney Transplant Practice.'' *American Journal of Transplantation* 18: 1168–1176. *https://pubmed.ncbi.nlm.nih.gov/29451350/.*

[359] Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures, 85 FR 61335 (September 29, 2020) (codified at 45 CFR part 512, subpart A).

Response: In response to the commenters, we investigated the methodology and data sources in the Axelrod et al. (2018) study that was used as an input in our calculations. Ultimately, we decided to keep the proposed estimate of $40,000 in savings to Medicare over a 10-year period for each additional kidney transplant furnished to a Medicare beneficiary compared to remaining on dialysis. The key validity of the Axelrod et al. (2018) study is that the authors focused strictly on costs involving either—(1) maintenance dialysis as a service (that is, the payment to dialysis facilities for regular maintenance dialysis); or (2) kidney transplant surgery (including related costs before and after transplant surgery) as reported on hospital cost reports and potential downstream costs related to graft failure and return to dialysis. Some commenters appeared to assume the study was accounting for all other Part A and Part B costs outside of these categories, which is not the case. Several commenters incorrectly assumed that the Axelrod et al. (2018) study did not include the costs of death on the waiting list; however, the mean costs of death were included in the authors' modeling for the following: death after transplantation, death on the waiting list, and death with function.

In addition to the type of costs included in the Axelrod et al. (2018) study, another reason why we cannot make direct comparisons to the USRDS data is that the Axelrod et al. (2018) study used two sources for their economic data: (1) Medicare claims data from the USRDS and estimates from a novel data set linking national registry data; and (2) hospital cost-accounting data from the University HealthSystem Consortium corporation. The authors explained that the latter source was included because Medicare diagnosis-related group (DRG)-based payments are poorly correlated with the actual cost of the transplantation procedure. In response, we investigated using hospital reported costs instead of Medicare paid amounts for transplant costs for our savings to Medicare estimate calculation. We found that this only made a material difference for some of the living donor kidney transplants, which are expected to be very small percentage of increased transplants in the model, so we did not see a need to adjust our assumptions in response to this detail.

Last, we considered additional factors that could potentially impact our estimate. Medicare spending extraneous to dialysis/transplant could be increased by transplantation because of positive impacts on longevity, for example, but on the other hand Medicare spending could be reduced to the extent that non-disabled recipients under the age of 65 would return to private health insurance after transplant. These (and other) opposing forces could push the average net Medicare impact materially higher or lower than the strict comparison in Axelrod et al. (2018). This is highly dependent on the mix of organs and patients that ultimately represent the increased transplant population in the model. Significant continued uncertainty in these areas necessitates a wide range for assuming the net spending impact per new transplant, and revisiting the evidence did not convince us the range should necessarily be updated in either direction.

Comment: A commenter suggested that there may be an error in Table III of the proposed rule. The commenter stated that the projected $100 million impact on FFS spending should be $105 million (assuming $40,000 per transplant × assuming 2,625 additional transplants = $105,000,000), yielding a mean net savings of $70 million to Medicare after projected net payments of $35 million to IOTA participants.

Response: The commenter incorrectly assumed that the row labeled, ''Impact on FFS Spending'' in Table III of the proposed rule was a direct calculation of the mean savings per transplant multiplied by the number of additional transplants. Instead, we assumed the average Federal spending impact could range from a cautious $20,000 increase to optimistically at most a $100,000 savings per additional transplant with a mode (as well as the mean) assumption being $40,000 savings. The mean of $100,000 reported for the Impact on FFS Spending in the 6-year total column in Table III of the proposed rule is from the average of 400 individual simulation trials, where the savings per additional transplant is a number between $20,000 and $100,000 generated by our actuarial model.

D. Estimated Burden on Participant Hospitals

While the model is focused on transplant outcome measures that would be calculated by CMS, there would likely be some additional burden for compliance for the IOTA participants (that is, transplant hospitals). To estimate the compliance cost we focused on § 512.442(c) that requires IOTA participants to review organ offer acceptance criteria with IOTA waitlist patients who are Medicare beneficiaries at least every 6 months that the Medicare beneficiary is on their waitlist. For this estimate, we assume that the IOTA participant will take a total of 15 minutes per patient per year to review the criteria at least twice a year with each patient. This assumption likely yields an upper estimate since the method (for example, patient visit, phone, email, or mail) of how the IOTA participant communicates the review with the patient is up to the IOTA participant and will likely vary by IOTA participant, potentially reducing the time to conduct the review. In addition, the patient may decline the review, resulting in the IOTA participant having fewer Medicare waitlist patients than what is used in our estimate.

We estimate that the average IOTA participant would have 200 waitlist patients who are Medicare primary payer or Medicare secondary payer beneficiaries per year and that it would take a clinician 15 minutes to review organ offer acceptance criteria with each patient each year. Using base wage information from BLS for a nurse practitioner (series 29–1171), we estimate the cost of completing these reviews to be $61.78 per hour. The base wage is then doubled [$61.78 × 2] to account for fringe benefits and overhead to equal an estimated cost of $123.56 per hour.[360] The cost of completing these reviews would then be $6,178.00 per hospital per year [200 Medicare waitlist patients × 0.25 hour per review each year × $123.56 hourly wage]. Therefore, the total cost would come out to $556,020.00 to complete the review of organ offer acceptance criteria based on the assumption that 90 active transplant hospitals will be selected as IOTA participants [$6,178.00 × 90 hospitals = $556,020.00]. Average total revenue for the transplant hospitals that may be selected to be an IOTA participant using inpatient hospital codes DRG–008 simultaneous pancreas-kidney transplant and DRG–652 kidney transplant generated from adult Medicare FFS beneficiaries with Medicare as their primary payer was $1.0 million in calendar year (CY) 2023. Therefore, the $6,178.00 cost per IOTA participant to review the organ offer acceptance criteria would represent 0.6 percent of the estimated total annual revenue per IOTA participant from

[360] Guidelines for the adjustment in base wages is based on the following report: Office of the Assistant Secretary for Planning and Evaluation (ASPE). 2017. ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices.'' *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

DRGs 653 and 008 when Medicare is the primary payer.

E. Regulatory Review Cost Estimation

We estimate the time it will take for a medical and health services manager to review the rule to be 13.33 hours [200,000 words/250 words per minute/60 minutes = 13.33 hours]. Using the wage information from the Bureau Labor of Statistics (BLS) for medical and health service managers (series 11–9111), we estimate that the cost of reviewing this rule is $129.28 per hour, including overhead and fringe benefits.[361] The cost of reviewing the rule would therefore be a $1,723.30 per hospital [13.33 hours × $129.28 per hour = $1,723.30] or a total cost of $155,097.00 [$1,723.30 × 90 hospitals = $155,097.00]. Using information from the OPTN, we estimate 230 active kidney transplant hospitals that are the potential IOTA participants would review this rule for a total cost of $396,359.00 [$1,723.30 per hospital × 230 hospitals = $396,359.00].[362] In addition, the $1,723.30 cost per IOTA participant to complete the regulatory review would represent 0.1 percent of the estimated total annual revenue from DRGs 653 and 008 from adult Medicare FFS beneficiaries with Medicare as their primary payer.

F. Alternatives Considered

The proposed rule in 42 CFR part 512 [CMS–5535–P] dated May 17, 2024 can be used as an example of alternatives considered for the IOTA Model prior to finalizing the rule. The main changes between the proposed rule and final rule are summarized in this section. The Achievement Domain included the following components in the proposed rule which were modified in the final rule:

- The transplant target was the highest number of deceased or living donor kidney transplants performed during baseline years trended forward by the national growth rate.
- The transplant count included a health equity performance adjustment. Any transplants performed for the underserved population identified in the equity paper (uninsured, Medicaid, dual eligible, Medicare LIS, NLDAC-eligible transplants) counted as 1.2 transplants.
- The thresholds used in the points allocation for the transplant targets included five cutoffs with a range of zero to 60 possible points awarded.

In the final rule, these components were changed to—(1) the transplant target was updated to equal to the average number of transplants performed during baseline years trended forward by the national growth rate; (2) the health equity performance adjustment was removed; and (3) the thresholds used in the point allocation for the transplant targets include eight cutoffs with a range of zero to 60 possible points awarded (see Table II).

The Efficiency Domain was finalized as proposed. The Quality Domain included the following components in the proposed rule which were modified in the final rule: (1) a Quality Measures Set (10 possible points) that included the CollaboRATE Shared Decision-Making Score, a 3-Item Care Transition Measure, and Colorectal Cancer Screening; and (2) a Composite Graft Survival Rate (10 possible points) was based on performance relative to national ranking with five cutoffs and a range of zero to 10 possible points awarded. In the final rule these components were changed to: (1) the Quality Measures Set was removed; and (2) the Composite Graft Survival Rate (20 possible points) is based on performance relative to target with six cutoffs and a range of 10 to 20 possible points awarded (see Table IV).

Last, for the payment methodology, the following component in the proposed rule was modified in the final rule: The maximum upside risk payment was $8,000 and downside risk payment was $2,000. In the final rule, this component was changed to: The maximum upside risk payment was increased to $15,000 and the maximum downside risk payment remained at $2,000 (see equations 7 and 8).

When these components were implemented together in modeling the proposed rule, the mean net projected savings of the IOTA Model totaled $65 million over 6 years, ranging from a savings of $151 million to a cost of $11 million at the 10th and 90th percentiles. Although the mean projected savings decreased after accounting for the final rule policies, significantly increased incentives are expected to increase the number of new transplants generated by the model and create a potential for slightly greater overall savings at the optimistic end of the projection range (the final rule 10th percentile is $152 million savings). Detailed explanation for why these model components changed from the proposed rule to the final rule is provided throughout various sections of the final rule.

Comment: A commenter requested that CMS predict what savings in the model would be if we were to include a pre-emptive transplant multiplier that would drive an uptick in pre-emptive transplantation and related savings.

Response: In the proposed rule, we stated that we considered offering differential credit for transplants by type. With this methodology, IOTA participants would receive bonus points and score higher for transplants that fit into categories that lead to more savings, such as living donor kidney transplants (LDK), high KDPI donors, or pre-emptive transplants, compared to other transplants. Addressing the comment directly, the pre-emptive nature of some transplants is only one of many complex and uncertain factors contributing to the financial impact of the average transplant potentially added in response to model incentives. However, we believe that counting all transplants the same would maximize flexibility for transplant hospitals in meeting their targets and minimizes the potential harm and unintended consequences the alternative system would create. Therefore, a pre-emptive transplant multiplier was not included in the final rule.

G. Impact on Beneficiaries

The upside and downside risk payments in this model are expected to at least marginally increase the number of kidney transplants provided to beneficiaries with ESRD. This model is projected to result in approximately 3,700 new transplants over the 6-year model performance period. Evidence shows that kidney transplants extend patients' lives and that such benefits have been increasing despite unfavorable trends in terms of donor and recipient risk factors.[363] Even if added transplants most often were to involve high Kidney Donor Profile Index (KDPI) organs (that are most often discarded historically), the average recipient would still be expected to benefit from increased quality of life and longevity.[364] In addition—though we did not explicitly assume specific benefits to beneficiaries—the model would include quality measures aimed at improving outcomes even for transplants that would have otherwise occurred absent the model. IOTA participants would be incentivized to improve the composite graft survival rate. The model could also improve the

[361] Bureau of Labor Statistics (BLS). May 2023. ''Occupational Employment and Wage Statistics.'' *https://www.bls.gov/oes/current/oes_nat.htm.*

[362] *https://optn.transplant.hrsa.gov.*

[363] Hariharan S, Irani AK, Danovitch G (2023). ''Long-Term Survival after Kidney Transplantation.'' *New England Journal of Medicine.* 385:729–43. *https://www.nejm.org/doi/full/10.1056/NEJMra2014530.*

[364] Axelrod DA, Schnitzler MA, Xiao H, et al. 2018. ''An Economic Assessment of Contemporary Kidney Transplant Practice.'' *American Journal of Transplantation* 18: 1168–1176. *https://pubmed.ncbi.nlm.nih.gov/29451350/.*

efficiency with which hospitals interact with organ procurement organizations and reduce the time from deceased organ donation to transplant surgery. These and other elements of the model have the potential to improve outcomes for the wider group of transplant patients beyond the fraction assumed to receive transplants under the model.

H. Accounting Statement and Table

The annualized monetized benefits and transfers in Table VI were calculated based on constant payments and constant discount interest rates. Using the row labeled Total as an example for how the results were calculated, the primary estimate of $4 million in total savings was based on a 2 percent discount rate, with a 6-year study period, and a net present value of $24 million in savings. Net present value for the primary estimate was based on the IOTA Model's mean net savings estimate for years July 1, 2025 through June 30, 2031 reported in the bottom row of Table V. The minimum and maximum annualized monetized total benefits and transfers reported in Table VI use the same calculation as the primary estimate, with the exception of the annual mean net savings replaced with the IOTA Model's annual mean net savings for the 10th and 90th percentiles.

TABLE VI: ACCOUNTING STATEMENT

Annualized monetized benefits and transfers (negative indicates savings). Dollars in millions.

	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
Costs to Medicare for Upside Risk Payments to IOTA Participants	$19	$14	$25	RIA Table V
Costs to IOTA Participants for Downside Risk Payments	$0	$0	$0	RIA Table V
Benefits via Savings from Increased Transplants	-$24	-$44	-$6	RIA Table V
Total	**-$4**	**-$25**	**$14**	**RIA Table V**

Notes: The total may not equal the sum of the preceding rows due to rounding. The costs to IOTA participants for negative payments are less than a million dollars for the primary, minimum, and maximum estimates.

TABLE VII: ADDITIONAL ESTIMATED COSTS FOR 2025-2031

Total costs reported for all IOTA participants. Dollars are not reported in millions.

Category	Costs	Frequency	Source Citation
Burden to IOTA participants	$556,020	Annual	Section IV.D. Estimated Burden on Participant Hospitals
Regulatory review	$396,359	One-time	Section IV.E. Regulatory Review Cost Estimation

I. Regulatory Flexibility Act (RFA)

Effects on IOTA participants in the model include the potential for additional upside risk payments from CMS to the IOTA participant of up to $15,000 per eligible kidney transplant or downside risk payments from the IOTA participant to CMS of up to $2,000 per eligible kidney transplant (refer to section IV.C. of this final rule (Detailed Economic Analysis) for a description of how upside and downside risk payments are calculated in the model). We project that payouts will far exceed the relatively small sum of downside risk payments expected over the 6-year model performance period. Only about $1 million in total downside risk payments are expected over 6 years spread across approximately 16 to 18 percent of IOTA participants expected to be charged downside risk payments from year to year. By contrast, we project over 6 years that $117 million in total upside risk payments would be made to between 33 to 43 percent of IOTA participants expected to earn payments in the model from year to year.

Under the RFA, agencies are to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). Although many IOTA participants (that is, transplant hospitals with NAICS 622110 General Medical and Surgical Hospitals) may be small entities as that term is used in the RFA, kidney transplants only represent a small fraction of the revenue such hospitals generate, and even the largest per transplant downside risk payment of $2,000 (which notably is expected to be a very rare outcome in general) would not represent a significant economic impact. Additional sources of financial burden on IOTA participants to consider include the estimated cost of $6,178.00 per IOTA participant per year to review the organ offer acceptance criteria with IOTA waitlist patients who are Medicare beneficiaries and the one-time cost of $1,723.00 per IOTA participant to have their medical and health services manager review this rule. Refer to the section titled, ''Estimated Burden on Participant Hospitals'' in the final rule for an explanation of how these burden estimates were determined. No comments were received during the public comment period on the RFA section on regulatory relief for small entities.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. The $6,178.00 cost per IOTA participant to review the organ offer acceptance criteria and the $1,723.30 cost per IOTA participant to complete the regulatory review would represent 0.6 percent and 0.1 percent, respectively, of the estimated total annual revenue per IOTA participant from DRGs 653 and 008 when Medicare is the primary payer. Based on these estimates, we do not believe that this threshold will be reached by the requirements in this final rule.

Therefore, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, under section 1102(b) of the Act, a regulatory impact analysis should be prepared if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We believe this final rule will not have a significant impact on small rural hospitals since small rural hospitals do not have the resources to perform kidney transplants. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

J. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately $183 million. This final rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

K. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 23, 2024.

List of Subjects in 42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare, Recordkeeping requirements.

For the reasons set forth in the preamble the Centers for Medicare & Medicaid Services amends 42 CFR part 512 as follows:

■ 1. The part heading for part 512 is revised to read as follows:

PART 512—STANDARD PROVISIONS FOR MANDATORY INNOVATION CENTER MODELS AND SPECIFIC PROVISIONS FOR THE RADIATION ONCOLOGY MODEL AND THE END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 2. The authority for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 3. The heading of subpart A is revised to read as follows:

Subpart A—Standard Provisions for Mandatory Innovation Center Models

■ 4. Revise § 512.100 to read as follows.

§ 512.100 Basis and scope.

(a) *Basis.* This subpart implements standard provisions for certain Innovation Center models, as that term is defined in this subpart.

(b) *Scope.* (1) The regulations in this subpart apply to the Radiation Oncology Model implemented under subpart B, the End-Stage Renal Disease (ESRD) Treatment Choices Model implemented under subpart C, and each Innovation Center model for which participation by Model participants is mandatory that begins its first performance period on or after January 1, 2025.

(2) This subpart sets forth the following:

(i) Basis and scope.

(ii) Definitions.

(iii) Beneficiary protections.

(iv) Cooperation in model evaluation and monitoring.

(v) Audits and record retention.

(vi) Rights in data and intellectual property.

(vii) Monitoring and compliance.

(viii) Remedial action.

(ix) Innovation Center model termination by CMS.

(x) Limitations on review.

(xi) Miscellaneous provisions on bankruptcy and other notifications.

(xii) Reconsideration review processes.

(3) Except as specifically noted in this subpart, these regulations do not affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including provisions regarding payment, coverage, or program integrity.

■ 5. Section 512.110 is amended by—

■ a. Adding, in alphabetical order, the definition of ''Governing documentation'';

■ b. Revising the definitions of ''Innovation Center model,'' ''Innovation Center model activities,'' ''Model beneficiary,'' and ''Model participant''; and

■ c. Adding, in alphabetical order, the definitions of ''Performance period'' and ''Standard provisions for Innovation Center models''.

The additions and revisions read as follows:

§ 512.110 Definitions.

* * * * *

Governing documentation means the applicable Federal regulations, and the model-specific participation agreement, cooperative agreement, and any addendum to an existing contract with CMS, that collectively specify the terms of the Innovation Center model.

* * * * *

Innovation Center model means an innovative payment and service delivery model tested under the authority of section 1115A(b) of the Act, including a model expansion under section 1115A(c) of the Act.

* * * * *

Innovation Center model activities mean any activities affecting the care of model beneficiaries related to the test of the Innovation Center model.

* * * * *

Model beneficiary means a beneficiary attributed to a model participant or otherwise included in an Innovation Center model.

* * * * *

Model participant means an individual or entity that is identified as a participant in the Innovation Center model.

* * * * *

Performance period means the period of time during which an Innovation Center model is tested and model participants are held accountable for cost and quality of care; the performance period for each Innovation Center model is specified in the governing documentation.

* * * * *

Standard provisions for Innovation Center models mean the provisions codified in 42 CFR part 512 subpart A.

* * * * *

■ 6. Section 512.190 is added to read as follows:

§ 512.190 Reconsideration review process.

(a) *Applicability of this section.* Section 512.190 is only applicable to the following:

(1) Innovation Center models that have waived section 1869 of the Act, or where section 1869 of the Act is not applicable for model participants.

(2) Model participants, unless the governing documentation for the Innovation Center model states otherwise.

(b) *Right to reconsideration.* The model participant may request reconsideration of a determination made by CMS in accordance with an Innovation Center model's governing documentation only if such reconsideration is not precluded by section 1115A(d)(2) of the Act, this subpart, or the governing documentation for the Innovation Center model for which CMS made the initial determination.

(1) A request for reconsideration by the model participant must satisfy all of the following criteria:

(i) Must be submitted to a designee of CMS (reconsideration official) who—

(A) Is authorized to receive such requests; and

(B) Did not participate in the determination that is the subject of the reconsideration request, or, if applicable, the timely error notice review process.

(ii)(A) Must include a copy of the initial determination issued by CMS; and

(B) Must contain a detailed, written explanation of the basis for the dispute, including supporting documentation.

(iii) Must be made within 30 days of the date of the initial determination for which reconsideration is being requested via email to an address as specified by CMS in the governing documentation for the Innovation Center model for which CMS made the initial determination.

(2) Requests that do not meet the requirements of paragraph (b)(1) of this section are denied.

(3) Within 10 business days of receiving a request for reconsideration, the reconsideration official sends CMS and the model participant a written acknowledgement of receipt of the reconsideration request. This acknowledgement sets forth all of the following:

(i) The review procedures.

(ii) A schedule that permits each party to submit position papers and documentation in support of the party's position for consideration by the reconsideration official.

(4) If the request is regarding a model-specific payment and the governing documentation specifies an initial timely error notice process, the model participant must satisfy the timely error notice requirements specified in the governing documentation before submitting a reconsideration request under paragraph (b) of this section. In the event that the model participant fails to timely submit an error notice with respect to a particular model-specific payment, the reconsideration review process would not be available to the model participant with regard to that model-specific payment.

(c) *Standards for reconsideration.* (1) The parties must continue to fulfill all responsibilities and obligations under the governing documentation during the course of any dispute arising under the governing documentation.

(2) The reconsideration consists of a review of documentation that is submitted timely and in accordance with the standards specified by the reconsideration official and are enumerated in paragraph (b)(3) of this section.

(3) The burden of proof is on the model participant to demonstrate to the reconsideration official with clear and convincing evidence that the determination is inconsistent with the terms of the governing documentation.

(d) *Reconsideration determination.* (1) The reconsideration determination is based solely upon both of the following:

(i) Position papers and supporting documentation that meet both of the following:

(A) Submitted timely to the reconsideration official in accordance with the schedule specified in paragraph (b)(3)(ii) of this section.

(B) The standards for submission under paragraph (b)(1) of this section.

(ii) Documents and data that were timely submitted to CMS in the required format before CMS made the determination that is the subject of the reconsideration request.

(2)(i) The reconsideration official issues the reconsideration determination to CMS and to the model participant in writing.

(ii) Absent unusual circumstances, in which case the reconsideration official reserves the right to an extension upon written notice to the model participant, the reconsideration determination is issued within 60 days of receipt of timely filed position papers and supporting documentation in accordance with the schedule specified in paragraph (b)(3)(ii) of this section.

(3) The reconsideration determination is final and binding 30 days after its issuance, unless the model participant or CMS timely requests review of the reconsideration determination in accordance with paragraphs (e)(1) and (2) of this section.

(e) *CMS Administrator review.* The model participant or CMS may request that the CMS Administrator review the reconsideration determination. The request must meet both of the following:

(1) Be made via email within 30 days of the date of the reconsideration determination to the address specified by CMS.

(2) Include a copy of the reconsideration determination and a detailed written explanation of why the model participant or CMS disagrees with the reconsideration determination.

(3) The CMS Administrator promptly sends the parties a written acknowledgement of receipt of the request for review.

(4) The CMS Administrator sends the parties notice of the following:

(i) Whether the request for review is granted or denied.

(ii) If the request for review is granted, the review procedures and a schedule that permits each party to submit a brief in support of the party's position for consideration by the CMS Administrator.

(4) If the request for review is denied, the reconsideration determination is final and binding as of the date the request for review is denied.

(5) If the request for review is granted all of the following occur:

(i) The record for review consists solely of—

(A) Timely submitted briefs and the evidence contained in the record of the proceedings before the reconsideration official; and

(B) Evidence as set forth in the documents and data described in paragraph (d)(1)(ii) of this section.

(ii) The CMS Administrator reviews the record and issues to CMS and to the model participant a written determination.

(iii) The written determination of the CMS Administrator is final and binding as of the date the written determination is sent.

■ 7. Adding Subpart D to read as follows:

Subpart D—Increasing Organ Transplant Access (IOTA) Model

Sec.

Subpart D—Increasing Organ Transplant Access (IOTA) Model

§ 512.400 Basis and scope.

(a) *Basis.* This subpart implements the test of the Increasing Organ Transplant Access (IOTA) Model under section 1115A(b) of the Act.

(b) *Scope.* This subpart sets forth the following:

(1) The method for selecting IOTA participants.

(2) The patient population.

(3) The methodology for IOTA participant performance assessment and scoring for purposes of the achievement domain, efficiency domain, and quality domain, including beneficiary attribution and transplant target calculation.

(4) The schedule and methodologies for the upside risk payment and downside risk payment.

(5) Data sharing.

(6) Other IOTA Model requirements.

(7) Beneficiary protections.

(8) Financial arrangements.

(9) Monitoring.

(10) Evaluation.

(11) Termination.

(12) Except as specifically noted in this subpart, the regulations under this subpart do not affect the applicability of other provisions affecting providers and suppliers under Medicare fee for service, including the applicability of provisions regarding payment, coverage, or program integrity.

(c) *Applicability.* IOTA participants are subject to the standard provisions for Innovation Center models specified in subpart A of this part 512 and in subpart K of part 403 of this chapter.

§ 512.402 Definitions.

For purposes of this subpart, the following definitions apply.

Achievement domain means the performance assessment category in which CMS assesses the IOTA participant's performance based on the number of transplants performed relative to the transplant target.

Alignment payment means a payment from an IOTA collaborator to an IOTA participant that is made in accordance with a sharing arrangement.

Annual attribution reconciliation means the yearly process in which CMS—

(1) Creates the final list of each IOTA participant's attributed patients for the prior performance year by retrospectively de-attributing from each IOTA participant any attributed patients that satisfy a criterion for de-attribution under § 512.414(c); and

(2) Creates a final list of each IOTA participant's attributed patients who remain attributed for the performance year being reconciled, subject to the attribution criteria under §§ 512.414(b)(1) and (2).

Annual attribution reconciliation list means the final cumulative record of attributed patients that CMS generates annually for whom each IOTA participant is accountable for during the applicable PY as described at § 512.414(c)(2).

Attributed patient means an IOTA waitlist patient or an IOTA transplant patient.

Attribution means the process by which CMS identifies the patients for whom each IOTA participant is accountable during the model performance period, as described in § 512.414.

Baseline year means a 12-month period within a 3-year historical baseline period, that begins 48 months (or 4 years) before the start of each model PY and ends 12 months (or 1 year) before the start of each model PY, as described in § 512.424.

Bypassed response means an organ offer not received due to expedited placement or a decision by a kidney transplant hospital to have all of its kidney transplant waitlist patients skipped during the organ allocation process based on a set of pre-defined filters selected by the kidney transplant hospital matching the characteristics of the potential organ to be transplanted.

Critical access hospital (CAH) means a hospital as defined in section 1861(mm)(1) of the Act.

Change in control means at least one of the following:

(1) The acquisition by any ''person'' (as this term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the IOTA participant representing more than 50 percent of the IOTA participant's outstanding voting securities or rights to acquire such securities.

(2) The acquisition of the IOTA participant by any other individual or entity.

(3) Any merger, division, dissolution, or expansion of the IOTA participant.

(4) The sale, lease, exchange, or other transfer (in one transaction or a series of transactions) of all or substantially all the assets of the IOTA participant.

(5)(i) The approval and completion of a plan of liquidation of the IOTA participant; or

(ii) An agreement for the sale or liquidation of the IOTA participant.

Collaboration agent means an individual or entity that is not an IOTA collaborator and that is a member of a PGP, NPPGP, or TGP that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is an IOTA collaborator.

Composite graft survival rate means the rolling unadjusted total number of functioning grafts relative to the total number of adult kidney transplants performed, as described in § 512.428.

CORF stands for comprehensive outpatient rehabilitation facility.

Days means calendar days unless otherwise specified by CMS.

Distribution arrangement means a financial arrangement between an IOTA collaborator that is an PGP, NPPGP, or TGP and a collaboration agent for the sole purpose of distributing some or all of a gainsharing payment received by the PGP, NPPGP, or TGP.

Distribution payment means a payment from an IOTA collaborator that is a PGP, NPPGP, or TGP to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments.

Donation service area (DSA) means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area (MSA) or does not include any part of such an area and that meets the standards of 42 CFR part 486 subpart G as defined in 42 CFR 486.302.

Downside risk payment means the lump sum payment the IOTA participant must pay to CMS after the close of a performance year if the IOTA participant's final performance score falls within the ranges specified in § 512.430.

Efficiency domain means the performance assessment category in which CMS assesses the IOTA participant's performance using the organ offer acceptance rate ratio as described in § 512.426.

EFT stands for electronic funds transfer.

Eligible attributed patient means an attributed patient that receives immunosuppressive drug coverage through Part B or Part D but that does not have secondary insurance that could provide cost sharing support.

Final performance score means the sum total of the scores earned by the IOTA participant across the achievement domain, efficiency domain, and quality domain for a given PY.

Gainsharing payment means a payment that is made from an IOTA participant to an IOTA collaborator, under a sharing arrangement as set forth in § 512.452 and in accordance with § 512.452(c).

Health equity goals mean the targeted outcomes relative to the health equity plan performance measures for the first PY and all subsequent PYs.

Health equity plan intervention means the initiative(s) the IOTA participant creates and implements to reduce target health disparities.

Health equity plan performance measure(s) means one or more quantitative metrics that the IOTA participant uses to measure the reductions in target health disparities arising from the health equity plan interventions.

Health equity project plan means the timeline for the IOTA participant to implement the IOTA participant's health equity plan.

HHA means a Medicare-enrolled home health agency.

Hospital has the meaning set forth in section 1861(e) of the Act.

Improvement benchmark rate means 120 percent of the IOTA participants' performance on the organ offer acceptance rate ratio as specified under § 512.426(c)(1)(ii)(A).

Initial attribution means the process by which CMS identifies and prospectively attributes patients who meet the criteria specified under § 512.414(a)(2)(b) to an IOTA participant prior to the model start date.

IOTA activities mean the activities related to promoting accountability for the quality, cost, and overall care for attributed patients and performance across the achievement domain, efficiency domain and quality domain, including any of the following:

(1) Managing and coordinating care.

(2) Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

(3) The provision of items and services pre- or post-transplant in a manner that reduces costs and improves quality.

(4) Carrying out any other obligation or duty under the IOTA Model.

IOTA collaborator means the following Medicare-enrolled providers and suppliers that enter into a sharing arrangement with an IOTA participant:

(1) Nephrologist.

(2) ESRD facility.

(3) Skilled nursing facility (SNF).

(4) Home health agency (HHA).

(5) Long-term care hospital (LTCH).

(6) Inpatient rehabilitation facility (IRF).

(7) Physician.

(8) Nonphysician practitioner.

(9) Therapist in a private practice.

(10) CORF.

(11) Provider or supplier of outpatient therapy services.

(12) Physician group practice (PGP).

(13) Hospital.

(14) CAH.

(15) Non-physician provider group practice (NPPGP).

(16) Therapy group practice (TGP).

IOTA participant means a kidney transplant hospital, as defined at § 512.402, that is required to participate in the IOTA Model under § 512.412.

IOTA transplant patient means a kidney transplant patient who receives a kidney transplant at the age of 18 years of age or older from an IOTA participant at any time during the model performance period and meets the criteria set forth in § 512.414(b)(2).

IOTA waitlist patient means a kidney transplant waitlist patient, regardless of payer type and waitlist status, who meets all of the following:

(1) Is alive.

(2) 18 years of age or older.

(3) Registered on a waitlist (as defined in § 512.402) to one or more IOTA participants, as identified by the OPTN computer match program.

IRF stands for inpatient rehabilitation facility which must meet all of the following:

(1) The general criteria set forth in § 412.22.

(2) The criteria to be classified as a rehabilitation hospital or rehabilitation unit set forth in §§ 412.23(b), 412.25, and 412.29 for exclusion from the inpatient hospital prospective payment systems specified in § 412.1(a)(1).

Kidney transplant means the procedure in which a kidney is surgically transplanted from a living or deceased donor to a transplant recipient, either alone or in conjunction with any other organ(s).

Kidney transplant hospital means a transplant hospital with a Medicare approved kidney transplant program.

Kidney transplant patient means a patient who was a transplant candidate, as defined in § 121.2, and received a kidney transplant furnished by a kidney transplant hospital, regardless of payer type.

Kidney transplant waitlist patient means a patient who is a transplant candidate, as defined in § 121.2, and who is registered to a waitlist for a kidney at one or more kidney transplant hospitals.

LTCH stands for long-term care hospital that meets the requirements as stated in 42 CFR part 483 subpart B.

Match run means a computerized ranking of transplant candidates based upon donor and candidate medical compatibility and criteria defined in OPTN policies.

Medicare kidney transplant means a kidney transplant furnished to a attributed patient in the IOTA Model whose primary or secondary insurance is Medicare fee for service (FFS), as identified in Medicare FFS claims with MS–DRGs 008, 019, 650, 651, and 652.

Member of the NPPGP or *NPPGP member* means a nonphysician practitioner or therapist who is an owner or employee of an NPPGP and who has reassigned to the NPPGP their right to receive Medicare payment.

Member of the PGP or *PGP member* means a physician, nonphysician practitioner, or therapist who is an owner or employee of the PGP and who has reassigned to the PGP their right to receive Medicare payment.

Member of the TGP or *TGP member* means a therapist who is an owner or employee of a TGP and who has reassigned to the TGP their right to receive Medicare payment.

Missing responses means organ offers that a kidney transplant hospital received from the OPO but did not submit a response (accepting or rejecting) in the allotted 1-hour timeframe from the time the offer was made per OPTN policy 5.6.B.

Model performance period means the 72-month period from the model start date and is comprised of 6 individual performance years.

Model-specific payment means a payment made by CMS only to IOTA participants, or a payment adjustment made only to payments made to IOTA participants, under the terms of the IOTA Model that is not applicable to any other providers or suppliers and includes, unless otherwise specified, both of the following:

(1) The IOTA Model upside risk payment.

(2) The IOTA Model downside risk payment.

Model start date means the date on which the model performance period begins, July 1, 2025.

National growth rate means the percentage increase or decrease in the number of kidney transplants performed over a 12-month period by all kidney transplant hospitals except for pediatric kidney transplant hospitals, as defined at § 512.402.

National Provider Identifier (NPI) means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in accordance with 45 CFR part 162.

Neutral zone means the final performance score range in which the IOTA participant neither owes a downside risk payment to CMS nor receives an upside-risk payment from CMS, in accordance with § 512.430(b)(2).

Non-pediatric facility means a kidney transplant hospital that furnishes more than 50 percent of their kidney transplants annually to patients 18 years of age or older.

Nonphysician practitioner means (except for purposes of 42 CFR part 510 subpart G) one of the following:

(1) A physician assistant who satisfies the qualifications set forth at § 410.74(a)(2)(i) and (ii) of this chapter.

(2) A nurse practitioner who satisfies the qualifications set forth at § 410.75(b) of this chapter.

(3) A clinical nurse specialist who satisfies the qualifications set forth at § 410.76(b) of this chapter.

(4) A certified registered nurse anesthetist (as defined at § 410.69(b)).

(5) A clinical social worker (as defined at § 410.73(a)).

(6) A registered dietician or nutrition professional (as defined at § 410.134).

NPPGP means an entity that is enrolled in Medicare as a group practice, includes at least one owner or employee who is a nonphysician practitioner, does not include a physician owner or employee, and has a valid and active TIN.

OPTN computer match program means a set of computer-based instructions which compares data on a cadaveric organ donor with data on transplant candidates on the waiting list and ranks the candidates according to OPTN policies to determine the priority for allocating the donor organ(s).

Organ procurement and transplantation network or *OPTN* means the network established under section 372 of the Public Health Service Act.

Organ procurement organization or *OPO* means an entity designated by the Secretary under section 1138(b) of the Act and under 42 CFR 486.304.

Part B and Part D immunosuppressive drug cost sharing support means cost sharing support related to immunosuppressive drugs covered by Medicare Part B, the Medicare Part B Immunosuppressive Drug Benefit (Part B–ID), or Medicare Part D that is provided by an IOTA participant to an eligible attributed patient as codified at § 512.456.

Pediatric kidney transplant hospital means a kidney transplant hospital that performs 50 percent or more of its transplants in a 12-month period on patients under the age of 18.

Performance year (PY) means a 12-month period beginning on July 1 and ending on June 30 of each year during the model performance period.

PGP stands for physician group practice.

Physician has the meaning set forth in section 1861(r) of the Act.

Post-transplant period means the 90-day period following an attributed patient's receipt of a kidney transplant.

Preliminary performance assessment and payment calculations means the process by which CMS—

(1) Assesses each IOTA participant's performance in accordance with §§ 512.424, 512.426, 512.428; and

(2) Calculates performance-based payments in accordance with § 512.430.

Provider of outpatient therapy services means an entity that is enrolled in Medicare as a provider of therapy services and furnishes one or more of the following:

(1) Outpatient physical therapy services as defined in § 410.60 of this chapter.

(2) Outpatient occupational therapy services as defined in § 410.59 of this chapter.

(3) Outpatient speech-language pathology services as defined in § 410.62 of this chapter.

Quality domain means the performance assessment category in which CMS assesses the IOTA participant's performance using a performance measure focused on improving the quality of transplant care as described in § 512.428.

Quality Health Information Network (QHIN) means a network of organizations that agrees to common terms and conditions regarding data exchange with each other (a ''Common Agreement'') and to the functional and technical requirements for such data exchange (as specified in the QHIN Technical Framework or ''QTF'') under section 4003(b) of the 21st Century Cures Act (Pub. L. 114–255).

Quarterly attribution list means the quarterly CMS-generated attributed patient list that CMS provides to the IOTA participant in advance of each quarter during the model performance period in accordance with § 512.414(c)(ii)(2).

Resource gap analysis means the resources needed to implement the health equity plan interventions and identifies any gaps in the IOTA participant's current resources and the additional resources needed.

Scientific Registry of Transplant Recipients or *SRTR* means the registry of information on transplant recipients established under section 373 of the Public Health Service Act.

Selected DSAs means those DSAs selected by CMS for purposes of selecting kidney transplant hospitals for participation in the IOTA Model.

Sharing arrangement means a financial arrangement to only share the upside risk payment and the downside risk payment lump-sum amount as set forth in § 512.452.

SNF stands for skilled nursing facility that meets all applicable requirements in section of 1819 of the Act.

Target health disparities mean health disparities experienced by one or more communities within the IOTA participant's population of attributed patients that the IOTA participant aims to reduce.

Targeted review process means the process in which an IOTA participant may dispute performance and payment calculations made, and issued, by CMS as set forth in § 512.434.

TGP means an entity that is enrolled in Medicare as a therapy group in private practice, includes at least one owner or employee who is a therapist in private practice, does not include an owner or employee who is a physician or nonphysician practitioner, and has a valid and active TIN.

Therapist means one of the following individuals as defined at § 484.4 of this chapter:

(1) Physical therapist.

(2) Occupational therapist.

(3) Speech-language pathologist.

Therapist in private practice means a therapist that complies with one of the following special provisions:

(1) For physical therapists in private practice in § 410.60(c) of this chapter.

(2) For occupational therapists in private practice in § 410.59(c) of this chapter.

(3) For speech-language pathologists in private practice in § 410.62(c) of this chapter.

Taxpayer identification number (TIN) means a Federal taxpayer identification

number or employer identification number as defined by the Internal Revenue Service in 26 CFR 301.6109–1.

Transplant hospital means a hospital that furnishes organ transplants as defined in 42 CFR 121.2.

Transplant physician means a physician who provides non-surgical care and treatment to transplant patients before and after transplant as defined in 42 CFR 121.2.

Transplant program means a component within a transplant hospital which provides transplantation of a particular type of organ as defined in 42 CFR 121.2.

Transplant recipient means a person who has received an organ transplant as defined in 42 CFR 121.2.

Transplant target means the target number of kidney transplants calculated by CMS for the IOTA participant to measure the IOTA participant's performance in the achievement domain, as described in § 512.424.

Underserved communities mean populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life as defined by Executive Order 13985 of January 20, 2021.

Upside risk payment means the lump sum payment CMS makes to an IOTA participant if the IOTA participant's final performance score for a performance year falls within the payment range specified in § 512.430.

Waitlist means a list of transplant candidates, as defined in 42 CFR 121.2, registered to the waiting list, as defined in 42 CFR 121.2, maintained by a transplant hospital in accordance with 42 CFR 482.94(b).

Increasing Organ Transplant Access Model Scope and Participation

§ 512.412 Participant eligibility and selection.

(a) *Participant eligibility.* A kidney transplant hospital is eligible to be selected as an IOTA participant, in accordance with the methodology described in paragraph (c) of this section, if the kidney transplant hospital meets both of the following criteria:

(1) The kidney transplant hospital annually performed 11 or more kidney transplants for patients aged 18 years or older, regardless of payer, each of the baseline years.

(2) The kidney transplant hospital annually performed more than 50 percent of its kidney transplants on patients 18 years of age or older each of the baseline years.

(b) *IOTA participant selection.* CMS uses the following process to select IOTA participants for inclusion in the model.

(1) *DSA stratification criteria.* CMS uses the following criteria to stratify DSAs using the list of DSAs as of January 1, 2024:

(i) Census division of the DSA.

(ii) Total number of adult kidney transplants performed per year across eligible kidney transplant hospitals in the DSA during PY 1's baseline years.

(2) *DSA stratification process.* Prior to sampling DSAs, CMS uses the following steps to group DSAs into mutually exclusive groups.

(i) CMS assigns each DSA to one of the nine Census Divisions. CMS assigns each DSA to the Census Division where the majority of the DSA's population resides. CMS determines each DSA's population, and the share of a DSA's population in the applicable Census Division(s) using data from the 2020 Census.

(A) CMS assigns the Puerto Rico DSA to the South Atlantic Census Divisions.

(B) CMS combines the Middle Atlantic and New England Census Divisions and all DSAs therewithin creating eight groups of Census Divisions.

(ii) CMS identifies all kidney transplant hospitals located in each DSA within each Census Division group.

(iii) For each DSA within its assigned Census Division group, CMS identifies the eligible kidney transplant hospitals using the criteria specified in paragraph (a) of this section.

(iv) Using data from each of the baseline years for PY 1, CMS determines the average number of adult kidney transplants performed annually by eligible transplant hospitals located in each DSA as follows:

(A) Sums the number of adult kidney transplants performed across eligible kidney transplant hospitals in a DSA during each of the baseline years for PY 1; and

(B) Divides each DSA's sum resulting from the calculation in paragraph (b)(2)(iv)(A) of this section by three to determine the average number of adult kidney transplants furnished during the baseline years for PY 1.

(v) CMS separates DSAs in each Census Division group into two mutually exclusive groups of the same size, based on the average number of adult kidney transplants performed annually across the baseline years for PY 1, except where there are an odd number of DSAs within a Census Division group:

(A) DSAs with a higher number of adult kidney transplants per year across the baseline years for PY 1.

(B) DSAs with a lower number of adult kidney transplants per year across the baseline years for PY 1.

(vi) Where there are an odd number of DSAs within a Census Division group CMS uses the methodology set forth in paragraph (b)(3) of this section.

(3) *Random sampling of DSAs.* (i) For each DSA group within a Census Division group containing an odd number of DSAs, CMS randomly selects one DSA and determines its participation in the IOTA Model with a 50 percent probability.

(ii) CMS randomly samples, without replacement, 50 percent of the remaining DSAs in each group within each Census Division group created in paragraph (b)(2)(v) of this section.

(c) *Selection of IOTA participants in selected DSAs.* All eligible kidney transplant hospitals in the selected DSAs are required to participate in the IOTA Model.

(d) *Notification of participation.* CMS notifies IOTA participants of their selection to participate in the IOTA Model in a form and manner chosen by CMS at least 3 months prior to the start of the model performance period.

§ 512.414 P Patient population.

(a) *General.* (1) CMS attributes kidney transplant waitlist patients and kidney transplant patients to IOTA participants based on the attribution criteria as described in paragraphs (b)(1) and (b)(2) of this section, for all of the following purposes:

(i) Sharing Medicare claims data for attributed beneficiaries with IOTA participants.

(ii) Assessing each IOTA participant's performance across the achievement domain, efficiency domain, and quality domain.

(iii) Determining performance-based payments paid to or by IOTA participants.

(2) Once a kidney transplant waitlist patient or kidney transplant patient is attributed to an IOTA participant, that respective patient may not opt out of attribution to an IOTA participant and remains attributed to the IOTA participant for the duration of the model performance period, unless the attributed patient meets the de-attribution criteria under paragraph (b)(3) of this section during annual attribution reconciliation as described in paragraph (b)(3) of this section.

(b) *Patient attribution and de-attribution criteria*—(1) *IOTA waitlist patient attribution.* (i) At the time CMS conducts attribution, as described in

paragraph (c) of this section, if a kidney transplant waitlist patient meets the definition of an IOTA waitlist patient, as defined at § 512.402, CMS attributes the kidney transplant waitlist patient as an IOTA waitlist patient to an IOTA participant.

(2) *IOTA transplant patient attribution.* (i) At the time CMS conducts attribution, as described in paragraph (c) of this section, CMS attributes a kidney transplant patient as an IOTA transplant patient if the kidney transplant patient meets all of the following:

(A) The definition of an IOTA transplant patient, as defined at § 512.402.

(B) Is 18 years of age or older at the time of the patient's kidney transplant.

(C) Is alive.

(3) *De-attribution from an IOTA participant.* During annual attribution reconciliation, CMS uses the fourth quarter attribution list for each IOTA participant and de-attributes any attributed patients who, as of the last day of the PY being reconciled, meet any of the following de-attribution criteria:

(A) An IOTA waitlist patient that was removed from and remains unregistered on an IOTA participant's kidney transplant waitlist.

(B) An IOTA waitlist patient that has died at any point during the PY.

(C) An IOTA transplant patient that has died at any point during the PY.

(D) An IOTA transplant patient who experiences transplant failure at any point during the model performance period and has not rejoined an IOTA participant's kidney transplant waitlist or received another transplant from an IOTA participant before the last day of the respective PY.

(c) *Attribution methodology.* CMS employs the following methodology to attribute kidney waitlist patients and kidney transplant patients to an IOTA participant after identifying all kidney waitlist patients and kidney transplant patients that meet the attribution criteria as specified in paragraphs (b)(1) and (b)(2) of this section:

(1)(i) *Initial attribution.* Prior to the model start date, CMS conducts initial attribution, as defined at § 512.402.

(ii) *Initial attribution list.* (A) CMS provides the initial attribution list to the IOTA participant no later than 15 days prior to the start of PY 1 and in a form and manner as determined by CMS.

(B) The initial attribution list includes a list of IOTA waitlist patients identified through initial attribution, effective on the model start date.

(2)(i) *Quarterly attribution.* CMS conducts attribution, as defined at § 512.402, on a quarterly basis after the model start date, and updates the quarterly attribution list, as defined at § 512.402, for each IOTA participant, except in the event of termination in accordance with § 512.466.

(ii) *Quarterly attribution list.* CMS provides the quarterly attribution list, as defined at § 512.402, to the IOTA participant no later than 15 days prior to the start of each quarter and in a form and manner determined by CMS. The quarterly attribution list includes, at minimum, all of the following:

(A) A list of all newly attributed patients, whose attribution to the IOTA participant becomes effective on the first day of the relevant upcoming quarter.

(B) A list of all attributed patients who continue to be attributed to the IOTA participant from the previous quarter.

(C) The dates in which attribution began, changed, or ended, where applicable for attributed patients.

(D) The attributed patient's data sharing preferences under § 512.440(b).

(3)(i) *Annual attribution reconciliation.* After the fourth quarter of each PY, CMS conducts annual attribution reconciliation as defined at § 512.402.

(ii) *Annual attribution reconciliation list.* CMS provides the annual reconciliation list to the IOTA participant before the second quarter of the following PY. Using the fourth quarter quarterly attribution list for each IOTA participant, the annual attribution reconciliation list identifies, at a minimum, all of the following, where applicable:

(A) A list of all attributed patients who remain attributed to the IOTA participant because they satisfied the attribution criteria under §§ 512.414(b)(1) and (2) for the respective PY.

(B) The dates in which attribution began, changed, or ended, where applicable.

(C) A list of all attributed patients who are de-attributed because they failed to satisfy the attribution criteria under § 512.414(b)(1) and (2).

(D) A list of all attributed patients who are de-attributed because they satisfy a de-attribution criterion under § 512.414(b)(3).

(E) The dates on which each attributed patient satisfied a de-attribution criterion as specified under § 512.414(b)(3).

(F) A list of the de-attribution criterion each attributed patient satisfied under § 512.414(b)(3).

Performance Assessment and Scoring

§ 512.422 Overview of performance assessment and scoring.

(a) *General.* (1) CMS establishes the performances measures described in §§ 512.424, 512.426, and 512.428 to assess IOTA participants in the achievement domain, efficiency domain and quality domain.

(2) CMS assigns each set of metrics within a domain a point value with the total possible points awarded to an IOTA participant across the three domains equaling 100, as described in §§ 512.424, 512.426, and 512.428.

(b) *Data sources.* (1) CMS uses Medicare claims data and Medicare administrative data about beneficiaries, providers, suppliers, and data from the OPTN, to calculate performance for the IOTA participant based on the methodologies under §§ 512.424, 512.426, and 512.428.

(2) CMS may also use model-specific data reported by an IOTA participant to CMS under the IOTA Model to calculate IOTA participant performance in the domains.

§ 512.424 Achievement domain.

(a) *General.* (1) After each PY, CMS calculates the number of kidney transplants that each IOTA participant performed for the respective PY, in accordance with the provisions in paragraph (d) of this section.

(2) CMS compares the number of kidney transplants that an IOTA participant performed during the PY to the IOTA participant's transplant target to determine the IOTA participant's score for the achievement domain.

(b) *Transplant target methodology.* CMS determines the IOTA participant's transplant target for each PY as follows:

(1) *Analysis of baseline years.* CMS analyzes the baseline years for the relevant PY and identifies:

(i) The mean number of deceased donor kidney transplants furnished by the IOTA participant to patients 18 years of age or older across the baseline years, as defined at § 512.402; and

(ii) The mean number of living donor kidney transplants furnished by the IOTA participant to patients 18 years of age or older across the baseline years, as defined at § 512.402.

(2) *Mean of kidney transplants.* CMS sums the numbers in paragraphs (b)(1)(i) and (ii) of this section.

(3) *National growth rate calculation.* CMS calculates the national growth rate, as defined at § 512.402, using the baseline years for the relevant PY as follows:

(i) Subtracts the total number of kidney transplants furnished to patients

18 years of age or older during the second baseline year from the total number of kidney transplants furnished to patients 18 years of age or older during the third baseline year.

(ii) Divides the amount resulting from the calculation in paragraph (b)(3)(i) of this section by the total number of kidney transplants furnished to patients 18 years of age or older during the third baseline year. The resulting amount is the national growth rate for the relevant PY.

(4) *Calculation of transplant target.* If the national growth rate calculated in paragraph (b)(3) of this section is—

(i) Positive, CMS multiples that national growth rate by the sum calculated in paragraph (b)(2) of this section. The resulting amount is an IOTA participant's transplant target for the relevant PY; or

(ii) Negative, CMS does not multiply the national growth rate by the sum calculated in paragraph (b)(2) of this section. The IOTA participant's transplant target for the relevant PY is the sum calculated in paragraph (b)(2) of this section.

(c) *Notification of transplant target.* CMS notifies the IOTA participant of the transplant target by the first day of the start of each PY in a form and manner determined by CMS.

(d) *Calculation of kidney transplants performed during the PY.* (1)(i) After each PY, CMS counts the number of kidney transplants performed by the IOTA participant on patients who were 18 years of age or older at the time of transplant, during the PY.

(ii) CMS identifies kidney transplants performed by the IOTA participant using OPTN data, regardless of payer, and Medicare claims data.

(2) CMS counts each kidney transplant described in paragraph (d)(1) of this section as one transplant.

(e) [Reserved]

(f) *Achievement domain scoring.* For each PY, CMS awards the IOTA participant zero to 60 points for its performance in the achievement domain.

(1) CMS compares the total number of kidney transplants identified under paragraph (d)(2) of this section to the IOTA participant's transplant target, as described in paragraph (b) of this section.

(2) CMS uses the following scoring methodology to determine an IOTA participant's score on the achievement domain.

Table 1 to Paragraph (f)(2)—IOTA Model Achievement Domain Scoring Methodology

Performance Relative to Transplant Target	Lower Bound Condition	Upper Bound Condition	Points Earned
125% of transplant target	Equals 125%	Greater than 125%	60
120% of transplant target	Equals 120%	Less than 125%	55
115% of transplant target	Equals 115%	Less than 120%	50
105% of transplant target	Equals 105%	Less than 115%	40
95% of transplant target	Equals 95%	Less than 105%	30
85% of transplant target	Equals 85%	Less than 95%	20
75% of transplant target	Equals 75%	Less than 85%	10
75% of transplant target	N/A	Less than 75%	0

§ 512.426 Efficiency domain.

(a) *General.* For each PY, CMS assesses each IOTA participant on the metric described in paragraph (b) of this section to determine the IOTA participant's score for the efficiency domain.

(b) *Metric included in the efficiency domain.* For each PY, CMS assesses the IOTA participant on the following metric:

(1) *Organ-offer acceptance rate ratio.* For each PY, CMS calculates the organ-offer acceptance rate ratio by dividing the number of kidneys the IOTA participant accepted by the risk-adjusted number of expected organ-offer acceptances using SRTR's methodology as described in equation 1 to paragraph (b)(1) introductory text of this section.

Equation 1 to Paragraph (b)(1) introductory text: Organ Offer Acceptance Rate Ratio

$$Organ\ Offer\ Acceptance\ Rate\ Ratio = \frac{Number\ of\ Acceptances + 2}{Number\ of\ Expected\ Acceptances + 2}$$

(i) CMS uses both of the following:

(A) SRTR data to calculate the organ-offer acceptance rate ratio.

(B) SRTR's adult kidney model strata risk-adjustment methodology and most available set of coefficients to calculate the number of expected organ-offer acceptances.

(ii) CMS includes all of the following kidney offers when calculating the organ-offer acceptance rate ratio for the IOTA participant:

(A) Offers that are ultimately accepted and transplanted.

(B) Offers to candidates on a single organ waitlist (except for kidney/pancreas candidates that are also listed for kidney alone).

(iii) CMS excludes the following kidney offers when calculating the organ-offer acceptance rate:

(A) Offers with multiple match runs from the same donor combined and duplicate offers.

(B) Offers with no match run acceptances.

(C) Offers that occurred after the last acceptance in a match run.

(D) Offers with a missing or bypassed response.

(E) Offers to multi-organ candidates (except for kidney/pancreas candidates that are also listed for kidney alone).

(c) *Efficiency domain scoring.* For each PY, CMS awards the IOTA participant 0 to 20 points for its performance in the efficiency domain.

(1) *General.* CMS determines the IOTA participant's score for the efficiency domain for each PY by taking the IOTA participant's score for the organ offer acceptance rate ratio, as described under paragraph (c)(2) of this section. This number is the IOTA participant's score for the efficiency domain for the PY.

(2) *Scoring for organ offer acceptance rate ratio.* CMS calculates the IOTA participant's achievement score, as described in paragraph (c)(2)(i) of this section, and improvement score, as described under paragraph (c)(2)(ii) of this section, for the organ offer acceptance rate ratio, compares the IOTA participant's achievement score and improvement score and awards to the IOTA participant the points that correspond to the higher score.

(i) *Achievement scoring.* CMS calculates the IOTA participant's achievement score based on the IOTA participant's performance on organ offer acceptance rate ratio relative to national ranking, including all eligible kidney transplant hospitals, using the scoring methodology described in table 1 to paragraph (c)(1)(i) of this section.

Table 1 to Paragraph (c)(1)(i)—IOTA Model Organ Offer Acceptance Rate Ratio Achievement Scoring

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
80th Percentile	Equals 80th percentile	Greater than 80th percentile	20
60th Percentile	Equals 60th percentile	Less than 80th percentile	15
40th Percentile	Equals 40th percentile	Less than 60th percentile	10
20th Percentile	Equals 20th percentile	Less than 40th percentile	6
20th Percentile	N/A	Less than 20th percentile	0

(ii) *Improvement scoring.* CMS compares the IOTA participant's organ offer acceptance rate ratio during the PY, calculated as described under paragraph (c)(1)(i) of this section, to the IOTA participant's improvement benchmark rate, calculated as described under paragraph (c)(1)(ii)(A) of this section.

(A) *Improvement benchmark rate.* CMS calculates an improvement benchmark rate for the IOTA participant. To determine an IOTA participant's improvement benchmark rate for a given PY, CMS multiplies an IOTA participant's organ offer acceptance rate ratio during the third baseline year by 120 percent.

(B) *Improvement score calculation.* For each PY, CMS uses the following methodology to determine each IOTA participant's improvement score on the organ offer acceptance rate ratio:

(*1*) If the IOTA participant's organ-offer acceptance rate ratio is greater than or equal to the improvement benchmark rate, CMS awards the IOTA participant 15 points in the efficiency domain.

(*2*) If the IOTA participant's organ offer acceptance rate ratio is equal to or less than the IOTA participant's organ-offer acceptance rate ratio in the third baseline year for that respective PY, CMS awards the IOTA participant 0 points in the efficiency domain.

(*3*) If the IOTA participant's organ offer acceptance rate ratio is greater than the IOTA participant's organ-offer acceptance rate ratio in the third baseline year for that respective PY but less than the improvement benchmark rate, CMS uses the following equation:

Equation 2 to Paragraph (c)(2)(ii)(B)(*3*)—IOTA Model Organ Offer Acceptance Rate Ratio Improvement Scoring Equation

$$15\,x\,\frac{Rate\ Earned\ in\ Performance\ Year\ -Third\ Baseline\ Year\ Rate}{Improvment\ Benchmark\ Rate-Third\ Baseline\ Year\ Rate}$$

§ 512.428 Quality domain.

(a) *General.* For each PY, CMS assesses each IOTA participant on the metric described under paragraph (b)(1) of this section to determine the IOTA participant's quality domain score, as described under paragraphs (c) through (e) of this section, for the quality domain.

(b) *Metrics included in the quality domain.* For each PY, CMS assesses each IOTA participant using the following quality metrics:

(1) *Post-transplant graft survival.* For each PY, CMS calculates an IOTA participant's composite graft survival rate by dividing the cumulative number of all functioning kidney grafts for the IOTA participant's IOTA transplant patients by the cumulative number of all kidney transplants performed by the IOTA participant during the first PY and all subsequent PYs on patients 18 years or older at the time of the transplant, as described in equation 1 to paragraph (b)(1) introductory text of this section.

Equation 1 to Paragraph (b)(1) introductory Text: Composite Graft Survival Rate

$$Composite\ Graft\ Survival\ Rate\ =\ \frac{\#\ of\ Functioning\ Grafts}{\#\ of\ Completed\ Kidney\ Transplants}$$

(i) For the first PY, CMS calculates the IOTA participant's composite graft survival rate based solely on the number of functioning grafts furnished to IOTA transplant patients during that PY and the number of completed kidney transplants during that PY, as described in paragraph (b)(1) of this section.

(ii) For all subsequent PYs, CMS calculates the IOTA participant's cumulative composite graft survival rate using the same calculation methodology described in paragraph (b)(1) of this section.

(iii) CMS excludes the following from the numerator when calculating the composite graft survival rate:

(A) Graft failure, based on OPTN adult kidney transplant recipient follow-up

forms for all completed kidney transplants to determine failed grafts as defined by SRTR.

(B) Re-transplant.

(C) Death.

(D) Patients who are under the age of 18 years of age at the time of the kidney transplant.

(E) Offers to multi-organ candidates (except for kidney/pancreas candidates that are also listed for kidney alone).

(iv)(A) When calculating the composite graft survival rate, CMS only includes kidney transplants for patients who are 18 years of age and older at the time of the kidney transplant in the number of kidney transplants performed by the IOTA participant during each PY in the denominator.

(B) CMS identifies kidney transplants performed by the IOTA participant using OPTN data, regardless of payer, and Medicare claims data.

(2) [Reserved]

(3) [Reserved]

(c) *Quality domain scoring.* For each PY, CMS awards the IOTA participant zero to 20 points for the IOTA participant's performance in the quality domain, in accordance with the following:

(1) For composite graft survival rate, as described under paragraph (d) of this section, the IOTA participant may receive up to 20 points.

(2) [Reserved]

(d) *Composite graft survival rate scoring.* CMS awards points to the IOTA participant based on the IOTA participant's performance on the composite graft survival rate, as described in paragraph (b)(1) of this section, ranked nationally, inclusive of all eligible kidney transplant hospitals. CMS awards points to the IOTA participant for composite graft survival rate as described in table 1 to paragraph (d) of this section:

Table 1 to Paragraph (d)—IOTA Model Composite Graft Survival Rate Scoring

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
80th Percentile	Equals 80th percentile	Greater than 80th percentile	20
60th Percentile	Equals 60th percentile	Less than 80th percentile	18
40th Percentile	Equals 40th percentile	Less than 60th percentile	16
20th Percentile	Equals 20th percentile	Less than 40th percentile	14
10th Percentile	Equals 10th percentile	Less than 20th percentile	12
10th Percentile	N/A	Less than 10th percentile	10

Payment

§ 512.430 Upside risk payment, downside risk payment, and neutral zone.

(a) *General.* CMS determines if an IOTA participant qualifies for an upside risk payment, downside risk payment, or the neutral zone for each PY based on the IOTA participant's final performance score, in accordance with paragraphs (b)(1) through (3) of this section.

(b) *Upside risk payment, neutral zone, and downside risk payment calculation methodology*—(1) *Upside risk payment calculation methodology.* If in PYs 1–6 the IOTA participant's final performance score is 60 points or above, CMS calculates the IOTA participant's upside risk payment as follows:

(i) Subtracts 60 from the IOTA participant's final performance score.

(ii) Divides the amount resulting from the calculation in paragraph (b)(1)(i) of this section by 40.

(iii) Multiplies the amount resulting from the calculation in paragraph (b)(1)(ii) of this section by $15,000.

(iv) Multiplies the amount resulting from the calculation in paragraph (b)(1)(iii) of this section by the total number of Medicare kidney transplants performed by the IOTA participant during the PY.

(2) *Neutral zone.* (i) For PY 1, an IOTA participant with a final performance score below 60 points qualifies for the neutral zone and neither owes a downside risk payment to CMS nor receives an upside risk payment from CMS.

(ii) For PYs 2 through 6, if an IOTA participant's final performance is between 41 to 59 points (inclusive), the IOTA participant qualifies for the neutral zone.

(3) *Downside risk payment calculation methodology.* If an IOTA participant is at or below 40 points in PYs 1 through 6, the IOTA participant qualifies for a downside risk payment. The downside risk payment is calculated as follows:

(i) For PY 1, this paragraph does not apply, and the IOTA participant does not owe a downside risk payment to CMS.

(ii) For PYs 2 through 6, CMS calculates the IOTA participant's downside risk payment as follows:

(A) Subtracts the IOTA participant's final performance score from 40.

(B) Divides the amount resulting from the calculation in paragraph (b)(3)(ii)(A) of this section by 40.

(C) Multiplies the amount resulting from the calculation in paragraph (b)(3)(ii)(B) of this section by $2,000.

(D) Multiplies the amount resulting from the calculation in paragraph (b)(3)(ii)(C) of this section by the total number of Medicare kidney transplants performed by the IOTA participant during the PY to calculate the amount of the IOTA participant's downside risk payment.

(c) [Reserved]

(d) *Upside risk payment and downside risk payment timeline.* (1) CMS conducts and calculates preliminary performance assessment and payment calculations at least 3 to 6 months after the end of each PY.

(2) CMS notifies the IOTA participant of their preliminary performance assessment and payment calculations in a form and manner determined by CMS at least 5 to 9 months after the end of each PY.

(3) CMS gives IOTA participants 30 days to review preliminary performance assessment and payment calculations and request targeted reviews under § 512.434.

(4) CMS notifies the IOTA participant of their final performance score and any associated upside risk payment or downside risk payment at least 30 days after notifying the IOTA participant of their preliminary performance assessment and payment calculations.

(5) *Upside risk payment.* After CMS notifies the IOTA participant of their final performance score and any associated upside risk payment, and by a date determined by CMS, CMS issues the upside risk payment to the tax identification number (TIN) on file for the IOTA participant in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS).

(6) *Downside risk payment.* After CMS notifies the IOTA participant of their final performance score and any associated downside risk payment and by a date determined by CMS, CMS

issues a demand letter to the TIN on file for the IOTA participant in PECOS for any downside risk payment owed to CMS.

(i) CMS includes all of the following details in the demand letter:

(A) IOTA participant performance in the model.

(B) Amount of downside risk payment owed to CMS by the IOTA participant.

(C) How the IOTA participant may make payments to CMS.

(ii) The IOTA participant must pay the downside risk payment to CMS in a single payment at least 60 days after the date which the demand letter is issued.

§ 512.434 Targeted review.

(a) *General.* Subject to the limitations on review in paragraph (c) of this section, an IOTA participant may submit a targeted review request for one or more calculations made, and issued by, CMS within the preliminary performance assessment and payment calculations, if either of the following occur:

(1) The IOTA participant believes an error occurred in calculations due to data quality or other issues.

(2) The IOTA participant believes an error occurred in calculations due to misapplication of methodology.

(b) *Requirements.* The request must satisfy the following criteria:

(1) Be submitted within 30 days, or another time period as specified by CMS, of receiving its preliminary performance assessment and payment calculations from CMS.

(2) Include supporting information in a form and manner as specified by CMS.

(c) *Limitations on review.* (1) CMS does not provide IOTA participants the ability to dispute the policy or methodology, as the targeted review process would be limited to the dispute of calculations. CMS would not consider targeted review requests regarding, without limitation, the following:

(i) The selection of the kidney transplant hospital to be an IOTA participant.

(ii) The attribution of IOTA waitlist patients and the attribution of IOTA transplant patients to the IOTA participant, or to any other kidney transplant hospital selected for participation in the IOTA Model, or to any kidney transplant hospital not selected for participation in the IOTA Model.

(iii) The methodology used for determining the achievement domain, efficiency domain, and quality domain.

(iv) The methodology used for calculating and assigning points for each metric within the achievement domain, efficiency domain, and quality domain.

(v) The methodology used for calculating the payment amount per Medicare kidney transplant paid to an IOTA participant.

(2) CMS may review a targeted review request that includes one or more of the limitations in paragraph (c)(1) of this section, provided that all remaining considerations of the request meet all other criteria for consideration by CMS in this section.

(d) *Targeted review process.* The IOTA participant must submit a request for targeted review in accordance with paragraphs (a) through (c) of this section. The process for a targeted review is as follows:

(1) *Initial and final assessments.* Upon receipt of a targeted review request from an IOTA participant CMS conducts an initial and final assessment as follows:

(i) *Initial assessment.* (A) CMS determines if the targeted review request meets the targeted review requirements in paragraph (b) of this section and contains sufficient information to substantiate the request.

(B) If the request is not compliant with paragraphs (a) through (c) of this section or requires additional information:

(*1*) CMS follows up with the IOTA participant to request additional information in a form and manner as specified by CMS.

(*2*) The IOTA participant must respond within 30 days of CMS's request for additional information in a form and manner as specified by CMS.

(*3*) An IOTA participant's non-responsiveness to the request for additional information from CMS may result in the closure of the targeted review request.

(ii) *Final assessment.* (A) Upon completion of an initial assessment, as described in paragraph (d)(1)(i) of this section, CMS determines whether it erred in calculation, as disputed by the IOTA participant.

(B) If a calculation error is found as a result of an IOTA participant's targeted review request—

(*1*) CMS—

(*i*) Notifies the IOTA participant within 30 days of any findings in a form and manner as specified by CMS; and

(*ii*) Resolves and corrects any resulting error or discrepancy in the amount of the upside risk payment or downside risk payment in a time and manner as determined by CMS.

(*2*) CMS' correction of any error or discrepancy may delay the effective date of an IOTA participant's upside risk payments or downside risk payments.

(2) *Targeted review decisions.* Targeted review decisions made by CMS are final, unless submitted for administrative review as described in § 512.190.

§ 512.436 Extreme and uncontrollable circumstances.

(a) *General.* CMS—

(1) Applies determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred and the affected area during the PY; and

(2) Has sole discretion to determine the period during which an extreme and uncontrollable circumstance occurred and the percentage of attributed patients residing in affected areas.

(b) *Downside risk payment.* In the event of an extreme and uncontrollable circumstance, as determined by the Quality Payment Program, CMS may reduce the amount of the IOTA participant's downside risk payment, if applicable, prior to recoupment. CMS determines the amount of the reduction by multiplying the downside risk payment by both of the following:

(1) The percentage of total months during the PY affected by the extreme and uncontrollable circumstance.

(2) The percentage of attributed patients who reside in an area affected by the extreme and uncontrollable circumstance.

Data Sharing

§ 512.440 Data sharing.

(a) *General.* CMS shares certain beneficiary-identifiable data as described in paragraph (b) of this section and certain aggregate data as described in paragraph (c) of this section with IOTA participants regarding attributed patients who are Medicare beneficiaries and performance under the model.

(b) *Beneficiary-identifiable data.* CMS shares beneficiary-identifiable data with IOTA participants as follows:

(1) CMS makes available certain beneficiary-identifiable data described in paragraphs (b)(4) and (5) of this section for IOTA participants to request for purposes of conducting health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of their attributed patients who are Medicare beneficiaries.

(2) An IOTA participant that wishes to receive beneficiary-identifiable data for its attributed patients who are

Medicare beneficiaries must do all of the following:

(i) Submit a formal request for the data, on an annual basis in a manner and form and by a date specified by CMS, which identifies the data being requested and attests that—

(A) The IOTA participant is requesting this beneficiary-identifiable data as a HIPAA covered entity or as a business associate, as those terms are defined at 45 CFR 160.103, to the IOTA participant's providers and suppliers who are HIPAA covered entities; and

(B) The IOTA participant's request reflects the minimum data necessary, as set forth in paragraph (b)(6) of this section, for the IOTA participant to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

(ii) Limit the request to Medicare beneficiaries whose name appears on the quarterly attribution list who have been notified in compliance with § 512.450 that the IOTA participant has requested access to beneficiary-identifiable data, and who did not decline having their claims data shared with the IOTA participant as provided in paragraph (b)(7) of this section.

(iii) Sign and submit a data sharing agreement with CMS as set forth in paragraph (b)(8) of this section.

(3) CMS shares beneficiary-identifiable data with an IOTA participant on the condition that the IOTA participant, its IOTA collaborators, and other individuals or entities performing functions or services related to the IOTA participant's activities observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and comply with the terms of the data sharing agreement described in paragraph (b)(8) of this section.

(4) CMS omits from the beneficiary-identifiable data any information that is subject to the regulations in 42 CFR part 2 governing the confidentiality of substance use disorder patient records.

(5) The beneficiary-identifiable data will include, when available, the following information:

(i) *Quarterly attribution lists.* For the relevant PY, CMS shares with the IOTA participant the quarterly attribution lists, which will include but may not be limited to the following information for each attributed patient:

(A) The year that CMS attributed the patient to the IOTA participant.

(B) The effective date of the patient's attribution to the IOTA participant.

(C) The effective date of the patient's de-attribution from the IOTA participant and the reason for such removal (if applicable).

(D) For Medicare beneficiaries, the attributed patient's data sharing preference.

(ii) *Beneficiary-identifiable claims data.* CMS makes available certain beneficiary-identifiable claims data for retrieval by IOTA participants no later than 1 month after the start of each PY, in a form and manner specified by CMS. IOTA participants may retrieve the following data at any point during the relevant PY. This claims data includes all of the following:

(A) Three years of historical Parts A, B, and D claims data files from the 36 months immediately preceding the effective date of each attributed patient who is a Medicare beneficiary's attribution to the IOTA participant.

(B) Monthly Parts A, B, and D claims data files for attributed patients who are Medicare beneficiaries.

(C) Monthly Parts A, B, and D claims data files for Medicare beneficiaries who have been de-attributed from the IOTA participant for claims with a date of service before the date the Medicare beneficiary was de-attributed from the IOTA participant.

(6) The IOTA participant must limit its attributed Medicare beneficiary identifiable data requests to the minimum necessary to accomplish a permitted use of the data.

(i) The minimum necessary Parts A and B data elements may include but are not limited to the following data elements:

(A) Medicare beneficiary identifier (ID).

(B) Procedure code.

(C) Gender.

(D) Diagnosis code.

(E) Claim ID.

(F) The from and through dates of service.

(G) The provider or supplier ID.

(H) The claim payment type.

(I) Date of birth and death, if applicable.

(J) Tax identification number (TIN).

(K) National provider identifier (NPI).

(ii) The minimum necessary Part D data elements may include but are not limited to the following data elements:

(A) Beneficiary ID.

(B) Prescriber ID.

(C) Drug service date.

(D) Drug product service ID.

(E) Quantity dispensed.

(F) Days supplied.

(G) Brand name.

(H) Generic name.

(I) Drug strength.

(J) TIN.

(K) NPI.

(L) Indication if on formulary.

(M) Gross drug cost.

(7)(i)(A) IOTA participants must send Medicare beneficiaries a notification about the IOTA Model and the opportunity to decline claims data sharing as required under § 512.450.

(B) Such notifications must do both of the following:

(*1*) State that the IOTA participant may have requested beneficiary-identifiable claims data about the Medicare beneficiary for purposes of its care coordination, quality improvement work, and population-based activities relating to improving health or reducing health care costs.

(2) Inform the Medicare beneficiary how to decline having his or her claims information shared with the IOTA participant in the form and manner specified by CMS.

(ii) Medicare beneficiary requests to decline claims data sharing remain in effect unless and until a beneficiary subsequently contacts CMS to amend that request to permit claims data sharing with IOTA participants.

(iii) The opportunity to decline having claims data shared with an IOTA participant under paragraph (b)(7)(i) of this section does not apply to any of the following:

(A) The aggregate data that CMS provides to IOTA participants under paragraph (c) of this section.

(B) The initial attribution lists that CMS provides to IOTA participants as defined at § 512.402 and specified under § 512.414(c)(1)(ii).

(C) The quarterly attribution lists that CMS provides to IOTA participants as defined at § 512.402 and specified under § 512.414(c)(2)(ii).

(D) The annual attribution reconciliation list that CMS provides to IOTA participants as defined at § 512.402 and specified under § 512.414(c)(3)(ii).

(8)(i) If an IOTA participant wishes to retrieve any beneficiary-identifiable data specified in paragraph (b) of this section, the IOTA participant must complete and submit, on an annual basis, a signed data sharing agreement, to be provided in a form and manner specified by CMS, under which the IOTA participant agrees to all of the following:

(A) To comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations at 45 CFR part 160 and part 164, subparts A and E, and the requirements of the IOTA Model set forth in this part.

(B) To comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the data sharing agreement.

(C) To contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the IOTA participant, including all IOTA collaborators, to the same terms and conditions to which the IOTA participant is itself bound in its data sharing agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data retrieved by the IOTA participant under the IOTA Model.

(D) That if the IOTA participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may do all of the following:

(*1*) Deem the IOTA participant ineligible to retrieve the beneficiary-identifiable data under paragraph (b) of this section for any amount of time.

(*2*) Terminate the IOTA participant's participation in the IOTA Model under § 512.466.

(*3*) Subject the IOTA participant to additional sanctions and penalties available under the law.

(ii) An IOTA participant must comply with all applicable laws and the terms of the data sharing in order to retrieve beneficiary-identifiable data.

(c) *Aggregate data.* (1) CMS shares aggregate performance data with IOTA participants, in a form and manner to be specified by CMS, which has been de-identified in accordance with 45 CFR 164.514(b). This aggregate data includes, when available, certain de-identified data detailing the IOTA participant's performance against the transplant target information for each PY.

§ 512.442 Transparency requirements.

(a) *Publication of transplant patient selection criteria.* The IOTA participant must publicly post on its website the criteria used by the IOTA participant for evaluating and selecting patients for addition to their kidney transplant waitlist by the end of PY 1.

(b) [Reserved]

(c) *Review of acceptance criteria.* IOTA participants must review transplant organ offer acceptance criteria with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist.

(1) The IOTA participant must conduct this review via patient visit, phone, email or mail on an individual basis, unless the Medicare beneficiary declines this review.

(2) [Reserved]

§ 512.446 Health equity plans.

(a) For each PY, an IOTA participant may voluntarily submit a health equity plan, by a date and in a form and manner determined by CMS, that meets the following requirements:

(1) Identifies target health disparities.

(2) Identifies the data sources used to inform the identification of target health disparities.

(3) Describes the health equity plan intervention.

(4) Includes a resource gap analysis.

(5) Includes a health equity project plan.

(6) Identifies health equity plan performance measure(s).

(7) Identifies health equity goals and describes how the IOTA participant will use the health equity goals to monitor and evaluate progress in reducing targeted health disparities.

(b) [Reserved]

Beneficiary Protections and Financial Arrangements, Beneficiary Incentives, and Compliance.

§ 512.450 Required beneficiary notifications.

(a) *General.* (1) IOTA participants must provide notice to attributed patients that they are participating in the IOTA Model.

(2) CMS provides a notification template that IOTA participants must use. The template, at minimum does all of the following:

(i) Indicates content that the IOTA participant must not change.

(ii) Indicates where the IOTA participant may insert its own content.

(iii) Includes information regarding the attributed patient's opportunity to opt-out of data sharing with IOTA participants and how they may opt out if they choose to do so.

(3) To notify attributed patients of their rights and protections and that the IOTA participant is participating in the IOTA Model, the IOTA participant must do all of the following:

(i) Prominently display informational materials in each of their office or facility locations where attributed patients receive treatment.

(ii) Include this notification in a clear manner on its public facing website.

(iii) Provide this notification to each attributed patient in a paper format.

(b) *Applicability of general Innovation Center model provisions.* (1) The requirements described in § 512.120(c) do not apply to the CMS-provided materials described in paragraph (a) of this section.

(2) All other IOTA participant communications that are descriptive model materials and activities as defined under § 512.110 must meet the requirements described in § 512.120(c).

§ 512.452 Financial sharing arrangements and attributed patient engagement incentives.

(a) *General.* (1) The IOTA participant—

(i) May enter into a sharing arrangement with an IOTA collaborator to make a gainsharing payment, or to receive an alignment payment, or both; and

(ii) Must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement.

(2) A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) The IOTA participant must develop, maintain, and use a set of written policies for selecting providers and suppliers to be IOTA collaborators.

(i) The selection criteria must include the quality of care delivered by the potential IOTA collaborator.

(ii) The selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among any of the following:

(A) The IOTA participant.

(B) Any IOTA collaborator.

(C) Any collaboration agent.

(D) Any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(iii) The written policies must contain criteria related to, and inclusive of, the anticipated contribution to performance across the achievement domain, efficiency domain, and quality domain by the potential IOTA collaborator.

(4) The board or other governing body of the IOTA participant must have responsibility for overseeing the IOTA participant's participation in the IOTA Model, including but not limited to all of the following:

(i) Arrangements with IOTA collaborators.

(ii) Payment of gainsharing payments.

(iii) Receipt of alignment payments.

(iv) Use of beneficiary incentives in the IOTA Model.

(5) If an IOTA participant enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the IOTA Model.

(b) *Requirements.* (1) A sharing arrangement must be—

(i) In writing;

(ii) Signed by the parties; and

(iii) Entered into before care is furnished to an attributed patient during the PY under the sharing arrangement.

(2) Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

(3) Participation in the sharing arrangement must require the IOTA collaborator to comply with the requirements of this model, as those pertain to their actions and obligations.

(4) The sharing arrangement—

(i) Must set out the mutually agreeable terms for the financial arrangement between the parties to guide and reward model care redesign for future performance across the achievement domain, efficiency domain, and quality domain;

(ii) Must not reflect the results of model PYs that have already occurred; and

(iii) Where the financial outcome of the sharing arrangement terms are known before signing.

(5) The sharing arrangement must require the IOTA collaborator and its employees, contractors (including collaboration agents), and subcontractors to comply with all of the following:

(i) The applicable provisions of this part (including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees).

(ii) All applicable Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement.

(iii) All other applicable laws and regulations.

(6) The sharing arrangement must require the IOTA collaborator to have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the IOTA Model that apply to its role as an IOTA collaborator, including any distribution arrangements.

(7) The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(8) The written agreement memorializing a sharing arrangement must specify all of the following:

(i) The purpose and scope of the sharing arrangement.

(ii) The identities and obligations of the parties, including specified IOTA activities and other services to be performed by the parties under the sharing arrangement.

(iii) The date of the sharing arrangement.

(iv) Management and staffing information, including type of personnel or contractors that would be primarily responsible for carrying out IOTA activities.

(v) The financial or economic terms for payment, including all of the following:

(A) Eligibility criteria for a gainsharing payment.

(B) Eligibility criteria for an alignment payment.

(C) Frequency of gainsharing or alignment payment.

(D) Methodology and accounting formula for determining the amount of a gainsharing payment that is substantially based on performance across the achievement domain, efficiency domain and quality domain, and the provision of IOTA activities.

(E) Methodology and accounting formula for determining the amount of an alignment payment.

(9) The sharing arrangement must not—

(i) Induce—

(A) The IOTA participant;

(B) The IOTA collaborator; or

(C) Any employees, contractors, or subcontractors of the IOTA participant or IOTA collaborator to reduce or limit medically necessary services to any attributed patient; or

(ii) Restrict the ability of an IOTA collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

(c) *Gainsharing payments and alignment payments.* (1) Gainsharing payments, if any, must meet all of the following:

(i) Be derived solely from upside risk payments.

(ii) Be distributed on an annual basis (not more than once per performance year).

(iii) Not be a loan, advance payment, or payment for referrals or other business.

(iv) Be clearly identified as a gainsharing payment at the time it is paid.

(2) To be eligible to receive a gainsharing payment an IOTA collaborator must contribute to performance across the achievement domain, efficiency domain or quality domain for the PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment. The contribution to performance across the achievement domain, efficiency domain, or quality domain criteria must be established by the IOTA participant and directly related to the care of attributed patients.

(3) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment:

(i) An IOTA collaborator other than PGP, NPPGP, or TGP must have directly furnished a billable item or service to an attributed patient that occurred in the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment.

(ii) An IOTA collaborator that is a PGP, NPPGP, or TGP must meet the following criteria:

(A) The PGP, NPPGP, or TGP must have billed for an item or service that was rendered by one or more PGP member, NPPGP member, or TGP member respectively to an attributed patient that occurred during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment.

(B) The PGP, NPPGP, or TGP must have contributed to IOTA activities and been clinically involved in the care of attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment.

(4) The total amount of a gainsharing payment for a PY paid to an IOTA collaborator that is a physician or nonphysician practitioner must not exceed 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that physician or nonphysician practitioner to the IOTA participant's attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being made.

(5) The total amount of a gainsharing payment for a PY paid to an IOTA collaborator that is a PGP, NPPGP, or TGP must not exceed 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that PGP, NPPGP, or TGP and furnished to the IOTA participant's attributed patients by the PGP members, NPPGP members, or TGP members respectively during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being made.

(6) The amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on contribution to the performance across the achievement domain, efficiency domain or quality

domain and the provision of IOTA activities. The methodology may take into account the amount of such IOTA activities provided by an IOTA collaborator relative to other IOTA collaborators.

(7) For a PY, the aggregate amount of all gainsharing payments that are derived from the upside risk payment the IOTA participant receives from CMS must not exceed the amount of that upside risk payment.

(8) No entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(9) An IOTA participant must not make a gainsharing payment to an IOTA collaborator that is subject to any action for noncompliance with this part, or the fraud and abuse laws, or for the provision of substandard care to attributed patients or other integrity problems.

(10) The sharing arrangement must require the IOTA participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on an upside risk payment or was based on the submission of false or fraudulent data.

(11) Alignment payments from an IOTA collaborator to an IOTA participant may be made at any interval that is agreed upon by both parties, and must not be—

(i) Issued, distributed, or paid prior to the calculation by CMS of a payment amount reflected in the notification of the downside risk payment;

(ii) Loans, advance payments, or payments for referrals or other business; or

(iii) Assessed by an IOTA participant if the IOTA participant does not owe a downside risk payment.

(12) The IOTA participant must not receive any amounts under a sharing arrangement from an IOTA collaborator that are not alignment payments.

(13) For a PY, the aggregate amount of all alignment payments received by the IOTA participant must not exceed 50 percent of the IOTA participant's downside risk payment amount.

(14) The aggregate amount of all alignment payments from a single IOTA collaborator to the IOTA participant may not be greater than 25 percent of the IOTA participant's downside risk payment over the course of a single PY for an IOTA collaborator.

(15) The amount of any alignment payments must be determined in accordance with a methodology that does not directly account for the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(16) All gainsharing payments and any alignment payments must be administered by the IOTA participant in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(17) All gainsharing payments and alignment payments must be made by check, EFT, or another traceable cash transaction.

(d) *Documentation requirements.* (1) The IOTA participant must do all of the following:

(i) Document the sharing arrangement contemporaneously with the establishment of the arrangement.

(ii) Maintain accurate current and historical lists of all IOTA collaborators, including IOTA collaborator names and addresses. With respect to these lists the IOTA participant must—

(A) Update such lists on at least a quarterly basis; and

(B) On a web page on the IOTA participant's website, the IOTA participant must—

(*1*) Publicly report the current and historical lists of IOTA collaborators; and

(*2*) Include any written policies for selecting individuals and entities to be IOTA collaborators required by the IOTA participant.

(iii) Maintain and require each IOTA collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum all of the following:

(A) Nature of the payment (gainsharing payment or alignment payment).

(B) Identity of the parties making and receiving the payment.

(C) Date of the payment.

(D) Amount of the payment.

(E) Date and amount of any recoupment of all or a portion of an IOTA collaborator's gainsharing payment.

(F) Explanation for each recoupment, such as whether the IOTA collaborator received a gainsharing payment that contained funds derived from a CMS overpayment of an upside risk payment or was based on the submission of false or fraudulent data.

(2) The IOTA participant must keep records of all of the following:

(i) Its process for determining and verifying its potential and current IOTA collaborators' eligibility to participate in Medicare.

(ii) A description of current health information technology, including systems to track upside risk payments and downside risk payments.

(iii) Its plan to track gainsharing payments and alignment payments.

(3) The IOTA participant must retain and provide access to, and must require each IOTA collaborator to retain and provide access to, the required documentation in accordance with §§ 512.460 and 1001.952(ii).

§ 512.454 Distribution arrangements.

(a) *General.* (1) An IOTA collaborator may distribute all or a portion of any gainsharing payment it receives from the IOTA participant only in accordance with a distribution arrangement, as defined at § 512.402.

(2) All distribution arrangements must comply with the provisions of this section and all other applicable laws and regulations, including the fraud and abuse laws.

(b) *Requirements.* (1) All distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to attributed patients under the distribution arrangement.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(5) The amount of any distribution payments from an NPPGP to an NPPGP member, or from a TGP to a TGP member must be determined in accordance with a methodology that is substantially based on contribution to performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA activities and that may take into account

the amount of such IOTA activities provided by a collaboration agent relative to other collaboration agents.

(6) The amount of any distribution payments from a PGP must be determined either in a manner that complies with § 411.352(g) of this chapter or in accordance with a methodology that is substantially based on contribution to performance across the achievement domain, efficiency domain and quality domain and the provision of IOTA activities and that may take into account the amount of such IOTA activities provided by a collaboration agent relative to other collaboration agents.

(7) Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to an attributed patient that occurred during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being distributed.

(8) Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, the total amount of distribution payments for a PY paid to a collaboration agent must not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by that PGP, NPPGP or TGP for items and services furnished by PGP members, NPPGP members or TGP members respectively to attributed patients that occurred during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being distributed.

(9) With respect to the distribution of any gainsharing payment received by a PGP, NPPGP, or TGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the IOTA collaborator from the IOTA participant.

(10) All distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(11) The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(12) The distribution arrangement must not—

(i) Induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(13) The IOTA collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.454, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any distribution payment(s).

(iii) The identity of each collaboration agent that received a distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any distribution payment.

(14) The IOTA collaborator may not enter into a distribution arrangement with any collaboration agent that has a sharing arrangement with the same IOTA participant.

(15) The IOTA collaborator must retain and provide access to and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.460.

§ 512.455 Enforcement authority.

(a) *OIG authority.* Nothing contained in the terms of the IOTA Model or this part limits or restricts the authority of the HHS Office of Inspector General, including its authority to audit, evaluate, investigate, or inspect the IOTA participant, IOTA collaborators, or any other person or entity or their records, data, or information, without limitation.

(b) *Other authority.* Nothing contained in the terms of the IOTA Model or this part limits or restricts the authority of any government agency permitted by law to audit, evaluate, investigate, or inspect the participant hospital, IOTA collaborators, or any other person or entity or their records, data, or information, without limitation.

§ 512.456 Beneficiary incentive: Part B and Part D immunosuppressive drug cost sharing support.

(a) *Cost sharing support for Part B and Part D immunosuppressive drugs.* For immunosuppressive drugs covered under Medicare Part B or Medicare Part D and prescribed to an attributed patient, the IOTA participant may subsidize, in whole or in part, the cost sharing associated with the immunosuppressive drugs under Part B and Part D immunosuppressive drug cost sharing support defined at § 512.402 if all of the following conditions are met:

(1) The attributed patient is an eligible attributed patient as defined at § 512.402.

(2) The IOTA participant must provide a written policy in a form and manner specified by CMS for the provision of Part B and Part D immunosuppressive drug cost sharing support that is approved by CMS before the PY in which the cost sharing support is made available.

(i) The IOTA participant must revalidate the written policy with CMS and in a form and manner specified by CMS for the provision of Part B and Part D immunosuppressive drug cost sharing support before its provision in a subsequent PY.

(ii) The IOTA participant's initial written policy and the revalidation of the written policy must establish and justify the criteria that qualify an eligible attributed patient to receive Part B and Part D immunosuppressive drug cost sharing support.

(iii) The IOTA participant's written policy and the revalidation of the written policy must include an attestation that the IOTA participant will not, in providing Part B and Part D immunosuppressive drug cost sharing support, take into consideration the type, cost, generic status, or manufacturer of the immunosuppressive drug(s) or limit an eligible attributed patients' choice of pharmacy.

(b) *Restrictions.* (1) An IOTA participant must not take into consideration the type, cost, generic status, or manufacturer of the immunosuppressive drug(s) or limit an eligible attributed patients' choice of pharmacy when providing Part B and Part D immunosuppressive drug cost sharing support.

(2) An IOTA participant may not receive financial or operational support for Part B and Part D immunosuppressive drug cost sharing support from pharmacies and pharmaceutical manufacturers.

(c) *Documentation.* (1) An IOTA participant must maintain contemporaneous documentation that includes all of the following:

(i) The identity of the eligible attributed patient to whom Part B and Part D immunosuppressive drug cost sharing support was provided.

(ii) The date or dates on which Part B and Part D immunosuppressive drug cost sharing support was provided.

(iii) The amount or amounts of Part B and Part B immunosuppressive drug cost sharing support that was provided.

(2) An IOTA participant must retain and make available records pertaining to Part B and Part D immunosuppressive drug cost sharing support to the Federal Government in accordance with § 512.460.

§ 512.458 Attributed patient engagement incentives.

(a) *General.* An IOTA participant may choose to provide any or all of the following types of attributed patient engagement incentives to an attributed patient under the conditions described in paragraph (b) of this section:

(1) Communication devices and related communication services directly pertaining to communication with an IOTA participant or IOTA collaborator to improve communication between an attributed patient and an IOTA participant or IOTA collaborator.

(2) Transportation to and from an IOTA participant and between other providers and suppliers involved in the provision of ESRD care.

(3) Mental health services to address an attributed patient's behavioral health symptoms pre- and post-transplant.

(4) In-home care to support the health of the attributed patient or the kidney transplant in the post-transplant period.

(b) *Conditions.* An IOTA participant may provide attributed patient engagement incentives of the type described in paragraphs (a)(1) through (4) of this section when all of the following conditions are met:

(1) An IOTA participant provides a written policy, in a form and manner specified by CMS, for the provision of attributed patient engagement incentives.

(2) CMS approves an IOTA participants written policy before the first PY in which an attributed patient engagement incentive is first made available.

(3) CMS revalidates the IOTA participant's written policy in a form and manner specified by CMS prior to each PY in which an attributed patient engagement incentive is offered subsequently.

(4) The IOTA participant includes in its written policy:

(i) A description of the items or services that will be provided as attributed patient engagement incentives.

(ii) An explanation of how each item or service that will be an attributed patient engagement incentive has a reasonable connection to any of the following:

(A) An attributed patient achieving and maintaining active status on a kidney transplant waitlist.

(B) An attributed patient accessing the kidney transplant procedure.

(C) The health of the attributed patient or the kidney transplant in the post-transplant period.

(D) A justification for the need for the attributed patient engagement incentives that is specific to the IOTA participant's attributed patient population.

(iii) An attestation that items that are attributed patient engagement incentives will be provided directly to an attributed patient.

(iv) An attestation that the IOTA participant will pay service providers directly for services that are attributed patient engagement incentives.

(v) An attestation that any items or services acquired by the IOTA participant that will be furnished as attributed patient engagement incentives will be acquired for the minimum amount necessary for an attributed patient to achieve the goals described in paragraphs (3)(ii)(A) through (C) of this paragraph.

(c) *Restrictions.* (1) An IOTA participant must provide items that are attributed patient engagement incentives directly to an attributed patient.

(2) An IOTA participant must pay service providers directly for any services that are offered as attributed patient engagement incentive.

(3) An IOTA participant must not offer an attributed patient engagement incentive that is tied to the receipt of items or services from a particular provider or supplier.

(4) An IOTA participant must not advertise or promote an item or service that is an attributed patient engagement incentive, except to make an attributed patient aware of the availability of the items or services at the time an attributed patient could reasonably benefit from them.

(5) An IOTA participant must not receive donations directly or indirectly to purchase attributed patient engagement incentives.

(6) An IOTA participant must retrieve items that that are attributed patient engagement incentives from the attributed patient when the attributed patient is no longer eligible for the that item or at the conclusion of the IOTA Model, whichever is earlier.

(i) Documented, diligent, good faith attempts to retrieve items that are attributed patient engagement incentives are deemed to meet the retrieval requirement.

(ii) [Reserved]

(7) Items that are communication devices:

(i) May not exceed $1,000 in retail value for any one attributed patient in any one PY;

(ii) Must remain the property of the IOTA participant;

(iii) Must be retrieved from the attributed patient by the IOTA participant—

(A) When the attributed patient is no longer eligible for the communication device or at the conclusion of the IOTA Model, whichever is earlier; and

(B) Before another communication device may be made available to the same attributed patient.

(d) *Documentation.* The IOTA participant must do all of the following:

(1) Maintain contemporaneous documentation of items and services furnished as attributed patient engagement incentives that includes, at minimum all of the following:

(i) The date the attributed patient engagement incentive is provided.

(ii) The identity of the attributed patient to whom the item or service was provided.

(2) Document all retrieval attempts of items that are attributed patient engagement incentives, including the ultimate date of retrieval.

(3)(i) Retain records pertaining to furnished attributed patient engagement incentives.

(ii) Make the records available to the Federal Government in accordance with § 512.460.

§ 512.459 Application of the CMS-sponsored Model Arrangements and Patient Incentives Safe Harbor.

(a) *Application of the CMS-sponsored Model Arrangements Safe Harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)(1)) is available to protect remuneration furnished in the IOTA Model in the form of the Sharing Arrangement's gainsharing payments, the Sharing Arrangement's alignment payments, and the Distribution Arrangement's distribution payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii), 512.452, and 512.454.

(b) *Application of the CMS-sponsored Model Patient Incentives Safe Harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect remuneration furnished in the IOTA Model in the form of Part B and Part D immunosuppressive drug cost sharing support and the attributed patient engagement incentives that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii), 512.456 and 512.458.

§ 512.460 Audit rights and records retention.

(a) *Right to audit.* The Federal Government, including CMS, HHS, and the Comptroller General, or their designees, has the right to audit, inspect, investigate, and evaluate any documents and other evidence

regarding implementation of the IOTA Model.

(b) *Access to records.* The IOTA participant and its IOTA collaborators must maintain and give the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, access to all such documents (including books, contracts, and records) and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the implementation of the IOTA Model, including without limitation, documents, and other evidence regarding all of the following:

(1) Compliance by the IOTA participant and its IOTA collaborators with the terms of the IOTA Model.

(2) The accuracy of model-specific payments made under the IOTA Model.

(3) The IOTA participant's downside risk payments owed to CMS under the IOTA Model.

(4) Quality measure information and the quality of services performed under the terms of the IOTA Model.

(5) Utilization of items and services furnished under the IOTA Model.

(6) The ability of the IOTA participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

(7) Contemporaneous documentation of cost sharing support furnished under Part B and Part D immunosuppressive drug cost sharing support that includes the following:

(i) The identity of the eligible attributed patient to whom Part B and Part D immunosuppressive drug cost sharing support was provided.

(ii) The date or dates on which Part B and Part D immunosuppressive drug cost sharing support was provided.

(iii) The amount or amounts of the cost sharing support provided to the attributed patient.

(8) Contemporaneous documentation of items and services furnished as attributed patient engagement incentives in accordance with § 512.458 that includes all of the following, at minimum:

(i) The date the attributed patient engagement incentive is provided.

(ii) The identity of the attributed patient to whom the item or service was provided.

(9) Patient safety.

(10) Any other program integrity issues.

(c) *Record retention.* (1) The IOTA participant and its IOTA collaborators must maintain the documents and other evidence described in paragraph (b) of this section and other evidence for a period of 6 years from the last payment determination for the IOTA participant under the IOTA Model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the IOTA participant at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the IOTA participant or its IOTA collaborators, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(2)(i) If CMS notifies the IOTA participant of the special need to retain a record or group of records in accordance with paragraph (c)(1)(i) of this section, the IOTA participant must maintain the records for such period of time as determined by CMS.

(ii) If CMS notifies the IOTA participant of a special need to retain records in accordance with paragraph (c)(1)(ii) of this section, the IOTA participant must notify its IOTA collaborators of this need to retain records for the additional period specified by CMS.

§ 512.462 Compliance and monitoring.

(a) *Compliance with laws.* The IOTA participant must comply with all applicable laws and regulations.

(b) *CMS monitoring activities.* (1) CMS, or its approved designee, may conduct monitoring activities to ensure compliance by the IOTA participant and IOTA collaborators with the terms of the IOTA Model under this subpart to—

(i) Understand IOTA participants' use of model-specific payments; and

(ii) Promote the safety of attributed patients and the integrity of the IOTA Model.

(2) Monitoring activities may include, without limitation, all of the following:

(i) Documentation requests sent to the IOTA participant and its IOTA collaborators, including surveys and questionnaires.

(ii) Audits of claims data, quality measures, medical records, and other data from the IOTA participant and its IOTA collaborators.

(iii) Interviews with the IOTA participant, including leadership personnel, medical staff, other associates, and its IOTA collaborators.

(iv) Interviews with attributed patients and their caregivers.

(v) Site visits to the IOTA participant and its IOTA collaborators, performed in a manner consistent with paragraph (c) of this section.

(vi) Monitoring quality outcomes and attributed patient data.

(vii) Tracking beneficiary complaints and appeals.

(viii) Monitoring the definition of and justification for the subpopulation of the IOTA participant's eligible attributed patients that may receive Part B and Part D immunosuppressive drug cost sharing support in accordance with § 512.456.

(ix) Monitoring the provision of attributed patient engagement incentives provided in accordance with § 512.458.

(x) Monitoring out of sequence allocation of kidneys by—

(A) Assessing the frequency at which IOTA waitlist patients, top-ranked on an IOTA participant's kidney transplant waitlist, receive the organ that was initially offered to them; and

(B) Determining the reasons behind cases where IOTA waitlist patients identified in paragraph (b)(x)(A) of this section, did not receive the kidney offered to them.

(3) In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including without limitation all Medicare claims submitted for items or services furnished to IOTA transplant patients or IOTA waitlist patients or both.

(c) *Site visits.* (1) The IOTA participant must cooperate in periodic site visits performed by CMS or its designees in order to facilitate the evaluation of the IOTA Model in accordance with section 1115A(b)(4) of the ACT and the monitoring of the IOTA participant's compliance with the terms of the IOTA Model, including this subpart.

(2) When scheduling the site visit, CMS or its designee provides, to the extent practicable, the IOTA participant with no less than 15 days advance notice of any site visit. CMS—

(i) Attempts, to the extent practicable, to accommodate a request for particular dates in scheduling site visits; and

(ii) Does not accept a date request from the IOTA participant that is more than 60 days after the date of the initial site visit notice from CMS.

(3) The IOTA participant must ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during all site visits.

(4) CMS may perform unannounced site visits at the office of the IOTA participant at any time to investigate concerns about the health or safety of attributed patients or other program integrity issues.

(5) Nothing in this part may be construed to limit or otherwise prevent

CMS from performing site visits permitted or required by applicable law.

(d) *Reopening of payment determinations.* (1) CMS may reopen an IOTA Model-specific payment determination on its own motion or at the request of the IOTA participant, within 4 years from the date of the determination, for good cause (as defined at § 405.986 of this chapter) except if there exists reliable evidence that the determination was procured by fraud or similar fault as defined at § 405.902 of this chapter. In the case of fraud or similar fault, CMS may reopen an IOTA Model specific payment determination at any time.

(2) CMS' decision regarding whether to reopen a model-specific payment determination is binding and not subject to appeal.

§ 512.464 Remedial action.

(a) *Grounds for remedial action.* CMS may impose one or more remedial actions described in paragraph (b) of this section if CMS determines that:

(1) The IOTA participant has failed to furnish 11 or more kidney transplants for patients aged 18 years or older, regardless of payer, during a PY or any baseline years.

(2) The IOTA participant or its IOTA collaborator has failed to comply with any of the terms of the IOTA Model, including this subpart.

(3) The IOTA participant has failed to comply with transparency requirements described at § 512.442.

(4) The IOTA participant or its IOTA collaborator has failed to comply with any applicable Medicare program requirement, rule, or regulation.

(5) The IOTA participant or its IOTA collaborator has taken any action that threatens the health or safety of an attributed patient.

(6) The IOTA participant or its IOTA collaborator has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model.

(7) The IOTA participant or its IOTA collaborator has undergone a change in control that presents a program integrity risk.

(8) The IOTA participant or its IOTA collaborator is subject to any sanctions of an accrediting organization or a Federal, State, or local government agency.

(9) The IOTA participant or its IOTA collaborator is subject to investigation or action by HHS (including the HHS Office of Inspector General or CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including any of the following:

(i) Being subject to the filing of a complaint or filing of a criminal charge.

(ii) Being subject to an indictment.

(iii) Being named as a defendant in a False Claims Act qui tam matter in which the Federal Government has intervened, or similar action.

(10) The IOTA participant or its IOTA collaborator has failed to demonstrate improved performance following any remedial action imposed under this section.

(11) The IOTA participant has misused or disclosed beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the applicable data sharing agreement.

(b) *Remedial actions.* If CMS determines that one or more grounds for remedial action described in paragraph (a) of this section has taken place, CMS may take one or more of the following remedial actions:

(1) Notify the IOTA participant and, if appropriate, require the IOTA participant to notify its IOTA collaborators of the violation.

(2) Require the IOTA participant to provide additional information to CMS or its designees.

(3) Subject the IOTA participant to additional monitoring, auditing, or both.

(4) Prohibit the IOTA participant from distributing model-specific payments, as applicable.

(5) Require the IOTA participant to terminate, immediately or by a deadline specified by CMS, its sharing arrangement with an IOTA collaborator with respect to the IOTA Model.

(6) Terminate the IOTA participant from the IOTA Model.

(7) Suspend or terminate the ability of the IOTA participant to provide Part B and Part D immunosuppressive drug cost sharing support in accordance with § 512.456 or attributed patient engagement incentives in accordance with § 512.458.

(8) Require the IOTA participant to submit a corrective action plan in a form and manner and by a deadline specified by CMS.

(9) Discontinue the provision of data sharing and reports to the IOTA participant.

(10) Recoup model-specific payments.

(11) Reduce or eliminate a model-specific payment otherwise owed to the IOTA participant.

(13) Any other action as may be permitted under the terms of this part.

§ 512.466 Termination.

(a) *Termination of IOTA participant from the IOTA Model by CMS.* CMS may immediately or with advance notice terminate an IOTA participant from participation in the model if CMS does any of the following:

(1) Determines that it no longer has the funds to support the IOTA Model.

(2) Modifies or terminates the IOTA Model in accordance with section 1115A(b)(3)(B) of the Act.

(3) Determines that the IOTA participant has done any of the following:

(i) Failed to comply with any model requirements or any other Medicare program requirement, rule, or regulation.

(ii) Failed to comply with a monitoring or auditing plan or both.

(iii) Failed to submit, obtain approval for, implement or fully comply with the terms of a corrective action plan.

(iv) Failed to demonstrate improved performance following any remedial action.

(v) Taken any action that threatens the health or safety of a Medicare beneficiary or other patient.

(vi) Submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model.

(vii) Undergoes a change in control.

(viii) Assigns or purports to assign any of the rights or obligations under the IOTA Model, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS.

(ix) Poses significant program integrity risks, including but not limited to—

(A) Is subject to sanctions or other actions of an accrediting organization or a Federal, State, or local government agency; or

(B) Is subject to investigation or action by HHS (including OIG and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

(b) *Termination of Model participation by IOTA participant.* The IOTA participant may not terminate their participation in the IOTA Model.

(c) *Financial settlement upon termination.* If CMS terminates the IOTA participant's participation in the IOTA Model, CMS calculates the final performance score and any upside risk payment or downside risk payment, if applicable, for the entire PY in which the IOTA participant's participation in the model was terminated.

(1) If CMS terminates the IOTA participant's participation in the IOTA Model, CMS determines the IOTA participant's effective date of termination.

(2) If CMS terminates the IOTA participant for any reasons listed under § 512.466:

(i) CMS does not make any payments of upside risk payment for the PY in which the IOTA participant was terminated; and

(ii) The IOTA participant will remain liable for payment of any downside risk payment up to and including the PY in which termination becomes effective.

(d) *Termination of the IOTA Model by CMS.* (1) The general provisions for the Innovation Center model termination by CMS listed under § 512.165 apply to the IOTA Model.

(i) CMS may terminate the IOTA Model for reasons including, but not limited to, those set forth in § 512.165(a).

(ii) If CMS terminates the IOTA Model, CMS provides written notice to IOTA participants specifying the grounds for model termination and the effective date of such termination.

(2) In accordance with section 1115A(d)(2) of the Act and § 512.170(e), termination of the IOTA Model under section 1115A(b)(3)(B) of the Act is not subject to administrative or judicial review.

(3) If CMS terminates the IOTA Model, the financial settlement terms described in paragraph (c) of this section apply.

§ 512.468 Bankruptcy and other notifications.

(a) *Notice of bankruptcy.* (1) If the IOTA participant has filed a bankruptcy petition, whether voluntary or involuntary, the IOTA participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the IOTA participant under the terms of each model tested under section 1115A of the Act in which the IOTA participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved.

(2) The notice of bankruptcy must meet all of the following:

(i) Be sent by certified mail no later than 5 days after the petition has been filed.

(ii) Contain—

(A) A copy of the filed bankruptcy petition (including its docket number); and

(B) A list of all models tested under section 1115A of the Act in which the IOTA participant is participating or has participated.

(b) *Change in control.* (1) The IOTA participant must provide written notice to CMS at least 90 days before the effective date of any change in control.

(2) CMS may terminate an IOTA participant from the IOTA Model under § 512.466 if the IOTA participant undergoes a change in control.

(c) *Prohibition on assignment.* (1) Unless CMS provides prior written consent, an IOTA participant must not transfer, including by merger (whether the IOTA participant is the surviving or disappearing entity), consolidation, dissolution, or otherwise any—

(i) Discretion granted it under the model;

(ii) Right that it has to satisfy a condition under the model;

(iii) Remedy that it has under the model; or

(iv) Obligation imposed on it under the model.

(2) The IOTA participant must provide CMS 90 days advance written notice of any such proposed transfer.

(3) This obligation remains in effect after the expiration or termination of the model, or the IOTA participant's participation in the model, and until final payment by the IOTA participant under the model has been made.

(4) CMS may condition its consent to such transfer on full or partial reconciliation of upside risk payments and downside risk payments.

(5) Any purported transfer in violation of this requirement is voidable at the discretion of CMS.

Waivers

§ 512.470 Waivers.

CMS waives the requirements of sections 1881(b), 1833(a) and 1833(b) of the Act only to the extent necessary to make the payments under the IOTA Model described in this subpart.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–27841 Filed 11–26–24; 4:15 pm]

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Part III

Department of Labor

Wage and Hour Division

29 CFR Part 525

Employment of Workers With Disabilities Under Section 14(c) of the Fair Labor Standards Act; Proposed Rule

DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Part 525

RIN 1235–AA14

Employment of Workers With Disabilities Under Section 14(c) of the Fair Labor Standards Act

AGENCY: Wage and Hour Division, Department of Labor.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Fair Labor Standards Act (FLSA or Act) authorizes the Secretary of Labor to issue certificates allowing employers to pay productivity-based subminimum wages to workers with disabilities, but only where such certificates are necessary to prevent the curtailment of opportunities for employment. Employment opportunities for individuals with disabilities have vastly expanded in recent decades, in part due to significant legal and policy developments. Based on that evidence, the Department has tentatively concluded that subminimum wages are no longer necessary to prevent the curtailment of employment opportunities for individuals with disabilities and thus proposes to phase out the issuance of section 14(c) certificates.

DATES: Interested persons are invited to submit written comments on this notice of proposed rulemaking (NPRM) on or before January 17, 2025.

ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN) 1235–AA14, by either of the following methods:

- *Electronic Comments:* Submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Address written submissions to: Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW, Washington, DC 20210.

Instructions: Response to this NPRM is voluntary. The Department requests that no business proprietary information, copyrighted information, or personally identifiable information be submitted in response to this NPRM. Commenters submitting file attachments on *https://www.regulations.gov* are advised that uploading text-recognized documents—*i.e.,* documents in a native file format or documents which have undergone optical character recognition (OCR)—enable staff at the Department to more easily search and retrieve specific content included in your comment for consideration.

Anyone who submits a comment (including duplicate comments) should understand and expect that the comment, including any personal information provided, will become a matter of public record and will be posted without change to *https://www.regulations.gov.* The Department posts comments gathered and submitted by a third-party organization as a group under a single document ID number on *https://www.regulations.gov.* All comments must be received by 11:59 p.m. ET on January 17, 2025, for consideration in this rulemaking; comments received after the comment period closes will not be considered.

The Department recommends that commenters submit their comments electronically via *https://www.regulations.gov* to ensure timely receipt prior to the close of the comment period. Please submit only one copy of your comments by only one method.

Docket: For access to the docket to read background documents or comments, go to the Federal eRulemaking Portal at *https://www.regulations.gov.* In accordance with 5 U.S.C. 553(b)(4), a summary of this rule may also be found at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Daniel Navarrete, Director, Division of Regulations, Legislation, and Interpretation, Wage and Hour Division (WHD), U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–0406 (this is not a toll-free number). Alternative formats are available upon request by calling 1–866–487–9243. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

Questions of interpretation or enforcement of the agency's existing regulations may be directed to the nearest WHD district office. Locate the nearest office by calling the WHD's toll-free help line at (866) 4US–WAGE ((866) 487–9243) between 8 a.m. and 5 p.m. in your local time zone, or log onto WHD's website at *https://www.dol.gov/agencies/whd/contact/local-offices* for a nationwide listing of WHD district and area offices.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

The FLSA generally requires that employees be paid at least the Federal minimum wage, currently $7.25 per hour, for every hour worked and at least one and one-half times their regular rate of pay for each hour worked over 40 in a single workweek. 29 U.S.C. 206(a), 207(a). Since its enactment in 1938 through today, section 14 of the FLSA has included a provision authorizing the Department to issue certificates permitting employers to pay workers at wage rates below the Federal minimum wage when the worker's disabilities impair their earning or productive capacity. The section 14 statutory provision, however, has always provided that such certificates may only be issued to the extent ''necessary to prevent curtailment of opportunities for employment.'' [1] As the Supreme Court explained in 1947, the language and legislative history of the section show that its purpose is to prevent the imposition of a full minimum wage from depriving those with ''physical handicaps'' of ''all opportunity to secure work.'' [2] However, as the Court emphasized, ''to have written a blanket exemption of all [such workers] from the Act's provisions might have left open a way for wholesale evasions. Flexibility of wage rates for them was therefore provided under the safeguard of administrative permits.'' [3] Hence, section 14(c) authorizes the Secretary to issue certificates allowing payment of subminimum wages to individuals with disabilities only when conditions make it ''necessary'' to do so.

The Department first promulgated regulations governing the issuance of these ''administrative permits'' in 1938, and last substantively updated them in 1989, more than 35 years ago. Since 1989 (and profoundly more so since the time the statutory provision was enacted and its implementing regulations were promulgated nearly 85 years ago), opportunities for employment have dramatically changed for individuals with disabilities. Fueled by the disability rights movement, societal and cultural assumptions, beliefs and expectations regarding the employment of individuals with disabilities have evolved, and opportunities for individuals with disabilities have

[1] 29 U.S.C. 214(c)(1).

[2] *Walling* v. *Portland Terminal Co.,* 330 U.S. 148, 151 (1947). The Department notes that some terminology used in this NPRM reflects the terms used in the statute and regulations at the time of their issuance or quotations from various sources. Quotations are attributable to the sources indicated and do not necessarily reflect the current views or terminology of the Department. Since the early 1990s, the government has replaced outdated and offensive terms like ''the handicapped'' with more respectful, person-first terminology, such as ''individuals with disabilities.'' Throughout this NPRM, the Department references outdated terms only when necessary to accurately reflect quoted sources or to illustrate changes that have occurred.

[3] *Id.*

dramatically expanded. Federal legislation and judicial precedent have established and enshrined fundamental legal protections requiring equal access, opportunities, and respect for individuals with disabilities in both education and employment. Of these legislative and judicial developments, the landmark Americans with Disabilities Act (ADA) of 1990,[4] enacted the year after the section 14(c) regulations were last substantively updated, has had a profound impact on employment opportunities for individuals with disabilities. In addition, the President and executive agencies have taken steps to end the payment of subminimum wages to workers with disabilities on certain government contracts. Numerous States and localities have prohibited or limited the payment of subminimum wages to workers with disabilities within their jurisdictions. In short, employment opportunities for individuals with disabilities have advanced significantly since the FLSA's enactment in 1938, when it was much more difficult for individuals with disabilities to secure employment at the full minimum wage.[5]

Although it is widely acknowledged that individuals with disabilities continue to face challenges in obtaining equal opportunity and treatment, the extent of legal protections, opportunities, resources, training, technological advancements, and supports has dramatically expanded since 1989, when the Department's regulation was last substantively updated, to assist individuals with disabilities both in obtaining and maintaining employment at or above the full minimum wage.[6] Employers similarly have substantially more resources and training available to recruit, hire, and retain workers with disabilities in employment at or above the full minimum wage. This comprehensive system of new approaches has rendered it unnecessary to depend upon subminimum wages to secure employment opportunities for individuals with disabilities and, given the enhanced opportunities for employment since the Department last substantively updated its regulations in 1989, vastly more individuals with disabilities—including intellectual or development disabilities (I/DD)—work at full-wage employment than work under section 14(c) certificates. Recognizing the expansion of full-wage employment options for individuals with disabilities, an increasing number of oversight and advisory reports, such as those published by the U.S. Commission on Civil Rights (USCCR) and the National Council on Disability (NCD), have vigorously called for a ''phase out'' of section 14(c) certificates. As another indication that subminimum wages are not necessary to prevent the curtailment of employment opportunities, an increasing number of States and localities, including many jurisdictions with higher minimum wages than the FLSA minimum wage, have prohibited or limited the payment of subminimum wages in their respective jurisdictions, and an increasing number of employers themselves are voluntarily opting out of paying subminimum wages, as is reflected in the rate at which the number of section 14(c) certificate holders has substantially declined in recent years.

Against this backdrop, the Department must fulfill its statutory mandate of assessing whether section 14(c) certificates continue to be necessary in order to prevent the curtailment of employment opportunities for individuals with disabilities. After careful review, consideration of input from stakeholders with a wide variety of viewpoints, and for the reasons discussed in this notice of proposed rulemaking, the Department preliminarily concludes that section 14(c) certificates that allow employers to pay subminimum wages to workers with disabilities are no longer necessary and thus proposes to amend 29 CFR part 525 to phase out the issuance of such certificates.

Accordingly, the Department proposes to stop issuance of new section 14(c) certificates and to phase out existing certificates over several years. At the conclusion of the phaseout period, this proposal would require only that subminimum wages no longer be paid to workers with disabilities. This proposed rule would not require workers to leave their current places of employment, where they often also receive a number of services, such as rehabilitation and training, nor would it require current section 14(c) certificate holders to amend the type of services that they currently provide or to modify the settings in which work is performed.[7]

The Department specifically proposes to cease issuance of new section 14(c) certificates to employers submitting an initial application on or after the effective date of a final rule and permit existing section 14(c) certificate holders, assuming all legal requirements are met, to continue to operate under section 14(c) certificate authority for up to 3 years after the effective date of a final rule. The Department is also requesting comment as to whether, if this proposed rule is finalized, it would be appropriate to grant an extension for existing section 14(c) certificate holders who demonstrate a need and seeks comments on the need for such an extension period, and, if needed, its scope, structure and length.

II. Background

A. Introduction

The FLSA provides basic labor protections including Federal minimum wage and overtime compensation requirements. Section 6 of the FLSA establishes that the Federal minimum wage for covered employees is currently $7.25 per hour, ''except as otherwise provided'' in the Act.[8] Since its enactment in 1938, the FLSA has authorized the Department to issue certificates permitting the employment of certain workers with disabilities at wage rates lower than the otherwise applicable Federal minimum wage ''to the extent necessary to prevent curtailment of opportunities for employment.'' [9] To provide appropriate contextual information about section 14(c), this section of the proposed rule provides a high-level summary of the Department's legal authority regarding the issuance of section 14(c) certificates, the relevant statutory and regulatory history pertaining to FLSA section 14(c), an overview of how the Department's Wage and Hour Division (WHD) administers section 14(c) certificates and enforces the section 14(c) provisions, and a description of how

[4] The ADA was subsequently amended by the ADA Amendments Act of 2008, 42 U.S.C. 12111 *et seq.* As discussed in section III.B, the ADA mandates equal employment opportunity for individuals with disabilities by prohibiting discrimination and requiring reasonable accommodation.

[5] *Id.*

[6] This expansion of employment opportunities, resources, training, and supports is applicable for all individuals with disabilities, including individuals with intellectual and developmental disabilities who comprised about 90 percent of the workers with disabilities still being paid subminimum wages as of August 2021. *See* U.S. Gov't Accountability Office, GAO–23–105116, ''Subminimum Wage Program: DOL Could Do More to Ensure Timely Oversight'' (2023) (2023 GAO Report), at 24, *https://www.gao.gov/products/gao-23-105116.*

[7] For example, if an employer currently employs a worker with disabilities to perform an assembly line job for 2 hours per day and then provides rehabilitation services to that same individual for 6 hours per day, this proposed rule would require only that the employer pay at least the full Federal minimum wage for the 2 hours of work performed by the worker. This proposed rule would not require any changes be made to the setting or rehabilitation services offered.

[8] 29 U.S.C. 206.

[9] 29 U.S.C. 214(c)(1).

employers are currently using certificates. The Department then discusses its recent review of section 14(c) and addresses the current need for rulemaking.

B. Statutory Authority

Section 14(c)(1) of the FLSA provides that the ''Secretary, to the extent necessary to prevent curtailment of opportunities for employment, shall by regulation or order provide for the employment, under special certificates, of individuals . . . whose earning or productive capacity is impaired by age or physical or mental deficiency'' at productivity-based subminimum wages.[10] The FLSA explicitly authorizes the Secretary to issue regulations governing the issuance of subminimum wage certificates.

In authorizing the Secretary to issue certificates allowing employers to pay subminimum wages, Congress included a significant statutory limitation by permitting the issuance of certificates only ''to the extent necessary to prevent curtailment of opportunities for employment.'' At the same time, Congress determined that the Secretary ''shall by regulation or order'' provide for subminimum wage certificates, thereby conferring authority upon the Department to determine whether that standard has been met and under what circumstances subminimum wages should be paid. To best implement the statute at this point in time, the Department proposes to exercise its authority to find that subminimum wages are no longer necessary to prevent the curtailment of employment opportunities for workers with disabilities and to phase out the issuance of section 14(c) certificates.[11]

The Secretary's issuance of certificates prior to permitting employers to pay a subminimum wage acts as a ''safeguard'' against widespread abuse.[12] Section 14(c) requires the curtailment clause determination to be made by the Secretary prior to permitting employers to pay a subminimum wage because the right to a minimum wage under the FLSA is not waivable. The provision places this obligation on the Secretary to safeguard the program against abuse and ensure that no individual employer or employee can effect a waiver of their rights, contrary to the FLSA.

It is a fundamental principle of FLSA jurisprudence that the Act's rights, including the right to the Federal minimum wage, cannot be waived. The Supreme Court's ''decisions interpreting the FLSA have frequently emphasized the nonwaivable nature of an individual employee's right[s] . . . under the Act'' and ''have held that FLSA rights cannot be abridged by contract or otherwise waived.'' [13] The Supreme Court has identified at least three reasons for this nonwaiver rule. First, the Court has determined that the Act constituted ''a recognition of the fact that due to the unequal bargaining power as between employer and employee, certain segments of the population required federal compulsory legislation to prevent private contracts on their part which endangered national health and efficiency.'' [14] According to the Court, the protective purposes of the Act thus ''require that it be applied even to those who would decline its protections''; otherwise, ''employers might be able to use superior bargaining power to coerce employees to . . . waive their protections under the Act.'' [15] Second, the FLSA sought to establish a ''uniform national policy of guaranteeing compensation for all work'' performed by covered employees.[16] Third, the Court has held that permitting employees to waive their FLSA rights is inconsistent with the explicit purpose of the Act to protect employers against unfair methods of competition.[17]

Accordingly, just as employees cannot choose to forego overtime compensation due, employees cannot choose to be paid subminimum wages. Rather, an employer may only pay subminimum wages to workers with disabilities after obtaining a certificate from the Secretary. In turn, the Secretary may only issue such certificates when the threshold statutory requirement is met, that is, the Secretary determines that such certificates are necessary to prevent the curtailment of employment opportunities.

Recognizing the uniqueness of the certificate process for subminimum wages, the Supreme Court has observed that in enacting the FLSA, Congress wished to increase opportunities for gainful employment, and not impose requirements that would deprive any worker of ''all opportunity to secure work.'' [18] The Court further recognized, however, that a ''blanket exemption'' of workers with disabilities from the minimum wage could have invited ''wholesale evasions'' and accordingly subminimum wages could only be paid under the very specific ''safeguard of administrative permits.'' [19] Thus, the Secretary continues to be responsible for monitoring the payment of subminimum wages and ensuring that the statutory prerequisites for both certificate issuance and use of such certificates have been met.

The FLSA expressly confers authority to the Department to make the determination under the curtailment clause that certificates are necessary to prevent the curtailment of employment opportunities prior to issuing certificates.[20] The most logical reading of the statutory phrase ''opportunities for employment'' is that the term ''opportunities'' refers to ''a time or place favorable for executing a purpose'' or ''a suitable combination of conditions.'' [21] Thus, the statutory language does not require a particular employment outcome for a worker with a disability being paid subminimum wages pursuant to a section 14(c) certificate. Rather, the statute requires the Department to evaluate the necessity of issuing section 14(c) certificates to prevent the curtailment of employment opportunities. In other words, the Department must consider whether the payment of subminimum wages is necessary to prevent the curtailment of ''a suitable combination of conditions,'' for employment opportunities, advancement, or progress broadly, not whether all workers attain a particular employment outcome, or a specific worker attains a particular job in a particular setting.

[10] 29 U.S.C. 214(c)(1).

[11] WHD has legal authority to require payment of the full Federal minimum wage for all hours worked by covered, non-exempt employees. As previously noted, this proposed rule would not require workers to leave their current places of employment, nor would it require current section 14(c) certificate holders to amend the type of services that they currently provide or to modify the settings in which work is performed.

[12] *Portland Terminal,* 330 U.S. at 151.

[13] *Barrentine* v. *Arkansas-Best Freight Sys., Inc.,* 450 U.S. 728, 740 (1981) (listing cases).

[14] *Brooklyn Sav. Bank* v. *O'Neil,* 324 U.S. 697, 706 (1945).

[15] *Tony & Susan Alamo Found.* v. *Sec'y of Labor,* 471 U.S. 290, 302 (1985) (citing *Barrentine,* 450 U.S. 728 and *Brooklyn Sav.,* 324 U.S. 697).

[16] *Jewell Ridge Coal Corp.* v. *Local No. 6167, UMWA,* 325 U.S. 161, 167 (1945).

[17] *See* 29 U.S.C. 202(a); *Brooklyn Sav.,* 324 U.S. at 710.

[18] *See Walling* v. *Portland Terminal,* 330 U.S. at 151–52.

[19] *Portland Terminal,* 330 U.S. at 151–52.

[20] The Secretary has exercised this authority in various ways. Although the statutory language states that a certificate for subminimum wages may be issued when productive capacity is impaired by ''age, physical or mental deficiency, or injury,'' the granting of certificates has historically focused on disability, and today employers are paying subminimum wages almost exclusively to workers with I/DD. As an example of the Department's exercise of its authority, the Department promulgated regulations in 1939 which stated that workers with ''temporary, or readily correctible, disabilities,'' and those ''where age alone is cited as a disability for a worker under 65,'' would be ineligible for a certificate. 29 CFR 524.7(a), (c) (1939).

[21] *See* ''Opportunity,'' Webster's New International Dictionary 1709 (1938 ed.).

The statute gives the Department discretion to determine whether the curtailment standard has been met, and the Department proposes that, at this time, the issuance of certificates does not appear to be necessary to prevent the curtailment of employment opportunities for individuals with disabilities. Today, the Department is proposing to find that, due to the legal, social, and technological changes since that determination was made in 1989, subminimum wage certificates are unnecessary to prevent employment curtailment. This proposed rule considers the framework that the Department's current section 14(c) regulations, last substantively revised in 1989, uses to determine whether subminimum wages are necessary to prevent curtailment of employment opportunities. The current regulations (explained in more detail below) presume, without further analysis, that subminimum wages are necessary to prevent the curtailment of employment opportunities provided that (i) an individual has a disability that impacts their productivity in performing a particular job offered by a single certificate-holding employer and (ii) the employer can demonstrate it has calculated a productivity-based wage rate in accordance with the regulations for that particular job. In adopting this approach, the 1989 regulations collapse the statutory curtailment clause requirement into the statutory requirement that any commensurate wage for a particular job must be ''related to the individual's productivity'' at that job. The regulatory framework from 1989 thus rests on an implicit assumption that the two statutory requirements are the same, that disability-related impacts on an individual's productivity at a particular task means that a subminimum wage was necessary in order to prevent the curtailment of employment opportunities. Given the substantial developments in law and policy that have occurred since the regulations were last updated nearly 35 years ago and the expansion of opportunities now available to individuals with disabilities, the Department proposes to take into account the current scope of those employment opportunities instead of assuming that certificates are necessary to prevent the curtailment of employment opportunities for individuals with disabilities.

Given this, the proposed rule proposes to fulfill the curtailment clause requirement by assessing whether subminimum wages are still necessary based on a comprehensive consideration of how employment opportunities are both curtailed and created across the employment market. In assessing the statutory curtailment clause requirement, the Department today has more tools at its disposal than ever before—such as, for example, information from the nearly half of States that have prohibited or limited the use of subminimum wages—to make a preliminary determination that the payment of subminimum wages is not necessary to prevent the curtailment of employment opportunities. Particularly in view of the substantial social, structural, and legal changes that have occurred since 1989 to systemically reshape employment opportunities for individuals with disabilities (also discussed in detail below), the Department proposes herein that this comprehensive approach better fulfills the Secretary's statutory obligation to provide for the issuance of certificates only when ''necessary.''

C. Overview of Statutory and Regulatory History of FLSA Section 14(c)

The FLSA provision allowing the payment of subminimum wages to certain workers with disabilities became effective when the FLSA was signed into law on June 25, 1938. As passed in 1938, section 14 of the FLSA instructed that the WHD Administrator, ''to the extent necessary in order to prevent curtailment of opportunities for employment, shall by regulations or by orders provide for . . . the employment of individuals whose earning capacity is impaired by age or physical or mental deficiency or injury, under special certificates issued by the Administrator, at such wages lower than the minimum wage applicable under section 6 [of the FLSA] and for such period as shall be fixed in such certificates.'' [22] As is plain from the statutory text, the precondition that certificates may only be issued to the extent necessary to prevent the curtailment of employment opportunities has been an essential part of the section 14 provision since enactment.

The legislative history shows that Congress intended to limit the circumstances under which subminimum wage certificates could be issued so as to avoid undermining the larger purposes of the FLSA and granted the Department authority to administer these limits. The initial legislative history of the Act includes statements from the joint Congressional hearings on the enactment of the FLSA in 1938 which addressed the purposes of establishing a Federal minimum wage and the Department's discretion in applying that standard under section 14. Congress explained that the Act ''provides a floor below which the hourly wage ought not to fall and a limit beyond which the working week should not be stretched. These are the rudimentary standards of human decency at which the relatively automatic provisions of the bill are directed.'' [23] Regarding the clause limiting the issuance of certificates to circumstances where they are ''necessary in order to prevent curtailment of opportunities for employment'' (the ''curtailment clause''), Congress further explained that ''even in the application of these rudimentary standards, a certain discretion is given to the enforcement agency so that it can protect the earning power of the workers and their opportunities for employment from unreasonable curtailment.'' [24] Additionally, Congress advised that, in considering subminimum wages, the Department was to give ''due consideration to the maintenance of the minimum standard of living, the health, efficiency, and well-being of the employees, and the avoidance of unreasonable curtailment of opportunities for employment and the earning power of the employees.'' [25]

The Department has exercised the authority Congress gave it to evaluate the curtailment clause throughout the history of its administration of section 14. As a reflection of the determination that payment of subminimum wages was, at that time, necessary under certain circumstances to prevent the curtailment of employment opportunities, the Department promulgated its initial regulations implementing section 14 in 1938. Among other matters, the initial regulations established procedures whereby certificates were issued on an individual basis, set a general wage floor at 75 percent of the FLSA section 6 minimum wage, and allowed for a lower wage rate if an investigation showed that it was justified.[26] The Department amended its regulations in 1939, exercising its ''curtailment clause'' authority to limit the issuance of certificates by specifying that, for

[22] Fair Labor Standards Act of 1938, Public Law 75–718, 52 Stat. 1060 (1938) (codified at 29 U.S.C. 214). The original version of the FLSA also provided for subminimum wage rates for learners, apprentices, and messengers. 29 U.S.C. 214(1).

[23] Fair Labor Standards Act of 1937: Joint Hearings on S. 2475 and H.R. 7200 Before the Senate Comm. on Educ. and Labor, and House Comm. on Labor, 75th Cong. 1st Sess. Part 1, p. 55 (June 2–5, 1937).

[24] *Id.*

[25] *Id.* at 57.

[26] 29 CFR 524.5 (1938).

example, certain groups of workers, including those with ''temporary, or readily correctible, disabilities,'' those ''where age alone is cited as a disability for a worker under 65,'' and those ''whose piecework earnings are generally equal to or above the statutory minimum [wage],'' would be ineligible for a certificate.[27] The Department also amended its regulations in 1940 to provide specific requirements governing the payment of subminimum wages to individuals with disabilities working in ''sheltered workshops.'' [28] The Department made a number of changes to its regulations implementing section 14 of the FLSA over the next 25 years, changing how certificates were issued and how wages were determined for workers.

In 1966, Congress amended the FLSA to, in relevant part, establish a wage floor for persons with disabilities in both general employment and in certain sheltered workshops at not less than 50 percent of the FLSA minimum wage.[29] The 1966 statutory amendments also created three special categories of certificates for workers who were not subject to the wage floor [30] and extended FLSA coverage to hospitals and other institutions as employers.[31] The statutory language limiting the issuance of certificates to only circumstances where subminimum wages were necessary to prevent the curtailment of opportunities for employment was not changed by these amendments. The 1966 FLSA amendments also required the Secretary to submit a study to Congress ''of wage payments to handicapped clients of sheltered workshops and of the feasibility of raising existing wage standards in such workshops.'' [32]

The 1966 amendments demonstrated Congress' continued intent to give the Department discretion to issue section 14 certificates based on a determination of need. In 1967, the Department updated its regulations based on the 1966 statutory amendments. That same year, the Department submitted its report to Congress, recognizing that the Congressional intent of the 1966 FLSA amendments was ''aimed at 'improving the economic circumstances of handicapped workers, speeding their movement into fully productive private employment, and assuring that such workers are not exploited through low wages.' '' [33] Reflecting the rapidly shifting views on the employment of individuals with disabilities since the FLSA was passed 28 years earlier, the report continued by noting that ''it is now clearly the intent of the Congress that handicapped workers' wages be raised to at least the minimum wage as soon as feasible.'' [34]

The Department's report made additional observations about subminimum wage employment and made recommendations on changes needed to support movement at that time from section 14(c) employment to full wage employment. In describing sheltered workshops, the Department observed that while individuals with disabilities being paid subminimum wages by the workshops (described as ''clients'' in the report) may be limited in their ability to produce, they were also limited by ''the frequently obsolete methods of organization and production of the workshop.'' [35] The report concluded that ''[t]o measure the 'worth' of a handicapped client by his 'productivity' while making him work with outmoded equipment, or on jobs long ago automated, or with modern equipment which is not adapted to the individual's needs is to foredoom the great majority of handicapped clients to subminimum wages.'' [36] Additionally, of particular note, the Department reported about the demographics of workers receiving subminimum wages in sheltered workshops, including by disability. The Department observed that, in 1967, workers with I/DD comprised approximately one-third of all workshop clients and were paid the lowest wages of any group of workers with disabilities employed under certificates.[37]

In 1971, the Department again amended its regulations to include, in part, the introduction of a new 25–50 percent wage floor for ''multi-handicapped and other workers whose earning capacity is severely impaired'' working under the sponsorship of a public rehabilitation agency.[38] In 1974, Congress amended the FLSA by moving the subminimum wage provision for workers with disabilities to section 14(c) of the Act but yet again left the substantive requirements, including the statutory ''curtailment clause,'' unchanged.[39] At this juncture, Congress's maintenance of the Department's authority, through the ''curtailment clause,'' to determine the extent to which subminimum wage certificates were necessary is especially notable in light of the Department's 1967 report seven years earlier, which, as discussed above, emphasized the Department's understanding that Congress sought to have individuals with disabilities earn full minimum wages ''as soon as feasible.'' [40]

In 1986, Congress amended the FLSA to eliminate the specific types of certificates and wage floors that previously applied to section 14(c) employment.[41] These revisions again retained the ''curtailment clause'' standard as a precondition governing the issuance of certificates. While the revised statute retained the basic requirement that workers with disabilities employed under section 14(c) certificates be paid commensurate wages, it added a requirement that the wages be ''related to the individual's productivity.'' In full, section 14(c)(1), which remains in effect today, provides that ''[t]he Secretary, to the extent necessary to prevent curtailment of opportunities for employment, shall by regulation or order provide for the

[27] 29 CFR 524.7(a), (c), and (d) (1939).

[28] 5 FR 655 (Feb. 13, 1940) (defining ''sheltered workshop'' as ''a charitable organization or institution conducted not for profit, but for the purpose of carrying out a recognized program of rehabilitation for individuals whose earning capacity is impaired by age or physical or mental deficiency or injury, and to provide such individuals with remunerative employment or other occupational rehabilitating activity of an educational or therapeutic nature.''); *see also* 29 CFR 525.1 (1940).

[29] Public Law 89–601, 80 Stat. 830, 843–44 (1966) (29 U.S.C. 214(d)(1)).

[30] *Id.* (29 U.S.C. 214(d)(2)(A)–(B), 214(d)(3)). The three categories of certificates for workers who were not subject to the wage floor established by the 1966 FLSA amendments included, in certain specified circumstances, ''handicapped workers engaged in work which is incidental to training or evaluation programs,'' ''multihandicapped individuals and other individuals whose earning capacity is so severely impaired that they are unable to engage in competitive employment,'' and ''handicapped clients in work activities centers.'' *Id.*

[31] *Id.* at 831–32 (29 U.S.C. 203(r), (s)).

[32] *See id.* at 845.

[33] U.S. Dep't of Labor, ''Sheltered Workshop Report of the Secretary of Labor and Technical Report on Wage Payments to Handicapped Clients in Sheltered Workshops'' (1967) (1967 DOL Report) at 1 (quoting Senate Report No. 1487, August 23, 1966, at 23).

[34] 1967 DOL Report at 1. The report did not explicitly address the curtailment clause regarding certificate issuance. However, as evidenced by the quoted passage, lawmakers' understanding of the potential employment of individuals with disabilities rapidly evolved since the 1938 passage of the FLSA. In 1938, Congressional documents were replete with references to individuals with disabilities as ''subnormal'' and, in contrast to the 1967 report cited herein, often assumed, without discussion, they were ''unable to compete with their fellow workers.'' *See, e.g.,* Fair Labor Standards Act of 1937: Joint Hearings on S. 2475 and H.R. 7200 before the Senate Comm. On Educ. And Labor; House Comm. On Labor, 75th Cong. 1st Sess. Part 1, p. 38 (June 2–5, 1937) (statement of Robert H. Jackson, Assistant Attorney General, U.S. Dep't of Justice); Cong. Rec. Vol. 83, Part 6, 75th Cong. 3d Sess. P. 7134 (May 19, 1938).

[35] 1967 DOL Report at 2.

[36] *Id.*

[37] *Id.* at 21.

[38] *See* 36 FR 50–51 (Jan. 5, 1971) (29 CFR 524.1(c)).

[39] *See* Public Law 93–259,88 Stat. 55, 72 (1974).

[40] *See* n. 34, above.

[41] *See* Pub. L. 99–486, 100 Stat. 1229 (1986) (29 U.S.C. 214).

employment, under special certificates, of individuals (including individuals employed in agriculture) whose earning or productive capacity is impaired by age, physical or mental deficiency, or injury, at wages which are: (A) lower than the minimum wage applicable under section 206 of this title, (B) commensurate with those paid to nonhandicapped workers, employed in the vicinity in which the individuals under the certificates are employed, for essentially the same type, quality, and quantity of work, and (C) related to the individual's productivity.'' [42] The 1986 statutory amendments also required that employers provide ''written assurances'' that wages for hourly workers be reviewed at least every 6 months, and that wages for all employees be adjusted at least once a year to reflect changes in the prevailing wages in the locality.[43] Additionally, the new language set forth a ''wage petition'' procedure by which an employee or their parent or guardian can ''petition the Secretary to obtain a review of'' the subminimum wage rate paid by the employer.[44] The revised statute also requires that the appeal process include a hearing before an Administrative Law Judge (ALJ), placing the burden on the employer to prove that the subminimum ''wage rate is justified as necessary in order to prevent curtailment of opportunities for employment.'' [45] Since these 1986 amendments, Congress has not directly amended the statutory text of section 14(c), but, as discussed in more detail below, Congress has passed several significant laws that impact employment opportunities for individuals with disabilities.

The Department's section 14(c) regulations have remained substantively untouched for the last 35 years.[46] In 1989, the last time the Department made significant regulatory updates regarding section 14(c), the Department among other things, amended and consolidated regulations governing the section 14(c) provisions to 29 CFR part 525 (the regulations had previously existed in three parts: parts 524, 525, and 529), addressed the 1986 amendments to the FLSA, and made other administrative changes.[47] In its 1989 regulations, the Department defined a ''worker with a disability'' as ''an individual whose earning or productive capacity is impaired by a physical or mental disability . . . for the work to be performed,'' and cautioned that ''a disability which may affect earning or productive capacity for one type of work may not affect such capacity for another.'' [48] The regulations also provide that ''[a]n individual whose earning or productive capacity is not impaired for the work being performed cannot be employed under a certificate issued pursuant to this part and must be paid at least the applicable minimum wage.'' [49]

The Department's 1989 regulations also state that the Department will consider four criteria in determining whether subminimum wage rates are necessary in order to prevent curtailment of opportunities for employment. As set out in the 1989 rule, these criteria, still in effect today, examine the impact of the worker's disability on their productivity compared to the earnings and productivity of experienced workers without disability doing essentially the same type of work and employed in the vicinity; as previously noted, the criteria do not include an assessment of the general scope of employment opportunities available to individuals with disabilities. The specific criteria are: (1) the nature and extent of the disabilities of the individuals employed as these disabilities relate to the individuals' productivity; (2) the prevailing wages of experienced employees not disabled for the job who are employed in the vicinity in industry engaged in work comparable to that performed at subminimum wage rates; (3) the productivity of the workers with disabilities compared to the norm established for nondisabled workers through the use of a verifiable work measurement method or the productivity of experienced nondisabled workers employed in the vicinity on comparable work; and (4) the wage rates to be paid to the workers with disabilities for work comparable to that performed by experienced nondisabled workers.[50] To determine whether these criteria are met, the Department's regulations also provide guidance on determining the prevailing wage in a vicinity using different methods, instructions on establishing piece rates and hourly rates for workers with disabilities, and procedures to be used in deciding petitions for review of a subminimum wage rate under section 14(c).[51] In determining whether subminimum wages are necessary to prevent curtailment of employment opportunities for individuals with disabilities, the 1989 regulations do not consider the opportunities generated by the employment market as a whole, do not contemplate structural measures such as pre-employment training and skill-matching job placement services, and, notably, were published a year prior to the 1990 passage of the original ADA, and thus do not take into account the fundamental anti-discrimination and reasonable accommodation protections of the ADA.

D. Administration, Use, and Enforcement of Section 14(c) Certificates Today

1. Administration and Enforcement of Certificates

The Department's WHD administers and enforces the section 14(c) provisions.[52] The administration, use, and enforcement of section 14(c) certificates is governed by the FLSA and WHD's current regulations at 29 CFR part 525, as explained above. Specifically, the current § 525.9 identifies the criteria that the Department considers in determining whether to issue a section 14(c) certificate. In effect, the current regulation conditions the issuance of a certificate on satisfaction of the standards set forth in other regulatory provisions governing the proper computation and payment of subminimum wages. Section 525.11 likewise provides that ''[u]pon consideration of the criteria cited in these regulations, a special certificate may be issued.'' The regulations also outline procedures, further elaborated upon in subregulatory guidance, that WHD generally must use to deny or revoke certificates as well as appellate procedures for stakeholders who may be ''aggrieved'' by any WHD certificate action.[53] Employees and their parents or guardians also have the ability to

[42] *Id.* (29 U.S.C. 214(c)(1)).

[43] *Id.* (29 U.S.C. 214(c)(2)(A), (B)).

[44] *Id.* (29 U.S.C. 214(c)(5)(A)).

[45] *Id.* (29 U.S.C. 214(c)(5)(B)–(G)).

[46] Since 1989, the only revisions to the section 14(c) regulations were technical corrections to the recordkeeping regulation at 29 CFR 525.16. *See* 82 FR 2221 (Jan. 9, 2017), and non-substantive updates to the regulation governing the administrative appeal process at 29 CFR 525.22. *See* 82 FR at 2228; 86 FR 1772 (Jan. 11, 2021).

[47] 54 FR 32920 (Aug. 10, 1989) (1989 final rule).

[48] *Id.* (29 CFR 525.3(d)).

[49] *Id.* (29 CFR 525.5(a). *See also* 29 CFR 525.12(b) (noting that a subminimum wage certificate applies only to such workers who ''are in fact disabled for the work they are to perform'')).

[50] *Id.* (29 CFR 525.9(a)).

[51] *Id.*

[52] The Secretary has delegated authority to WHD to issue regulations governing FLSA section 14(c), as well as to administer and enforce the section 14(c) provisions. *See* Sec'y of Labor's Order No. 01–2014, Delegation of Authority and Assignment of Responsibility to the Administrator, Wage and Hour Division, 79 FR 77527 (Dec. 24, 2014) (Secretary's Order No. 01–2014).

[53] 29 CFR 525.11(b) and 525.13 (certificate denials), 525.17 (certificate revocations), and 525.18 (administrative review process).

petition for review of their subminimum wage rates.[54]

If an employer applies for and is issued a section 14(c) certificate, the certificate allows the employer to pay individualized subminimum wage rates to workers with disabilities whose disabilities impact their productivity on the work being performed that are ''commensurate'' with the rates paid to workers without a disability performing the same type of work in the vicinity.[55] Generally, to determine the proper commensurate wage rate, an employer must: (1) identify the prevailing wage rate paid to experienced workers without disabilities performing essentially the same type, quality, and quantity of work in the vicinity where the worker with a disability is employed, often by conducting a prevailing wage survey; (2) determine the productivity standard for experienced workers without disabilities (the ''standard setter'') against which the productivity of the worker with disabilities must be measured; and (3) assess the quality and quantity of the productivity of the worker with a disability.[56] Employers generally determine the productivity of both the standard setter and the worker with a disability on a particular job by performing an observational stopwatch time study (''time study'').[57] Employers holding a section 14(c) certificate must also maintain adequate documentation of each worker's disability that impairs their productivity for the work performed, each required step that the employer took in determining the relevant commensurate wage, and time and pay records. Employers must also conduct periodic evaluations and make appropriate updates to the wage rates.[58]

In 2014, the Workforce Innovation and Opportunity Act (WIOA) established new limitations on the payment of a subminimum wage in section 511 of the Rehabilitation Act of 1973 (Rehabilitation Act or section 511), which became effective in 2016.[59] As discussed further in section III.B. below, section 511 prohibits an employer who holds a section 14(c) certificate from paying a subminimum wage to a worker with a disability unless the worker receives certain services and information prior to, and/or during, as applicable, their employment at subminimum wages.[60] The Secretary has authority to enforce the terms under which individuals are employed at a subminimum wage, including the section 511 provisions, and WHD has issued guidance providing detailed instructions on the requirements.[61]

As previously discussed, an employer must obtain an authorizing certificate from WHD as a prerequisite to paying subminimum wages to workers with disabilities. The certificate application requires employers to provide WHD information about themselves and a snapshot of information about the way they use or seek to use the subminimum wage certificate.[62] WHD reviews each application to determine whether to issue or deny a certificate. Having an active section 14(c) certificate does not provide the employer with a good faith defense should violations of section 14(c) or other provisions of applicable law be found during an investigation of the employer.

Certificates issued to employers by WHD have both an effective date and an expiration date and are generally valid for either 1 or 2 years, depending on the employer type (discussed in more detail below). To remain authorized to pay subminimum wages, the employer must properly and timely file an application for renewal with WHD before the expiration of its certificate.[63] Employers submit applications to renew certificate authority in the same manner as when seeking an initial application but are required to provide additional information, including a snapshot of information about the applicant's workforce paid a subminimum wage during their last completed fiscal quarter. If an application for renewal has been properly and timely filed with WHD, the employer's existing subminimum wage certificate remains in effect and its authority to pay subminimum wages continues while the application for renewal is under review.[64]

Each year, WHD investigates a number of section 14(c) certificate holders to determine their compliance with all the provisions and requirements of section 14(c) as well as their compliance with section 511.[65] WHD may initiate these cases due to a complaint or based upon agency selection. In fiscal year 2023, WHD concluded 89 investigations of employers holding section 14(c) certificates, found violations in approximately 88 percent of cases, and recovered more than $2 million in back wages for nearly 3,000 workers.[66] WHD checks for compliance with the section 511 requirements in every investigation of an employer holding a section 14(c) certificate and, since 2016, has identified violations of these provisions in more than 250 investigations. If WHD discovers a violation of the section 14(c) or section 511 requirements during the course of an investigation, WHD can assess back wages in addition to seeking action by the employer to ensure future compliance with the applicable laws. In certain circumstances, WHD can also assess liquidated damages and civil monetary penalties and can also revoke the employer's section 14(c) certificate.[67] Certificate revocation is an enforcement tool that WHD uses in certain circumstances such as misrepresentations or false statements made in obtaining the certificate or egregious violations of statutory requirements. In cases where employers

[54] 29 U.S.C. 214(c)(5), and 29 CFR 525.22.

[55] Although the term ''subminimum wages'' typically refers to wage rates that are less than the Federal minimum wage, section 14(c) certificates also allow the payment of wages that are less than the required prevailing wage to workers who have disabilities for the work being performed on Federal contracts subject to the McNamara-O'Hara Service Contract Act (SCA) and the Walsh-Healey Public Contracts Act. *See* 41 U.S.C. 6701 *et seq.,* 6501 *et seq.* The SCA's implementing regulations generally incorporate the ''conditions and procedures'' governing section 14(c) employment set forth in 29 CFR 525. 29 CFR 4.6(o).

[56] *See* 29 CFR 525.10; 29 CFR 525.12; WHD Field Operations Handbook (FOH) 64g05, *https://www.dol.gov/agencies/whd/field-operations-handbook/Chapter-64.*

[57] *See* FOH 64g06.

[58] 29 CFR 525.16.

[59] 29 U.S.C. 794g.

[60] Section 511 generally requires that youth with disabilities who are age 24 or younger complete certain activities, including pre-employment transition services under section 113 of the Rehabilitation Act or transition services under the Individuals with Disabilities Education Act (IDEA) (to the extent either of these services are available to them), an application for vocational rehabilitation services, and career counseling, information and referrals, to enable them to explore, discover, experience, and attain competitive integrated employment before they are employed at subminimum wage rates. *See* 29 U.S.C. 794g. Section 511 also requires that all workers with disabilities who are paid subminimum wages, regardless of their age, receive regular career counseling information and referrals and information about self-advocacy, self-determination, and peer mentoring training opportunities in their local area, every 6 months during the first year of employment and annually thereafter. *Id.*

[61] *See* U.S. Dep't of Labor, ''Materials for Employers with Section 14(c) Certificates,'' April 2024, *https://www.dol.gov/agencies/whd/workers-with-disabilities/employers.*

[62] *See* U.S. Dep't of Labor, ''14(c) Certificate Application,'' April 2024, *https://www.dol.gov/agencies/whd/workers-with-disabilities/section-14c/apply.*

[63] 29 CFR 525.13(b).

[64] *Id.*

[65] Enforcement data collected by the Department's enforcement agencies can be found at: *https://enforcedata.dol.gov/views/data_catalogs.php.* The ''Wage and Hour Compliance Action Data'' dataset contains all concluded WHD compliance actions since fiscal year 2005. The dataset includes whether any violations were found, the back wage amount, number of employees due back wages, and civil money penalties assessed.

[66] *Id.*

[67] 29 U.S.C. 214(c), 216(c); 29 CFR 525.17.

do not voluntarily agree to pay back wages and come into compliance, WHD can also file suit in Federal court to resolve violations of the law.

2. Use of Section 14(c) Certificates

In recent decades, the estimated number of workers with disabilities paid subminimum wages has dramatically declined, as has the number of employers holding section 14(c) certificates. In 2001, the U.S. Government Accountability Office (GAO) estimated that approximately 424,000 workers with disabilities were paid subminimum wages while working for 5,612 employers holding section 14(c) certificates.[68] As of May 1, 2024, the Department's data shows there were 801 employers with either an issued certificate or a pending certificate application.[69] Employers with an issued certificate reported paying approximately 40,579 workers at subminimum wages in their previously completed fiscal quarter.[70] The number of employers holding or pursuing a section 14(c) certificate as of May 1, 2024, had dropped by nearly 86 percent from those in 2001. Further, there were roughly one-tenth the number of workers being paid subminimum wages under section 14(c) certificates as there were in 2001—approximately a 90 percent reduction over that 23-year period.[71] Additionally, very few employers seek new section 14(c) certificates; over 97 percent of certificate applications received annually seek renewal of an existing section 14(c) certificate.[72]

WHD issues section 14(c) certificates to business establishments, community rehabilitation programs (CRPs), hospitals/patient worker facilities, and school-work experience programs (SWEPs). The overwhelming majority of current certificate holders are CRPs, representing approximately 93 percent of current certificate holders in 2023.[73] In the context of section 14(c), WHD defines CRPs as ''not-for-profit agencies that provide rehabilitation and employment for people with disabilities.'' [74] Such establishments are sometimes referred to as ''sheltered workshops'' [75] as they typically are facility-based and often serve workers with disabilities in sheltered, or segregated, settings. Only a small number of private-sector, for-profit businesses hold certificates for the payment of subminimum wages, as reflected by the fact that only approximately 4 percent of current section 14(c) certificate holders are businesses.[76] [77]

Many CRPs provide both employment and other services, such as rehabilitation and training, and receive public funding. GAO has noted that many employers holding a section 14(c) certificate pay their operating costs through a mix of public funding and public and private contracts for goods or services.[78] Specifically, GAO noted in a 2021 report that Medicaid is the largest source of Federal funds for day and employment services (such as those provided by CRPs) for individuals with developmental disabilities.[79] Likewise, in a 2020 report, the USCCR found that ''the majority of community rehabilitation programs which provide supports and services for people with intellectual and developmental disabilities to obtain a job are funded by the vocational rehabilitation [program].'' [80] As the USCCR explained, in addition to Medicaid funding noted by GAO, the vocational rehabilitation funding includes U.S. Department of Education program grants under the Rehabilitation Act, in addition to State and local funding used for match purposes under the Vocational Rehabilitation program.[81]

As noted above, Congress removed any wage floor for section 14(c) employment nearly 40 years ago. As summarized in the table below, in a 2023 report, the GAO analyzed section 14(c) data for 62 percent of renewal certificates for the period covering 2019 to 2021 and found that more than 50 percent of workers in the data analyzed were paid less than $3.50 per hour, while approximately 14 percent were paid at or above the current Federal minimum wage of $7.25 per hour.[82] Nearly 5 percent of workers were paid 25 cents per hour or less. Approximately 14 percent were paid $1.00 per hour or less. GAO observed that higher-paid workers under section 14(c) certificates were more likely to be paid by the hour, while lower-paid workers were more likely to be paid on a piece rate basis [83] (a piece rate fixes a wage payment on each completed unit of work).[84] Using WHD's administrative data of issued certificates that were valid in the first two quarters of fiscal year 2024 (between October 2023 and

[68] U.S. Gov't Accountability Off., GAO–01–886, ''Special Minimum Wage Program: Centers Offer Employment and Support Services to Workers With Disabilities, But Labor Should Improve Oversight'' 10, 18 (2001) (2001 GAO Report).

[69] *See* U.S. Dep't of Labor, ''14(c) Archive,'' June 2024, *https://www.dol.gov/agencies/whd/workers-with-disabilities/section-14c/certificate-holders/archive.*

[70] *Id.* The Department notes that data collected by the Department from section 14(c) applications is not census data. Data is derived from information received by WHD during the certificate application process, which is used for the purposes of determining whether to issue a certificate. The application requires the employer to provide a snapshot of its operations and workforce that is paid a subminimum wage during its most recently completed fiscal quarter at the time of its renewal application, and the submission date varies per applicant. Because certificates are issued to the employer, not individuals employed at subminimum wages, the specific number of employees may change over the duration of the certificate. The certificate application data is self-reported by employers and is not independently verified by WHD. Additionally, the data provided reflects active certificates as of the date that the Department's website list was revised and does not include the number of employees on ''pending'' 14(c) certificates.

[71] The Department notes that the May 1, 2024, employee count (40,579) does not reflect any employment changes an employer may have made subsequent to the data provided to WHD in its certificate application nor does it reflect the workers with disabilities paid under pending renewal certificates. Notwithstanding, the Department believes this data comparison remains valid and would be little changed with these additional data points.

[72] This statistic is compiled from WHD's listing of 14(c) certificate holders between October 1, 2020, and April 1, 2024. WHD maintains a listing of employers who hold or have applied for 14(c) certificates at *https://www.dol.gov/agencies/whd/workers-with-disabilities/section-14c/certificate-holders.*

[73] WHD listing of certificate holders from October 1, 2023, indicating that approximately 93 percent of certificate holders are CRPs, *https://www.dol.gov/agencies/whd/workers-with-disabilities/reports-to-congress.*

[74] FOH 64k00.

[75] FOH 64b00.

[76] WHD listing of certificate holders from October 1, 2023, *https://www.dol.gov/agencies/whd/workers-with-disabilities/reports-to-congress.*

[77] Currently, the small number of private sector businesses amongst section 14(c) certificate holders is a marked contrast to the Congressional understanding of how such certificates would be used at the time of the original enactment of section 14 in 1938. During the debate preceding the passage of the FLSA, members of Congress focused on the provision as being intended for employment in the private sector, discussing the impact on ''industry,'' ''manufacturers,'' and ''small businessmen.'' 82 Cong. Rec., 88–89 (1937).

[78] *See* 2001 GAO Report at 14; *see also* U.S. Gov't Accountability Office, GAO–21–260, ''Subminimum Wage Program: Factors Influencing the Transition of Individuals with Disabilities to Competitive Integrated Employment'' (2021), at 6, *https://www.gao.gov/products/gao-21-260* (''2021 GAO Report'').

[79] *Id.* at 6, n.19.

[80] U.S. Comm'n on Civ. Rts., ''Subminimum Wages: Impacts on the Civil Rights of People with Disabilities,'' *https://www.usccr.gov/files/2020/2020-09-17-Subminimum-Wages-Report.pdf,* at 6 n.101 (2020) (''USCCR Report'').

[81] *See, for example,* USCCR Report at 9 (explaining that in Vermont, sites that have transitioned from subminimum wage employment use Federal and State funding to provide employment and non-work services for individuals with disabilities).

[82] *See* 2023 GAO Report at 16. A worker employed under a section 14(c) certificate may be paid more than the Federal hourly minimum wage of $7.25 if the prevailing wage upon which their productivity-based commensurate wage is based exceeds the Federal minimum wage.

[83] *Id.* at 18–19.

[84] FOH 64g06(a)(1).

March 2024), WHD found that approximately 16 percent of workers were reported by the employer on their most recent application (reflecting average hourly wages from their prior fiscal quarter) to have been paid at least the current Federal minimum wage of $7.25 per hour while nearly 49 percent made less than $3.50 per hour. Based on WHD's administrative data, approximately 10 percent made $1.00 per hour or less and nearly 2 percent made 25 cents per hour or less.

Scope of data studied	GAO's 2019 to 2021 analysis	WHD's October 2023 to March 2024 analysis
	62 percent of renewal certificates	administrative data of issued certificates
Workers paid 25 cents or less per hour	Nearly 5 percent	Nearly 2 percent.
Workers paid $1.00 or less per hour	Approximately 14 percent	Approximately 10 percent.
Workers paid less than $3.50 per hour	More than 50 percent	Nearly 49 percent.
Workers paid at or above the current Federal minimum wage of $7.25 per hour	Approximately 14 percent	Approximately 16 percent.

Most workers currently employed under section 14(c) certificates have I/DD as their primary disability. In the years immediately after section 14(c) was enacted, it was assumed that workers with a wide range of disabilities, including physical disabilities, might be paid subminimum wages. Over time, however, subminimum wage payments to all groups other than individuals with I/DD substantially diminished. As noted above, in 1967, one-third of workers in sheltered workshops were individuals with I/DD.[86] In 2001, GAO estimated that three-quarters of workers employed under a section 14(c) certificate experienced some form of I/DD.[87] By 2021, GAO estimated approximately 90 percent of workers employed under a section 14(c) certificate experienced I/DD.[88]

E. Comprehensive Review of Section 14(c)

On September 26, 2023, Acting Secretary Julie Su announced that the Department would conduct a comprehensive review of the section 14(c) program. As part of this review, between October 20, 2023, and November 20, 2023, the Department held a series of stakeholder engagement sessions to hear diverse views on section 14(c) from members of the public, including workers with disabilities and their family members, disability rights advocates, service providers, and section 14(c) certificate holders.

In holding these listening sessions, the Department received wide-ranging feedback about section 14(c), including viewpoints regarding the impacts of potentially ceasing to issue 14(c) certificates in the future. Approximately 2,000 individuals participated in these sessions. During these listening sessions, the Department heard from individuals and groups that oppose permitting employers to pay subminimum wages under section 14(c); those stakeholders emphasized, among other points, that the payment of subminimum wages is outdated, discriminatory, and no longer needed to provide employment opportunities for individuals with disabilities. The Department also heard from individuals and groups in support of the continued payment of subminimum wages who focused, among other things, on the importance of individuals with disabilities, and their families, being able to choose whether to remain in their subminimum wage jobs and on the benefits that they have experienced in such employment. The Department deeply valued those listening sessions and it greatly appreciates and has considered the wide-ranging and diverse input gathered from them in the formulation of this proposed rule. The Department also welcomes comments from the general public, including any individuals or entities who participated in these earlier listening sessions, on its proposed rule.

The Department has included the section 14(c) regulations on its long-term Regulatory Agenda for many years and has carefully reviewed the history of section 14(c) and its current operations. In crafting this proposal, the Department consulted with other Federal agencies to better understand how their programs may intersect with the employment of workers under section 14(c) as well as to discuss any foreseeable impacts to those programs if changes were to be made to the section 14(c) regulations. In addition, the Department has extensively reviewed numerous oversight reports, existing data, and information concerning relevant trends in the availability of supports for employment opportunities for workers with disabilities. The Department has also reviewed numerous examples of legislative, policy, and executive actions at all levels of government and analyzed their effect on the employment of workers with disabilities. The Department summarizes this research and analysis, and presents its conclusions based on this comprehensive review, below.

III. Need for Rulemaking

A. Introduction

Since 1938, the FLSA has authorized the Secretary to issue certificates to employers permitting them to pay workers whose disabilities impair their earning or productive capacity at wage rates below the Federal minimum wage rate.[89] WHD is responsible for administering the issuance of certificates and enforcing the provisions of section 14(c). The Department issued its most recent substantive revisions to the regulations pertaining to the issuance of section 14(c) certificates in 1989, more than 35 years ago. Since 1989, and even more so since 1938, employment opportunities have changed dramatically for workers with disabilities. In stark contrast to the New Deal era in which section 14(c) was enacted, disability rights are now enshrined in Federal civil rights laws and enforced by the Federal government.[90] Through the disability rights movement, advocates, including self-advocates, have worked to ensure that individuals with disabilities have the same access to employment and

[86] 1967 DOL Report at 21.

[87] 2001 GAO Report at 19.

[88] 2023 GAO Report at 24. The Department notes that GAO's findings in this area generally match the Department's internal data, derived from the information self-reported by certificate holders; the Department cites to the GAO herein as an independent source. From WHD's listing of section 14(c) certificate holders between October 2020, and April 2024, the percentage of workers identified by their employers on their certificate applications as having I/DD as their primary disability was 91 percent.

[89] *See* 29 U.S.C. 214(c).

[90] *See, e.g.,* U.S. Dep't of Justice, Civil Rights Div., ''The Americans with Disabilities Act (ADA) protects people with disabilities from discrimination,'' *https://www.ada.gov/;* U.S. Equal Emp't Opportunity Comm'n, ''What Laws Does EEOC Enforce?,'' *https://www.eeoc.gov/statutes/laws-enforced-eeoc;* 42 U.S.C. 12101 *et seq.* (1990); 29 CFR part 1630.

other opportunities as others and that individuals with disabilities are not subject to segregation and discrimination on the basis of a disability.[91] This access includes the legal right to reasonable accommodation and prohibitions on discrimination in the workplace. During this time, largely due to the efforts of self-advocates and their allies, society's views about what it means to live and work with a disability have evolved. In contrast to historical approaches that may have viewed disability as a deficiency that needed to be ''fixed'' or ''cured'' or as a tragic condition, current understandings emphasize the social model of disability, which identifies structural and social barriers as the primary reason that individuals with disabilities experience limitations on full engagement in all aspects of community life, focuses on removing those barriers to facilitate full engagement, and recognizes disability as a natural part of the human experience.[92] Thus, there has been a striking and consistent movement away from the medical [93] and charitable [94] models of disability, toward a social model of disability focused on various barriers which may hinder full and effective participation in society.[95]

The successes of the disability rights movement and the changing views regarding disability have been reflected in legislative, legal, policy, and programmatic changes that have broadly influenced available employment options for individuals with disabilities today. As described below, there have been several significant pieces of Federal legislation that have vastly expanded opportunities for individuals with disabilities, requiring better access and accommodations in educational, work, and community settings.[96] Supreme Court and other judicial precedent has amplified the impacts of this legislation, most notably by requiring that individuals with disabilities be able to live, work, and play in the most integrated setting appropriate to their needs.[97] As part of this movement, various non-partisan entities, including the USCCR and the National Council on Disability (NCD), along with a number of non-profit advocacy organizations, have published detailed reports urging the cessation of subminimum wage payments to individuals with disabilities.[98] Multiple States and localities have prohibited or are in the process of phasing out the payment of subminimum wages, and, as discussed below, for nearly a decade, the Federal government has maintained a wage floor above the FLSA's Federal minimum wage for certain government contracts that fully applies to workers with disabilities who work on or in connection with those contracts. Simultaneously, numerous Federal, State, and local programs have emerged to increase access to opportunities for competitive integrated employment (CIE) [99] for workers with disabilities.[100] Amidst these advancements, the employment experiences of workers with many types of disabilities indicate that subminimum wages are unnecessary to safeguard their employment opportunities. In 2023, the unemployment rate for individuals with disabilities was as low as has ever been recorded.[101]

As a result of these changes, today, subminimum wage employment under section 14(c) certificates is no longer the most common form of employment for individuals with disabilities. It bears emphasizing that, currently, only a miniscule fraction of those working individuals with disabilities are employed by section 14(c) certificate holders; in the present day, millions of individuals with disabilities who are working are doing so without section 14(c) certificates.[102] Also, as the number

[91] *See, e.g.,* Nicole LeBlanc, ''Why Employment Matters: A Resource Guide by and for Self-Advocates Interested in Pursuing Competitive, Integrated Employment,'' Administration on Disability Employment Technical Assistance Center, September 2021, *https://aoddisabilityemploymenttacenter.com/wp-content/uploads/2021/10/DETAC-2021-GEN-3_Final_508.pdf.*

[92] Arlene S. Kanter, ''The Law: What's Disability Studies Got To Do With It or an Introduction to Disability Legal Studies,'' 42 Columbia Human Rights Law Review 403, 410 (2011) (''2011 Kanter Paper'').

[93] The medical model generally views disability as some deficiency to be ''fixed'' or ''cured.'' ''As a result of viewing disability through a medical lens, societies have erected large institutions to protect and exclude people with disabilities from society.'' 2011 Kanter Paper at 420; *see also* Samuel R. Bagenstos, ''Subordination, Stigma, and 'Disability' '', 86 Va. L. Rev. 397, 427 (2000) (''2000 Bagenstos Paper'') (citations omitted) (''Indeed, virtually the entire ideology of the modern disability rights movement can be seen as a reaction to that 'medical/pathological paradigm' of disability.'').

[94] ''People who work with blind, deaf, autistic, developmentally disabled, and/or physically disabled individuals often see their clients' or patients' impairment as a great personal tragedy. Yet, people with disabilities do not necessarily see their own lives that way.'' 2011 Kanter Paper at 412, 414.

[95] *See, e.g.,* World Health Organization Policy on Disability (2021), *https://iris.who.int/bitstream/handle/10665/341079/9789240020627-eng.pdf?sequence=1.* ''By relying on the social model of disability, it is impossible to say that any person is 'unable' or 'unqualified' to exercise rights or to participate fully in society. Instead, it is affirmatively the obligation of society to change or adapt its services, programs, facilities, systems, and other entities, so that all people can exercise their rights to the best of their ability, regardless of their particular impairment.'' 2011 Kanter Paper at 427–28.; *see also* 2000 Bagenstos Paper at 427–28.

[96] For example, legislation such as the Americans with Disabilities Act, 42 U.S.C. 12101 *et seq,* and the Workforce Innovation and Opportunity Act, 29 U.S.C. 3101 et seq, are discussed in detail later in this section.

[97] *See Olmstead* v. *L.C. ex rel. Zimring,* 527 U.S. 581 (1999); *see also Tennessee* v. *Lane,* 541 U.S. 509 (2004); *Toyota Motor Manufacturing, Kentucky, Inc.* v. *Williams,* 534 U.S. 184 (2002); *Sutton* v. *United Air Lines, Inc.,* 527 U.S. 471 (1999); *Cedar Rapids Community School District* v. *Garret F.,* 526 U.S. 66 (1999).

[98] *See, for example,* USCCR Report; National Council on Disability (NCD), ''Has the Promise Been Kept? Federal Enforcement of Disability Rights Laws (Part 1),'' (October 2018), *https://www.ncd.gov/report/has-the-promise-been-kept-federal-enforcement-of-disability-rights-laws-part-1-october-2018/(''2018 NCD Progress Report'');* NCD, ''Report on Subminimum Wage and Supported Employment'' (2012), *https://www.ncd.gov/report/national-council-on-disability-report-on-subminimum-wage-and-supported-employment/* (''2012 NCD Report'').

[99] The term ''competitive integrated employment'' (CIE) is defined at 29 U.S.C. 705(5), and in the Department of Education's regulations at 34 CFR 361.5(c)(9). Those regulations define CIE as work that is performed on a full-time or part-time basis for which an individual is: compensated at or above minimum wage and comparable to the customary rate paid by the employer to employees without disabilities performing similar duties and with similar training and experience; receiving the same level of benefits provided to other employees without disabilities in similar positions; at a location where the employee interacts with other individuals without disabilities; and presented opportunities for advancement similar to other employees without disabilities in similar positions. *See also https://www.dol.gov/agencies/odep/program-areas/cie.*

[100] The Department of Education amended regulations at 34 CFR parts 361 and 363, and established new part 397, in response to the WIOA amendments to the Rehabilitation Act. These amended and new regulations govern the State Vocational Rehabilitation Services program and the State Supported Employment Services program, and placed greater emphasis on the achievement of CIE. *See* U.S. Dep't of Education, *State Vocational Rehabilitation Services Program; State Supported Employment Services Program; Limitations on Use of Subminimum Wage,* Final Regulations, 81 FR 55630 (Aug. 19, 2016).

[101] *See* U.S. Dep't of Labor, Bureau of Labor Statistics, ''Economic News Release: Persons with a Disability: Labor Force Characteristics Summary,'' Feb. 22, 2024, *https://www.bls.gov/news.release/pdf/disabl.pdf* (noting that the unemployment rate for individuals with a disability was 7.2 percent in 2023, and also stating that ''[i]n 2023, 22.5 percent of people with a disability were employed—the highest recorded ratio since comparable data were first collected in 2008'' and that such rate reflected a 1.2 percentage point increase from 2022); *see also* U.S. Dep't of Labor, Bureau of Labor Statistics, ''Data Retrieval: Labor Force Statistics (CPS)'', *https://www.bls.gov/webapps/legacy/cpsatab6.htm* (making available historical data on unemployment and employment rates).

[102] As discussed above, as of May 1, 2024, employers with an issued certificate reported to the Department that they paid approximately 40,579 workers at subminimum wages in their previously completed fiscal quarter. This is a tiny fraction of the total number of individuals with disabilities working today, as in each month in the first half

Continued

of workers being paid subminimum wages under section 14(c) certificates has continued to shrink,[103] available data indicates that the numbers of individuals with I/DD (who, as discussed above, comprise approximately 90 percent of the workers paid subminimum wages by section 14(c) certificate holders today), working for full Federal minimum wages (or higher) has continued to grow.[104] Specifically, as shown by a 2023 Thinkwork Report, there are now many more individuals with I/DD who are being paid full wages than who are being paid subminimum wages; the Department has preliminarily assessed that the total number of working individuals with I/DD is at least twice the total number of individuals working under section 14(c) certificates.[105] In other words, the existing data—though limited—shows that, by a significant margin, most workers with I/DD do not rely on subminimum wages to gain employment opportunities and have demonstrated therein that section 14(c) certificates are no longer necessary for them to do so. The Department welcomes comments on this data and the Department's preliminary analysis.[106]

Cognizant of this changed employment landscape, the Department now assesses, pursuant to its statutory mandate, whether the issuance of section 14(c) certificates authorizing the payment of subminimum wages is necessary to prevent the curtailment of opportunities for employment for workers with disabilities.

B. Federal Legislation, Regulations, and Supreme Court Precedent

The current section 14(c) regulations were promulgated prior to having the benefit of nearly all the most significant legislative and legal developments regarding individuals with disabilities, and thus do not contemplate the protections, rights, and opportunities created by these developments. The discussion that follows is intended to highlight several of the most notable and relevant of these developments since 1989, and is not intended to provide a comprehensive survey of all such changes.[107] The Department requests comments on the discussion of these developments and the Department's analysis of them, as well as comments on any other Federal legislative or judicial development relevant to whether the continued issuance of section 14(c) certificates is necessary to prevent curtailment of opportunities for employment of individuals with disabilities.

1. The Americans With Disabilities Act and the Supreme Court's Olmstead Decision

Perhaps the most foundational of these developments was the enactment of the Americans with Disabilities Act (ADA) in 1990.[108] The ADA, as amended by the ADAAA, among other things, prohibits discrimination on the basis of disability in the workplace and in the provision of public programs, services, and activities. Title I of the ADA, enforced by the U.S. Equal Employment Opportunity Commission (EEOC), applies to private employers and State or local governments and prohibits discrimination ''against a qualified individual on the basis of disability in regard to job application procedures, the hiring, advancement, or discharge of employees, employee compensation, job training, and other terms, conditions, and privileges of

of 2024, over 7 million individuals 16 years and over with a disability were employed in the civilian labor force. *See* U.S. Dep't of Labor, Bureau of Labor Statistics, ''Data Retrieval: Labor Force Statistics (CPS)'' *https://data.bls.gov/pdq/SurveyOutputServlet.* Additionally, cross-referencing these data points, the Department estimates that, nationwide, there are only approximately 4,000 individuals with disabilities other than I/DD who are paid subminimum wages.

[103] *See* section II.C.2, above, reflecting the decline in numbers of employees being paid subminimum wages from approximately 424,000 in 2001 to about 40,579 in 2024.

[104] *See* Agnieszka Zalewska, Jean Winsor & John Butterworth, ''Intellectual and Development Disabilities Agencies' Employment and Day Services,'' Data Note Plus, no. 87 (2023) (''2023 Thinkwork Report''), at 8–9, *https://www.thinkwork.org/sites/default/files/2024-01/DN_87_R_0.pdf.* This report, supported in part by the Administration on Disabilities, Administration for Community Living, U.S. Department of Health and Human Services, builds on annual and bi-annual surveys of State I/DD agencies spanning several decades and compiles data from all States (noting some States for which data is not available). Of particular relevance here, the report includes a chart depicting that, in 2021, approximately 130,000 clients of State agencies serving individuals with I/DD worked in integrated employment, while noting that in 2022, approximately 59,000 total individuals participated in subminimum wage jobs. While this report, which focuses on integration, does not directly compare the number of workers with I/DD being paid full wages to the number of workers paid subminimum wages (nor does it offer data sets about those populations from the same year), in publishing this specific data, it nevertheless supports the conclusion that more individuals with I/DD now are paid full wages, as the total number of individuals with I/DD who are reported as working in integrated settings is more than twice the estimated total number of all individuals working under section 14(c) certificates. As discussed in previous sections, the overwhelming majority of section 14(c) certificate holders are CRPs who typically provide work in non-integrated settings. Most of the approximately 130,000 reported workers with I/DD in integrated settings are likely paid at minimum wage or higher rates, compared to the report's estimates of approximately 59,000 reported workers paid subminimum wages who are primarily employed by non-integrated CRPs. Moreover, the ratio of individuals with I/DD working for full wages to individuals working for subminimum wages is likely far higher than the estimate reported here because the ThinkWork report only collects data about those individuals who are tracked by State I/DD agencies. The report thus does not capture individuals who have secured full-wage work without the assistance or knowledge of those agencies. Therefore, the report's identification of approximately 130,000 individuals with I/DD working in integrated settings likely undercounts the total actual number of individuals with I/DD working for full wages.

[105] *Id.*

[106] The Department requests comments reflecting any 2022, 2023, and 2024 updates on similar reporting from State I/DD agencies about the numbers of their clients working in integrated employment, as well as any other comments relating to the declining numbers of individuals working for subminimum wages in comparison to the growing numbers of individuals with I/DD working for full wages.

[107] This section provides only highlights of certain key laws; however, the Department notes there are numerous pieces of legislation over the last several decades that have incorporated ways to enhance career opportunities for workers with disabilities. For example, when Congress enacted the Rehabilitation Act of 1973, section 504 of that law required that programs receiving Federal financial assistance operate without discrimination on the basis of disability. 29 U.S.C. 794. Modeled after the language of the Civil Rights Act of 1964, the Rehabilitation Act of 1973, and subsequent amendments, also prohibited discrimination on the basis of disability by Federal agencies and contractors in their employment practices. In enacting and amending the Act, Congress enlisted all programs receiving Federal funds in an effort ''to share with handicapped Americans the opportunities for an education, transportation, housing, health care, and jobs that other Americans take for granted.'' 123 Cong. Rec. 13,515 (1977) (statement of Senator Humphrey). The 1998 amendments made to the Rehabilitation Act stated that among other things, ''[i]t is the policy of the United States that all programs, projects, and activities receiving assistance under this Act shall be carried out in a manner consistent with . . . [the] pursuit of meaningful careers, based on informed choice, of individuals with disabilities.'' 29 U.S.C. 701(c) (1998). The amendments further stated that workers were to develop an individualized plan for employment that ''to the maximum extent appropriate, results in employment in an integrated setting.'' *Id.*

[108] *See* 42 U.S.C. 12101 (1990). In 2008, Congress passed the ADA Amendments Act (ADAAA) which made a number of changes to the ADA definition of ''disability'' to ensure broad coverage, making it easier for individuals seeking the protection of the ADA to establish that they have a disability that falls within the meaning of the statute. *See* ADA Amendments Act of 2008, Public Law 110–325 (S. 3406), September 25, 2008*; see also https://archive.ada.gov/nprm_adaaa/adaaa-nprm-qa.htm.* Under the Federal equal employment opportunity laws that the EEOC enforces, including the ADA, an employer cannot ask an employee to prospectively waive their rights to protection. *See, e.g., Lester* v. *O'Rourke,* No. 17–cv–1772, 2018 WL 3141796, at *4–6 (N.D. Ill. June 27, 2018). In addition, employers may not interfere with the protected right of an employee to file a charge, testify, assist, or participate in any manner in an investigation, hearing, or proceeding. *See, e.g.,* EEOC, ''Enforcement Guidance on non-waivable employee rights under EEOC enforced statutes,'' *https://www.eeoc.gov/laws/guidance/enforcement-guidance-non-waivable-employee-rights-under-eeoc-enforced-statutes.*

employment.'' [109] Title I also requires employers to provide reasonable accommodations to qualified individuals—an individual who, with or without reasonable accommodation, can perform the essential functions of the employment position that they hold or desire.[110] Under the ADA, the term ''reasonable accommodation'' means: (1) modifications or adjustments to a job application process that enable a qualified applicant with a disability to be considered for the position such qualified applicant desires; (2) modifications or adjustments to the work environment, or to the manner or circumstances under which the position held or desired is customarily performed, that enable an individual with a disability who is qualified to perform the essential functions of that position; or (3) modifications or adjustments that enable a covered entity's employee with a disability to enjoy equal benefits and privileges of employment as are enjoyed by its other similarly situated employees without disabilities.[111] A reasonable accommodation may include, but is not limited to, making existing facilities used by employees readily accessible to and usable by individuals with disabilities, job restructuring, part-time or modified work schedules, acquisition or modification of equipment, appropriate adjustment or modifications of examinations, training materials, or policies, and other similar accommodations for individuals with disabilities.[112] An employer is required to provide such reasonable accommodations, unless it ''can demonstrate that the accommodation would impose an undue hardship on the operation of the business of such covered entity.[113] Examples of reasonable accommodations may include modifying job tasks, improving accessibility in a work area, changing the presentation of tests or training materials, providing an aid or service to increase access (such as specialized computer software), providing alternative formats for feedback (such as verbally instead of in writing), or job restructuring (such as providing checklists to ensure task completion).[114]

Title II of the ADA, enforced by the U.S. Department of Justice (DOJ), prohibits discrimination on the basis of disability by State and local government entities.[115] It requires that State and local governments ensure equal access for individuals with disabilities (for example, in public education, employment, transportation, recreation, health care, social services, courts, voting, and town meetings). Additionally, DOJ's Title II regulations require public entities to ''administer services, programs, and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities.'' Appendix B to the regulation implementing Title II explains that ''the most integrated setting'' is one that ''enables individuals with disabilities to interact with nondisabled persons to the fullest extent possible.'' [116]

In 1999, in *Olmstead* v. *L.C.,* the Supreme Court issued a landmark decision that held that Title II of the ADA prohibits the unjustified segregation of individuals with disabilities.[117] The Court held that public entities are required to provide community-based services to persons with disabilities when (1) such services are appropriate; (2) the affected persons do not oppose community-based treatment; and (3) community-based services can be reasonably accommodated, taking into account the resources available to the entity and the needs of others who are receiving disability services from the entity.[118] The Court explained that this holding reflected two judgments. First, ''institutional placement of persons who can handle and benefit from community settings perpetuates unwarranted assumptions that persons so isolated are incapable or unworthy of participating in community life.'' [119] Second, ''confinement in an institution severely diminishes the everyday life activities of individuals, including family relations, social contacts, work options, economic independence, educational advancement, and cultural enrichment.'' [120]

Under Department of Justice regulations, a public entity may be found in violation of this integration mandate if it administers programs in a manner that results in unjustified segregation of persons with disabilities.[121] DOJ has explicitly recognized that a public entity may be found in violation of the ADA's integration mandate if it plans, administers, operates, funds, or implements employment services in a way that unjustifiably segregates individuals with disabilities.[122] As discussed below, DOJ has taken action to enforce the integration mandate, with broad impacts to employment opportunities for workers with disabilities.

Title III of the ADA, also enforced by DOJ, pertains to public accommodations. Under Title III, individuals with disabilities cannot be discriminated against on the basis of disability in the ''full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who owns, leases (or leases to), or operates a place of public accommodation.'' [123] Places of public accommodation may include, for example, restaurants, retail stores, hotels, movie theaters, private schools, recreational facilities, and transportation services run by private entities.

As DOJ has explained, when workers with disabilities are given access to employment opportunities pursuant to the ADA and *Olmstead* ''in the most integrated setting appropriate to their needs, they have the opportunity to live fuller lives, be more integrated into the community, and gain financial independence to 'move proudly into the

[109] 42 U.S.C. 12112(a). An individual with a disability is defined by the ADA as a person who has a physical or mental impairment that substantially limits one or more major life activities, a person who has a history or record of such an impairment, or a person who is regarded as having such an impairment. *Id.* at Sec. 12102(1). To be ''regarded as'' having such an impairment, an individual must establish that they have been subjected to a discriminatory action because of an actual or perceived physical or mental impairment, whether or not the impairment limits or is perceived to limit a major life activity. *Id.* at Sec. 12102(3).

[110] *See* 42 U.S.C. 12111.

[111] 29 CFR 1630.2(o)(1).

[112] 42 U.S.C. 12111(9).

[113] The term ''undue hardship'' means an action requiring significant difficulty or expense when considered in light of several factors set forth in the ADA statute. 42 U.S.C. 12111(10), 12112(b)(5)(A).

[114] Many workplace accommodations are no-cost or low-cost, and resources exist to help individuals with disabilities and their employers identify accommodations. *See, e.g.,* ADA National Network Fact Sheet—Reasonable Accommodations in the Workplace (2018), *https://adata.org/factsheet/reasonable-accommodations-workplace;* Job Accommodation Network (JAN), *https://askjan.org/.*

[115] 42 U.S.C. 12131, 12132.

[116] 28 CFR part 35, app. B, 703 (2023) (addressing 28 CFR 35.130(d)).

[117] *See* 527 U.S. 581, 583, 597, 602 (1999).

[118] *Id.* at 607.

[119] *Id.* at 600.

[120] *Id.* at 601.

[121] *See* 28 CFR 35.130(b)(1) (prohibiting a public entity from discriminating ''directly or through contractual, licensing or other arrangements, on the basis of disability''); 28 CFR 35.130(b)(2) (''A public entity may not deny a qualified individual with a disability the opportunity to participate in services, programs, or activities that are not separate or different, despite the existence of permissibly separate or different programs or activities.'').

[122] *See* U.S. Dep't of Justice, Civil Rights Div., ''Questions and Answers on the Application of the ADA's Integration Mandate and *Olmstead* v. *L.C.* to Employment and Day Services for People with Disabilities,'' *https://www.ada.gov/assets/pdfs/olmstead-employment-qa.pdf (''DOJ ADA Integration Mandate Q&As'').*

[123] 42 U.S.C. 12182(a).

economic mainstream of American life.' '' [124] This access fulfills the goals of the ADA to ''assure equality of opportunity, full participation, independent living, and economic self-sufficiency.'' [125] Moreover, EEOC and DOJ have explained that the ADA is fully applicable to workers with disabilities regardless of the work site or how much they are paid. For example, ''Title I's coverage can include individual service provider entities or sheltered workshops in their capacity as private employers,'' prohibiting discrimination regarding various terms and conditions of employment.[126] Additionally, DOJ has explicitly recognized that a public entity may be found in violation of the ADA's Title II integration mandate if it plans, administers, operates, funds, or implements employment services in a way that unjustifiably segregates individuals with disabilities.[127] Finally, under Title III of the ADA, individuals with disabilities cannot be discriminated against on the basis of disability in a place of public accommodation, which can include an individual service provider entity or a sheltered workshop.[128]

The legal protections for individuals with disabilities arising out of the ADA and the Supreme Court's *Olmstead* decision have profoundly impacted the rights and employment opportunities available to individuals with disabilities. This has resulted in changes to workforce development and vocational rehabilitation systems to more fully support individuals with disabilities in achieving and maintaining CIE, as discussed below. The Department's regulations implementing section 14(c) were last updated prior to the enactment of the ADA and therefore do not take into account changes to the employment landscape for individuals with disabilities in light of the fundamental anti-discrimination and reasonable accommodation protections of the ADA, or those protections as later interpreted by *Olmstead.* Although many section 14(c) certificate holders are subject to both the FLSA and the ADA,[129] the Department's current regulation addressing the section 14(c) curtailment clause did not, and could not, have taken into account the changes in employment opportunities that would arise as a result of the ADA and the plethora of legal and policy developments that have occurred as a result of this landmark legislation. For instance, the Department did not consider (and could not have considered) when it last promulgated its section 14(c) regulations how the ADA's reasonable accommodation and workplace modification requirements may affect a worker's productivity, nor did the Department consider other ADA provisions that have expanded the employment opportunities available to individuals with disabilities. Today, the Department's assessment of whether section 14(c) certificates are necessary cannot ignore the dramatic expansion of employment opportunities for individuals with disabilities.

2. Additional Federal Legislation, Executive Orders, and Regulatory Changes Expanding Opportunities for Workers With Disabilities

A wide range of other significant legislative and executive actions have had a profound impact on employment opportunities and outcomes for individuals with disabilities, particularly over the last decade. These legal and policy developments have fundamentally altered the landscape in which individuals with disabilities learn and work, beginning from their earliest educational opportunities and settings.

i. Individuals With Disabilities Education Act

In 1975, Congress passed the Education for All Handicapped Children Act (EHA), which addressed the rights and educational needs of students with disabilities. In 1990 EHA was reauthorized and retitled to the Individuals with Disabilities Education Act (IDEA).[130] IDEA provides funding to States, which must provide early intervention services and a free appropriate public education to eligible infants, toddlers, and children with disabilities.[131] IDEA states that ''[a]lmost 30 years of research and experience has demonstrated that the education of children with disabilities can be made more effective by having high expectations for such children and ensuring their access to the general education curriculum in the regular classroom, to the maximum extent possible . . . .'' [132] IDEA further states that this focus on high expectations and inclusion is intended to meet developmental goals and challenging expectations, and, as particularly relevant here, that students with disabilities are ''prepared to lead productive and independent adult lives, to the maximum extent possible.'' [133] Notably, the 1990 reauthorization also mandated that as a part of a student's individualized education program (IEP), an individual transition plan must be developed to help each student transition to post-secondary life, including employment opportunities.[134] Subsequent guidance has been released about the benefits of inclusion, for example, in 2015, the U.S. Department of Health and Human Services (HHS) and U.S. Department of Education issued a joint policy statement about the importance of the inclusion of children with disabilities in early childhood programs. The Departments updated and reiterated the statement in 2023.[135] For nearly 50 years, children with disabilities have benefited from increased access to high-quality education from early childhood to high school, providing them with better

[124] *See* DOJ ADA Integration Mandate Q&As, *https://www.ada.gov/assets/pdfs/olmstead-employment-qa.pdf* (quoting President George H.W. Bush, Remarks at the Signing of the Americans with Disabilities Act, July 26, 1990, *https://perma.cc/VNU4-HR7P*).

[125] *See* 42 U.S.C. 12101(a)(7); *see also* DOJ ADA Integration Mandate Q&As.

[126] *Id.; see also* 42 U.S.C. 12112(a).

[127] *See* DOJ ADA Integration Mandate Q&As.

[128] *Id.; see also* 42 U.S.C. 12181(7)(K).

[129] The Department notes that holding a section 14(c) certificate does not protect an employer from charges pursuant to the ADA, *see* FOH 64a02(c).

[130] Educ. of the Handicapped Act Amendments of 1990, Public Law 101–476, 104 Stat. 1103 (1990) (codified at 20 U.S.C. 1400). Subsequent reauthorizations included reauthorizations in 1997 and 2004.

[131] *See* 20 U.S.C. 1400 *et seq.* and U.S. Department of Education, ''About IDEA,'' *https://sites.ed.gov/idea/about-idea* (recording that early intervention, special education, and related services were provided to more than 8 million eligible infants, toddlers, children, and youth with disabilities in school year 2022–2023).

[132] 20 U.S.C. 1400(c)(5). A multitude of studies and academic literature have concluded that students with disabilities make more progress when educated in integrated, rather than segregated, settings. *See, e.g.,* Meghan Cosier, Julie Causton-Theoharis, & George Theoharis, ''Does access matter? Time in general education and achievement for students with disabilities,'' Remedial and Special Educ. 34(6)(2013), at 323–332; Rachel Sermier Dessemontet, Gerard Bless, & D. Morin. ''Effects of inclusion on the academic achievement and adaptive behaviour of children with intellectual disabilities,'' Journal of Intellectual Disability Research 56(6) (2012) at 579–587.

[133] 20 U.S.C. 1400(c)(5)(A)(ii).

[134] The term ''individualized education program'' (IEP) means a written statement for each child with a disability that is developed, reviewed, and revised in accordance with 20 U.S.C. 1414(d). *See* 20 U.S.C. 1401(14); *see also* 34 CFR 300.320.

[135] *See* U.S. Dep't of Health and Human Services and U.S. Dep't of Education, ''Policy Statement on Inclusion of Children with Disabilities in Early Childhood Programs,'' November 28, 2023, *https://sites.ed.gov/idea/idea-files/policy-statement-inclusion-of-children-with-disabilities-in-early-childhood-; see also Endrew F.* v. *Douglas County School Dist.,* 580 U.S. 386, 399 (2017) (affirming the promise of IDEA and holding that in order ''[t]o meet its substantive obligation under the IDEA, a school must offer an IEP reasonably calculated to enable a child to make progress appropriate in light of the child's circumstances.'')

preparation for employment than past generations of students with disabilities.

As educational reforms took hold, competitive integrated employment became the goal of many youths with disabilities, including those with I/DD. The groundbreaking National Longitudinal Transition Study-2 (NLTS2), funded by the U.S. Department of Education and published in 2005, identified a strong desire among youth with disabilities to participate in competitive employment. Specifically, the NLTS2 found that among the 70 percent of secondary school students with disabilities who identified employment as a goal for the post-school years, 62 percent had a goal to work in competitive employment, while only 3 percent wished to work in ''sheltered'' employment.[136] As indicated in the NLTS2, students generally preferred competitive employment rather than employment at a sheltered workshop regardless of the type of disability experienced.[137]

ii. Workforce Innovation and Opportunity Act

In 2014, WIOA,[138] a comprehensive Federal law enacted to improve workforce development and training services for workers and jobseekers, including various groups such as youth and workers with disabilities, amended the Rehabilitation Act to add section 511.[139] Section 511 of the Rehabilitation Act limits the ability of employers to pay subminimum wages to workers with disabilities, even when the employer holds a section 14(c) certificate. Section 511 requires that individuals with disabilities who are age 24 or younger complete requirements designed to enable the individual to explore, discover, experience, and attain CIE, including receiving pre-employment transition services under the Vocational Rehabilitation program or transition services under IDEA (to the extent either of those services are available to the individual with a disability), applying for vocational rehabilitation services, and receiving career counseling and information and referral services, before they are employed at subminimum wages. Section 511 also requires that all workers with disabilities who are paid subminimum wages, of any age, receive regular career counseling, information and referrals, and information about self-advocacy, self-determination, and peer mentoring training opportunities in their local area once every 6 months for the first year of subminimum wage employment and annually thereafter.[140] Section 511 was intended to help stop the pipeline by which youth with disabilities were going straight from school to subminimum wage employment.[141] This provision was also enacted to ensure that workers with disabilities who are currently paid subminimum wages are regularly provided with counseling and information about supports and resources available to them in their locality that may support them in obtaining CIE.[142]

iii. Achieving a Better Life Experience Act

In further support of competitive employment for workers with disabilities, in 2014, Congress enacted the Achieving a Better Life Experience Act (ABLE Act), which allows individuals with disabilities to establish tax-advantaged savings accounts, subject to certain restrictions, without jeopardizing access to public benefits. ABLE accounts allow individuals with disabilities to maintain resources and save for expenses while maintaining eligibility for critical public benefits such as Medicaid and other means-tested programs. In 2020, the Internal Revenue Service (IRS) released final ABLE regulations.[143] The regulations noted that in enacting the ABLE Act, ''Congress recognized the special financial burdens borne by families raising children with disabilities and the fact that increased financial needs generally continue throughout the lifetime of an individual with a disability.'' [144] Legislation such as the ABLE Act facilitates workers' transitions from subminimum wage jobs to jobs paying competitive wages because workers now are able to save more without jeopardizing access to means-tested public benefits such as health care.[145]

iv. Executive Orders 13658 and 14026

In 2014 and 2021 respectively, Executive Orders 13658 and 14026 directed federal agencies to contract only with entities willing to pay an hourly minimum wage (raised by Executive Order 14026) for workers performing on or in connection with covered Federal construction and service contracts.[146] Workers covered by the Executive Orders, and due the full applicable Executive Order minimum wage rates, include workers with disabilities whose wages are calculated pursuant to section 14(c) certificates.[147] Executive Order 13658 stated that ''raising the pay of low-wage workers increases their morale and the productivity and quality of their work'' and explicitly stated that the Order applies to workers whose wages are calculated pursuant to section 14(c).[148]

[136] Mary Wagner, Lynn Newman, Renee Cameto, Nicolle Garza, & Phyllis Levine, ''After High School: A First Look at the Postschool Experiences of Youth with Disabilities. A Report from the National Longitudinal Transition Study–2 (NLTS2),'' SRI International, April 2005, pp. 5–3 to 5–4, *www.nlts2.org/reports/2005_04/nlts2_report_2005_04_complete.pdf.*

[137] *Id.*

[138] 29 U.S.C. 794g; *also see https://www.congress.gov/113/bills/hr803/BILLS-113hr803enr.pdf.*

[139] The Rehabilitation Act was the first Federal legislation to address access and equity for individuals with disabilities. This Act promoted successful employment outcomes by requiring that programs receiving Federal financial assistance operate without discrimination on the basis of disability. The Rehabilitation Act develops and implements comprehensive and coordinated programs of vocational rehabilitation for individuals with disabilities to maximize their employability, independence, and integration into the workplace. *See* 29 U.S.C. 701.

[140] 34 CFR part 397.

[141] Section 113 of the Rehabilitation Act described a specific set of services, Pre-employment transition services, that are intended to improve and expand vocational rehabilitation services for students with disabilities, facilitating their transition from educational services to postsecondary life. *See* 29 U.S.C. 733 and 34 CFR 361.65(a)(3). At least 15 percent of each State's federal funding allotment for vocational rehabilitation services must be reserved for Pre-employment transition services. *See* 29 U.S.C. 730(d)(1). Through these provisions, the Rehabilitation Act and its regulations emphasized the provision of Pre-employment transition services to students with disabilities, providing new opportunities for them to explore careers and receive the training and supports to increase the likelihood of achieving CIE. *See* 34 CFR 361.48.

[142] 29 U.S.C. 794g; 34 CFR part 397. Additionally, throughout WIOA, there are multiple references to ensuring that people with disabilities have access to the training providers and services and supports needed to succeed in CIE. Other sections of WIOA provide funding to States in order to develop programs that support workers with disabilities.

[143] *See* Guidance Under Section 529A: Qualified ABLE Programs, 85 FR 74010 (Nov. 19, 2020).

[144] 85 FR 74010.

[145] ''The ABLE Act states that funds in an ABLE account will not affect eligibility for federally-funded, means-tested benefits such as SSI and Medicaid.'' *See* ABLE National Resource Center, *https://www.ablenrc.org/what-is-able/debunking-able-myths/.*

[146] On April 27, 2021, President Joseph R. Biden, Jr. issued Executive Order 14026, ''Increasing the Minimum Wage for Federal Contractors.'' 86 FR 22835. The order builds on the foundation established by Executive Order 13658, ''Establishing a Minimum Wage for Contractors,'' signed by President Barack Obama on February 12, 2014. *See* 79 FR 9851. The Department notes that, at the time of the drafting of this NPRM, there are several pending lawsuits challenging the President's authority to have issued Executive Order 14026. Such cases are not discussed herein because they are beyond the scope of this proposed rule, which simply highlights the issuance of the Executive Order as an example of the profound legal and policy developments that have impacted individuals with disabilities in recent decades.

[147] *See* 86 FR at 22835; 79 FR at 9851.

[148] 79 FR 9851, Executive Order 13658, ''Establishing a Minimum Wage for Contractors,'' February 12, 2014, *https://*

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Executive Order 14026 similarly extended the full Executive Order minimum wage to workers with disabilities performing on or in connection with covered Federal contracts, stating, among other benefits, that raising the minimum wage has the effects of ''boosting workers' health, morale, and effort.'' [149]

v. Home and Community-Based Services ''Settings Rule''

In addition to legislative and presidential action, other Federal agencies have also promulgated regulations consistent with expanding CIE opportunities for workers with disabilities. For example, in 2014, HHS's Centers for Medicare and Medicaid Services (CMS) issued the Home and Community Based Settings (HCBS) ''Settings Rule'' that focused on various aspects of residential and employment settings for individuals with disabilities. The rule emphasized that individuals have free choice of providers for services in their service plan, including employment services.[150] These regulations further stipulate that the ''setting is integrated in and supports full access of individuals receiving Medicaid HCBS to the greater community, including opportunities to seek employment and work in competitive integrated settings . . . to the same degree of access as individuals not receiving Medicaid HCBS.'' [151]

vi. U.S. AbilityOne Commission 2022 Final Rule

The AbilityOne Program provides the Federal Government with services and products procured through a nationwide network of approximately 450 non-profit entities that employ individuals who are blind or have significant disabilities.[152] In 2022, the U.S. AbilityOne Commission (Commission) issued a final rule prohibiting the payment of subminimum wages under section 14(c) to employees on contracts within the AbilityOne Program.[153] The 2022 AbilityOne final rule adds a new requirement for non-profit agencies that seek both initial and continuing qualification to participate in the AbilityOne Program: namely, such agencies must certify that, when paying workers on AbilityOne contracts, they will not use section 14(c) certificates. In its 2022 final rule, the Commission states that ''ending wage disparities between employees based solely on disability places the economic power of individuals with disabilities on par with their work colleagues who do not have disabilities and paying the same wage to individuals with disabilities and those without conveys a message of equality and a commitment to inclusion.'' [154] The Commission explained that ending the payment of subminimum or sub-prevailing wages on AbilityOne contracts was designed to help break cycles of poverty and dependence for workers with disabilities, and instead shift the focus on assisting workers with disabilities to move to careers of meaningful employment.[155] The Commission further explained that societal expectations of people with disabilities had changed and that the availability of reasonable accommodations and employment supports had significantly changed the employment landscape for workers with disabilities.[156] The final rule was published on July 21, 2022, and took effect 90 days later on October 19, 2022. Nonprofit agencies seeking qualification to participate in the AbilityOne program were allowed to apply for a single extension of up to 12 months if they provided required support for the need of the extension and a corrective action plan detailing how they planned to achieve compliance during the requested extension period.

As of September 30, 2023, no employee on an AbilityOne contract was being paid a subminimum wage.[157] AbilityOne's final rule prohibiting the payment of subminimum wages marked a noteworthy step away from the use of subminimum wage certificates.

In sum, legislation, judicial precedent, and regulatory initiatives have fundamentally and profoundly altered the rights, protections, access, and opportunities available to individuals with disabilities. These evolving changes to the employment landscape have dramatically altered access to employment opportunities and available supports for workers with disabilities.

vii. Strategies, Initiatives, and Resources Focused on Increasing Competitive Integrated Employment Opportunities

Alongside these legislative, executive, and judicial developments clarifying and expanding the rights and opportunities of individuals with disabilities, virtually all of which occurred after Congress last amended section 14(c) and the Department last substantively updated the section 14(c) regulations, a number of strategies focused on increasing CIE have also emerged. The proliferation of resources and strategies to increase CIE since 1989 demonstrates to the Department that there are numerous alternatives to subminimum wage employment, as well as many additional pathways to employment at or above the full Federal minimum wage for individuals with disabilities. The diversity of available supports, services, and strategies to facilitate the attainment of CIE for workers with disabilities indicates that subminimum wages are no longer a strategy that is necessary to prevent curtailment of opportunities for employment for these workers. One example is Employment First, which is a national framework centered on the premise that all individuals, including those individuals with the most significant disabilities, are capable of full participation in CIE and community life.[158] Under Employment First, public systems and States are urged to align policies, regulatory guidance, and reimbursement structures to commit to CIE as the priority option with respect to the use of publicly-financed day and employment services for youth and adults with significant disabilities.[159] Many States have formally committed to the Employment First framework through official executive proclamation or formal legislative action.[160] The Association of People Supporting Employment First (APSE) website reports that, to date, every State has taken some Employment First action, with 31 States having passed Employment First legislation, 16 States having issued Employment First executive orders, and 32 States having administrative policies and/or

obamawhitehouse.archives.gov/the-press-office/2014/02/12/executive-order-minimum-wage-contractors.

[149] 86 FR at 22835.

[150] 79 FR 2948 (Jan. 16, 2014).

[151] 42 CFR 441.530(a)(1)(i).

[152] *See* AbilityOne Program, FAQs, *https://www.abilityone.gov/abilityone_program/faqs.html#1.*

[153] 87 FR 43427 (July 21, 2022).

[154] 87 FR 43428–43429.

[155] 87 FR 43428.

[156] 87 FR 43429.

[157] *See* U.S. AbilityOne Commission, ''Fiscal Year 2023 Performance and Accountability Report,'' at 95, *https://www.abilityone.gov/commission/performance.html.* In fiscal year 2022, approximately 36,000 people who are blind or have significant disabilities were employed through the AbilityOne program. *Id.* at 7.

[158] U.S. Dep't of Labor, Office of Disability Emp't Policy, ''Employment First,'' *https://www.dol.gov/agencies/odep/initiatives/employment-first.*

[159] *Id.* There are multiple additional initiatives that have developed from Employment First, including the National Expansion of Employment Opportunities Network (NEON) and the Advancing State Policy Integration for Recovery and Employment (ASPIRE) initiatives.

[160] *Id.*

regulations in place in support of the Employment First framework.[161]

The methods of assisting individuals to obtain and maintain competitive employment have evolved over the past several decades, further enhancing these CIE programs. For example, research shows that the development of supported employment, the Individual Placements and Supports (IPS) model, and customized employment methodologies have been used to successfully implement CIE for workers with disabilities.[162] Specifically, the IPS model is designed to assist individuals with serious mental health conditions and involves a multi-disciplinary team that employs eight strategies: competitive employment, systematic job development, rapid job search, integrated services, benefits planning, time-limited supports, worker preferences, and zero exclusion of participants.[163] This coordination of medical care and supported employment has been described as a standardization of evidence-based supported employment.[164]

The Department of Labor's Office of Disability Employment Policy (ODEP), established in 2001, led the research that built evidence for customized employment, ''a process for achieving competitive integrated employment or self-employment through a relationship between employee and employer that is personalized to meet the needs of both.'' [165] Customized employment tailors job tasks to fit the individual who will be performing the work, and this strategy has been shown to be particularly beneficial for people with disabilities who might not have been successful in CIE using other training and employment strategies. In 2014, customized employment was included in Title IV of the WIOA as a strategy under the definition of supported employment.

Finding these methodologies effective, various Federal agencies have adopted them, and funded their use, through their programs and initiatives. For example, supported employment was added to the Rehabilitation Act in 1986 to help more workers with disabilities obtain employment. Customized employment emerged first through grant programs beginning in 2001 and was added to WIOA in 2014. The development and implementation of these strategies for successful CIE align with the emergence of the social model of disability as well as with person-centered planning. Strategies consistent with the social model of disability that decrease barriers and increase access to opportunities and focus on the individual needs of each worker have created new pathways for workers with disabilities to find, and maintain, the right jobs for them.

ODEP has also led several initiatives focused on promoting CIE and aiding States and service providers in implementing CIE strategies. For example, the Campaign for Disability Employment, an ODEP-funded outreach effort, showcases supportive, inclusive workplaces for all workers and brings together several leading disability and business organizations convened by ODEP to work together to address disability employment, demonstrating the increased collaboration among employers to advance employment options for workers with disabilities.[166] The Disability Employment Initiative (DEI), funded by ODEP and the Department's Employment and Training Administration, awarded more than $123 million through the initiative to 49 projects in the public workforce system in 28 States to improve education, training, and employment outcomes of youth and adults with disabilities.[167]

In addition, through the Employment First State Leadership Mentoring Program, ODEP supported 24 States in their strategic efforts to increase CIE for individuals with disabilities, including those with significant disabilities.[168] ODEP has also established the National Expansion of Employment Opportunities Network (NEON) to collaborate with CRPs to extend CIE for the people they serve through provider transformation. ODEP explains that this process ''realigns'' disability service provider agencies' business models ''from providing work opportunities in segregated settings or at subminimum wages to providing CIE for people with disabilities.'' [169] This robust level of programming and State participation allows the refocusing of many State resources from programs relying on the payment of subminimum wages to workers with disabilities to programs that support CIE opportunities. In 2012, ODEP began and actively maintains an Employment First Community of Practice (COP) of nearly 3,000 State agency and service provider professionals, researchers, policy makers, workers and family members, and Federal officials. The COP shares CIE challenges and solutions, resources, events, and successes. In March 2024, ODEP launched an online CIE Transformation Hub of practical Federal resources that support CIE organized by target audience—individuals with disabilities and family members, employment service providers, State agencies, and employers.[170]

Since 2021, the U.S. Department of Education's Rehabilitation Services Administration (RSA),[171] has administered demonstration programs with discretionary grants through the Disability Innovation Fund (DIF) to support innovative activities aimed at increasing CIE.[172] In 2022, RSA made DIF awards to 14 vocational rehabilitation agencies to, as the Department of Education has explained, ''decrease the use of subminimum wages and increase access to competitive integrated employment for people with disabilities.'' [173] In recent

[161] *See https://apse.org/home-v2-2/employment-first/* for a state-by-state summary. As of June 2024, all 50 States (as well as the District of Columbia) are listed on this website, with Idaho having taken Employment First action other than legislation, executive order, or administrative policies/regulations. Many States ''have a combination of legislation, Executive action and/or State Agency policy in place.'' *Id.*

[162] *See, e.g.,* Joonas Poutanen, Matti Joensuu, Kirsi Unkila & Piurjo Juvonen-Posti, ''Sustainable employability in Supported Employment and IPS interventions in the context of the characteristics of work and perspectives of the employers: a scoping review protocol,'' BMJ Open 12(6) (June 17, 2022), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9207909/* (''The sustainable employment outcomes and cost-effectiveness of SE and IPS have been well reported.'').

[163] *See https://ipsworks.org/index.php/what-is-ips/.*

[164] *See* Gary R. Bond, Robert E. Drake & Deborah R. Becker, ''An update on randomized controlled trials of evidence-based supported employment.'' Psychiatric Rehabilitation Journal, 31(4) (April 2008), 280–290, *https://doi.org/10.2975/31.4.2008.280.290.*

[165] *See* U.S. Dep't of Labor, Office of Disability Emp't Policy, ''Customized Employment,'' *https://www.dol.gov/agencies/odep/program-areas/customized-employment.*

[166] U.S. Dep't of Labor, Office of Disability Emp't Policy *https://www.dol.gov/agencies/odep/initiatives/campaign-for-disability-employment.*

[167] U.S. Dep't of Labor, Office of Disability Emp't Policy *https://www.dol.gov/newsroom/releases/odep/odep20160914.*

[168] *See supra* note 159.

[169] *See* U.S. Dep't of Labor, Office of Disability Emp't Policy, ''National Expansion of Employment Opportunities Network (NEON),'' *https://www.dol.gov/agencies/odep/initiatives/neon.*

[170] U.S. Dep't of Labor, Office of Disability Emp't Policy, *https://www.dol.gov/agencies/odep/program-areas/cie/hub.*

[171] To assist individuals with disabilities in the pursuit of gainful employment, RSA administers and manages programs that assist individuals with disabilities to achieve employment outcomes. One of these programs, the State Vocational Rehabilitation Services Program, provides State formula grant programs to vocational rehabilitation (VR) agencies providing a wide variety of services to individuals with significant disabilities, including individuals with the most significant disabilities.

[172] *See* Consolidated Appropriations Act, Public Law 117–103, 136 Stat. 49, 479 (2022).

[173] U.S. Dep't of Educ., ''Education Department Awards $177 Million in New Grants to Increase Competitive Integrated Employment for People with Disabilities,'' *https://www.ed.gov/news/press-*

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years, DIF grant projects have focused on improving the outcomes of individuals with disabilities through, for example, (1) career advancement programs, (2) transition from subminimum wage to CIE programs, and (3) ''pathways to partnerships programs'' that seek to support projects that foster the establishment of close ties among agencies—such as State vocational rehabilitation agencies, State educational agencies, local educational agencies, and federally funded Centers for Independent Living—to actively collaborate to support coordinated transition processes for children and youth with disabilities.[174] These 5-year grants are awarded to States as cooperative agreements to support innovative activities aimed at increasing CIE for youth and other individuals with disabilities.[175]

A landmark agreement in Oregon, the *Lane* v. *Brown* settlement agreement, illustrates some of this legal, legislative, and policy progression. In 2012, a class action complaint was filed in district court on behalf of individuals with I/DD alleging that by unnecessarily segregating them and other similar individuals with I/DD in sheltered workshops receiving public funds, Oregon was in violation of Title II of the ADA and section 504 of the Rehabilitation Act.[176] DOJ intervened in the lawsuit as a plaintiff, and a statewide settlement agreement was signed in 2015 requiring, among other things, that Oregon decrease State support of sheltered workshops for individuals with I/DD and expand access to supported employment services that allow the opportunity to work in CIE settings. As a result, Oregon implemented a number of competitive and supported employment strategies to support individuals with disabilities in the State, including training for school districts and those providing support services, new grants, reallocation of funding and technical assistance to support CIE.[177] These strategies accelerated the transition for workers with disabilities from employment under the prior sheltered workshop model to a CIE model within the State, ultimately ending the payment of subminimum wages to workers with disabilities in Oregon. In 2016, the year that this settlement was reached and approved by the court, there were 1,405 people working in sheltered workshops in Oregon.[178] Through this transition, Oregon placed 1,138 individuals from the class who had previously worked for subminimum wages into CIE, exceeding the targets set by the consent judgment. Additionally, by September 2020, all sheltered workshops except one had converted to providing supported, full-wage employment opportunities.[179]

In sum, a wide range of resources and programs have emerged in recent years that are focused on increasing competitive integrated employment. These supports and services assist workers in obtaining and maintaining employment at or above the full Federal minimum wage and also assist employers in transitioning their business models to integrated workplaces where the minimum wage is paid to all workers. Today, subminimum wage employment under section 14(c) certificates is no longer the most common form of employment for individuals with disabilities, including individuals with I/DD. As the number of workers being paid subminimum wages under section 14(c) certificates continues to shrink, the numbers of workers with disabilities, including workers with I/DD, working in integrated settings for full wages continues to grow.[180]

C. Third Party Reports Regarding Section 14(c)

In the context of the changes that have taken place over the past several decades in opportunities for employment for individuals with disabilities, both public and private entities (including from the nonprofit, academic, and business sectors) have published relevant reports and statements regarding subminimum wage employment. Though, as discussed below, some organizations remain in strong support of the continuation of section 14(c) certificate issuance, many of these reports, from governmental and non-governmental organizations alike, have compiled substantial evidence that subminimum wages are no longer a necessary method of providing employment opportunities to individuals with disabilities. In this subsection, the Department reviews key aspects of these reports, which represent the culmination of years of findings and conclusions, most of which provide support for the Department's proposal to end the issuance of section 14(c) certificates.

1. Government Oversight Reports

In recent years,[181] a number of Federal government agencies and committees have studied the payment of subminimum wages to workers with disabilities and generated oversight reports. These agencies and committees brought together a wide range of individuals from across government and the non-profit and business sectors to share their expertise and experience regarding the payment of subminimum wages to workers with disabilities and corresponding models of employment. In general, these oversight entities have sharply criticized the continued payment of subminimum wages as an outdated method to support workers with disabilities and reflect a broad consensus that subminimum wages are not necessary to provide opportunities for employment of individuals with disabilities, including opportunities for individuals with I/DD Accordingly, many recommend that a phase out of section 14(c) certificates should begin immediately. The Department notes that

releases/education-department-awards-177-million-new-grants-increase-competitive-employment-people-disabilities.

[174] U.S. Dep't of Educ., Rehabilitation Services Administration (RSA), ''RSA Programs,'' *https://rsa.ed.gov/about/programs.*

[175] *See* 29 U.S.C. 705(5); *see also* Dep't of Educ., RSA, ''Disability Innovation Fund,'' *https://rsa.ed.gov/about/programs/disability-innovation-fund-pathways-to-partnerships.*

[176] The Department notes that, on May 9, 2024, HHS published a final rule which modernized and strengthened the implementing regulations for section 504 of the Rehabilitation Act, which prohibits discrimination on the basis of disability in programs and activities that receive Federal financial assistance. *See* 89 FR 40066 (May 9, 2024). The rule, among other things, clarifies obligations to provide services in the most integrated setting, appropriate to the needs of individuals with disabilities, and updates existing requirements to make them consistent with the ADA. *See* HHS, Section 504 of the Rehabilitation Act of 1973 Part 84 Final Rule: Fact Sheet, *https://www.hhs.gov/civil-rights/for-individuals/disability/section-504-rehabilitation-act-of-1973/part-84-final-rule-fact-sheet/index.html.* Section 84.76 of HHS's updated section 504 regulations specifically requires all recipients of Federal financial assistance from HHS to administer their programs and activities in the most integrated setting appropriate to the needs of a qualified person with a disability. *See* 45 CFR 84.76; 89 FR 40066, 40117.

[177] Oregon Dep't of Human Services, ''*Lane* v. *Brown* Settlement Agreement Report,'' *https://www.oregon.gov/odhs/employment-first/Documents/lane-v-brown-settlement-message-2022-06-21.pdf.*

[178] *Id.*

[179] *See* Disability Employment TA Center, The Components of Integrated Employment Service Systems, p.11 (July 2022), *https://aoddisabilityemploymenttacenter.com/wp-content/uploads/2022/07/Components-of-Integrated-Employment-Part-II-FINAL-Final.pdf.* In addition to the Oregon settlement, in 2014, DOJ entered into a statewide settlement agreement in Rhode Island to resolve violations of the ADA for approximately 3,250 Rhode Islanders with I/DD. *See* U.S. Dep't of Justice, ''Department of Justice Reaches Landmark Americans With Disabilities Act Settlement Agreement With Rhode Island,'' April 8, 2014, *https://www.justice.gov/usao-ri/pr/department-justice-reaches-landmark-americans-disabilities-act-settlement-agreement-rhode.*

[180] *See* discussion in section III.A.

[181] This section is not an exhaustive listing of all such Federal government oversight reports relating to individuals with disabilities, but rather focuses on recent reports that specifically consider the role of section 14(c) and subminimum wages in the employment of those individuals.

there are no equivalent government oversight reports that favor the continued issuance of section 14(c) certificates (at least beyond a phaseout period). The Department welcomes comments on its analysis of the selected reports discussed in this proposed rule as well as comments on any other reports relevant to whether the continued issuance of section 14(c) certificates is necessary to prevent the curtailment of employment opportunities for individuals with disabilities.

i. U.S. Commission on Civil Rights Report on Subminimum Wages

The USCCR is an independent, bipartisan, fact-finding Federal agency established in part to study discrimination or denial of equal protection by reason of race, color, religion, sex, age, disability, or national origin. In 2020, the USCCR issued a comprehensive 349-page report entitled ''Subminimum Wages: Impacts on the Civil Rights of People with Disabilities'' (USCCR Report).[182] The USCCR concluded that payment of subminimum wages should be eliminated through a planned phaseout period that allows for the transition among service providers and individuals with disabilities.[183] In making this recommendation, the USCCR emphasized its finding that ''[p]eople with intellectual and developmental disabilities who are currently earning subminimum wages under the 14(c) program are not categorically different in level of disability from people with intellectual and developmental disabilities currently working in competitive integrated employment.'' [184] Especially given the comprehensive nature of the USCCR report, the Department gives weight to the report's key factual findings and recommendations in proposing to phase out issuance of section 14(c) certificates.

To generate the report, the USCCR collected data, reports, and testimony from ''Members of Congress, Labor and Justice Department officials, self-advocates and workers with disabilities, family members of people with disabilities, service providers, current and former public officials, and experts on disability employment and data analysis;'' received thousands of public comments both in favor of and in opposition to the use of section 14(c) certificates; held a public hearing; and conducted in-person visits to both full-wage and subminimum wage worksites.[185]

During the USCCR's hearings, they heard testimony from employers who provided insight into the impact of phasing out subminimum wages on their operations. For example, the USCCR heard from some employers who had transitioned away from the use of subminimum wages that, based on their experiences, section 14(c) certificates were no longer necessary to prevent curtailment of employment opportunities for individuals with disabilities. The Chief Executive Officer (CEO) of Melwood, a non-profit organization that transitioned their employees to at least the full minimum wage in 2013 and withdrew its section 14(c) certificate in 2016, testified that phasing out subminimum wages had positively impacted Melwood's operations, resulting in higher morale and productivity, and contributed to its ongoing successes.[186] Additionally, the CEO reflected on what she believed were the negative impacts of using section 14(c) certificates, testifying that ''time trials caused our employees to feel extremely anxious and stressed, as employees knew that their performance could reduce their wages and harm their ability to live happy independent lives,'' and that ''the average employee lost five hours of productive time as a result of each time trial, not including the loss of productivity due to the anxiety distraction.'' [187] The USCCR also spoke with employers who employed individuals with I/DD but who had never held a section 14(c) certificate, and those employers spoke positively of their experiences.[188]

The USCCR also collected extensive testimony from, among others, individuals with I/DD and their family members, current and former section 14(c) certificate holders, and employers of individuals with I/DD. The USCCR found that ''[p]ersons with disabilities who have transitioned out of 14(c) workshops were adamantly against the program.'' [189] For example, the USCCR interviewed a worker in Vermont who, after that State eliminated the payment of subminimum wages, had transitioned to working in integrated employment, where he received more than minimum wage and had opportunities for advancement.[190] Reflecting on his previous experiences working for subminimum wages pursuant to a section 14(c) certificate, the worker explained that he believed that his former employer had been ''using'' his disability ''against'' him, and that he would ''do more and get less than everyone else.'' [191]

As another key part of its review, the USCCR conducted intensive case studies of three States that, at the time of the report's publication, still permitted payment of subminimum wages (Virginia, Arizona, and Missouri), and compared those States to three States that had taken steps to eliminate subminimum wages (Vermont, Maine, and Oregon). In general, the USCCR's case studies detailed many successful transitions from subminimum wages to full wages. In terms of data regarding employment outcomes in those States, the USCCR noted both the complexity and insufficiency of available statistics. Summarizing its analysis of state-level employment data collected from those six States in 2016 and 2017, the USCCR explained that ''contrary to the popular belief that ending subminimum wages will lead to job losses, the eradication of subminimum wages correlates with increased employment for people with disabilities'' in certain States.[192] The USCCR expressly noted, however, that ''importing these data over a wider range of states shows even more complexity.'' [193] Recognizing that the results of the then-existing data regarding impact of state-level legislation prohibiting subminimum wages was ''mixed,'' the USCCR concluded that ''[t]he success of states like Oregon and Vermont show that there is a path forward[ ]; moreover, even concerned family members in those states eventually embraced a supported transition from 14(c) to competitive integrated employment.'' [194]

In addition to receiving comments urging the elimination of subminimum wages, however, the USCCR also noted that ''the majority of the public

[182] USCCR Report. The U.S. Commission on Civil Rights was established by Congress in 1957 and submits reports and recommendations to the President and Congress based upon their studies. Two members dissented from the conclusions of the 2020 report.

[183] *Id.* at 223.

[184] *Id.* at 221.

[185] *Id.* at i.

[186] USCCR Report at 50–51.

[187] *Id.* at 50.

[188] In a briefing to the USCCR, for example, Microsoft explained that, since 2013, its Supported Employment Program had placed over 280 individuals with I/DD in full-wage jobs at Microsoft. *Id.* at 48 (*citing* Brian Collins, briefing transcript at 272–73 and 274–75). Microsoft observed that employing workers with I/DD had added strength to the company because those workers tended to be longer-term employees (thus reducing recruitment, turnover, and onboarding costs) and tended to challenge the status quo and teach colleagues about ''communication, inclusion, and empathy.'' *Id.* at 49.

[189] *Id.* at xi.

[190] *Id.* at 198.

[191] *Id.*

[192] *Id.* at 143–45.

[193] *Id.*

[194] *Id.* at 217.

comments the Commission received were from parents who support the continued operation of 14(c) workshops unchanged.'' [195] These public comments included ''family members of persons with disabilities working in 14(c) workshops . . . who stated it was their 'CHOICE' to work there and that they were against elimination of the 14(c) program.'' As one family member of a person with a disability wrote to the USCCR, ''We are NOT concerned with lower pay. We ARE concerned that the rights of our family member to work in a fulfilling, safe, stable job where he enjoys being part of a community is at risk due to the wage debate'' (emphasis in original).[196]

The USCCR also found several other notable aspects of subminimum wage employment. In a chapter of its Report, the USCCR broadly reviewed the roles of different government agencies in relationship to section 14(c). The USCCR detailed the extensive use of public funds to support existing sheltered workshops. Among other key points, the USCCR found that some States have used HHS and Medicaid funding to fund worker supports necessary for those workers to access employment at the full minimum wage; this same funding is frequently used to fund non-profit employers who use section 14(c) certificates in other States.[197] In other words, in some instances, funds could be shifted from supporting subminimum wage employment to supporting full-wage employment. Of note, the USCCR stated that transition away from subminimum wages could be ''aided by the provision of accommodations such as a job coach, peer support, or specialized training or other supports that allow persons with disabilities to effectively work in integrated settings,'' and that funds once used to fund employment under section 14(c) certificates (such as at CRPs) could be redirected to these purposes.[198] The USCCR explained that ''[s]tate-level phase outs of the use of the 14(c) program have been developed and designed for State service providers and other stakeholders to ensure that a competitive integrated employment model does not result in a loss of critical services to individuals with disabilities including former 14(c) program participants.'' [199]

As part of its review, the USCCR collected and analyzed data about the use of section 14(c) certificates. Summarizing this analysis, the USCCR concluded that ''the Department of Labor's enforcement data as well as several key civil rights cases and testimony from experts show that with regard to wage disparities, the program is rife with abuse and difficult to administer without harming employees with disabilities, as reflected in over 80 percent of cases investigated.'' [200] The USCCR based this finding in part on WHD enforcement data that, as discussed above, shows that WHD investigations of section 14(c) certificate holders reveal high rates of FLSA violations. The USCCR made no analysis of or conclusions about the types or severity of violations found in WHD investigations. However, the USCCR highlighted a well-documented case involving egregious civil rights abuses connected to an employer who had formerly held a section 14(c) certificate, the *Hill Country Farms* case.[201] In that case, both the Department and the EEOC successfully recovered substantial damages for the workers based on, respectively, the employer's willful violations of the FLSA and the employer's severe abuse and discrimination in violation of the ADA.[202] In addition to highlighting the ''disability-based harassment, discrimination and abuse'' experienced by these workers, the USSCR commented that ''[t]his case does not directly address whether 14(c)'s permitting payment of subminimum wages violates the ADA, but it does illustrate that Title I ADA violations are possible under those circumstances.'' [203]

In sum, the USCCR's qualitative and quantitative study of the use and cessation of section 14(c) certificates—encompassing employer, worker, family, government, and expert perspectives—substantially aided the Department's review of whether section 14(c) certificates are still necessary to prevent curtailment of employment opportunities for workers with disabilities. Furthermore, given this body of evidence, the Department finds the USCCR's conclusion that subminimum wages are no longer necessary to be compelling.

ii. National Council on Disability Reports Relevant to Payments of Subminimum Wages

The National Council on Disability (NCD) is an independent Federal agency charged with advising Congress, the President, and other entities on policy related to people with disabilities. NCD has issued several reports related to section 14(c), including two reports that specifically favor the cessation of subminimum wages, finding that such practices are not necessary to prevent curtailment of opportunities for employment of individuals with disabilities. As with the USCCR report, the NCD's thorough analysis, spanning nearly a decade, undergirds the Department's finding that subminimum wages are no longer necessary to prevent curtailment of employment opportunities for individuals with disabilities.

In 2012, the NCD issued a report recommending that section 14(c) be phased out.[204] In this report, published prior to the passage of WIOA, NCD recommended many reforms similar to those that were subsequently enacted, including ''mandatory information sharing to workers,'' and expansion of supported education and postsecondary education and training for individuals

[195] *Id.* at xi.

[196] *Id.* at 175.

[197] *Id.* at xiv and 179–80.

[198] *Id.* at xi–xii. Similarly, recent non-governmental reports have also emphasized the role that States' and organizations' programmatic choices play in determining whether individuals with disabilities have opportunities for subminimum or full-wage employment. For example, in 2024, New America released a report analyzing States' efforts to end payment of subminimum wages. This report examined the usage of programs that New America deemed to support successful transitions from subminimum to full wages, including ''Medicaid expansion, benefits counseling, and tax-deferred savings accounts.'' The report analyzed States' efforts to put in place supportive employment policies and programs and noted a wide disparity of approaches among States in these areas. Among other conclusions in the report, New America observed that States that did not seek to limit or eliminate the use of subminimum wages often also did not engage in as many supportive employment or financial security initiatives. *See* New America, ''Pennies on the Dollar: The Use of Subminimum Wage for Disabled Workers across the United States: Momentum to Change the Subminimum Wage'' (2024), *https://www.newamerica.org/education-policy/reports/the-use-of-subminimum-wage-for-disabled-workers-across-the-us/.*

[199] 2020 USCCR Report at xvi.

[200] *Id.* at vi–vii.

[201] In that case, Hill Country Farms, doing business as Henry's Turkey Service, employed a group of men with intellectual disabilities for approximately 20 years at an Iowa turkey processing plant where the employer subjected the workers to ''abusive verbal and physical harassment; restricted their freedom of movement; and imposed other harsh terms and conditions of employment such as requiring them to live in deplorable and sub-standard living conditions, and failing to provide adequate medical care when needed.'' U.S. Equal Emp't Opportunity Comm'n, *https://www.eeoc.gov/eeoc/newsroom/release/5-1-13b.cfm* (May 1, 2013). The employer also paid only pennies per hour—$65 a month in cash wages even when company time sheets reflected that they worked more than 40 hours a week. U.S. Dep't of Labor, *https://www.dol.gov/newsroom/releases/whd/whd20110427* (April 27, 2011).

[202] *Solis* v. *Hill Country Farms,* 808 F. Supp. 2d 1105 (S.D. Iowa 2011), *aff'd,* 469 Fed. App'x 498 (8th Cir. 2012); *EEOC* v. *Hill Country Farms, Inc.,* 899 F. Supp. 2d 827 (S.D. Iowa 2012), *aff'd,* 564 Fed. App'x 868 (8th Cir. 2014).

[203] 2020 USCCR Report at 25.

[204] 2012 NCD Report.

with disabilities.[205] NCD recommended that section 14(c) ''should be phased out gradually to provide adequate time for transition to new alternatives.'' [206] To facilitate that proposed phaseout, NCD outlined in their 2012 report a ''comprehensive system of support that will result in greater opportunities for people with disabilities.'' [207]

Among its key findings, the 2012 NCD report noted that work in subminimum wage settings generally did not provide a stepping stone to full-wage work but was instead almost always an end-placement. As NCD observed citing back to a 2001 GAO report, ''Sheltered workshops are ineffective at transitioning people with disabilities to integrated employment. According to the 2001 investigation by [GAO] into the 14(c) program, only approximately 5 percent of sheltered workshop employees left to take a job in the community.'' [208]

In a follow-up 2018 report, NCD again focused on the issue of whether subminimum wages were necessary to secure employment opportunities for individuals with disabilities. NCD reiterated its recommendation to phase out the use of section 14(c) certificates, labelling continued certificate issuance as ''even more evidently outdated and ineffective than it was six years ago.'' [209] NCD termed the continued issuance of section 14(c) certificates a form of ''economic disenfranchisement'' of ''great significance to the overall health of our nation's economy and society.'' [210] The report found that the ''landscape of law and policy has been considerably expanded'' to allow transitions from sheltered workshops into competitive integrated employment. NCD found that, despite these advances, those working under section 14(c) certificates remain ''confined'' to ''sheltered workshops where they perform manual tasks that are often mismatched with their particular strengths and also with their preferences and interests as employees . . . even though new technologies, services, and supports exist that would allow them to succeed in competitive integrated employment.'' [211] The NCD report, echoing the Department's findings discussed above in its report to Congress nearly 50 years earlier, posited that the ''sheltered workshop business model, itself, rather than the impact of disability on productivity, incentivizes low wages and correspondingly disincentivizes reasonable accommodations, better job matches, and more integrated employment services.'' [212]

In its 2018 report, NCD described ''successful examples of transformation from six States [of organizations] where providers have transitioned services from sheltered workshops that paid 14(c) subminimum wages to rival models of individualized supported and customized employment services . . . .'' [213] In reviewing these examples, NCD analyzed ''key success factors'' in each of these organization case studies, including factors such as the presence of staff versed in ''employment first'' strategies, a strong organizational commitment to inclusion of individuals with disabilities in socially valued roles, collaboration with supported employment organizations, high expectations for outcomes, the fostering of an incentivizing link between an individual's work performance and ''a paycheck,'' a business-oriented emphasis on placing employees where they will meet employers' real needs, and fostering the self-advocacy skills of individuals with disabilities.[214]

NCD also made site visits and highlighted the stories of individuals. In one example, NCD wrote ''[a] person with I/DD who was accused of being a 'slow worker' in the sheltered workshop became 'a raging success' working competitively in a family restaurant. He was better matched, and therefore performed better, in a job where he could interact with customers.'' NCD also described, in specific detail, the methodologies of agencies in several States providing supportive employment services, such as individualized job matching and community networking strategies.[215] NCD noted that ''families' viewpoints often change from hesitance about working in the community to full support after they see how successful a family member can be in a typical work setting, and how that success can run to other domains of life.'' [216]

Based on its review, NCD made several recommendations in its 2018 report. For example, NCD recommended that disability policy should focus on ''increased capacity for sustained funding for integrated supported and customized employment,'' improving technical assistance, benefits counseling, business engagement strategies, and developing resources and innovations to allow people with disabilities to do current and future available jobs.[217] In conclusion, NCD recommended current certificate holders should be given time to phase out subminimum and sub-prevailing wages, while the Department's issuance of ''new'' certificates should immediately cease.[218]

In an additional 2018 report entitled ''National Disability Policy: A Progress Report,'' (2018 NCD Progress Report), NCD also extensively reviewed WHD's administration and enforcement efforts under section 14(c).[219] Among other findings, NCD noted that WHD had recognized the need to focus enforcement efforts on areas ''where large numbers of vulnerable workers are found,'' such as workers employed by holders of section 14(c) certificates.[220] As part of this effort, NCD reported that WHD conducted extensive investigations of such employers between 2008 and 2017. During that period, as also discussed in section II.D.1 (''Administration and Enforcement of Certificates''), NCD ''documented 'a high prevalence' of FLSA and other violations among the 14(c) certificate holders investigated. In many instances, employers were unaware of the requirements of Section 14(c) or did not implement the requirements appropriately.'' [221]

The 2018 NCD Progress Report also highlighted the intersection between section 14(c) and anti-discrimination civil rights protections. This report, among many other recommendations, called for more collaboration between WHD and civil rights enforcement agencies; as an example of this type of activity, NCD highlighted that as a result of a WHD investigation of a certificate holder in Rhode Island, WHD made a referral to DOJ's Civil Rights Division. DOJ then found ''unnecessary segregation of adults and serious risks of unnecessary segregation of students in violation of the ADA and the U.S. Supreme Court *Olmstead* decision,'' resulting in a court ordered settlement agreement with the State of Rhode Island and the city of Providence.[222]

[205] *Id.* at 10.

[206] *Id.* at 18.

[207] *Id.*

[208] *Id.* at 10.

[209] Nat'l Council on Disability, ''National Disability Employment Policy from the New Deal to the Real Deal: Joining the Industries of the Future,'' Letter of Transmittal, 2018, *https://www.ncd.gov/report/national-disability-employment-policy-from-the-new-deal-to-the-real-deal-joining-the-industries-of-the-future/* (2018 New Deal NCD Report).

[210] *Id.* at 12.

[211] *Id.* at 13–14.

[212] *Id.* at 53.

[213] *Id.* at Transmittal Letter.

[214] *Id.* at 66, 70, 73–74, 78, 83.

[215] *Id.*

[216] *Id.* at 76.

[217] *Id.* at 14.

[218] *Id.* at 99–100.

[219] 2018 NCD Progress Report.

[220] *Id.* at 68–69.

[221] *Id.* at 69–70.

[222] *Id.* at 74.

The Department considers the NCD reports insightful in analyzing changed employment opportunities for individuals with disabilities, especially as the NCD documented the impact of these changes in reports spanning several years. Furthermore, it is relevant that NCD not only found that subminimum wage employment is unnecessary given the alternatives, but also put forward evidence that many employees working under section 14(c) certificates may, despite positive intentions, experience negative outcomes.

iii. Report of the Advisory Committee on Increasing Competitive Integrated Employment for Individuals With Disabilities

In 2014, the Advisory Committee on Increasing Competitive Integrated Employment for Individuals with Disabilities (Advisory Committee) was established under section 609 of the Rehabilitation Act, as amended by section 461 of the WIOA.[223] The Advisory Committee was created to advise the Secretary and Congress in three areas: (1) ways to increase competitive integrated employment opportunities for individuals with intellectual or developmental disabilities or other individuals with significant disabilities; (2) the use of the section 14(c) certificate program for the employment of individuals with I/DD or other individuals with significant disabilities; and (3) ways to improve oversight of the use of such certificates.[224] The Advisory Committee was established according to the provisions of the Federal Advisory Committee Act, which helps ensure the independent nature of the Advisory Committee in providing advice and recommendations to the Secretary. Especially as Congress specifically created the Advisory Committee to independently study questions closely related to the Department's charge to determine whether continued issuance of certificates is necessary, the Department gives weight to the Committee's relevant findings.

Members of the Advisory Committee included Federal members,[225] self-advocates for individuals with I/DD, providers of employment services, representatives of national disability advocacy organizations for adults with I/DD, academic experts, representatives from the employer community or national employer organizations, and other individuals or representatives with expertise on increase opportunities for CIE for individuals with disabilities. The Advisory Committee worked for 2 years on its study of the topics mentioned above. In evaluating these issues, the Advisory Committee held 10 public meetings during which individuals and organizations provided testimony and public comments. The Advisory Committee also received ''more than 2,000 letters, emails and personal video messages from people with disabilities, and other citizens and organizations across the nation that helped inform the work of the committee and its final recommendations.'' [226]

As the culmination of these efforts, in September 2016, the Advisory Committee issued a detailed report (Committee Report) that included six chapters discussing that increasing CIE will require substantial capacity building, including for youth, in the marketplace, and within the Federal government itself.[227] The Advisory Committee, among other conclusions, recommended that Congress repeal section 14(c) through a multi-year phaseout.[228] The Advisory Committee further recommended that WHD ''engage in stronger enforcement'' of section 14(c) certificates and require both States and individual applicants to submit more information (including information about States' and applicants' efforts to work towards alternatives to the payment of subminimum wages) to show that the issuance of certificates would be necessary to prevent the curtailment of employment opportunities for individuals with disabilities.[229]

The Advisory Committee observed that ''one by-product of subminimum wage employment is a culture with a low expectation for competitive integrated employment.'' [230] The Committee further concluded that the ''current widespread practice of paying workers subminimum wages, based on assumptions that individuals with disabilities cannot work in typical jobs, or on assumptions about the unavailability of alternative work opportunities, is antithetical to the intent of modern federal policy and law.'' [231] The Advisory Committee explained that modern Federal policy and laws are ''based on the assumption that all individuals with disabilities are capable of, and have a right to, CIE.'' [232]

The Advisory Committee further recommended that vocational rehabilitation services for individuals with disabilities focus more on practices demonstrated to produce positive outcomes in full-wage employment. For example, the Advisory Committee explained that research shows providing experience in community-based workplaces performing actual work tasks is a superior training strategy compared with providing ''work readiness training'' in sheltered workshops.[233] Similarly, the Advisory Committee made recommendations regarding supportive employment practices based on its finding of the importance of factors such as ''work experience and [competitive integrated employment] during secondary school years'' and family expectations about employment.[234]

As with the other government oversight reports discussed above, the Department finds the thorough conclusions of the Advisory Committee to be highly relevant to the Department's analysis, and, in particular, the Department notes the import of the Committee's congressional mandate. Specifically, the Advisory Committee's conclusions regarding the availability of alternatives to section 14(c) certificates informed the development of this proposed rule; the Committee Report provides a picture of the employment landscape for workers with disabilities that does not rely upon subminimum wages.

[223] 29 U.S.C. 795n.

[224] *Id.*

[225] The Advisory Committee's Federal membership consisted of the following agency leaders or their designee: Department of Labor's Assistant Secretary of ODEP, the Assistant Secretary for Employment and Training Administration (ETA), and the WHD Administrator; the HHS Commissioner of the Administration on Intellectual and Developmental Disabilities; CMS Director; the Commissioner of the Social Security Administration (SSA) and the Department of Education's RSA Commissioner.

[226] Advisory Committee on Increasing Competitive Integrated Employment for Individuals with Disabilities, ''Final Report,'' 2016, at p. iv, *https://www.dol.gov/sites/dolgov/files/odep/topics/pdf/acicieid_final_report_9-8-16.pdf.*

[227] *Id.* at 1–4.

[228] *Id.* at 2.

[229] *Id.* at 30.

[230] *Id.* at 28.

[231] *Id.* at 29.

[232] *Id.*

[233] *Id.* at 10.

[234] *Id.* at 21. The Department notes that in addition to the agency reports discussed herein, in 2018, the minority staff of the U.S. Senate Committee on Health, Education, Labor, and Pensions reached a similar conclusion that the evidence does not support the continued payment of subminimum wages and the Department should no longer issue new section 14(c) certificates. Minority Staff of S. Comm. on Health, Educ., Labor, and Pensions, ''Disability Employment: Outdated Laws Leave People with Disabilities Behind in Today's Economy,'' Comm. Print 2018, *https://web.archive.org/web/20181224100838/https://www.murray.senate.gov/public/_cache/files/84084732-e011-470a-b246-1cdab87755c3/staff-report-on-employment-for-people-with-disabilities-10-29-2018-pm-.pdf.*

iv. U.S. Government Accountability Office Reports

Unlike the government agency reports detailed above, GAO has not directly addressed the question of whether it is still necessary to permit payment of subminimum wages to promote employment opportunities for individuals with disabilities. However, GAO has issued multiple reports addressing various aspects of the use and operation of section 14(c) certificates, and in doing so, has generated significant data and analysis relevant to this proposed rule.[235] The Department found this data and analysis to be helpful in its review of section 14(c) and development of this NPRM.

In 2023, GAO issued a report addressing the Department's oversight of employers using section 14(c) certificates. In this report, in addition to its primary recommendations regarding section 14(c) certificate processing, GAO emphasized that participation of employers using section 14(c) certificates has markedly decreased, tracking a steady decline over the decade from 2010 to 2019.[236] GAO attributed this decline to changing Federal laws and policies, changing State policies (such as state-level phaseouts of the use of subminimum wages), and shifts in employer and worker views.[237]

In the 2023 report, GAO also published important demographic and statistical data about employers holding section 14(c) certificates and the employees they were paying subminimum wages. GAO confirmed that, currently, CRPs are the ''vast majority of 14(c) employers,'' and that ''almost all 14(c) workers had an intellectual or developmental disability.'' [238] GAO estimated that approximately 70 percent of section 14(c) workers were 25–54 years old, with approximately 26 percent 55 years or older, and only approximately 4 percent 18–24 years old.[239] As already noted above, GAO found that the majority of workers paid under section 14(c) certificates in the data they analyzed were paid less than $3.50 per hour, approximately 14 percent were paid less than one dollar per hour, and approximately 5 percent were paid less than 25 cents per hour.[240] GAO also found that ''few 14(c) workers'' engaged in competitive employment, including being paid at least minimum wage in an integrated work setting.[241]

Additionally, in 2021, GAO issued a report on ''Factors Influencing the Transition of Individuals with Disabilities to Competitive Integrated Employment.'' [242] GAO identified 32 factors that may influence transitions away from subminimum wages to competitive integrated employment.[243] GAO did not find a consensus across the individuals it interviewed about the most significant factors influencing ''14(c)–to–CIE transition.'' [244] Instead, ''each of the 32 factors was identified by at least one interviewee to be among the most important in influencing an individual's transition to CIE.'' [245] Additionally, many interviewees emphasized that the factors were heavily inter-related. GAO also emphasized the potential impact of the COVID–19 pandemic, noting uncertainty about such impacts at the time of the report's publication.[246] As a backdrop to its study of factors that might influence individuals' transition to CIE, GAO noted legislative changes—such as WIOA—that promote access to employment at full wages.[247] Additionally, GAO highlighted a ''shift in federal and state priorities'' away from reliance on section 14(c), and noted that ''at least 40 states have adopted legislation or state policy stating that integrated employment in the community is the first and preferred option for people with disabilities . . . . '' [248]

GAO's interviews with employees identified several factors that inhibited transitions to CIE, including the individuals' age, concern for maintaining benefits, desire for a social community, concern for safety of non-sheltered working environment, and ''views'' about an individuals' skills.[249] Observing that family members' judgments were often decisive even when differing from the preferences of employees themselves, GAO recounted that ''one participant told us that family members may not see the individual's potential for accomplishing work because they remember times when the person struggled.'' [250] Interviewees also noted that ''people who have been exposed to CIE, including through real-world, authentic experiences, almost always choose CIE . . . because they have a more accurate perception of what it entails.'' [251]

Regarding the views of employers, GAO listed factors that might influence a section 14(c) certificate holder's decision to transition away from subminimum wages, a process GAO referred to as ''provider transformation.'' [252] GAO found that the factors most relevant to whether section 14(c) holders transitioned from subminimum wages to CIE were, in addition to resource-related factors, ''14(c) certificate holder leadership views, 14(c) certificate holder's use of person-centered approach to employment planning, 14(c) certificate holder's mission or business model, 14(c) certificate holder's access to training and technical assistance, and 14(c) certificate holder's provision of ongoing supports for CIE.'' [253]

Finally, GAO noted several policy and economic factors that could influence transition away from subminimum wages. Among these factors, GAO identified State resources supporting CIE, State policies ''allowing public benefits to continue while working,'' ''federal support for 14(c) employment versus CIE,'' the overall unemployment rate, available transportation, and available employment services.[254]

In sum, while GAO's reports did not directly address whether section 14(c) certificates were necessary to prevent curtailment of opportunities for employment, the Department found them relevant in several ways, as reflected by the information discussed above. In particular, GAO's 2023 report provided additional insight into the demographics of the workers with disabilities currently working under section 14(c) certificates while GAO's 2021 report provided a better understanding of many of the challenges potentially faced by employers in transitioning from section 14(c) subminimum wage employment to an alternative model. The Department's proposed phaseout approach, discussed in greater detail below, is intended to

[235] Additional GAO reports include GAO–81–116519, ''Stronger Fed. Efforts Needed for Providing Emp't Opportunities and Enforcing Labor Standards in Sheltered Workshops'' (1981), *https://www.gao.gov/products/hrd-81-99;* GAO–01–886, ''Special Minimum Wage Program: Centers Offer Emp't and Support Servs. to Workers with Disabilities, But Labor Should Improve Oversight'' (2001), *https://www.gao.gov/products/gao-01-886;* and GAO–12–594, ''Students with Disabilities: Better Fed. Coordination Could Lessen Challenges in the Transition from High School'' (2012), *https://www.gao.gov/products/gao-12-594*.

[236] *See* 2023 GAO Report.

[237] *Id.* at 14–15.

[238] *Id.* at 2.

[239] *Id.* at 26.

[240] *Id* at 17.

[241] *Id.*

[242] 2021 GAO Report.

[243] *Id.* at 13.

[244] *Id.* at 13.

[245] *Id.*

[246] *Id.* at 2.

[247] *Id.* at 1.

[248] *Id.* at 1–2.

[249] *Id.* at 14.

[250] *Id.* at 19.

[251] *Id.*

[252] *Id.*

[253] *Id.* at 20.

[254] *Id.* at 25–27.

mitigate against such potential transition difficulties.

2. Non-Governmental Assessments of Certificate Issuance Under Section 14(c)

In recent years, not-for-profit, academic, and advocacy organizations have also issued many reports and shared public comments on the payment of subminimum wages to individuals with disabilities.[255] This proposed rule does not include a complete survey of these reports and viewpoints. Rather, the reports noted here are a sampling of non-governmental views on subminimum wage payments under section 14(c). The Department notes that these reports reflect a wide range of the views on the use of section 14(c) certificates and subminimum wage employment of workers with disabilities.

In general, most (but not all) organizations that advocate on behalf of individuals with disabilities strongly oppose reliance on the payment of subminimum wages to generate employment opportunities for individuals with disabilities. For example, in 2011, the National Disability Rights Network (NDRN),[256] a non-profit membership organization for the federally mandated State Protection and Advocacy Systems and Client Assistance Programs for individuals with disabilities, issued a report detailing their review of ''segregated work, sheltered environments, and the sub-minimum wage to determine whether they meet the needs of people with disabilities and whether they comply with federal law.'' [257] NDRN found that workers with disabilities in ''sheltered workshops'' using section 14(c) certificates are often ''stuck'' indefinitely, without a meaningful option of other employment, because workers under section 14(c) certificates are not provided with effective, transferable skills training in such settings.[258] Among many recommendations to Congress, States, and Federal agencies, NDRN called for the cessation of section 14(c) certificate issuance.[259] NDRN explained that ''[i]n the best of situations, sheltered environments, segregated work, and the sub-minimum wage does not truly provide a meaningful experience for workers with disabilities. Workshop tasks are often menial and repetitive, the environment can be isolating, and the pay is often well below the Federal minimum wage. In the worst situations, the segregated and sheltered nature of the lives of workers with disabilities leaves them vulnerable to severe abuse and neglect.'' [260]

Conversely, some organizations and individuals vigorously support the continued issuance of section 14(c) certificates. For example, the non-profit organization A Voice of Reason (VOR), which is a grassroots advocacy organization that consists primarily of families of individuals with I/DD, posted a public letter in 2021 opposing the elimination of section 14(c) certificates. In the letter, VOR stated that it is important to preserve ''opportunities for those who can succeed in competitive integrated employment as well as those who cannot.'' [261] VOR elaborated that section 14(c) gives ''thousands of individuals with I/DD the opportunity to work in a specialized environment that nurtures them and fits their abilities.'' [262] VOR asserted that for these individuals ''[w]ithout 14(c) certificates, they would lose any opportunity to work.'' [263] The Department received similar feedback in its listening sessions from parents and other proponents of section 14(c).

While acknowledging dissenting views, the Department relies on the significant quantitative and qualitative evidence discussed throughout these third-party reports that supports the preliminary conclusion that section 14(c) certificates are no longer necessary to prevent curtailment of opportunities for employment for workers with disabilities. The Department welcomes comments on its review and analysis of the reports mentioned in this section or other recent reports that consider the role of section 14(c) certificates and subminimum wages in the employment of workers with disabilities.

D. State Elimination of Subminimum Wages and Other Relevant Data

1. State Elimination of Payments of Subminimum Wages to Individuals With Disabilities

An increasing number of States and localities [264] have prohibited, limited, or plan to phase out the payment of subminimum wages to workers with disabilities, suggesting that these States and localities have reached the conclusion that such certificates are no longer necessary or appropriate in their jurisdictions.[265]

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[255] *See, e.g.,* Nat'l Fed'n of the Blind, Letter to the Secretary of Labor, *https://nfb.org/sites/nfb.org/files/2021-06/Letter%20to%20Secretary%20Walsh%20regarding%2014c.pdf* (June 21, 2021) (''We believe Section 14(c) of the FLSA is a discriminatory practice and we have long been fighting to end it . . . 14(c) certificates have been a source of systemic abuse and corruption . . . [and] can no longer be justified, even under the FLSA's own terms . . .''); Minn. Disability Law Ctr., ''Ending the Subminimum Wage in Minnesota: A Report from the Minnesota Disability Law Center,'' *https://mylegalaid.org/wp-content/uploads/2024/03/Ending-the-Subminimum-Wage-in-Minnesota_October-2022_Text-Version.pdf* (October 2022) (among other findings, recommending the State government ''[pa]ss legislation to phase out the payment of subminimum wages in Minnesota by a specific date with funding to implement the phase out.''); Association of People Supporting Employment First (APSE), ''Trends and Current Status of 14(c),'' *https://apse.org/wp-content/uploads/2021/10/10_20_21-APSE-14c-Update-REV.pdf* (October 2021) (presenting data in support of APSE's call for complete phase out of the use of 14(c) certificates); Jean Winsor, Cady Landa, Cady, Andrew Perumal, and John Butterworth, ''The Power of Disability Employment: The Impact to Arizona's Economy,'' ThinkWork!, *https://www.thinkwork.org/sites/default/files/files/Arizona_whole%20report_Final.pdf* (October 2019) (finding that increasing the number of workers with disabilities will positively impact Arizona's economy).

[256] On December 13, 2021, the Department's WHD and NDRN renewed a memorandum of understanding (MOU) establishing a collaborative relationship to promote compliance with laws of common concern. *See https://www.dol.gov/agencies/whd/workers-with-disabilities/national-disability-rights-network-mou.* This MOU built upon the foundation established by a prior MOU entered into between WHD and NDRN in December 2015. Although WHD and NDRN collaborate on certain enforcement and training-related matters, the Department did not independently consult with NDRN about the development of this proposed rule.

[257] Nat'l Disability Rights Network, ''Segregated and Exploited: The Failure of the Disability Service System to Provide Quality Work,'' 2011, A Letter from the Executive Director, *https://www.ndrn.org/wp-content/uploads/2019/03/Segregated-and-Exploited.pdf* at 7.

[258] *Id.* at 32–33.

[259] *Id.* at 46.

[260] *Id.* at 7.

[261] A Voice of Reason, ''In Support of Protecting Vocational Centers and 14(c) Wage Certificates,'' *https://vor.net/images/stories/2020-2021/VOR_-_In_Support_of_Protecting_Vocational_Centers_and_14c_Wage_Certificates_2-4-21.pdf; see also* Coalition for Preserving 14(c) White Paper (2022), *https://employmentchoice.org/protecting-employment-for-individuals-with-i-dd-coalition-white-paper-2022/.*

[262] *Id.*

[263] *Id.*

[264] At the local level, Chicago, Seattle, Denver, and Reno are among the localities that have passed city-specific bans on the payment of subminimum wages. *See* APSE ''Trends and Current Status of 14(c)'' at 8 (July 2023), *https://apse.org/wp-content/uploads/2023/09/APSE-14c-Update-REV-0723.pdf.*

[265] It bears mentioning that there have also been litigation and consent decrees aimed at the enforcement of *Olmstead's* integration mandates that have resulted in States eliminating the payment of subminimum wages. For example, as discussed in greater detail in section III above, following a settlement agreement (*see* Settlement Agreement, *Lane* v. *Brown,,* No. 3:12–cv–00138, *https://www.justice.gov/media/1237561/dl*), Oregon transitioned many workers from sheltered workshops to CIE. An important part of Oregon's progress was investing in the employment support agencies to learn how to properly implement CIE programs. ''Oregon's efforts have resulted in the state being recognized in 2020 by the U.S. Commission on Civil Rights as a leader in eliminating subminimum wage and in transitioning to integrated employment.'' Or. Dep't Hum. Servs., ''*Lane* v. *Brown* Settlement Agreement Report,'' at 2 (Jan. 2022), *https://www.oregon.gov/odhs/employment-first/Documents/lane-v-brown-settlement-message-2022-06-21.pdf.*

i. Legal Developments at the State Level Eliminating or Curtailing Subminimum Wage Payments

A number of States have statutes, regulations, or other guidance regarding the payment of subminimum wages to workers with disabilities, further narrowing the universe of workers being paid below the Federal minimum wage. Significantly, nearly one-third of States have already passed laws entirely prohibiting (or planning to prohibit through a phase out) the payment of subminimum wages to workers with disabilities. To date, Alaska,[266] California,[267] Colorado,[268] Delaware,[269] Hawaii,[270] Maine,[271] Maryland,[272] Nevada,[273] New Hampshire,[274] Oregon,[275] Rhode Island,[276] South Carolina,[277] Tennessee,[278] Virginia,[279] and Washington [280] have all passed legislation or executive orders prohibiting (or planning to prohibit through a phase out) the payment of subminimum wages to at least some workers with disabilities in their State. These bills were often passed with bipartisan support and with the support of broad coalitions of stakeholders. Several additional States are considering similar legislation.[281] Other States have limited or restrained the payment of subminimum wages in various ways, such as Texas (prohibiting payment of subminimum wages by CRPs participating in State use contracts, with limited exceptions),[282] Illinois (executive order prohibiting payment of subminimum wages for work performed by employees of State not-for-profit vendors, including subcontractors),[283] Kansas (limiting payment of subminimum wages to no less than 85 percent of the State minimum wage),[284] Minnesota (limiting payments to no less than 50 percent of the State minimum wage, with some exceptions) and New Mexico (limiting payment of subminimum wages to no less than 50 percent of the State minimum wage),[285] West Virginia, Nebraska, and New York (subminimum wages only permissible in certain

[266] As of December 2022, no employer in Alaska is permitted to pay an individual with a disability less than the State minimum wage, due to the repeal of the State statute which previously allowed for the use of subminimum wage certificates. *See* Alaska Stat. Ann. sec. 23.10.070 (2022).

[267] In 2021, California enacted Senate Bill 639, implementing a multi-year phaseout of the use of licenses authorizing a subminimum wage. *See* Cal. Lab. Code. sec. 1191 (2022).

[268] On June 29, 2021, Colorado enacted Senate Bill 21–039, which was designed to phase out the use of subminimum wages for employees with disabilities by 2025. *See* Colo. Rev. Stat. Ann. sec. 8–6–108.7 (2021). As of July 2023, 2 years sooner than initially contemplated by the legislation, employers in Colorado are prohibited from paying an individual with a disability less than the State minimum wage. *See* Press Release, Polis-Primavera Administration Eliminates Subminimum Wages for People with Disabilities Two Years Ahead of Schedule (Oct. 31, 2023), *https://www.colorado.gov/governor/news/10901-polis-primavera-administration-eliminates-subminimum-wages-people-disabilities-two-years.*

[269] In 2021, Delaware enacted the Jamie Wolfe Employment Act, which repealed the State statutory provision permitting the payment of subminimum wages and prohibited the payment of subminimum wages after January 31, 2024. *See* Del. Code. Ann. tit. 19 sec. 905 (2024); Del. Code. Ann. tit. 19 sec. 752 (2024).

[270] In 2021, Hawaii enacted Senate Bill 793, which immediately repealed the authority of the Director of Labor and Industrial Relations to permit the employment of individuals with disabilities at a subminimum wage. *See* Hawaii Rev. Stat. Ann. sec. 387–9 (2021).

[271] In 2020, Maine enacted Legislative Document 1874, which, effective June 16, 2020, amended its minimum wage law to state that the Director of Labor Standards ''may not'' issue a certificate authorizing an employer to pay a subminimum wage to an employee with a disability. *See* Me. Rev. Stat. Ann. tit. 26, sec. 666 (2020).

[272] In 2016, Maryland enacted the Ken Capone Equal Employment Act, which amended its minimum wage law to abolish the payment of subminimum wages to persons with disabilities after October 1, 2020. *See* Md. Code Ann., Lab. & Empl. sec. 3–414 (2016).

[273] In 2023, Nevada enacted Assembly Bill 259, which phases out the use subminimum wages in Nevada by January 1, 2028, *see* Assemb. 259, 82d Sess. sec. 12 (Nev. 2023), and prohibits providers of jobs and training services from entering into new contracts that included the payment of subminimum wages on or after January 1, 2025. *See id.,* sec. 8 (amending Nev. Rev. Stat. secs. 608.250 and 435.305).

[274] In 2015, New Hampshire enacted Senate Bill 47, which generally prohibited the payment of subminimum wages to workers with disabilities as of July 6, 2015. *See* N.H. Rev. Stat. Ann. sec. 279:22 (2024).

[275] In 2019, Oregon enacted Senate Bill 494, which banned the payment of subminimum wages to workers with disabilities after June 30, 2023. *See* Or. Rev. Stat. Ann. sec. 653.033 (2019).

[276] In 2022, Rhode Island enacted Senate Bill 2242, which banned the payment of subminimum wages to workers with disabilities after June 15, 2022. *See* R.I. Gen. Laws Ann. sec. 28–12–9 (2022).

[277] In 2022, South Carolina enacted Senate Bill 533, which phases out the use of section 14(c) certificates which allow the payment of subminimum wages in the State by August 1, 2024. *See* S.C. Code Ann. sec. 41–6–10 (2022); 2022 S.C. Act No. 209, sec. 3(C)(1).

[278] In 2022, Tennessee enacted the Tennessee Integrated and Meaningful Employment Act, which states that, effective July 1, 2022, Tennessee employers must pay at least the Federal minimum wage to all workers with disabilities. *See* Tenn. Code Ann. sec. 50–2–114 (a).

[279] In 2023, Virginia enacted House Bill 1924 to phase out the use of the subminimum wages by 2030. As part of the phase out, no new authorizations were permitted after July 1, 2023; however, any employer that was certified prior to July 1, 2023, is permitted to continue paying employees pursuant to section 14(c) until 2030. *See* Va. Code Ann. sec. 40.1–28.9(A)(9) (2023)

[280] In 2021, Washington enacted Senate Bill 5284 which phases out the use of subminimum wage certificates for private employers. *See* Wash. Rev. Code Ann. sec. 49.46.170(2) (2021). For private employers, no new certificates were issued after July 31, 2023, and the last potential date a certificate can remain valid under the law is July 30, 2026. *See id.* sec 49.46.170(2)–(3); *see also* Wash. Dep't of Labor & Indus. & Wash. Dep't of Social & Health Servs., ''Subminimum Wage Certificates'' at 2 (2023), *https://www.lni.wa.gov/agency/_docs/2023SubMinimumWageCertificatesReport.pdf.* As to State employers, ''no state agency'' is permitted to ''employ an individual to work under a special certificate . . . for the employment of individuals with disabilities at less than the minimum wage'' as of July 1, 2020. *Id.* sec. 49.46.170(1) (2021). Any certificate issued to a State agency expired on June 30, 2020. *Id.*

[281] For example, House Bill 793 in Illinois, which would ban the payment of subminimum wages to workers with disabilities by 2030, passed the Illinois House in May 2024 and is currently pending in the Illinois Senate. *See* Illinois General Assembly-Bill Status, *https://ilga.gov/legislation/billstatus.asp?DocNum=793&GAID=17&GA=103&DocTypeID=HB&LegID=142668&SessionID=112.*

[282] In 2019, Texas enacted Senate Bill 753, which ended the use of subminimum wages in its State Use Program. *See* Tex. Hum. Res. Code Ann. sec. 122.0076(a) (2019). A community rehabilitation program may not participate in the program administered under this chapter ''unless each worker with a disability employed by the program is paid at least the federal minimum wage . . .''; the provision, however, contains an exceptions clause. *See id.* sec. 122.0076(a), (b).

[283] On October 4, 2021, Illinois Governor JB Pritzker issued Executive Order 2021–26, which required that contracts and sub-contracts with State agencies that participate in the State Use Program must pay ''no less than the applicable local, if higher, or Illinois minimum wage for all employees performing work on the contract, notwithstanding any provision that would permit payment of a lower wage rate.'' *See* Ill. Exec. Order 2021–26, *https://www.illinois.gov/government/executive-orders/executive-order.executive-order-number-26.2021.html.*

[284] *See* Kan. Admin. Regs. 49–31–5(b) (2024). Additionally, on February 8, 2024, Kansas enacted the Disability Employment Act, which incentivizes employers to pay employees with disabilities the State minimum wage. The Act established the ''sheltered workshop transition fund,'' in order to ''facilitate[ ] transitions by Kansas sheltered workshop employers away from employing individuals with disabilities under a certificate issued by the United States Secretary of Labor under 29 U.S.C. [ ] 214(c) and toward paying all such employees at least the minimum wage,'' by providing matching grants to sheltered workshops that commit to paying at least the minimum wage. *See* 2024 Kan. Sess. Laws Ch. 1, sec. 2(a). The Act also provides a tax incentive for purchases of goods and services from ''qualified vendors,'' which include vendors that do ''not employ individuals under a certificate issued by the United States Secretary of Labor under 29 U.S.C. [ ] 214(c).'' Kan. Stat. Ann sec. 79–32,273(b) & (e)(1)(A)(iv) (2024).

[285] *See* Minn. Stat. Ann. sec. 177.28, subd. 5 (2007); Minn. R. 5200.0030 (2008); N.M. Stat. Ann. sec. 50–4–23. Additionally, from 2021–24 Minnesota established a task force ''to develop a plan and make recommendations to phase out payment of subminimum wages to people with disabilities on or before August 1, 2025.'' *See* 2021 Minn. Laws, First Spec. Sess., ch. 7, art. 17, sec. 14.

settings or by certain employers),[286] and Arizona (pursuant to a policy statement, an employer must pay an ''employee'' with a disability at least the State minimum wage; however under Arizona's guidance, a worker in a CRP, vocational training program or service recipient program may not be an employee in certain circumstances under Arizona state law).[287]

Additionally, although Vermont does not have any formal legislation [288] specifically to disallow the payment of subminimum wages to workers with disabilities, the Vermont Division of Disability and Aging Services does ''not support center-based or group supported employment services'' and there have been no active section 14(c) certificate holders in Vermont for many years.[289] USCCR notes in its 2020 Report that ''Vermont achieved an end to subminimum wage and segregated employment by ending funding for new entrants into sheltered workshops in 2000, which also began a three year phase-out of all subminimum wage, sheltered employment.'' In sum, 15 states have laws that prohibit or are in the process of prohibiting subminimum wage payments, and an additional nine states have limited or restrained the payment of subminimum wages, resulting in nearly half of the States eliminating or restricting such payments. As discussed below, the Department's analysis yields no statistical evidence that employment or the labor force participation rate of individuals with cognitive disabilities, such as I/DD, differed in states that have adopted laws, policies, or regulations that end the payment of subminimum wages relative to states that do allow subminimum wages.[290]

ii. Data From Vermont Regarding Long-Term Impacts of Elimination of Subminimum Wage Payments

While many States have moved away from subminimum wage payments relatively recently, data and studies regarding Vermont's decision to end funding for sheltered workshops and phase out all subminimum wage employment offer insight into how elimination of the payment of subminimum wages to individuals with disabilities impacted the long-term employment opportunities of those workers. Despite this longstanding absence of the payment of subminimum wages under section 14(c) certificates in Vermont, that absence does not appear to have negatively impacted employment rates of workers with I/DD when compared with national employment rates. Instead, as observed by the USCCR in its 2020 report, from 2008 to 2016–2017, the rate of employment for workers with I/DD in Vermont rose from 35.8 percent to 42 percent, more than double the national average employment rate in 2016–2017 for this group.[291]

Additionally, academic research from Vermont also shows that workers' transitions away from a sheltered workshop, subminimum wage model are often positive, despite those workers' (and their families') initial opposition to such changes. For example, years after Vermont eliminated subminimum wage employment, a researcher at the University of Vermont published a case study based on extensive interviews with individuals with I/DD and their family members.[292] Some of the individuals had previously worked for subminimum wages, and their interviews speak to deep anxieties about the elimination of subminimum wages.[293] At the beginning of the transition in Vermont, parents of workers with disabilities expressed fear of the future, with particular emphasis on issues of safety where an adult child was leaving a sheltered workshop setting.[294] However, parents reported that as their children with disabilities ''spent more time in the community, the fears of abuse and ridicule did not materialize[.]'' [295] Moreover, the workers with disabilities generally reported positive feelings about their new jobs.[296] As discussed above, the USCCR made similar findings based on its case studies in Vermont.[297]

E. Summary of Analysis and Conclusion

Congress gave the Secretary the authority to issue certificates allowing employers to pay subminimum wages to individuals with disabilities but not without restriction and not in perpetuity. Instead, Congress included a significant statutory limitation on the Department's authority, allowing the issuance of certificates only to the extent ''necessary to prevent curtailment of opportunities for employment,'' and conferred authority upon the Department to determine whether that standard has been met.

Given the expanded legal protections and opportunities for employment of individuals with disabilities available today, to comply with the terms of the statute, the Department must determine whether the FLSA's standard continues to be met. When Congress first enacted the subminimum wage provision of the FLSA in what is now known as section 14(c), the employment opportunities available to individuals with disabilities were a fraction of what they are today. Through the Department's comprehensive review culminating with this rulemaking, the Department has reflected on the substantial progress, resources, and supports for workers with disabilities that have emerged over the last several decades. After extensively reviewing and analyzing the issues, developments, and reports discussed in this proposed rule, holding listening sessions, and partnering closely with agencies within and outside of the Department, as well as the Department's extensive experience administering and enforcing section 14(c) certificates, the Department preliminarily finds that subminimum

[286] W. Va. Code Ann. sec. 21–5C–1(f)(8) (limited to non-profit sheltered workshops); Neb. Rev. Stat. Ann. sec. 48–1202(3)(i) (limited to rehabilitation programs receiving public funding); N.Y. Lab. Law secs. 651(5)(i); 655(5)(c)(2) (limited to charitable, educational, or religious employers).

[287] Indus. Comm'n of Ariz., ''Substantive Policy Statement Regarding Application of Arizona Minimum Wage Act to Work Activities Performed by Individuals with Disabilities,'' (Mar. 29 2007), *https://www.azica.gov/sites/default/files/migrated_pdf/Labor_MinWag_SubstantivePolicyDisabilities_32907-2.pdf.* State laws do not affect whether an individual is an employee under the FLSA.

[288] 2020 USCCR Report at 181 (noting that Vermont eliminated the payment of subminimum wages in practice in 2002 but did not pass legislation banning subminimum wages at that time). The District of Columbia and Wyoming similarly do not have any formal legislation in place, yet do not report any workers receiving subminimum wages under section 14(c) certificates. *See https://www.dol.gov/agencies/whd/workers-with-disabilities/section-14c/certificate-holders.*

[289] *See id.*

[290] *See e.g.,* preliminary regulatory impact analysis discussion in section VII.E (''Transfers''). The Department further notes that nationwide and for decades, there has been growth in the number of individuals with disabilities who participate in State-funded non-work supportive rehabilitation programming (such programs, which offer both enrichment to individuals with disabilities and respite to caregivers, often consist of activities such as taking adult education classes, support for daily activities, and participating in social activities). *See* 2023 Thinkwork Report at 3. This broader trend appears to be unrelated to State action related to the cessation of subminimum wage employment under section 14(c) certificates. As discussed above, in Oregon, the overwhelming majority of former sheltered workshop employees transitioned to full-wage jobs, exceeding the goal for the numbers of individuals entering into CIE placement set forth in the settlement agreement. *See* Oregon Dep't of Human Servs., ''*Lane* v. *Brown* Settlement Agreement Report,'' *https://www.oregon.gov/odhs/employment-first/Documents/lane-v-brown-settlement-message-2022-06-21.pdf.*

[291] *Id.* at 180–81 (*citing* Univ. Mass. Boston, Inst. for Community Inclusion, StateData.info, ''State Employment Snapshot: Vermont,'' *https://www.statedata.info/statepages/Vermont*).

[292] Bryan Dague, ''Sheltered Employment, Sheltered Lives: Family Perspectives of Conversion to Community-Based Employment,'' 37 J. of Vocational Rehab. 1 (Jan. 2012).

[293] *Id.* at 4–5.

[294] *Id.* at 5–7.

[295] *Id.* at 7.

[296] *Id.* at 8.

[297] *See, e.g.,* 2020 USCCR Report at 198.

wages are no longer necessary to prevent curtailment of employment opportunities for individuals with disabilities. Accordingly, the Department proposes to amend 29 CFR part 525 to phase out the issuance of section 14(c) certificates.

Under the Department's current regulation at 29 CFR 525.9, ''in order to determine that special minimum wage rates are necessary in order to prevent the curtailment of opportunities for employment,'' the Administrator considers whether a certificate applicant has satisfied the standards set forth in other regulatory provisions governing the proper computation and payment of subminimum wages. The current regulations thus focus on whether a certificate applicant has properly evaluated and calculated productivity-based wage rates for workers with disabilities at specific jobs (and under the specific conditions) offered by the employer. The statute does not require the framework currently in place, however and this regulatory methodology, now 35 years old, could not have taken into account today's more structural, comprehensive strategies for preventing curtailment of employment opportunities for individuals with disabilities. However, the Secretary now has the benefit of being able to take such strategies and developments into account. Thus, to comply with the terms of the statute, the Department must determine whether the statute's prerequisite—that payment of subminimum wages be necessary to prevent the curtailment of employment opportunities—can be met given the current demonstrated systemic and nationwide advances in employment opportunities for individuals with disabilities.

In the introductory section of the ADA Amendments Act of 2008, Congress states that ''in enacting the ADA, Congress recognized that physical and mental disabilities in no way diminish a person's right to fully participate in all aspects of society, but that people with physical or mental disabilities are frequently precluded from doing so because of prejudice, antiquated attitudes, or the failure to remove societal and institutional barriers.'' [298] With this context in mind, the Department takes note of the historical evolution of the use of section 14(c) certificates. When first enacted, Congress focused significantly on private industry and small businesses,[299] and a far broader swath of U.S. workers were being paid subminimum wages based on age, disability, or injury.[300] Over time, the use of section 14(c) certificates has narrowed to almost exclusively one setting—CRPs rather than private sector opportunities—and has constricted to consist almost exclusively of workers with I/DD. As other groups experiencing different disabilities (*e.g.,* age-related, addiction-related, those experiencing blindness) have already generally moved away from working for subminimum wages to employment at or above the full minimum wage, so too now are workers with I/DD. Specifically, as to these workers, reports show, among the general population of workers with I/DD, working in integrated settings for at least the minimum wage is now far more common than working for subminimum wages.[301] At the same time, the number of section 14(c) certificates has dwindled, with a decades-long downward trend and with the vast majority of certificates now being renewals, with only a few new applications.

Today, the issuance of section 14(c) certificates may be self-reinforcing, with the continued use of certificates facilitating workers continuing to only receive subminimum wages despite the potential to engage in other full-wage employment opportunities, which is contrary to the statute's intent of providing for certificates only when necessary.[302] As noted by NDRN, workers with disabilities in sheltered workshops using section 14(c) certificates are often ''stuck'' indefinitely, without a meaningful option of other employment, because workshop tasks are often menial and repetitive, the environment can be isolating, and workers under section 14(c) certificates are not provided with effective, transferable skills training in such settings.[303] DOJ has similarly observed that workers with disabilities in community rehabilitation programs typically have ''no opportunity for advancement'' and ''often earn extremely low wages when compared to people with disabilities in integrated employment, resulting in stigmatization and a lack of economic independence.'' [304] Given this, the Department is cognizant that today, the issuance of section 14(c) certificates may, inadvertently and counterintuitively, even contravene the statute's intent of promoting opportunities for gainful employment.[305]

In light of these realities, as well as the legal and policy developments discussed above, the Department preliminarily finds that today, the issuance of subminimum wage certificates is no longer necessary to prevent the curtailment of employment opportunities. Moreover, the evidence indicates such certificates themselves may, in fact, sometimes contribute to the curtailment of employment opportunities at or above the full Federal minimum wage for some workers with disabilities.

The disability rights movement, led by a broad coalition of stakeholders including self-advocates, has forged a path toward increased equity, self-determination, and inclusion, thereby expanding access to and opportunities available for employment. As discussed above, this movement has resulted in a very different—and improved—legal and policy landscape than existed in 1938 or even 1989 when section 14(c) regulations were last substantively updated, reflecting the 1986 amendments to the FLSA.

An array of Federal legislation has substantially broadened opportunities

[298] 42 U.S.C. 12101 note (2008).

[299] Congressional Record, Vol. 82, Part I, 75th Cong. 2d Sess., p. 88.

[300] For example, in the 1967 report to Congress, the Department noted that there were sheltered workshops paying subminimum wages for older workers, workers who were blind, workers with tuberculosis, workers who were epileptic, workers with alcoholism, workers who were paraplegic, and workers experiencing mental illness, among others. *See generally* U.S. Dep't of Labor, ''Sheltered Workshop Report of the Secretary of Labor and Technical Report on Wage Payments to Handicapped Clients in Sheltered Workshops,'' September 1967.

[301] *See, e.g.,* Agnieszka Zalewska, Jean Winsor, & John Butterworth, ''Intellectual and Developmental Disabilities Agencies' Employment and Day Services (1988–2021),'' *ThinkWork, Data Note Plus,* Issue 87 (2023), at 8, *https://www.thinkwork.org/sites/default/files/2024-01/DN_87_R_0.pdf. See also* NLTS2, Exhibit 5–2, noting the vast majority of youths with I/DD having a transition goal of competitive or supported employment (79 percent) compared to sheltered employment (14 percent).

[302] *See, e.g.,* ''Legal Foundations for Protection and Advocacy Entities,'' Part 1 (July 15, 2021) 5, n.22, *https://aoddisabilityemploymenttacenter.com/wp-content/uploads/2021/07/DETAC_BY_Resource_PA_Legal_Foundations_Pt_1_Final_508.pdf* (explaining that research demonstrates that a very low percentage of workers—less than 5 percent—transition from sheltered workshops being paid subminimum wages to integrated or community-based employment at full wages) (citations omitted); *see also* U.S. Dep't of Justice Civil Rights. Div., ''Questions and Answers on the Application of the ADA's Integration Mandate and *Olmstead* v. *L.C.* to Employment and Day Services for People with Disabilities,'' p.1 (''The work of individuals with disabilities in segregated settings is often highly regimented and typically offers no opportunity for advancement.'').

[303] Nat'l Disability Rights Network, ''Segregated and Exploited: The Failure of the Disability Service System to Provide Quality Work,'' 2011, A Letter from the Executive Director, *https://www.ndrn.org/wp-content/uploads/2019/03/Segregated-and-Exploited.pdf* at 32–33.

[304] *See* DOJ ADA Integration Mandate Q&As.

[305] *See Portland Terminal,* 330 U.S. at 151.

and access, while legal precedent has bolstered these nationwide laws. Most significantly, over the past several decades, the ADA and the Supreme Court's *Olmstead* decision have profoundly impacted the rights and employment opportunities available to individuals with disabilities. These legal developments have resulted in changes to workforce development and vocational rehabilitation systems that provide more support to individuals with disabilities in achieving and maintaining employment at or above the full minimum wage, as discussed above. While the ADA has been the catalyst for substantial change and progress in the legal landscape affecting workers with disabilities, the section 14(c) regulations could not have contemplated this progress or incorporated the fundamental anti-discrimination and reasonable accommodation protections of the ADA. Additionally, the ADA's broad legal protections (made more broadly applicable through the ADAA [306]), coupled with *Olmstead's* integration mandate and the array of employment-related programs, and supports for workers with disabilities discussed in this proposed rule, fundamentally alters the assessment as to whether subminimum wages are necessary to prevent curtailment of employment opportunities. The Department is also cognizant of the Department of Justice's conclusion that public entities (*i.e.,* state and local governments) may be in violation of the ADA's integration and equal employment opportunity mandates if they plan, administer, operate, fund, or implement any services—including employment or day services—in a way that unjustifiably segregates individuals with disabilities.

The Department also takes notice of the multitude of Federal and State programs encouraging CIE that do not rely on the payment of subminimum wages to workers. There is now an extensive and continually growing network of supports for workers with disabilities to access full-wage employment opportunities in a variety of ways, as evidenced by the fact that all States and the District of Columbia have taken Employment First actions. The opportunities available to workers with intellectual or developmental disabilities have been fundamentally changed by these laws, regulations, executive orders, and policy initiatives. As a result, more than ever before, these workers have the chance to ''move proudly into the economic mainstream of American life.'' [307]

The Department is further persuaded by the overwhelming evidence and arguments put forward by the majority of disability-focused government, academic, and advocacy organizations illustrating that section 14(c) certificates are no longer necessary. Non-partisan Federal agencies that have studied the issue in depth, such as the USCCR and NCD, have published detailed reports concluding that the payment of subminimum wages is unnecessary to create employment opportunities for individuals with disabilities, including individuals with I/DD, and that section 14(c) certificates may actually be detrimental to the population they are intended to help. Indeed, as noted above, the USCCR found there is little distinction among characteristics of the I/DD workforce that receives at least the full Federal minimum wage and the characteristics of the I/DD workforce that receives subminimum wages. The Department finds it particularly noteworthy that, as evidenced in the USCCR findings, workers with disabilities being paid at least the full minimum wage experience similar disabilities and have similar support needs as workers with disabilities being paid subminimum wages, and finds this compelling evidence to preliminarily conclude that section 14(c) certificates are no longer necessary to prevent the curtailment of employment opportunities. Indeed, individual experiences of workers in States where subminimum wages have been phased out also demonstrate that there are not insurmountable barriers to transitioning to employment at or above the full Federal minimum wage, as evidenced by the experience of the lead plaintiff in *Lane* v. *Brown.* Prior to filing her suit, Paula Lane worked on an assembly line packaging gloves for 66 cents an hour.[308] Subsequently, Lane found work at full wages in a community setting.[309]

Nearly half of U.S. States have now prohibited or limited the payment of subminimum wages. Additionally, as further discussed in section VII, although the unemployment rate for individuals with disabilities remains relatively high compared to the entire population (though it is trending in a favorable direction), the available data demonstrates that there is a strong demand for CIE opportunities, that subminimum wage employment does not typically lead to competitive integrated employment, and that the States that have abolished subminimum wages have not, in general, seen a comparative decrease in employment opportunities for individuals with disabilities. The Department finds that Oregon's experiences—and the amount of data available due to the *Lane* v. *Brown* settlement agreement, discussed above—are especially instructive in considering why subminimum wages are no longer necessary. In a relatively short time period, Oregon was able to meet or exceed the numerical metrics of the *Lane* v. *Brown* settlement agreement regarding, among other things, the reduction in sheltered workshop hours, the provision of supported employment services, and achieving competitive integrated employment for the numbers of individuals specified in the settlement agreement.[310] The Department notes that the Oregon example sheds light on the fact that current employers of workers receiving subminimum wages are usually publicly funded, and that States which have stopped the payment of subminimum wages can achieve positive outcomes in part by redirecting these funds away from sheltered workshops or other jobs where subminimum wages are being paid toward full wage employment opportunities.[311] Similarly, nearly 25 years ago, Vermont achieved an end to subminimum wage by, in part, ending funding for new entrants into sheltered workshops.[312] These examples also highlight the shift in employer demographics for certificate holders—from the ''industry,'' ''manufacturers,'' and ''small businessmen'' who were the potential section 14(c) employers discussed during the floor debate in 1937 to the vast majority of certificate holders today being CRPs, many of whom receive some type of public funding. While most of the employers envisioned in 1937 were market-driven private sector employers, today's section 14(c) employers are commonly enmeshed with public funding streams

[306] *Supra* note 110.

[307] President George H.W. Bush, Remarks at the Signing of the Americans with Disabilities Act (July 26, 1990), *https://perma.cc/VNU4-HR7P.*

[308] Disability Rights Oregon, ''Lawsuit: State Required to Limit Use of Sheltered Workshops,'' *https://www.droregon.org/litigation-resources/lane-v-brown.*

[309] *Id.*

[310] Final Report to the Court of the Independent Reviewer, *Lane* v. *Brown,* Civil Action No. 3:12–cv–00138–ST (D. Or.), *https://www.centerforpublicrep.org/wp-content/uploads/FINALLaneIRFinalReporttotheCourt6.30.22.pdf.*

[311] *Id.* Specifically, Oregon ceased funding and closed all sheltered workshops within a matter of a few years, and instead increased access to supported employment services and CIE for workers with I/DD, expanded evidence-based transition practices, developed an agency infrastructure across State agencies, and, critically, enhanced Federal and State funding to support access to CIE.

[312] USCCR Report at 180.

that may be able to be redirected, as several States such as Oregon and Vermont have already demonstrated.

The Department finds that the evidence from Oregon and Vermont's experiences further supports its preliminary conclusion that payment of subminimum wages is no longer necessary to prevent the curtailment of employment opportunities for workers with disabilities. As described in Section VII, the Department's analysis yields no statistical evidence that employment or the labor force participation rate of individuals with cognitive disabilities differed in States that have adopted laws, policies, or regulations that do not allow the payment of subminimum wages. However, the Department's analysis did show a statistically significant increase in average hourly wage rates of such individuals. The Department believes the results of this analysis, while not dispositive, further support its preliminary conclusion that employment opportunities exist for workers with disabilities that are independent from section 14(c) certificates. The Department welcomes comments on States' experiences in prohibiting or limiting the payment of subminimum wages to workers with disabilities.

The Department recognizes and deeply values the lived experiences of workers as well as families who may have a loved one working under a section 14(c) certificate and who may wish to continue in their current positions under which they are paid subminimum wages. The Department welcomes public comment on this proposed rule. The Department also emphasizes that nothing in this proposal would require existing section 14(c) certificate holders to amend the services they currently provide, including employment services, other than by paying all workers the full required minimum wage for all covered work, as of the phaseout effective date, as explained below. The Department notes that, as a general matter, the empirical evidence reviewed does not indicate that workers transitioning from subminimum wage employment have had negative outcomes. As outlined above and discussed in a number of reports referenced herein, many more workers with disabilities are working in competitive integrated employment and workers and their families have expressed positive feelings about new opportunities and spending more time in the community, as noted, for example, by families in Vermont who have experienced this transition. Congress has directed that employment of workers with disabilities at subminimum wages may occur only if the Secretary determines it is necessary to prevent the curtailment of employment opportunities for workers with disabilities. Thus, in considering its obligations under the section 14(c) provisions to evaluate opportunities for employment for workers with disabilities, it is appropriate for the Department to consider how the evolution described above impacts whether the payment of subminimum wages to workers with disabilities is necessary to prevent the curtailment of employment opportunities for workers with disabilities. The Department must also enforce this statutory mandate in the broader context of the FLSA generally, including the fundamental principle that FLSA rights cannot be waived by workers or employers, and consider whether, even if workers would agree to work for subminimum wages, it is necessary to continue granting certificate authority permitting payment of wages below the current Federal minimum wage of $7.25 per hour.

The Department's analysis as set forth in this proposed rule preliminarily indicates workers with disabilities—including workers with I/DD—no longer need subminimum wages for employment opportunities. With expanded opportunities and legal protections, both compared to the enactment of section 14(c) in 1938 and the last substantive update to the section 14(c) regulations in 1989, and with opportunities for full-wage employment now substantially more common than subminimum wage employment, the Department proposes to phase out issuance of section 14(c) certificates based on its tentative conclusion that these certificates are no longer necessary to prevent the curtailment of employment opportunities for workers with disabilities.

IV. Discussion of Proposed Regulatory Changes

The Department proposes to revise 29 CFR 525.1 to explain that, as evidenced by the analysis set forth above in the Need for Rulemaking section, the Secretary has preliminarily determined that section 14(c) certificates are no longer necessary to prevent the curtailment of opportunities for employment of individuals with disabilities. The Department further proposes to revise that regulation to explain, in light of this determination, that the Secretary will cease issuing new certificates immediately as of the effective date of a final rule and that certificates will only be available to renewing applicants for a limited phaseout period ending 3 years after the effective date of a final rule. The Department further proposes to revise 29 CFR 525.1 to clarify that this part remains in effect during the phaseout period. The contours of the Department's proposed certificate phaseout are explained below in greater detail. The Department seeks comments on the structure of the proposed phaseout, including the proposed length of the phaseout period and any potential extensions to the defined phaseout period, factors affecting the sufficiency of any phaseout period, and states' and organizations' experience with phasing out the use of subminimum wages.

A. Phaseout

The Department proposes that WHD would no longer issue new section 14(c) certificates in response to initial applications postmarked or submitted online on or after the effective date of the final rule because the Department preliminarily finds such certificates are no longer necessary to prevent the curtailment of employment opportunities for individuals with disabilities. Employers that do not hold a valid section 14(c) certificate or that have not timely and properly filed a renewal application as of the effective date of the final rule would not have authority to pay subminimum wages and neither they nor the workers whom they employ would be actively utilizing a section 14(c) certificate for their respective operations or jobs. Accordingly, proposed 29 CFR 525.7 states that only applicants who are seeking to renew a certificate pursuant to proposed 29 CFR 525.13, but not initial applicants, may apply for certificates. The Department also proposes to amend 29 CFR 525.7 to provide minor clarifying edits regarding the certificate application process.

For employers who hold a valid section 14(c) certificate at the time of the effective date of a final rule and seek to renew that certificate, the Department proposes, at 29 CFR 525.13, that it would continue to process renewal applications for such existing certificate holders for a 3-year period beginning on the effective date of a final rule, with all renewals granted within that period expiring no later than the date that is 3 years after the effective date of a final rule. The Department proposes that a phaseout period would allow those employers to prepare and transition to the payment of minimum wages required under the law. Based on the Department's experience, the Department preliminarily finds this

multi-year phaseout period would provide time for employers who are paying subminimum wages pursuant to section 14(c) certificates, if needed, to make necessary adjustments to their operation and funding models. Likewise, affected workers with disabilities who would be due higher wages under the Department's proposed rule may, for example, use the phaseout period to explore new workplace accommodations, participate in additional job training or vocational services, or receive counseling about public benefits and income. Finally, the proposed phaseout period would also provide time for States and other entities to adjust budget allocations, staffing, and disability service delivery programs, as needed, to continue to support workers with disabilities and service providers after the phaseout period ends and the payment of subminimum wages is prohibited for workers with disabilities. As discussed below in section V., State statutes containing multi-year phaseouts have phaseout periods that range from 2 years to 7 years, with many states opting for a 2- or 3-year phaseout. The Department proposes that 3 years should be sufficient to allow for transitions away from subminimum wage employment but seeks comments on the need for, length of, and factors affecting any phaseout period. As specified at proposed 29 CFR 525.13(b), all section 14(c) certificates renewed on or after a final rule's effective date would expire at or before the end of that phaseout period, and under the proposed rule, if finalized, the Department would no longer issue any section 14(c) certificates after the last day of that phaseout period. The Department proposes to make conforming edits to 29 CFR 525.2, 525.9, and 525.11(c) to ensure that stakeholders understand the proposed phaseout.

The Department also notes that, as discussed above, many oversight and advocacy reports that recommend an end of the payment of subminimum wages concluded that such plans should include a phaseout period but varied in providing recommendations concerning the length of the phaseout period. For example, NCD recommended a gradual phaseout of the use of subminimum wages to allow time for modernization of employment service systems that would promote successful transitions for people currently working under section 14(c) certificates.[313] In another example, the USCCR also recommended a multi-year phaseout ''to allow transition among service providers and people with disabilities to alternative service models . . . .'' but did not specify a length for the phaseout period.[314] The Department further notes that many such reports recommend that a gradual end of subminimum wages should be accompanied by simultaneous movement of workers with disabilities into integrated employment. However, the Department's authority and its proposed rule do not require any change to employment settings during the phaseout period or anytime thereafter.

In accordance with this phaseout proposal, the Department proposes to modify 29 CFR 525.7 to reflect that the Department would no longer accept initial applications for a section 14(c) certificate as of the effective date of a final rule. Moreover, the Department proposes in 29 CFR 525.11 that section 14(c) certificate holders, assuming all legal requirements are met, may continue to operate under section 14(c) certificate authority for up to 3 years after the effective date of a final rule. Because the Department proposes that this phaseout would lead to a cessation of all certificate issuance, the Department does not propose any changes to the operational requirements of the section 14(c) regulations, such as the procedures for determining a commensurate wage, for employers who hold a valid certificate during the phaseout period.

The Department requests comments on the length and structure of the proposed phaseout period and any evidence that supports those comments, including data, case studies, explanations of program or funding structures, and the personal experiences of employers and employees. The Department's proposal to phase out section 14(c) over several years is intended to avoid disruptions to services, supports, and funding streams needed to transition workers from being paid subminimum wages while still timely phasing out subminimum wage payments to individuals with disabilities. The Department specifically invites comment on how it may implement any proposed phaseout in a manner that further reduces potential disruptions. The Department also invites comment on how State and publicly funded entities may be impacted by a phase out of section 14(c), including comments relevant to the length of the phase-out period.

Finally, the Department proposes to revise 29 CFR 525.18, which sets forth an administrative appeal process for any person aggrieved by any action of the Administrator taken pursuant to the regulations, to explain that any administrative review granted cannot result in section 14(c) certificate authority being extended beyond the phaseout period.

B. Request for Comments Related to Potential Extensions

In reviewing phaseouts of subminimum wages, the Department observes that the State of Washington allowed for a one-time extension period of up to 12 months in its phaseout of subminimum wages.[315] Similarly, the AbilityOne Commission granted limited extensions no longer than 12 months when it phased out subminimum wages.[316] The Department has not proposed such an extension framework in this proposed rule. As discussed above, the Department proposes that a 3-year phaseout period should be sufficient for most, if not all, employers that currently hold section 14(c) certificates to adjust their operations and funding structures such that they can transition away from subminimum wages by the end of that period. However, if the Department finalizes the proposal herein that current section 14(c) certificate holders may renew their certificates to allow payment of subminimum wages until 3 years from the effective date of a final rule, the Department anticipates considering whether any potential extension framework should be added to the final rule, and seeks comments accordingly.

The Department requests comments on all aspects of a possible limited

[313] 2018 NCD Report at 99–100.

[314] USCCR Report at 223.

[315] Wash. Rev. Code Sec. 49.46.170, [Washington Minimum Wage Act; Minimum Wage and Labor Standards; State Agencies Prohibited From Employing Individuals With Disabilities At Less Than Minimum Wage Beginning July 1, 2020; No New Special Certificates May Be Issued After July 31, 2023], Wages & Hours P 50–41016; *see also* Washington Department of Labor and Industries, 2023 Annual Report to the Legislature, p.2, *https://www.lni.wa.gov/agency/_docs/2023SubMinimumWageCertificatesReport.pdf* (Most private certificate holders were subject to a two-year phaseout, with a possible one-time, one-year extension for a total of three years).

[316] Prohibition on the Payment of Subminimum Wages Under 14(c) Certificates as a Qualification for Participation as a Nonprofit Agency Under the Javits Wagner O'Day Act, 87 FR 43427, 43428 (July 21, 2022) (codified at 41 CFR part 51) (''However, an [non-profit agency] may apply for an extension for up to 12-months in order to come into compliance if it can provide evidence for why it cannot make the wage adjustments by the effective date (due to budgetary limitations, because doing so will necessarily harm employees, or for other good cause) and if it provides a corrective action plan describing the steps it intends to take to achieve compliance within the approved extension period.''). The Commission noted, in implementing a 90-day effective period for its rule, that its position on phasing out use of section 14(c) had been announced in a 2019 notification and resources supporting transition were invested even prior to the rulemaking.

extension provision beyond the end of the proposed 3-year phaseout period, including whether an extension provision would be appropriate, the duration of any such extension(s), the showing (including any documentation) an employer must make to receive an extension, the criteria by which requests for extension should be reviewed, and the procedures by which employers apply for extension(s).

For example, the Department requests comments as to the length of time any extension might extend (including whether any potential extension should be limited to a maximum of 3, 6, 12, or 18 months, or some other period). The Department further requests comment as to whether any employer should be able to receive more than one extension, and if multiple extensions are allowed, whether there should be a maximum limit on the total number of extensions granted to a certificate holder (*e.g.,* each certificate holder would only be entitled to two time-limited extensions). Similarly, the Department requests comments on whether there should be a maximum time limit on the total number of extensions granted to a certificate holder (*e.g.,* each certificate holder would be eligible for multiple extensions, but not to exceed a total extension period of 12 months). Likewise, the Department also seeks comments on whether, if extensions were to be available, certificate holders should be required to demonstrate good cause for any extension request. The Department welcomes public comment on what a certificate holder might need to present to demonstrate such good cause as well as the specific documentation needed to support such cause. For example, the Department welcomes comment on whether, if an extension were to be available, it should be granted only when there are unique factual circumstances outside of an employer's control, a need for additional time for the employer to complete an orderly transition from the payment of subminimum wages, and a need to avoid undue disruptions impacting workers with disabilities currently employed at subminimum wages.

C. Severability

The Department proposes that the regulatory text include a severability provision in part 525 so that if one or more of the provisions in part 525 is held invalid or stayed pending further agency action, the remaining provisions would remain effective and operative. The Department proposes to add this provision as § 525.25. The proposed provision explains that each provision is capable of operating independently from one another, and that if any provision of part 525 is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from the regulation and shall not affect the remainder thereof.

V. Alternatives to the Proposed Rule

In developing this proposed rule, the Department considered a wide range of alternative regulatory approaches. For example, the Department considered whether to allow workers with disabilities who are currently paid subminimum wages to ''opt out'' of the proposed phaseout of section 14(c) certificates set forth in this proposed rule. In other words, the Department evaluated whether to permit such workers to choose to continue receiving subminimum wage payments where they believe such continuity would be beneficial. However, after consideration and analysis, the Department has determined that such a regulatory alternative would not be legally permissible or advisable as a policy matter.

In this proposed rule, the Department has preliminarily concluded that payment of subminimum wages is not necessary to prevent curtailment of opportunities for employment. In the absence of such need, an opt-out provision would be akin to allowing a waiver of the FLSA's requirement to pay minimum wages. As discussed in section II.D. above, it is well-established that the right to the full Federal minimum wage cannot be waived by individual workers or employers. The Supreme Court has consistently and explicitly held that ''FLSA rights cannot be . . . waived because this would 'nullify the purposes' of the statute and thwart the legislative policies it was designed to effectuate.'' [317] The Department is foreclosed, as a legal matter, from allowing workers with disabilities, or their families or guardians, to ''opt out'' of receiving the full Federal minimum wage on an individual basis. Rather, the FLSA is clear that an employer may only pay subminimum wages to workers with disabilities after obtaining a certificate from the Department and that such certificates can only be issued when the Department decides that they are necessary to prevent the curtailment of employment opportunities. Congress did not grant the Department unconditional authority to issue subminimum wage certificates, or to permit subminimum wage payments based on such workers' preferences.

Finally, the Department rejected this alternative because it would likely result in formidable administrative challenges for both WHD and employers, as well as confusion on the part of workers.

The Department also considered alternative regulatory approaches to the proposed phaseout of section 14(c) certificates. As detailed above, the Department proposes to: (1) cease issuance of new section 14(c) certificates to employers submitting an initial application on or after the effective date of a final rule and (2) permit existing section 14(c) certificate holders, assuming all legal requirements are met, to continue to operate under section 14(c) certificate authority for up to 3 years after the effective date of a final rule.

Among the alternative approaches that were considered the Department also considered whether to use a different phaseout period. The Department declined to propose a shorter phaseout period (or no phaseout period) because, as explained in this proposed rule, individuals with disabilities who have been working for employers holding a section 14(c) certificate, employers who have held a section 14(c) certificate, and government entities may need time to transition to the payment of the full minimum wage in order to mitigate disruptions that might potentially otherwise cause curtailment of employment opportunities. At the same time, the Department also declined to propose a longer phaseout period. As discussed in section III.D.1.i., many States have already passed laws prohibiting (or planning to prohibit) the payment of subminimum wages through a phase out.[318] State statutes containing multi-year phaseouts range from 2 years to 7 years, with many states opting for a 2- or 3-year phaseout. In view of this, the Department thus believes that 3 years should be sufficient to allow for transitions away from subminimum wage employment. Furthermore, the Department is concerned that a longer period might incentivize delay of effective transition measures.

[317] *Barrentine,* 450 U.S. at 740 (quoting *Brooklyn Sav.,* 324 U.S. at 707).

[318] *See* section III.D.1.i. for a fuller discussion of State phaseout periods.

The Department also considered revising its existing regulations to change the process and evidence employers would need to provide in order to demonstrate that the payment of a subminimum wage is necessary to prevent the curtailment of employment opportunities. The Department did not propose such changes because, as explained elsewhere in this proposal, given the statutory legal authority requiring the Department to determine the necessity of certificates (to the extent necessary to prevent the curtailment of opportunities for employment), the best approach is to examine the standard based on a comprehensive consideration of how employment opportunities are both currently curtailed and created across the employment market rather than on the framework set out in the 1989 regulations reflecting the presumption that subminimum wages are necessary where productivity measures are satisfied. As this proposal explains, the Department's preliminary findings are that employment opportunities exist sufficiently apart from section 14(c) certificates to justify the proposed determination to stop issuing certificates through a multi-year phaseout. Given this belief and the Department's proposed determination, a change to only alter the requirements of holding a certificate may not fully meet the Department's statutory obligation under the curtailment clause given the changed opportunities for employment currently.

The Department also considered proposing an additional extension period beyond the 3-year phaseout period. However, as stated above, the Department proposes that a 3-year phaseout period should be sufficient for most, if not all, employers that currently hold section 14(c) certificates, to adjust their operations and funding structures such that they can transition away from subminimum wages by the end of that period. Furthermore, any extension option increases the risk of use of certificates beyond an actual period of demonstrated need for orderly transition, and might undercut the incentive for those employers to make efficient and timely plans to move away from subminimum wages. However, as noted above, the Department seeks comments about a potential extension option.

VI. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* and its attendant regulations, 5 CFR part 1320, require the Department to consider the agency's need for its information collections, their practical utility, the impact of paperwork and other information collection burdens imposed on the public, and how to minimize those burdens. The PRA typically requires an agency to provide notice and seek public comments on any proposed collection of information contained in a proposed rule. *See* 44 U.S.C. 3506(c)(2)(B); 5 CFR 1320.8.

This rulemaking would revise the burdens for the existing information collection previously approved under Office of Management and Budget (OMB) control number 1235–0001, Fair Labor Standards Act Special Employment Provisions. The 1235–0001 information collection encompasses information collected pursuant to FLSA sections 11(d), 14(a), and 14(b), as well as section 14(c). As required by the PRA, the Department has submitted information collections as revisions to existing collections to OMB for review to reflect changes to existing burdens that will result from and are limited to the implementation of this section 14(c) rulemaking.

Summary: FLSA section 14(c) authorizes the Department to issue certificates permitting employers to pay workers whose disabilities impair their earning or productive capacity at wage rates below the Federal minimum wage. The Department has promulgated regulations at 29 CFR 525 to administer and enforce section 14(c) of the FLSA. This NPRM, if finalized, would impose new information requirements revising an existing information collection.

Purpose and use: This proposed rule, which would revise 29 CFR part 525, would result in the Department no longer issuing new section 14(c) certificates in response to initial applications postmarked or submitted online on or after the effective date of a final rule. Pursuant to the proposed rule, the Department would permit existing section 14(c) certificate holders, assuming all legal requirements are met, to continue to operate under section 14(c) certificate authority and re-apply for continued certificate authority for up to 3 years after the effective date of a final rule. In addition, as discussed above, the Department proposes that a 3-year phaseout period should be sufficient for most, if not all, employers that currently hold section 14(c) certificates to adjust their operations and funding structures such that they can transition away from subminimum wages by the end of that period. However, the Department also requests comments on all aspects of a possible limited extension provision beyond the end of the proposed 3-year phaseout period.

This proposed rule, if finalized, would impact the collection by reducing the number of employers that hold section 14(c) certificates throughout the phaseout period, and thereby also reduce employees employed under section 14(c) certificates. However, ultimately, 3 years from the effective date of a final rule, there would be no section 14(c) certificates and no employees employed under section 14(c) certificates, which would eliminate the burden associated with this collection.

WHD obtains PRA clearance under OMB control number 1235–0001 for an information collection with respect to subminimum wage employment. An Information Collection Request (ICR) has been submitted to revise the approval and adjust the burdens for this collection.

Information and technology: There is no particular order or form of records prescribed in the current regulations or in the proposed rule. An employer may meet the requirements of this proposed rule using paper or electronic means. The Department has enhanced the section 14(c) certificate application process by implementing an online electronic application platform to submit Forms WH–226 and WH–226A; this platform can be found on the Department's website at: *https://section14c.dol.gov/.* The Department also makes Forms WH–226 and WH–226A and instructions for completing them available in a fillable Adobe PDF format for downloading and printing from the Department's website at: *https://www.dol.gov/agencies/whd/forms/wh226.* Respondents currently have the option of either mailing the form(s) or completing and submitting an application using the section 14(c) online application system.

Minimizing Small Entity Burden: While information collections, *i.e.,* WH–226 and WH–226A, may involve a substantial number of small businesses or non-profit agencies, the collections do not have a significant impact on those small entities. Forms WH–226 and WH–226A collect information necessary for the Department to determine if an employer qualifies for a certificate. The data collection gathers additional information on individual workers to better assist the agency in preventing abuse of a vulnerable worker population. The Department has provided detailed item-by-item instructions and online tools such as wage calculators to assist all employers, including small entities, in completing these forms and complying with the statutory and regulatory requirements. The Department also has an online

electronic platform for submission of the information.

Public comments: As part of its continuing effort to reduce paperwork and respondent burden, the Department conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the PRA. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

The Department seeks comments on this NPRM and its potential impact to public burdens associated with ICR 1235–0001, Fair Labor Standards Act Special Employment Provisions. Detailed calculations indicating respondents, responses, burden hours, and burden costs are contained in the supporting statement found at *www.reginfo.gov.*

Commenters may send their views on the Department's PRA analysis in the same way they send comments in response to the NPRM as a whole (*e.g.,* through the *www.regulations.gov* website), including as part of a comment responding to the broader NPRM. Alternatively, commenters may submit a comment specific to this PRA analysis by sending an email to *WHDPRAComments@dol.gov.* While much of the information provided to OMB in support of the information collection request appears in the preamble, interested parties may obtain a copy of the supporting statements for the affected ICR by sending a written request to the mail address shown in the **ADDRESSES** section at the beginning of this preamble. Alternatively, a copy of the ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free of charge from the *RegInfo.gov* website by visiting *http://www.reginfo.gov/public/do/PRAMain.*

OMB and the Department are particularly interested in comments that:

- Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Total burden for the affected information collection, including the burdens that will be affected by this proposed rule and any changes are summarized as follows:

Type of review: Revision to currently approved information collections.

Agency: Wage and Hour Division, Department of Labor.

Title: Fair Labor Standards Act Special Employment Provisions.

OMB Control Number: 1235–0001.

Affected public: Private sector, not-for-profits, businesses or other for-profits, and Individuals or Households.

Estimated number of respondents: 335,167 (0 from this rulemaking).

Estimated number of responses: 1,338,561 (0 from this rulemaking).

Frequency of response: On occasion.

Estimated annual burden hours: 671,464 (0 from this rulemaking).

Estimated annual burden costs (capital/startup): $0 ($0 from this rulemaking).

Estimated annual burden costs (*operations/maintenance*): $2,284 ($0 from this rulemaking).

Estimated annual burden costs: $32,404,730 ($0 from this rulemaking).

VII. Analysis Conducted in Accordance With Executive Order 12866, Regulatory Planning and Review, Executive Order 13563, Improving Regulation and Regulatory Review, and Executive Order 14094

Under Executive Order 12866 (as amended by Executive Order 14094), OMB's Office of Information and Regulatory Affairs (OIRA) determines whether a regulatory action is significant and, therefore, subject to the requirements of the Executive order and OMB review. As amended by Executive Order 14094, section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as a regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, territorial, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive order. OIRA has determined that this proposed rule is a ''significant regulatory action'' under section 3(f)(1) of Executive Order 12866, as amended.

Executive Order 13563 directs agencies to, among other things, propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; that it is tailored to impose the least burden on society, consistent with obtaining the regulatory objectives; and that, in choosing among alternative regulatory approaches, the agency has selected those approaches that maximize net benefits. Executive Order 13563 recognizes that some costs and benefits are difficult to quantify and provides that, when appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts. The analysis below outlines the impacts that the Department anticipates may result from this proposed rule and was prepared pursuant to the above-mentioned executive orders.

A. Background and Need for Rulemaking

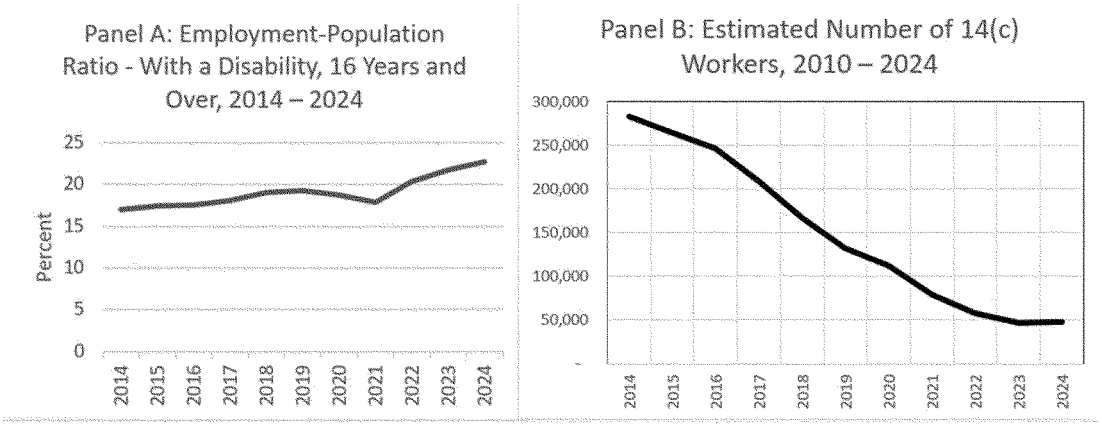
The FLSA generally requires that employees be paid at least the Federal minimum wage, currently $7.25 per hour, for every hour worked and at least one and one-half times their regular rate of pay for each hour worked over 40 in a single workweek.[319] Since its enactment in 1938 through today, section 14 of the FLSA has included a provision authorizing the Department to issue certificates permitting employers to pay workers whose disabilities impair their earning or productive capacity at wage rates below the Federal minimum wage. That statutory provision, however, has always provided a significant condition precedent: such certificates may only be issued to the extent ''necessary to prevent curtailment of opportunities for employment.'' [320]

[319] 29 U.S.C. 206(a), 207(a).

[320] 29 U.S.C. 214(c)(1).

Since the Department first promulgated regulations governing the issuance of section 14(c) certificates in 1938, and even since the Department last substantively updated those regulations more than 35 years ago, opportunities for employment have dramatically changed for individuals with disabilities. In recent years, the employment rate for individuals with disabilities has generally climbed (Figure 1, Panel A). During the same time period, the estimated number of individuals working under section 14(c) certificates has declined (Figure 1, Panel B).

Figure 1. Employment and Section 14(c) Workers 2014 – 2024



Notes: Employment-population ratios calculated using the average monthly ratios for the year ending in May of each year to align with Panel B. Ratios are based on data from the Current Population Survey (CPS), which is the primary source for labor force statistics. CPS tends to estimate a lower number of disabled workers compared to other nationally representative surveys, such as the American Community Survey (ACS), which is more commonly used for population estimates. However, the changes in trends over time are similar across both surveys.

Sources: Panel A: U.S. Bureau of Labor Statistics, Employment-Population Ratio—With a Disability, 16 Years and over [LNU02374597], retrieved from *https://data.bls.gov/timeseries/LNU02374597,* September 30, 2024; Panel B: WH–226A form data of issued and pending certificates, May 1 (2014 through 2024).

Fueled by the disability rights movement, societal and cultural assumptions, beliefs, and expectations regarding the employment of individuals with disabilities have evolved, and opportunities for individuals with disabilities have dramatically expanded. Federal legislation and judicial precedent have established and enshrined fundamental legal protections requiring equal access, opportunities, and respect for individuals with disabilities in both education and employment. Of these legislative and judicial developments, the landmark Americans with Disabilities Act (ADA), enacted in 1990, the year after the section 14(c) regulations were last substantively updated, has had a profound impact on employment opportunities for individuals with disabilities. In addition, the President and executive agencies have taken steps to end the payment of subminimum wages to workers with disabilities on certain government contracts. Numerous States and localities have prohibited or limited the payment of subminimum wages to workers with disabilities within their jurisdictions.

Although it is widely acknowledged that individuals with disabilities continue to face challenges in obtaining equal opportunity and treatment, the extent of legal protections, opportunities, resources, training, technological advancements, and supports has dramatically expanded since regulations were first promulgated over 85 years ago, and since 1989, when the Department's regulations were last substantively updated, to assist individuals with disabilities both in obtaining and maintaining employment at or above the full Federal minimum wage. Employers similarly have substantially more resources and training available to recruit, hire, and retain workers with disabilities in employment at or above the full Federal minimum wage. Recognizing the expansion of full-wage employment options for individuals with disabilities, an increasing number of oversight and advisory reports have vigorously called for a ''phase out'' of section 14(c) certificates. As another indication that subminimum wages are not necessary to prevent the curtailment of employment opportunities, an increasing number of States and localities, including many jurisdictions with higher minimum wages than the FLSA minimum wage, have prohibited or limited the payment of subminimum wages in their respective jurisdictions. Furthermore, an increasing number of employers themselves are voluntarily opting out of paying subminimum wages, as is reflected in the rate at which the number of section 14(c) certificate holders has substantially declined in recent years, while at the same time the employment rate for people with disabilities has generally climbed. Due to expanded opportunities both compared to the enactment of the section 14 provisions and promulgation of initial regulations in 1938 and the last substantive update to the section 14(c) regulations in 1989, with opportunities for full-wage employment now substantially more common than subminimum wage employment, the Department preliminarily concludes that the issuance of section 14(c) certificates is no longer necessary to prevent the curtailment of employment opportunities for individuals with disabilities.

Accordingly, the Department proposes to phase out the issuance of section 14(c) certificates. The Department specifically proposes to: (1) cease issuance of new section 14(c)

certificates to employers submitting an initial application on or after the effective date of a final rule and (2) permit existing section 14(c) certificate holders, assuming all legal requirements are met, to continue to operate under section 14(c) certificate authority for up to 3 years after the effective date of a final rule. The Department requests comments on all aspects of a possible limited extension provision beyond the end of the proposed 3-year phaseout period, including whether an extension provision would be appropriate, the duration of any such extension(s), the showing (including any documentation) an employer must make to receive an extension, the criteria by which requests for extension should be reviewed, and the procedures by which employers apply for extension(s).

B. Number of Affected Workers and Employers

The entities that will be directly affected by this proposed rule are section 14(c) certificate holders and workers with disabilities being paid a subminimum wage by a certificate holder. According to WHD's data on section 14(c) certificate holders as of May 1, 2024, there were 801 employers who had certificates that were either issued or pending.[321] Employers holding issued certificates reported paying approximately 40,579 workers at subminimum wages in their previously completed fiscal quarter.[322]

The Department has provided additional data below about the hours, earnings, and primary disability of workers reported by employers on applications for section 14(c) certificates. In addition to these workers, there may be other categories of workers affected by this proposed rule, such as youth with disabilities looking to enter employment, or non-working individuals with disabilities who may choose to enter the labor force if there is an increase in full-wage employment options (see section VII.D.4. for an additional discussion on this population). The Department welcomes comments regarding other types of workers who may be affected by the proposed rule.

1. Form WH–226A—Information Collected

When applying for a section 14(c) certificate to employ workers with disabilities at subminimum wages, employers must fill out form WH–226A, which asks for information about workers who were paid subminimum wages at each job site, including the type of work being performed, average hourly earnings, average weekly hours worked, and the primary disability that affects the worker's productivity for the job most performed.[323] The data discussed here reflects what employers have entered on their application forms.[324] Data is for May 1, 2024, and reflects the applicant's most recently completed fiscal quarter at the time they applied.[325]

According to this data, the mean ''average hourly earnings'' for workers on section 14(c) certificates is $4.08, and the median ''average hourly earnings'' is $3.46. These workers work a mean of 11.45 hours per week. Form WH–226A also asks certificate holders about the primary disability that affects each subminimum wage worker's productivity for the job at which they have worked the most number of hours over the most recently completed fiscal quarter. As shown in Table 1, the vast majority (about 91 percent) of workers being paid subminimum wages under section 14(c) certificates have I/DD reported as their primary disability.

TABLE 1—WORKERS ON SECTION 14(c) CERTIFICATES BY PRIMARY DISABILITY

Primary disability	Share of workers on section 14(c) certificates
Age Related Disability	0.09%
Hearing Impairment	0.14
Intellectual/Developmental Disability	90.96
Neuromuscular Disability	0.68
Psychiatric Disability	4.34
Substance Abuse	0.02
Visual Impairment	0.21
Other	3.41

2. Section 14(c) Workers Demographics—Race, Age, and Ethnicity

The WHD section 14(c) application form does not ask for any other demographic data on section 14(c) certificate workers. For their 2023 report, GAO surveyed community rehabilitation program (CRP) employers to estimate the percentage of section 14(c) workers employed by CRPs in August 2021 by race and ethnicity and by age. As shown in Table 2, GAO estimated that a large share of these workers are White and fall between the ages of 25 and 54, which aligns with demographic breakdowns found in the overall employed population.[326]

[321] WHD, 14(c) Certificate Holders, May 1, 2024, *https://www.dol.gov/agencies/whd/workers-with-disabilities/section-14c/certificate-holders.* Note that some of these entities (34 employers) report having zero workers paid a subminimum wage, so this may be an overestimate of the actual number of affected entities. Based on this list, employers operate in the following 38 States: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Texas, Utah, Virginia, Wisconsin, and West Virginia. The remaining 12 States, plus the District of Columbia, had no section 14(c) employers on the list.

[322] *Id.* Note that the number of workers paid subminimum wages are only reported for entities that have issued certificates and does not represent workers that may be employed by employers with subminimum wage payment authority listed as pending.

[323] The information collected from the form WH–226A is submitted by applicants and may include inaccuracies, such as instances when an employer reports a piece rate instead of an hourly wage rate or miscalculates the wage. Inaccuracies may also be the result of data entry errors. The Department presents this information to provide context for the general status of workers on section 14(c) certificates. The summary data presented here does not reflect any changes an employer made after submission of its application, including those based upon the Department's oversight of section 14(c) through its application processes and enforcement actions.

[324] WHD collects this data for the purpose of processing applications to provide employers with certificates authorizing the payment of subminimum wages to workers with disabilities under section 14(c). Although the data from the application forms is not collected for comprehensive statistical analysis, it is the best data that the Department has on the population of workers paid subminimum wages under section 14(c) certificates and is useful to provide context for purposes of this analysis.

[325] In this data set, the effective dates for the certificates range from July 2022 to the present.

[326] For example, in the overall employed population in the U.S., White workers represent 76.5 percent of all employed persons, and workers ages 25 to 54 represent 64 percent of all employed persons. U.S. Dep't of Labor, Bureau of Labor Statistics, BLS Current Population Survey, Employment Status of the Civilian Population by Age, Sex, and Race, 2023, *https://www.bls.gov/cps/cpsaat03.htm.*

TABLE 2—ESTIMATED PERCENTAGE OF SECTION 14(c) WORKERS REPORTED TO BE EMPLOYED BY COMMUNITY REHABILITATION PROGRAMS IN AUGUST 2021, BY RACE/ETHNICITY AND AGE

	Estimated share of workers on section 14(c) certificates (%)
Racial/ethnicity Category:	
White (Not Hispanic or Latino)	78
Black or African American (Not Hispanic or Latino)	14
Asian (Not Hispanic or Latino)	1
Native American or Alaska Native (Not Hispanic or Latino)	1
Hispanic or Latino	5
All other race/ethnicity categories	2
Age:	
18–24 years old	4
25–54 years old	70
55 years old or older	26

Source: GAO Survey of Community Rehabilitation Program employers, 2023 GAO Report

Aside from the information discussed in this section, the Department is unaware of any data source that regularly publishes additional up-to-date demographic information specifically on workers employed by section 14(c) certificate holders. The Department's Bureau of Labor Statistics (BLS) publishes data on all workers with a disability, including sex, race, age, and educational attainment.[327] However, workers who are currently employed under section 14(c) certificates are only a small subset of all workers with a disability. The Department welcomes comments and data on the demographics of workers with disabilities employed under section 14(c) certificates.

3. Affected Employers

As discussed in section II.C.2., WHD issues section 14(c) certificates to business establishments, community rehabilitation programs (CRPs), hospitals/patient worker facilities, and school-work experience programs (SWEPs). The overwhelming majority of current certificate holders are CRPs, representing approximately 93 percent of current certificate holders as of May 1, 2024. In the context of section 14(c), WHD defines CRPs as ''not-for-profit agencies that provide rehabilitation and employment for people with disabilities.'' [328] Such establishments are sometimes referred to as ''sheltered workshops'' as they typically are facility-based and often serve workers with disabilities in sheltered or segregated settings. At the time of drafting, only 30 private-sector, for-profit businesses hold certificates for the payment of subminimum wages, representing 4 percent of total certificate holders. Apart from CRPs and business establishments, the remaining certificates are held by hospitals or residential care facilities that employ patients, representing 3 percent of total certificate holders, and ''school work experience programs'' that represent less than half of one percent of total certificate holders.

In the WHD data reviewed, the expiration dates for certificates fall between May 2024 and early 2026. The Department assumes that a share of the certificate holders with certificates expiring before the publication of the final rule would reapply and be granted new certificates with later expiration dates (no later than 3 years after the effective date of a final rule). The Department does not have information to estimate exactly how many certificate holders will choose to reapply. As of May 1, 2024, 779 of the 801 employers holding or seeking a certificate (97 percent) were renewals, but the overall trend of certificate holders has been in a steady decline over the past decade (the number of pending and issued certificate holders was 2,820 in April 2015 and has declined every year since). If this trend continues, fewer certificate holders may choose to reapply in the future even absent any regulatory action. Furthermore, the publication of the proposed rule may impact certificate holders' choices if they anticipate that certificates are going to be phased out if the rule is finalized as proposed. There may also be changes to State or local laws during this time period that may affect whether certificate holders operating in those states or localities reapply for a certificate. Similarly, employers in States that have already begun a phaseout of subminimum wages may choose not to reapply before expiration of the phaseout period. As of May 1, 2024, there are 53 certificate holders located in States that are in the process of phasing out the payment of subminimum wages.[329]

The number of certificate holders has declined over recent years, and the Department expects that trend to continue. In 2001, the GAO estimated that approximately 424,000 workers with disabilities were paid subminimum wages while working for 5,612 employers holding section 14(c) certificates.[330] As mentioned above, as of May 1, 2024, that number dropped to approximately 40,579 workers with disabilities being paid subminimum wages to employers with issued certificates, while 801 employers held or were seeking section 14(c) certificates, representing a decline in certificate holders of almost 86 percent.[331] All impacts discussed in this

[327] U.S. Dep't of Labor, Bureau of Labor Statistics, BLS Current Population Survey, ''Employment status of the civilian noninstitutional population by disability status and selected characteristics, 2023 annual averages,'' *https://www.bls.gov/news.release/disabl.t01.htm.*

[328] WHD Field Operations Handbook (FOH) 64k00, *https://www.dol.gov/agencies/whd/field-operations-handbook/Chapter-64.*

[329] California (38), Colorado (1), Nevada (4), and South Carolina (10). WHD, 14(c) Certificate Holders, May 1, 2024, *https://www.dol.gov/agencies/whd/workers-with-disabilities/section-14c/certificate-holders.*

[330] U.S. Gov't Accountability Office, GAO–01–886, ''Special Minimum Wage Program: Centers Offer Employment and Support Services to Workers with Disabilities, But Labor Should Improve Oversight'' (2001) (2001 GAO Report) at 10, 18.

[331] The Department notes that data collected by the Department from section 14(c) applications is not census data. Data is derived from information received by WHD during the certificate application process, which is used for the purposes of determining whether to issue a certificate. The application requires the employer to provide a snapshot of its operations and workforce that is paid a subminimum wage during its most recently completed fiscal quarter at the time of its renewal application, and the submission date varies per applicant. Because certificates are issued to the employer, not individuals employed at

regulatory impact analysis use the current number of certificate holders at the time of drafting, but the Department expects this may be an overestimate, as the number of certificate holders could likely decline by the time of publication of the final rule given the overall trends in the number of certificate holders. For example, as of May 1, 2023, the number of employers holding or seeking a section 14(c) certificate was 931, meaning that the number of certificate holders declined by almost 14 percent over the year. If a similar decline were to occur over the forthcoming year, the number of certificate holders could be below 700 by May 2025. Additionally, the data includes certificate holders in states that have plans to phase out the payment of subminimum wages for workers with disabilities in the near future, which could also result in a lower number of certificate holders at the time of the final rule.

C. Costs

1. Regulatory Familiarization Costs

This proposed rule would impose direct costs on section 14(c) certificate holders by requiring them to review the regulation. To estimate these ''regulatory familiarization costs,'' three pieces of information must be estimated: (1) the number of affected certificate holders; (2) a wage level for the employees reviewing the rule; and (3) the amount of time spent reviewing the rule. As discussed above, WHD data shows that there are 801 employers who had certificates that were either issued or pending as of May 1, 2024.[332] The Department assumes that each of these entities would incur some regulatory familiarization costs, and that each certificate holder would spend an average of 2 hours reviewing this proposed rule. The Department assumes that each reviewer will spend 1 minute per page reviewing the regulatory text,[333] which is equivalent to 5 double-spaced pages at the time of publication. They will also review sections of the preamble and any compliance assistance materials as appropriate, so the Department has added significant additional time for that review.

The Department assumes that a Compensation, Benefits, and Job Analysis Specialist (SOC 13–1141) with a median hourly wage of $35.83 will review the rulemaking.[334] The Department also assumes that benefits are paid at a rate of 45 percent of the base wage [335] and overhead costs are paid at a rate of 17 percent of the base wage, resulting in an hourly rate of $58.04 in 2023 dollars. Therefore, the total regulatory familiarization cost to employers is $92,980 (801 entities × 2 hours × $58.04). Although the issuance of section 14(c) certificates would be phased out over multiple years under this proposal, the Department assumes that most affected entities will review the rule when it is published.[336] Therefore, all regulatory familiarization costs are assumed to occur in Year 1 following publication of the rule. Total annualized rule familiarization costs over the first 10 years are estimated to be $12,373, assuming a 7 percent discount rate.

2. Adjustment Costs

As discussed further in Section VII.D., if the issuance of section 14(c) certificates is phased out, employers who are certificate holders might choose to respond in a few different ways. If certificate holders only serve workers with disabilities who are paid the subminimum wage, they might choose to continue operations as they are but pay at least the full Federal minimum wage to those workers. These certificate holders may instead choose to close their organization.[337] Certificate holders who employ other workers (at or above minimum wage) might choose to replace affected workers with disabilities with the other workers; or they might choose to no longer employ workers with disabilities who had been paid subminimum wages under section 14(c), spread the work of those workers to other employees, and not hire any new workers. If certificate holders are already providing rehabilitation or other non-work services to individuals with disabilities, they may alternatively decide to discontinue the employment of these workers while still providing them with those services. Certificate holders will likely incur some adjustment costs under each of these scenarios. If they choose to transition all workers with disabilities to at least the full minimum wage, the increased wage cost would be considered a transfer (discussed below), but they could still incur some adjustment costs associated with updating payroll systems, etc. If entities choose to hire new workers or spread work to existing workers, they may incur hiring costs or adjustment costs associated with these activities. The Department assumes that these costs would likely be incurred by each certificate holder at different points in time prior to when their current certificate expires, so the total costs would be spread out over multiple years.

Because there are many uncertainties in exactly how each certificate holder would respond to this proposed rule, and how the costs would be spread over the proposed phaseout period, the Department has not provided a definitive estimate of adjustment costs. However, as an example, if all certificate holders incurred an average of 1 hour of adjustment costs, the total cost would be $46,490 (801 entities × 1 hour × $58.04). These costs would be spread over multiple years as employers transition their pay practices or change their operation models. The Department welcomes comments and data from certificate holders that would help inform an estimate of adjustment costs.

3. Costs to Workers Employed Under Section 14(c) Certificates

The Department acknowledges that this rule may also result in some costs to workers currently paid subminimum wages under section 14(c) certificates. Although any changes in the wages they receive, the hours they work, or their employment status would be considered a transfer and are discussed below, there could be follow-on effects that would lead to costs for these workers. For example, if a certificate holder does not retain its section 14(c) workers at the full minimum wage, the worker may need to spend time looking for employment at or above the full Federal minimum wage or may need to obtain

subminimum wages, the specific number of employees may change over the duration of the certificate. The certificate application data is self-reported by employers and does not reflect any changes made by the employer after its submission. Additionally, the data provided reflects active certificates as of the date that the Department's website list was revised and does not include the number of employees on ''pending'' section 14(c) certificates.

[332] As discussed above, this may be an overestimate of the number of employers who will review the final rule, as some of these certificate holders operate in States that are phasing out the payment of subminimum wages to workers with disabilities in the near future.

[333] Brysbaert, Marc (April 12, 2019), ''How many words do we read per minute? A review and meta-analysis of reading rate,'' *https://doi.org/10.31234/osf.io/xynwg.*

[334] U.S. Dep't of Labor, Bureau of Labor Statistics, Occupational Employment and Wage Statistics survey (OEWS), May 2023, *https://www.bls.gov/news.release/ocwage.t01.htm.*

[335] The benefits-earnings ratio is derived from BLS's Employer Costs for Employee Compensation (ECEC) data using variables CMU1020000000000D and CMU1030000000000D. The Department averaged the four quarters of 2023 to get a full-year 2023 ratio.

[336] There may be some certificate holders who re-review the regulations if/when they decide to re-apply for their certificate during a phaseout period. However, the Department has not estimated rule familiarization costs in future years. The Department welcomes comments that would help inform this estimate.

[337] The Department does not have data to estimate how many certificate holders would close their organization following the changes proposed in this rule but welcomes comments from certificate holders to help inform this estimate.

additional support services or other meaningful non-work activities to replace the time previously spent in subminimum wage employment. They could incur transition and job search costs associated with these activities. These transition costs include the cost of time spent learning about available resources, time for eligibility determinations, time spent on waitlists, training costs, etc. There may be some employers who will choose not to retain the workers working under section 14(c) certificates; a subset of those workers may be unable to find replacement employment or support services. For this group of workers, they may incur costs associated with reduced well-being from no longer being employed or due to a reduction in hours worked. Some of their families may also incur increased care costs, if they need to find or provide care for their family member for the time that was previously spent working at subminimum wages. However, as discussed throughout this rulemaking, the Department believes that a wide range of strategies, opportunities, and supports exist that can minimize this outcome. Although there may be time required for workers to transition from subminimum wage jobs, the Department believes that the phaseout approach proposed in this rule would help ensure that workers will ultimately be able to make this transition.

Additionally, the Department acknowledges workers may also have concerns about potential limitations on their disability benefits due to an increase in their wages. In response to such concerns, some workers with disabilities may choose to leave the workforce or limit the number of hours they work. The Department is unable to specifically quantify these potential cost impacts but notes workers receiving Supplemental Security Income or Disability Insurance have access to free employment support resources, such as the Social Security Administration's ''Ticket to Work'' program, that allows enrolled workers with disabilities to improve their earning potential. Likewise, as addressed in the preamble, the availability of resources such as ABLE accounts, allow workers with disabilities to accumulate savings without jeopardizing access to certain public benefits, thus minimizing this concern.

The Department does not have data to quantify costs to workers currently employed under section 14(c) certificates but welcomes comments and input to help inform this estimate, including comments on available resources that address the impacts that earnings may have on disability benefits.

D. Cost Savings

Any increased costs for certificate holders could be balanced out, in part, by the cost savings of no longer applying for section 14(c) certificates and no longer participating in the activities required to maintain their certificate and determine appropriate commensurate subminimum wage rates for workers. Currently, employers who wish to apply for a section 14(c) certificate may submit their application to WHD in one of two ways: completing their application online or submitting completed forms WH–226 and WH–226A. When applying for a certificate, applicants are responsible for providing information related to their employment operations and the subminimum wage workers employed during the applicant's most recently completed fiscal quarter, including details on hours, wages, job descriptions, and primary disability. Any affected entity that would have renewed their application in absence of this rule could likely experience some cost savings following this rule, since they no longer would be filling out an application for and maintaining a section 14(c) certificate. As an example, in the Paperwork Reduction Act Supporting Statement for these regulations, the Department estimates that for employers who are renewing their application for a section 14(c) certificate, it will take them 75 minutes to fill out form WH–226 and 2 hours to fill out form WH–226A, for a total of 3.25 hours. If these forms are filled out by a Compensation, Benefits, and Job Analysis Specialist (SOC 13–1141) with a full-loaded wage of $58.04, each employer who was planning to renew their section 14(c) certificate application would save $188.63 per application cycle. In order to calculate an illustrative estimate of the potential total maximum cost savings, the Department assumes all 447 certificate holders with certificates expiring in the next year (between the dates of May 1, 2024, and May 1, 2025) would decide to renew their application for a section 14(c) certificate in absence of this proposed rulemaking. If these certificate holders no longer have to fill out the application following the rule, the total potential annual cost savings would be $84,318 ($188.63 × 447). The true cost savings is likely somewhat lower, because all certificate holders may not choose to re-apply when their certificate expires, due to both overall downward trends in the number of certificate holders and potential expectations of a phasing out of section 14(c) certificates based on the publication of this proposed rule.

Employers who no longer hold a section 14(c) certificate to pay subminimum wages would also be relieved of several operations costs required to remain in compliance with the section 14(c) provisions. For example, employers would no longer conduct prevailing wage surveys used to determine worker commensurate wage rates for each type of work paid at a subminimum wage. This would relieve the employer of their at least annual task of ascertaining the wage rates paid to the experienced nondisabled workers of other employers in the vicinity, usually obtained by surveying comparable firms in the area that employ primarily nondisabled workers doing similar work. The appropriate size of such a survey sample depends on the number of firms doing similar work but generally would include at least three firms. Employers would also be relieved of conducting time studies of both hourly paid workers as well as staff that do not have disabilities for the work being performed (''standard setters''). To maintain compliance with section 14(c), employers must review the wages of all subminimum wage employees at least once every 6 months. The work measurement or time study process involves a review with respect to the quantity and quality of work of each hourly-rated worker with a disability as compared to that of workers engaged in similar work or work requiring similar skills that do not have a disability for the work performed. With the prevailing wage rate for each job and the productivity measurement of each individual worker, the employer must calculate the commensurate wage rate for each worker and implement that wage rate no later than the first complete pay period following the evaluation. These steps would have to be repeated more frequently if an employee changes jobs or the job's structure is changed. Section 14(c) certificate holders also have compliance responsibilities under section 511 of the Rehabilitation Act that require them to obtain, review, and maintain certain documentation of services provided to youth employees prior to subminimum wage employment as well as services required for all subminimum wage employees every 6 months for the first year of employment and annually thereafter. Also, employers must inform each worker paid subminimum wages of local training opportunities for self-advocacy, self-determination, and peer mentoring. (See section III.B.2.ii. for an overview of these requirements.)

Therefore, section 14(c) certificate holders would no longer be conducting many hours of work for each worker that was previously employed under their certificate.

While the Department does not require a specific method for employers to conduct time studies and therefore does not have definitive data on how long it takes employers to complete all these activities, a common method for performing time studies is for the employer to conduct at least 3 separate 25-minute time studies for both the standard setter and hourly paid worker with a disability, which would be at least 75 minutes per typical time study per job worked for each worker.[338] Because time studies of workers with disabilities must occur at least every 6 months, this cost could be 2.5 hours per year per worker. If we were to attribute this cost savings to all current employers with pending or issued certificates (801), and assuming even only 1 employee per each employer, the total cost savings could be at least $116,225 (801 employers × 2.5 hours × $58.04), spread over multiple years as certificates expire. Given that, at the time of drafting, WHD data shows employers with issued certificates employed approximately 40,579 workers under section 14(c) certificates,[339] the Department anticipates the cost savings would be significantly greater.

The Department welcomes comments and data to help inform an estimate of cost savings to certificate holders, including data specific to section 511 compliance responsibilities.

E. Transfers and Other Aspects of Changing Employment Arrangements

The Department expects that if the issuance of section 14(c) certificates is phased out as discussed in this proposed rule, workers currently paid subminimum wages under these certificates would be impacted in various ways. Some of these workers will transition to employment at the full minimum wage while others may lose their subminimum wage employment but will be able to transition to other vocational rehabilitation services and supports available to them. Workers may observe impacts on their earnings, employment status, or hours worked. In this section, the Department discusses a full range of potential transfer impacts associated with this proposed rule and presents evidence to help narrow that potential range. Because of the many uncertainties discussed throughout this section, the Department has not provided quantitative estimates but has instead provided information to help illustrate the potential impact. The Department welcomes comments providing additional data that would help inform an estimate of transfers or other effects not already quantified.

1. Potential Range of Effects

The Department acknowledges that workers employed under section 14(c) certificates may be affected differently by this proposed rule and, therefore, has presented a range of effects here to provide context on potential transfers. The highest potential transfers to workers would be if 100 percent of current workers employed under section 14(c) certificates transition to full-wage employment for the same number of hours they are currently working following the phaseout of section 14(c) certificates, resulting in all affected workers receiving wage increases to the full minimum wage.[340] The other end of the range of possible impacts would occur if only a fraction of workers currently employed under section 14(c) certificates transition to full-wage employment, resulting in a significant loss of earnings (some portion of which would be lost surplus, or the value of the earnings above and beyond the value of leisure). To provide points of reference, the Department has conducted a sensitivity analysis using the following assumptions of the percentage of section 14(c) workers who transition to full-wage employment: 100 percent, 75 percent, 50 percent, and 25 percent.

In order to calculate the upper bound of transfers for the sensitivity analysis, the Department calculated the difference between each worker's reported average hourly earnings and the greater of the Federal minimum wage or State minimum wage for the State in which their employer operates.[341] If all workers on section 14(c) certificates receive wage increases to minimum wage (either as a result of wage increases from their current employer or if they find new employment at the minimum wage) while maintaining their current hours, the total gain in annual earnings would be $174.8 million.[342] This annual estimate would likely take multiple years to phase in as employers make changes leading up to the expiration of their certificate.

For additional potential transfer estimates (*i.e.,* total increased earnings to workers who keep their job at a higher wage, accompanied by loss in earnings to those workers who lose their job), the Department assumed that a percentage (75 percent, 50 percent, and 25 percent) of randomly selected workers would remain employed and be paid the minimum wage. *See* Table 3. If 75 percent of current workers under section 14(c) certificates remain employed and are paid the minimum wage, the Department estimates that transfers from employers to workers would be $131.7 million (additional wages to the workers remaining employed), and the changes from workers to employers would be $27.1 million in wages no longer being paid to the quarter of workers who are no longer employed. With 50 percent or 25 percent of workers remaining employed, transfers (*i.e.,* decrease in wage costs to still-employed workers) and changes (*i.e.,* wages lost by newly-unemployed workers) would be as shown in Table 3, below.

[338] Guidance based on WHD Section 14(c) Online Calculators User Guide, *https://www.dol.gov/sites/dolgov/files/WHD/legacy/files/calculatorGuide.pdf.*

[339] WHD, 14(c) Certificate Holders, May 1, 2024, *https://www.dol.gov/agencies/whd/workers-with-disabilities/section-14c/certificate-holders.*

[340] Workers receiving wage increases as a result of the proposed rule would be subject to both Federal and State minimum wage requirements. Estimates of transfers in States with minimum wage rates higher than the Federal minimum wage incorporated the cost increase to the higher State minimum wage rate.

[341] Due to difficulties in assessing each certificate holder's local area, the analysis did not take into account that some localities may have minimum wages that are higher than the State minimum wage. The differences between a worker's average hourly earnings and local minimum wage could be greater than the difference calculated here, leading to an underestimate of transfers. Additionally, some workers may find new employment at a wage rate above their State or local minimum wage, which could also lead to an underestimate of transfers.

[342] The average of the difference between the applicable minimum wage and the section 14(c) wage is $6.49 and the average of the reported average number of hours worked per week is 11.45. Multiplying the increase in weekly earnings when section 14(c) workers earn the applicable minimum wage by the number of workers by 52 weeks ($76.86 × 43,748 × 52) equals $174.8 million per year.

Percentage of workers in minimum wage employment (%)	Percentage of workers who lose employment (%)	Total transfers from employers to workers (in millions)	Newly-unemployed workers' lost wages (in millions)
100	0	$174.8	$0
75	25	131.7	27.1
50	50	87.7	54.7
25	75	43.8	81.7

The Department requests comments providing quality empirical research on the effects of phasing out the payment of wages below the Federal minimum wage on employment, earnings, or other outcomes for workers with disabilities.

2. Illustrative Analysis To Help Inform Estimates

In order to help narrow the range of potential effects, the Department has performed an illustrative analysis to help assess the impact of phasing out section 14(c) certificates on labor force outcomes for workers with disabilities. As discussed above in section III.D., in recent years, an increasing number of States and localities have prohibited, limited or planned to phase out the payment of subminimum wages to workers with disabilities. The Department conducted an analysis looking at employment and earnings outcomes for individuals with I/DD in states that have phased out the issuance of section 14(c) certificates compared to the states that continue to allow the payment of subminimum wages to workers with disabilities. If, as the Department has stated, the cessation of section 14(c) certificates does not lead to adverse labor market outcomes for workers currently employed under these certificates, then one would expect to find no statistically significant difference between the employment and labor force participation outcomes for workers with disabilities in states that have phased out the payment of subminimum wages for workers with disabilities compared to those that have not. Thus, the Department used data from the American Community Survey (ACS) from 2013 to 2023 in regression analyses to look at employment and labor force status for workers with cognitive difficulties in states that have banned the payment of subminimum wages for workers with disabilities versus those that have not.[343]

The Department notes that there may be some uncertainties in the data that prevent the conclusions of the analysis from being applied to a definitive transfer estimate. First, phaseouts of the payment of subminimum wages were implemented gradually in many states and in some instances are still ongoing. This phased elimination complicates the measurement of the timing of the effect of disallowing subminimum wages because it is unclear how much of the impact will occur immediately versus what will occur over time as current certificates expire. Second, multiple states have prohibited the payment of subminimum wages to individuals with disabilities in recent years; thus, state data representing their prohibition are not yet fully represented in the ACS.[344] Third, complete ACS data on disability status and other variables is not available for the year 2020 due to data collection issues during the COVID–19 pandemic. Lastly, the overall population of workers with cognitive difficulties in the ACS is not a perfect representation of the specific population of workers employed under section 14(c) certificates.[345]

The Department conducted an analysis comparing the change in labor force outcomes for workers with disabilities in states that stopped the payment of subminimum wages with the changes in outcomes for workers with disabilities in states that did not. Specifically, the Department looked for differences in employment status (measured by the variable asking if an individual worked last week) and labor force status (whether an individual was in the labor force).[346] In the regression model, the Department used year fixed effects to control for any common factors that affected all states equally in each year, such as the business cycle or the COVID–19 pandemic. The Department used state fixed effects to control for any unobserved characteristics that are specific to each State and do not vary over time, such as the relative size of the population of individuals with disabilities or the availability of social services. The Department also controlled for observable factors that vary by State and year and could affect the outcomes of interest, such as the labor market outcomes for workers with no cognitive disabilities, since that could reflect overall labor market conditions.

Despite including year fixed effects to account for common yearly shocks, analyzing workforce trends by State and year highlights a potential pitfall in using 2020 data. The differences-in-differences approach assumes that State-specific trends in the relevant labor force measures prior to the change in subminimum wage laws are similar across all States, known as the ''parallel trends'' assumption. The pandemic caused significant disruptions in each State's labor markets, which are reflected in the outcomes for that year. As a result, the assumption of parallel trends is less likely to hold as systemic changes such as the pandemic may have disproportionately affected different

[343] ACS identifies other groups of individuals with disabilities, such as hearing and visual disabilities, independent living difficulties, self-care difficulties, and ambulatory disabilities. This analysis focuses on individuals with cognitive difficulties, as this group would be more directly affected by the proposed rule due to its larger participation in section 14(c) certificate employment. For purposes of this analysis, the Department assumes that the ACS category of cognitive difficulties is most similar to the population of interest, workers with I/DD. As noted above, based on WHD section 14(c) certificate data as of May 1, 2024, individuals with I/DD comprised about 91 percent of the workers with disabilities being paid subminimum wage.

[344] For a fuller discussion of the States that have enacted legislation prohibiting or limiting the payment of subminimum wages, see section III.D. of this proposal.

[345] As noted in section VII.B.1., most workers employed under 14(c) certificates have I/DD listed as their primary disability. The disability questions in the ACS are much more general than the specific requirements of an I/DD diagnosis. Thus, it is likely that respondents with cognitive difficulties in the ACS include individuals who do not meet the definition for having I/DD. It is uncertain how well the ACS respondents with cognitive difficulties represent the labor market behaviors of individuals working under section 14(c) certificates, but the Department believes that there is no clearly better data available. For a more detailed discussion, *see* Havercamp, S.M., Krahn, G., Larson, S., Weeks, J.D. and the National Health Surveillance for IDD Workgroup (2019), ''Working Through the IDD Data Conundrum: Identifying People with Intellectual Disability and Developmental Disabilities in National Population Surveys,'' Washington, DC: Administration on Intellectual and Developmental Disabilities, *https://acl.gov/sites/default/files/Aging%20and%20Disability%20in%20America/National_Data_Paper_AIDD-ACL_09.25.2019%20508%20compliant.pdf.*

[346] The Department used a differences-in-differences approach to compare changes in these measures before and after payments were stopped to States that did not stop payment of subminimum wages.

groups in each State's labor force. Moreover, the ACS was also heavily affected in 2020, leading the data to fail the Statistical Data Quality Standard from the Census Bureau for that year.[347] Given these concerns, the 2020 data were excluded from the analysis. To check the validity of the parallel trend assumption, the Department visually inspected these States' trends from 2010 to 2022, which indicated that the pre-treatment trends were largely parallel despite variation around each State's average that makes the visual interpretation less clear. These findings remain consistent when controlling for State- and year-fixed effects.[348] While it is impossible to completely ascertain the validity of the parallel trend assumption because it relates to a counterfactual world where the policy change did not occur, this evidence suggests that the estimation assumption is reasonable in this context.

The Department performed two different analyses, one focusing on the States that enacted an immediate transition away from the payment of subminimum wages, and one including states that gradually phased out the policy. The Department did not find significant differences in the results of these two analyses on employment or labor force participation.

The Department's analysis yields no statistical evidence that employment or the labor force participation rate of individuals with cognitive disabilities differed in States that stopped the payment of subminimum wages.[349] The findings of this analysis do not support that the changes in this proposed rule would lead to statistically detectable adverse labor force outcomes for workers employed under section 14(c) certificates. Due to the uncertainties discussed above, the Department has not applied the results of this analysis to a definitive transfers estimate. However, these results can help to narrow the range of potential transfer effects, suggesting that the lower loss of employment estimate of transfers may be more likely to be realized than the higher loss of employment.[350]

3. Additional Evidence

In 2015, in response to a class action complaint that was filed on behalf of individuals with I/DD, the State of Oregon entered into a statewide settlement agreement that required, among other things, that Oregon decrease State support of sheltered workshops for individuals with I/DD and expand access to supported employment services that allow the opportunity to work in CIE settings. Oregon implemented competitive and supported employment strategies, ultimately ending the payment of subminimum wages to workers with disabilities in Oregon. A 2022 report on the changes made following the settlement agreement reported that in 2016—the year the settlement was reached and approved by the court, there were 1,405 people working in sheltered workshops in Oregon, and by 2021, that number had declined to zero.[351] This report also noted that Oregon placed 1,138 individuals from the class who had previously worked for subminimum wages into CIE.[352] This data shows that it is possible, with the right supports, for large numbers of workers with disabilities earning the subminimum wage to transition to full-wage employment opportunities. Although the evidence comes from just one State, the Department believes that the results could be scalable, and that it further serves to narrow our estimated impacts in the direction of more affected workers finding employment at the full Federal minimum wage. *See* discussion in section VII.B.; Figure 1, Panel A (Employment-Population Ratio—With a Disability, 16 Years and Over, 2014—2024).

As discussed in section III, legislative, policy, and programmatic changes have broadly influenced available options for workers with disabilities today. Because of these changes, and the evidence discussed above, the Department believes that this proposed rule would not result in widespread negative labor force outcomes for individuals with disabilities.

4. Other Transfers or Behavior-Change Effects

The Department also considered additional impacts that may occur as a result of this proposed rule. For example, it could be possible for some affected workers to see a reduction in hours worked. If the certificate holder chooses to retain the section 14(c) workers and pay them the full Federal minimum wage, they may also choose to offset increased labor costs by providing fewer hours of work for these workers. The Department has not estimated a change in hours that may result from this rule but believes that the change could be minimal given that the current average number of hours worked by workers on section 14(c) certificates is very low (as discussed in section VII.B., the mean number of hours worked by this population is 11.45 hours per week.) Nevertheless, the Department welcomes comments on the extent to which this could occur.

Following the changes proposed in this rule, some workers who were previously employed under section 14(c) certificates could also experience a change in eligibility for certain entitlement programs, and therefore a change in the public benefits that they receive. Any change in benefits would depend on a number of factors, including whether each individual finds employment at or above the full minimum wage following the phaseout of section 14(c) certificates, the number of hours they work, and other factors. The Department has not quantified this change in benefits, because there is no data available on all of the benefits currently received by workers under section 14(c) certificates, and any change in benefits depends heavily on the situation of each individual. However, the Department welcomes comments or data to better understand this potential transfer.

Additionally, there may be some impacts that go beyond the affected workers employed under section 14(c) certificates. For example, some certificate holders employ support staff to assist the workers with disabilities

[347] According to Census documentation, ''[B]ecause of the underlying quality concerns, the Census Bureau urges caution in using the experimental estimates as a replacement for standard 2020 ACS 1-year estimates. Users should evaluate the estimates and alternatives to determine if they are suited for their needs.'' *https://www.census.gov/newsroom/press-releases/2021/experimental-2020-acs-1-year-data.html.* Specifically, ''the Census Bureau does not recommend comparing the 2020 ACS 1-year experimental estimates with our standard ACS estimates or the decennial census, or comparing the 2020 1-year PUMS data with standard pre-tabulated products or PUMS-based estimates from previous years.'' *https://www.census.gov/newsroom/press-releases/2021/changes-2020-acs-1-year.html.*

[348] A formal statistical analysis to confirm parallel trends in the pre-treatment period would need to test the divergence in the outcomes before the policy change. However, there are difficulties to applying the test in this context. First, subminimum wage bans were implemented at different times across States, resulting in a staggered treatment period. Second, the partial introduction of the policy in some States introduces further complexity. This makes it challenging to select a single year as the benchmark that applies uniformly to all States, rendering a formal statistical test impractical.

[349] The Department notes that, given the nuanced and evolving nature of these State laws, the classification of these States, laws, and relevant enactment dates is complex. The Department welcomes comment and data from the public on this analysis and the Department's preliminary conclusion that there is no statistical evidence that employment or the labor force participation rate of individuals with cognitive disabilities differed in States that stopped the payment of subminimum wages.

[351] Oregon Department of Human Services, ''*Lane* v. *Brown* Settlement Agreement Report,'' *https://www.oregon.gov/odhs/employment-first/Documents/lane-v-brown-settlement-message-2022-06-21.pdf.*

[352] *Id.*

being paid subminimum wages. These support staff generally provide job coaching, assist the worker with their tasks, and may perform portions of the job, if necessary. They may also assist in communicating on behalf of the employee or providing necessary training including job-related and soft skills. If a certificate holder chooses to no longer employ workers with disabilities, they may also no longer require the services of the support staff, potentially leading to a reduction in employment for the support staff workers. Conversely, if a certificate holder chooses to transition by providing non-work rehabilitation services to individuals with disabilities, they may need to increase their support staff to help with these activities. Even if an employer chooses to transition workers with disabilities to full-wage employment, they may also choose to retain existing support staff, increase these staff, or hire other support staff to assist workers.

The Department welcomes comments and data on additional impacts that could occur following this rule.

F. Benefits

As discussed above, the Department expects that, following the changes proposed in this rule, many current workers with disabilities paid subminimum wages under a section 14(c) certificate will transition to full-wage employment opportunities. The increased wages could improve the financial strength and personal well-being of these workers, while also enhancing the overall equity and inclusion of workers with disabilities in the workplace. For example, in a review of 17 studies on the impacts of CIE on economic, psychological, and physical health outcomes for individuals with intellectual and developmental disabilities, researchers found that workers in CIE are paid higher wages and have better career prospects than individuals in sheltered workshops or non-work activities.[353] They also found a positive relationship between CIE and health outcomes such as quality of life, self-determination, personal independence, locus of control, autonomy, and reduced support needs. On the other hand, the Department has heard from some individuals with disabilities and their families about the benefits that they have experienced in section 14(c) employment. For example, some individuals have explained that they feel safe in their current jobs, view their jobs as providing a secure and stable work community, and feel proud to earn wages, regardless of the amount of those wages. The Department welcomes comments from the public, including individuals with disabilities, their family members, and entities employing workers on section 14(c) certificates, on the benefits of section 14(c) employment. Working in concert with the broader societal shifts in opportunities for workers with disabilities, this proposed rule could also lead to spillover effects for the overall population of individuals with disabilities. In 2023, the labor force participation rate for persons with a disability was 24.2 percent, compared to 68.1 percent for persons with no disability.[354] The changes in this proposed rule could help reduce this gap in labor force participation. If individuals with a disability view subminimum wage employment as the only option for them, they may choose to remain out of the workforce. They may be more likely to look for a job if they know that they would be paid at least the full minimum wage. For example, the National Longitudinal Transition Study-2 (NLTS2) found that there was a strong desire among youth with disabilities to participate in competitive employment. Specifically, the NLTS2 found that among the 70 percent of secondary school students with disabilities who identified employment as a goal for the post-school years, 62 percent had a goal to work in competitive employment, while only 3 percent wished to work in ''sheltered'' employment.[355] By phasing out the issuance of section 14(c) certificates and ending subminimum wage employment for workers with disabilities, this rule could lead to an increase in labor force participation among individuals with disabilities more broadly.

Businesses may also find it beneficial to integrate workers with disabilities into their workplace. For example, employers working with job coaches can identify work solutions that will resolve company needs and result in mutually beneficial employment relationships for employers and employees with disabilities. Additional potential benefits to employers are expansion of their talent pool, creation of more inclusive workplaces, and promotion of compliance with EEOC law.[356] The Department also welcomes comments providing additional information on the impacts of increasing labor force participation of people with disabilities.

As explained throughout this notice of proposed rulemaking, the Department has proposed to phase out section 14(c) certificates because the Department's preliminary conclusion is that such certificates do not continue to be necessary in order to prevent the curtailment of employment opportunities for individuals with disabilities. The Department also predicts, as evidenced in the transfers analysis above, that a significant share of workers currently employed under section 14(c) certificates will be able to transition to full-wage employment. The Department would welcome additional data to quantify the various benefits of this proposed rule.

VIII. Initial Regulatory Flexibility Analysis (IRFA)

The Regulatory Flexibility Act of 1980 (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), hereafter jointly referred to as the RFA, requires that an agency prepare an initial regulatory flexibility analysis (IRFA) when proposing, and a final regulatory flexibility analysis (FRFA) when issuing, regulations that will have a significant economic impact on a substantial number of small entities.

A. Reasons Why Action by the Agency Is Being Considered and Statement of Objectives and Legal Basis for the Proposed Rule

The FLSA generally requires that employees be paid at least the Federal minimum wage, currently $7.25 per hour, for every hour worked and at least one and one-half times their regular rate of pay for each hour worked over 40 in a single workweek. 29 U.S.C. 206(a), 207(a). Since its enactment in 1938 through today, section 14 of the FLSA has included a provision authorizing the Department to issue certificates permitting employers to pay workers whose disabilities impair their earning

[353] Taylor, Joshua et al., ''The Impact of Competitive Integrated Employment on Economic, Psychological, And Physical Health Outcomes for Individuals With Intellectual and Developmental Disabilities,'' Journal of Applied Research in Intellectual Disabilities: JARID vol. 35,2 (2022): pp. 448–459, *https://doi.org/10.1111/jar.12974.*

[354] U.S. Dep't of Labor, Bureau of Labor Statistics Bureau of Labor Statistics, Current Population Survey, Table A–6. Employment status of the civilian population by sex, age, and disability status, not seasonally adjusted, *https://www.bls.gov/webapps/legacy/cpsatab6.htm.*

[355] Mary Wagner, Lynn Newman, Renee Cameto, Nicolle Garza, and Phyllis Levine, ''After High School: A First Look at the Postschool Experiences of Youth with Disabilities. A Report from the National Longitudinal Transition Study-2 (NLTS2),'' SRI International, April 2005, pp. 5–3 to 5–4, *https://www.nlts2.org/reports/2005_04/nlts2_report_2005_04_complete.pdf.*

[356] Virginia Commonwealth University, ''Supporting Individuals with Significant Disabilities: The Roles of a Job Coach,'' *https://dors.maryland.gov/crps/Documents/RSM2_0800-4.pdf.*

or productive capacity at wage rates below the Federal minimum wage. That statutory provision, however, has always imposed an important prerequisite: such certificates may only be issued to the extent ''necessary to prevent curtailment of opportunities for employment.'' [357] Given the profound legal and policy developments that have vastly expanded employment opportunities and rights for individuals with disabilities since the Department last substantively updated regulations governing section 14(c) in 1989, and even more so since the Department first promulgated regulations upon enactment in 1938, the Department preliminarily concludes that subminimum wages are no longer necessary to prevent the curtailment of employment opportunities for individuals with disabilities.

The Department specifically proposes to cease issuance of new section 14(c) certificates to employers submitting an initial application on or after the effective date of a final rule and permit existing section 14(c) certificate holders, assuming all legal requirements are met, to continue to operate under section 14(c) certificate authority for up to 3 years after the effective date of a final rule.

B. Description of the Number of Small Entities to Which the Proposed Rule Will Apply

The proposed rule will impact entities who currently hold a section 14(c) certificate at the time of publication of the final rule. While it could, in theory, also impact those who were previously interested in applying for a section 14(c) certificate, the percentage of applications that WHD receives from initial applicants (*i.e.,* applicants who have not previously applied for a section 14(c) certificate) is very small. From the May 1, 2024, WHD data, only 3 percent of applicants indicated that they were filing an initial application. Both the number of total certificate holders and initial applicants has been trending downward over time and the Department expects that the trend would continue even in absence of this proposed rule. Therefore, the Department does not expect the net number of affected entities to be higher than the number of current certificate holders.

The overwhelming majority of current certificate holders are Community Rehabilitation Programs (CRPs), representing approximately 93 percent of current certificate holders as of May 2024. In the context of section 14(c), WHD defines CRPs as ''not-for-profit agencies that provide rehabilitation and employment for people with disabilities.'' Only a small percentage of current certificate holders are private-sector, for-profit businesses, as discussed in section VII.B.

To estimate the impact of eliminating section 14(c) certificates on small entities, the Department first determined whether current section 14(c) certificate holders were ''small'' as defined by the SBA. SBA broadly defines an entity (whether a ''business'' or a nonprofit ''organization'') as ''small'' if it is ''independently owned and operated'' and is ''not dominant in its field of operation.'' More concretely, SBA defines an entity as small if its employees or annual revenues are less than the threshold published in its Table of Size Standards.[358] Although affected entities fall under different NAICS, for the vast majority of section 14(c) certificate holders, the applicable size standard is $20 million in revenues. To perform this task, the Department began with the list of entities currently holding a valid section 14(c) certificate, then used the entity's name, IRS Employer Identification Number (EIN), and address to ascertain the primary NAICS code, sales/revenue, and number of employees in business databases and other online searches.[359] The Department determined that 636 of these firms, which consists of both non-profit and for-profit entities, are small using the SBA size standard based on the primary NAICS code of each entity, which represent the Department's best estimate given inherent uncertainties in publicly available data, especially for for-profit organizations. Table 4 contains the number of and percentage of small entities by major industry NAICS code. Table 5 contains the distribution of these small entities by NAICS code and entity type, as reported on form WH–226.

TABLE 4—NUMBER AND PERCENTAGE OF SMALL ENTITIES BY NAICS

6-digit NAICS	NAICS description	Number of small entities	Percentage of small entity certificate holders (%)
623220	Residential Mental Health and Substance Abuse Facilities	29	4.6
624120	Services for the Elderly and Persons with Disabilities	39	6.1
624190	Other Individual and Family Services	68	10.7
624310	Vocational Rehabilitation Services	277	43.6
813319	Other Social Advocacy Organizations	20	3.1
Other NAICS [a]		203	31.9
All		636	100

Note:
[a] The five most frequent NAICS codes within the ''Other NAICS'' category are 611110 (Elementary and Secondary Schools), 621420 (Outpatient Mental Health and Substance Abuse Centers), 623990 (Other Residential Care Facilities), 621498 (All Other Outpatient Care Centers), and 623110 (Nursing Care Facilities (Skilled Nursing Facilities)). Of the 203 entities in the ''Other NAICS'' category, 66 entities are in one of these five NAICS codes.

[357] 29 U.S.C. 214(c).

[358] SBA size standards by NAICS code are available at *https://www.sba.gov/document/support-table-size-standards.* SBA guidance defines both small businesses and small non-profit organizations as entities that are ''independently owned and operated and not dominant in its field, with no indication that the size standards for businesses are not applicable to organizations.'' See ''How to Comply with the Regulatory Flexibility Act,'' *https://advocacy.sba.gov/wp-content/uploads/2019/07/How-to-Comply-with-the-RFA-WEB.pdf.* SBA defines a governmental jurisdiction as ''small'' if it has a population of less than 50,000 residents.

[359] The IRS Tax Exempt Organization Search Tool, *https://apps.irs.gov/app/eos/,* was used to obtain revenue from tax-exempt filings, which includes all public support. DemographicsNow and AtoZdatabases were also used to obtain more recent revenue than available on the IRS Tax Exempt Organization Search Tool, to collect information on the number of employees, and for revenues of for-profit entities.

TABLE 5—DISTRIBUTION OF SMALL ENTITIES, BY ENTITY TYPE AND NAICS CODE

6-Digit NAICS	NAICS description	Businesses	CRPs	Hospitals or residential care facilities that employ patients	SWEPs	Total
623220	Residential Mental Health and Substance Abuse Facilities.	2	27	0	0	29
624120	Services for the Elderly and Persons with Disabilities	0	39	0	0	39
624190	Other Individual and Family Services	2	66	0	0	68
624310	Vocational Rehabilitation Services	8	267	0	1	276
813319	Other Social Advocacy Organizations	0	19	1	0	20
Other NAICS[b]		15	180	6	2	203
All[a]		27	589	7	3	635

Note: "Entity Type" is as designated based on the "Certificate Type" listed in the current section 14(c) certificate holders list, available at *https://www.dol.gov/agencies/whd/workers-with-disabilities/section-14c/certificate-holders/archive.* If an entity lists more than one certificate type, and one of those types is Community Rehabilitation Program, the entity is categorized as a CRP. Entities with certificate types of "Business Establishment" only are categorized as Businesses and entities with certificate types of "Hospital/Patient Worker Facility" only are categorized as Hospitals or Residential Care Facilities that Employ Patients.

[a] One entity has a Certificate Type of "Unknown" in NAICS code 624310 (Vocational Rehabilitation Services) and is excluded from this table.

[b] The five most frequent NAICS codes within the "Other NAICS" category are 611110 (Elementary and Secondary Schools), 621420 (Outpatient Mental Health and Substance Abuse Centers), 623990 (Other Residential Care Facilities), 621498 (All Other Outpatient Care Centers), and 623110 (Nursing Care Facilities (Skilled Nursing Facilities)). Of the 203 entities in the "Other NAICS" category, 66 entities are in one of these five NAICS codes.

C. Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

There are no reporting or recordkeeping requirements associated with this proposed rule. Thus, the direct costs to affected entities would be rule familiarization costs, adjustment costs, and potential payroll increases if they choose to retain their workers currently employed under section 14(c) certificates and pay the full minimum wage. As discussed in section VII.C.1, total rule familiarization costs are $92,980 (801 employers × 2 hours × $58.04), and the per entity cost is $116 ($58.04 × 2 hours) in Year 1. As discussed in section VII.C.2., the Department did not provide a definitive estimate of adjustment costs, because of the uncertainties of how and when each certificate holder would respond to the rule. However, as an example, if certificate holders incurred an average of 1 hour of adjustment costs, their per entity cost would be $58.04.[360]

Using aggregate data on workers employed under section 14(c) certificates as submitted by employers on form WH–226A, the Department calculated the mean increase in wage cost per employee and the total number of section 14(c) workers by State. These additional wage costs represent the maximum transfers from employers to workers because they are calculated based on each section 14(c) worker being paid the applicable minimum wage (*i.e.,* the greater of the State or Federal minimum wage) and working for the same number of hours as they currently work. The Department calculated total wage cost by multiplying the mean increase in wage cost per employee in each State by the sum of the number of section 14(c) workers for all certificate holders in the state. The Department added the upper bound of wage costs, regulatory familiarization cost, and adjustment costs to estimate the total cost of the rule for small entities.

The Department calculated the sum of the revenue of the small entities holding section 14(c) certificates by state using the revenues associated with each small entity identified in the business databases as described in the previous section.[361] The Department then divided total cost to small section 14(c) certificate holders by aggregated revenues to yield the estimated cost to revenue ratios by NAICS code as shown in Table 6. Many of these ratios of cost to revenue are greater than the generally accepted threshold of one percent that indicates a significant impact. The results presented in this table assume that public funding streams to nonprofit CRPs remain constant. To the extent that public funding streams change as a result of implementation of this proposal, nonprofit revenues from that source will directly increase or decrease.

[360] For additional discussion of adjustment costs, see section VII.C.2.

[361] The Department imputed revenue using the number of employees for five entities for which revenue was not found.

TABLE 6—ESTIMATED RATIOS OF COMPLIANCE COST TO REVENUE FOR SMALL ENTITIES CURRENTLY HOLDING VALID SECTION 14(c) CERTIFICATES, BY NAICS CODE

6-Digit NAICS [a]	Proportion of revenue impacted														Total
	<1%		1%–2%		2%–3%		3%–4%		4%–5%		5%–10%		≥10%		
623220	15	51.7%	4	13.8%	2	6.9%	5	17.2%	1	3.4%	2	6.9%	0	.....	29
624120	10	25.6%	4	10.3%	7	17.9%	3	7.7%	2	5.1%	6	15.4%	7	17.9%	39
624190	13	19.1%	13	19.1%	10	14.7%	5	7.4%	2	2.9%	12	17.6%	13	19.1%	68
624310	51	18.4%	30	10.8%	28	10.1%	30	10.8%	16	5.8%	45	16.2%	77	27.8%	277
813319	7	35.0%	1	5.0%	5	25.0%	1	5.0%	1	5.0%	1	5.0%	4	20.0%	20
Other NAICS [b]	68	33.5%	21	10.3%	18	8.9%	14	6.9%	14	6.9%	24	11.8%	44	21.7%	203
Total	164	25.8%	73	11.5%	70	11.0%	58	9.1%	36	5.7%	90	14.2%	145	22.8%	636

Note:
[a] NAICS descriptions are 623220 (Residential Mental Health and Substance Abuse Facilities), 624120 (Services for the Elderly and Persons with Disabilities), 624190 (Other Individual and Family Services), 624310 (Vocational Rehabilitation Services), and 813319 (Other Social Advocacy Organizations).
[b] The five most frequent NAICS codes within the ''Other NAICS'' category are 611110 (Elementary and Secondary Schools), 621420 (Outpatient Mental Health and Substance Abuse Centers), 623990 (Other Residential Care Facilities), 621498 (All Other Outpatient Care Centers), and 623110 (Nursing Care Facilities (Skilled Nursing Facilities)). Of the 203 entities in the ''Other NAICS'' category, 66 entities are in one of these five NAICS codes.
[c] Of the 636 small entities affected, 598 (or 94%) are Community Rehabilitation Programs (CRPs), the majority of which are non-profit. As discussed in the preamble, many CRPs provide employment and other services, such as rehabilitation and training, and receive public funding. Such entities also often pay their operating costs through a mix of public funding and public and private contracts for goods or services. CRPs generally operate differently than private, for-profit small businesses and do not focus on earning profit through their operations. For the cost-revenue ratio calculations of the 598 CRPs, the Department used their total receipts, which includes grants and donations, instead of just revenue. Therefore, the cost-revenue ratios in Table 6 may not accurately reflect the cost impact on their operational continuity.

TABLE 7—ESTIMATED RATIOS OF COMPLIANCE COST TO REVENUE FOR SMALL ENTITIES CURRENTLY HOLDING VALID SECTION 14(c) CERTIFICATES, BY ENTITY TYPE

Entity type	Proportion of revenue impacted														All entities
	<1%		1%–2%		2%–3%		3%–4%		4%–5%		5%–10%		≥10%		
Businesses	8	29.6%	1	3.7%	4	14.8%	1	3.7%	1	3.7%	4	14.8%	8	29.6%	27
CRPs	147	24.6%	72	12.0%	66	11.0%	57	9.5%	34	5.7%	86	14.4%	136	22.7%	598
Hospitals or Residential Care Facilities that Employ Patients	7	100.0%	0	.....	0	.....	0	.....	0	.....	0	.....	0	.....	7
School Work Experience Program (SWEP)	2	66.7%	0	.....	0	.....	0	.....	0	.....	0	.....	1	33.3%	3
Total [a]	164	25.8%	73	11.5%	70	11.0%	58	9.1%	35	5.5%	90	14.2%	145	22.8%	635

Note: ''Entity Type'' is as designated based on the ''Certificate Type'' listed in the current section 14(c) certificate holders list, available at *https://www.dol.gov/agencies/whd/workers-with-disabilities/section-14c/certificate-holders/archive.* If an entity lists more than one certificate type, and one of those types is Community Rehabilitation Program, the entity is categorized as a CRP. Entities with certificate types of ''Business Establishment'' only are categorized as Businesses and entities with certificate types of ''Hospital/Patient Worker'' only are categorized as Hospitals or Residential Care Facilities that Employ Patients.
[a] One entity has a Certificate Type of ''Unknown'' with a proportion of revenue impacted of 4%–5% but is excluded from this table.

The Department has concerns about the accuracy of the underlying data used to calculate these ratios. For example, although the Department was able to verify revenue data for most nonprofit organizations using Form 990 filings with the IRS, other entities' revenue data listed in the business databases may be inconsistent with other company data. Business database listings for other affected section 14(c) certificate holders may show reasonable values for revenue compared to employees but list a number of section 14(c) workers on their form WH–226A that is many times larger than the total number of employees listed in the business database.[362] Finally, some entities appear to have multiple conflicting records in the same database.

The Department considered using other data sources to estimate the impact of this proposed rule on small entities. One option is to use revenue data from the Statistics of U.S. Businesses (SUSB).[363] However, to estimate revenues from SUSB data would require determining the appropriate employment size class of the entity. As described above, due to the prevalence of part-time employment, and duplication in counting the number of employees using section 14(c) certificates, strong assumptions would be required to assign each entity to an employment size class. Furthermore, SUSB only publishes revenue data every 5 years (the Economic Census years and has not yet published revenue data from the 2022 Economic Census). While it is

[362] Some examples of certificate holders for which the respective number of section 14(c) employees greatly exceeds the business database listing for total employees are: 182 versus 2, 102 versus 1, 42 versus 4, and 51 versus 2. Of the 655 small entities, 66 have data values such that the number of section 14(c) workers is at least five times greater than the total number of employees listed in a business database. The WHD application for a section 14(c) certificate requires employers to provide data about the workers with disabilities employed at each separate work site or location. Applicants must include workers corresponding to each work site, and therefore, summary data may count workers multiple times if that worker works for the employer at multiple locations. However, these potential duplicates likely do not account for the large differences noted. Moreover, as explained above in section VII.B.1, the information collected from the form WH–226A is submitted by applicants and may include inaccuracies, such as instances when an employer reports a piece rate instead of an hourly wage rate or miscalculates the wage.

[363] United States Census Bureau, Statistics of U.S. Businesses, *https://www.census.gov/programs-surveys/susb.html.*

possible to inflate 2017 revenues to represent 2022 dollars, that again requires a strong assumption given the impact of COVID on the economy between 2017 and 2022. The Department welcomes comments and data that could provide a more accurate measure of the costs of this proposed rule relative to revenues of affected small entities.

As discussed in section VII.E.1., the Department estimated payroll costs [364] as an upper bound corresponding to a scenario in which all workers on section 14(c) certificates were to find employment at the full minimum wage. However, actual costs are likely to be somewhat lower, as it is possible not all affected subminimum wage workers will transition to employment at the full minimum wage for the same number of hours worked at subminimum wages. For those employers that choose to do so, their increased payroll costs will depend on the number of current workers they have employed under section 14(c) certificates, and their current wages.

In addition, the Department expects costs could be offset by cost savings for affected employers. These cost savings consist of no longer applying for section 14(c) certificates and no longer participating in the activities required to maintain their certificate and determine appropriate commensurate subminimum wage rates for workers. As discussed in section VII.D., the cost savings of no longer filling out the application forms for a section 14(c) certificate could save employers $188.63 annually, while the cost savings of no longer performing time studies of the work of a ''standard setter'' and the hourly paid worker with a disability could save employers, at least, $116.08 (2.5 hours × $58.04) annually.

The Department welcomes comments and data that could help refine the estimates of payroll costs for affected small employers.

D. Alternatives to the Proposed Rule

The Department considered various regulatory alternatives in the formation of this proposed rule. For example, the Department also considered proposing different phaseout periods. As detailed above, the Department proposes that WHD will no longer issue new section 14(c) certificates for initial applications postmarked or submitted online on or after the effective date of the final rule. For employers who seek to renew a section 14(c) certificate, the Department proposes a phaseout period of 3 years from the effective date of the final rule during which those employers may continue to hold a valid section 14(c) certificate (provided that they comply with the statutory and regulatory requirements for certificate holders) and WHD will continue to process renewal applications.

The Department considered proposing both a shorter and longer phaseout period. However, the Department declined to propose a shorter phaseout period (or no phaseout period) because some individuals with disabilities who have been working for employers holding a section 14(c) certificate, employers who have held a section 14(c) certificate, and government entities may need more time to mitigate potential disruptions that might otherwise cause curtailment of employment opportunities. A shorter phaseout period would also be more burdensome on small entities. The Department also declined to propose a longer phaseout period because, in most cases, 3 years should be sufficient to allow for such transitions, and because a longer period might incentivize delay of effective transition measures. As explained above, States that enacted laws containing multi-year phaseouts ranged from 2 years to 7 years, with many States adopting a 2- or 3-year phaseout. The Department has also considered proposing an extension period but instead asks stakeholders to comment on the necessity of any extensions and if so, their scope, structure, and length.

E. Relevant Federal Rules Duplicating, Overlapping, or Conflicting With the Proposed Rule

The Department is unaware of any Federal rules which duplicate, overlap, or conflict with the proposed rule.

IX. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA),[365] requires agencies to prepare a written statement for rulemaking that includes any Federal mandate that may result in increased expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of $200 million ($100 million in 1995 dollars adjusted for inflation to 2023) or more in at least one year. This rulemaking is not expected to exceed that threshold. *See* section VII. for an assessment of anticipated costs, transfers, and benefits.

X. Executive Order 13132, Federalism

The Department has (1) reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism and (2) determined that it does not have federalism implications. The proposed rule would not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

XI. Executive Order 13175, Indian Tribal Governments

This proposed rule would not have tribal implications under Executive Order 13175 that would require a tribal summary impact statement. The proposed rule would not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

List of Subjects in 29 CFR Part 525

Administrative practice and procedure, Equal employment opportunity, Individuals with disabilities, Minimum Wages, Reporting and recordkeeping requirements, Vocational rehabilitation, Wages.

■ 1. The authority citation for part 525 continues to read as follows:

Authority: 52 Stat. 1060, as amended (29 U.S.C. 201–219); Pub. L. 99–486, 100 Stat. 1229 (29 U.S.C. 214).

■ 2. Revise § 525.1 to read as follows:

§ 525.1 Introduction.

The Fair Labor Standards Act (FLSA) authorizes the Secretary of Labor, to the extent necessary to prevent curtailment of opportunities for employment, to issue certificates to employers to pay workers whose disabilities impair their earning or productive capacity at commensurate wage rates below the Federal minimum wage rate. In view of the legal and policy developments that have expanded access to employment opportunities for individuals with disabilities since Congress first included the provision for subminimum wages in 1938 and since the Department last substantively updated its regulations in 1989, the Secretary has determined that subminimum wages are no longer necessary to prevent the curtailment of opportunities for employment for individuals with disabilities, see § 525.9. In light of this determination, the Secretary will cease issuing new certificates immediately as of [EFFECTIVE DATE OF FINAL RULE]

[364] For additional discussion of payroll costs, see section VII.E.

[365] 2 U.S.C. 1501 *et seq.*

and certificates will be available only to renewing applicants for a limited phaseout period ending [DATE 3 YEARS AFTER THE EFFECTIVE DATE OF FINAL RULE]. See § 525.13.

■ 3. Revise § 525.2 to read as follows:

§ 525.2 Purpose and scope.

The regulations in this part govern the issuance and cessation of all certificates authorizing the employment of workers with disabilities at special minimum wages pursuant to section 14(c) of FLSA.

■ 4. Revise § 525.7 to read as follows:

§ 525.7 Application for certificates.

(a) As of [EFFECTIVE DATE OF FINAL RULE], an application for a certificate may be filed only by an applicant seeking to renew a certificate pursuant to § 525.13. An applicant seeking to renew a certificate may do so by completing an online application or submitting paper application forms provided by the Wage and Hour Division. For more information and to access the online application system or download forms, see the Wage and Hour Division website at *https://www.dol.gov/agencies/whd/workers-with-disabilities/section-14c/apply,* or its successor website.

(b) The employer must provide answers to all of the applicable questions contained in the application.

(c) The application must be signed by the employer or the employer's authorized representative.

■ 5. Revise § 525.9 to read as follows:

§ 525.9 Criteria for employment of workers with disabilities under certificates at special minimum wage rates.

(a) As of [EFFECTIVE DATE OF FINAL RULE], the Secretary has determined that certificates allowing for the payment of subminimum wage rates for workers with disabilities are no longer necessary to prevent the curtailment of opportunities for employment.

(b) Pursuant to the regulations set forth above related to certificate phaseout, in order to be granted a renewal certificate authorizing the employment of workers with disabilities at special minimum wage rates during the phaseout period, the employer must provide the following written assurances concerning such employment:

(1) In the case of individuals paid hourly rates, the special minimum wage rates will be reviewed by the employer at periodic intervals at a minimum of once every six months; and,

(2) Wages for all employees will be adjusted by the employer at periodic intervals at a minimum of once each year to reflect changes in the prevailing wages paid to experienced nondisabled individuals employed in the locality for essentially the same type of work.

■ 6. Revise § 525.11 to read as follows:

§ 525.11 Issuance of certificates.

(a) Upon consideration of the criteria cited in these regulations, a special certificate may be issued.

(b) If a special minimum wage certificate is issued, a copy will be sent to the employer. If denied, the employer will be notified in writing and told the reasons for the denial, as well as the right to petition under § 525.18.

(c) Certificates will not be issued to any employer after [3 YEARS FROM THE EFFECTIVE DATE OF FINAL RULE].

■ 7. Revise § 525.13 to read as follows:

§ 525.13 Renewal of special minimum wage certificates.

(a) Applications may be filed for renewal of special minimum wage certificates.

(b) If an application for renewal has been properly and timely filed, an existing special minimum wage certificate will remain in effect until the application for renewal has been granted or denied. No certificate will be valid as of [DATE 3 YEARS AFTER EFFECTIVE DATE OF FINAL RULE] regardless of any pending renewal application.

(c) Workers with disabilities may not continue to be paid special minimum wages after notice that an application for renewal has been denied.

(d) Except in cases of willfulness or those in which the public interest requires otherwise, before an application for renewal is denied facts or conduct which may warrant such action shall be called to the attention of the employer in writing and such employer shall be afforded an opportunity to demonstrate or achieve compliance with all legal requirements.

■ 8. Revise § 525.18 to read as follows:

§ 525.18 Review.

Any person aggrieved by any action of the Administrator taken pursuant to this part may, within 60 days or such additional time as the Administrator may allow, file with the Administrator a petition for review. Such review, if granted, shall be made by the Administrator. Other interested persons, to the extent it is deemed appropriate, may be afforded an opportunity to present data and views. Any review granted cannot result in section 14(c) certificate authority being extended beyond [DATE 3 YEARS AFTER THE EFFECTIVE DATE OF FINAL RULE].

■ 9. Add § 525.25 to read as follows:

§ 525.25 Severability.

The provisions of this part are separate and severable and operate independently from one another. If any provision of this part is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision must be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding will be one of utter invalidity or unenforceability, in which event the provision will be severable from this part and will not affect the remainder thereof.

Jessica Looman,

Administrator, Wage and Hour Division.

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