FEDERAL REGISTER

Vol. 89 Friday,
No. 129 July 5, 2024

Pages 55495–55882

OFFICE OF THE FEDERAL REGISTER

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2315; Airspace Docket No. 22–AEA–26]

RIN 2120–AA66

Establishment, Amendment, and Revocation of Multiple Air Traffic Service (ATS) Routes; Eastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes United States Area Navigation (RNAV) Routes Q–221 and Q–227; amends Very High Frequency Omnidirectional Range (VOR) Federal Airways V–35, V–147, and V–270 and RNAV Routes T–440 and T–445; and revokes VOR Federal Airway V–36 and Jet Routes J–132, J–223, and J–227 in the eastern United States. The FAA is taking this action due to the planned decommissioning of the Elmira, NY (ULW), VOR/Distance Measuring Equipment (VOR/DME). This action is in support of the FAA's VOR Minimum Operational Network (MON) Program.

DATES: Effective date 0901 UTC, September 5, 2024. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at *www.regulations.gov* using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/*. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Brian Vidis, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the Air Traffic Service (ATS) route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

History

The FAA published a NPRM for Docket No. FAA 2023–2315 in the **Federal Register** (89 FR 2522; January 16, 2024), proposing to amend three VOR Federal airways and two RNAV routes; and to revoke one VOR Federal airway and three Jet routes in the eastern United States. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

In a previous NPRM, Docket No. FAA–2023–1835 in the **Federal Register** (88 FR 68516; October 4, 2023), the FAA proposed to establish RNAV Routes Q–221 and Q–227. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Differences From the NPRM

The NPRM published for Docket No. FAA 2023–2315 in the **Federal Register** (89 FR 2522; January 16, 2024) contained a typographical error in the summary section. The summary section stated that the NPRM was proposing to revoke two VOR Federal airways. This should have stated that it was proposing to revoke one VOR Federal Airway. This final rule corrects this error.

In a previous NPRM, Docket No. FAA–2023–1835 in the **Federal Register** (88 FR 68516; October 4, 2023), the FAA proposed to establish RNAV Routes Q–221 and Q–227. No comments were received. The FAA decided to establish RNAV Route Q–221 and Q–227 in this docket as they mitigate the loss of navigation capability due to the removal of Jet Route J–227 that is revoked in this action.

Incorporation by Reference

Jet Routes are published in paragraph 2004, United States Area Navigation Routes (Q-routes) are published in paragraph 2006, Domestic VOR Federal Airways are published in paragraph 6010(a), and United States Area Navigation Routes (T-routes) are published in paragraph 6011 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. FAA Order JO 7400.11H is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by establishing RNAV Routes Q–221 and Q–227; amending VOR Federal Airways V–35, V–147, and V–270 and RNAV Routes T–440 and T–445; and revokes VOR Federal Airway V–36 and Jet Routes J–132, J–223, and J–227 in the eastern United States. This action is due to the decommissioning of the Elmira, NY (ULW), VOR/DME. The ATS route changes are described below.

J–132: Prior to this final rule, J–132 extended between the Elmira, NY (ULW), VOR/DME and the Huguenot, NY (HUO), VOR/DME. The FAA removes the route in its entirety.

J–223: Prior to this final rule, J–223 extended between the La Guardia, NY (LGA), VOR/DME and the intersection of the La Guardia VOR/DME 310° and Elmira, NY (ULW), VOR/DME 110° radials (CORDS Fix). The FAA removes the route in its entirety.

J–227: Prior to this final rule, J–227 extended between the Armel, VA (AML), VOR/DME and the Elmira, NY (ULW), VOR/DME. The FAA removes the route in its entirety.

Q–221: Q–221 is a new route that extends between the Armel, VA (AML), VOR/DME and the DLMAR, PA, waypoint (WP). Q–221 overlays Jet Route J–220 between the Armel VOR/DME and the DLMAR WP which is co-located with the Stonyfork, PA (SFK), VOR/DME.

Q–227: Q–227 is a new route that extends between the Armel, VA (AML), VOR/DME and the STUBN, NY, WP. Q–227 overlays Jet Route J–227 between the Armel VOR/DME and the STUBN WP which is co-located with the Elmira, NY (ULW), VOR/DME.

V–35: Prior to this final rule, V–35 extended between the Dolphin, FL (DHP), VOR/Tactical Air Navigation (VORTAC) and the Pecan, GA (PZD), VOR/DME; between the intersection of the Dublin, GA (DBN), VORTAC 309° and the Athens, GA (AHN), VOR/DME 195° radials (SINCA Fix) and the Morgantown, WV (MGW), VOR/DME; and between the Philipsburg, PA (PSB), VORTAC and the Syracuse, NY (SYR), VORTAC. The FAA removes the airway segments between the Stonyfork, PA (SFK), VOR/DME and the Syracuse VORTAC. As amended, the route extends between the Dolphin VORTAC and the Pecan VOR/DME; between the SINCA Fix and the Morgantown VOR/DME; and between the Philipsburg VORTAC and the Stonyfork VOR/DME.

V–36: Prior to this final rule, V–36 extended between the Elmira, NY (ULW), VOR/DME and the intersection of the La Guardia, NY (LGA), VOR/DME 310° and the Stillwater, NJ (STW), VOR/DME 043° radials. The FAA removes the route in its entirety.

V–147: Prior to this final rule, V–147 extended between the Yardley, PA (ARD), VOR/DME and the Rochester, NY (ROC), VOR/DME. The FAA removes the airway segments between the Wilkes-Barre, PA (LVZ), VORTAC and the Geneseo, NY (GEE), VOR/DME. As amended, the route extends between the Yardley VOR/DME and the Wilkes-Barre VORTAC, and between the Geneseo VOR/DME and the Rochester VOR/DME.

V–270: Prior to this final rule, V–270 extended between the Elmira, NY (ULW), VOR/DME and the Boston, MA (BOS), VOR/DME. The FAA removes the airway segment between the Elmira VOR/DME and the Binghamton, NY (CFB), VOR/DME. Additionally, the FAA removes the Delancey, NY (DNY), VOR/DME from the route and replaces it with the intersection of the Binghamton VOR/DME 088° and the Sparta, NJ (SAX), VORTAC 344° radials (DANZI Fix). Replacement of the Delancey VOR/DME with the DANZI Fix provides continued connection to other ATS routes in the route structure. As amended, the route extends between the Binghamton VOR/DME and the Boston VOR/DME.

T–440: Prior to this final rule, T–440 extended between the Elmira, NY (ULW), VOR/DME and the TALLI, PA, Fix. The FAA removes the Elmira VOR/DME and replaces it with the STUBN, NY, WP which is located 60 feet southeast of the Elmira VOR/DME. The amended RNAV route mitigates the removal of airway segments of V–147 and provides RNAV route structure continuity. As amended, the route extends between the STUBN WP and the TALLI Fix.

T–445: Prior to this final rule, T–445 extended between the Harrisburg, PA (HAR), VORTAC and the AIRCO, NY, Fix. The FAA removes the Elmira, NY (ULW), VOR/DME and replaces it with the STUBN, NY, WP which is located 60 feet southeast of the Elmira VOR/DME. As amended, the route continues to extend between the Harrisburg VORTAC and the AIRCO Fix.

The navigational aid radials listed in the VOR Federal airway description regulatory text of this final rule are stated in degrees True north.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action of establishing RNAV Routes Q–221 and Q–227; amending VOR Federal Airways V–35, V–147, and V–270 and RNAV Routes T–440 and T–445; and revoking VOR Federal Airway V–36 and Jet Routes J–132, J–223, and J–227 in the eastern United States, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and paragraph 5–6.5b, which categorically excludes from further environmental impact review ''Actions regarding establishment of jet routes and Federal airways (see 14 CFR 71.15, *Designation of jet routes and VOR Federal airways*) . . .''. As such, this airspace action is not expected to cause any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J–132 [Removed]

* * * * *

J–223 [Removed]

* * * * *

J–227 [Removed]

* * * * *

Paragraph 2006 United States Area Navigation Routes.

* * * * *

Q–221 Armel, VA (AML) to DLMAR, PA [New]

Armel, VA (AML)	VOR/DME	(Lat. 38°56′04.53″ N, long. 077°28′00.13″ W)
DLMAR, PA	WP	(Lat. 41°41′42.56″ N, long. 077°25′11.02″ W)

* * * * *

Q–227 Armel, VA (AML) to STUBN, NY [New]

Armel, VA (AML)	VOR/DME	(Lat. 38°56′04.53″ N, long. 077°28′00.13″ W)
OGESY, PA	WP	(Lat. 40°44′13.65″ N, long. 077°26′11.63″ W)
STUBN, NY	WP	(Lat. 42°05′38.58″ N, long. 077°01′28.68″ W)

* * * * *

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–35 [Amended]

From Dolphin, FL; INT Dolphin 266° and Cypress, FL, 110° radials; INT Cypress 110° and Lee County, FL, 138° radials; Lee County; INT Lee County 326° and St. Petersburg, FL, 152° radials; St. Petersburg; INT St. Petersburg 350° and Cross City, FL, 168° radials; Cross City; Greenville, FL; to Pecan, GA. From INT Dublin, GA, 309° and Athens, GA, 195° radials; Athens; Electric City, SC; Sugarloaf Mountain, NC; Holston Mountain, TN; Glade Spring, VA; Charleston, WV; INT Charleston 051° and Elkins, WV, 264° radials; Clarksburg, WV; to Morgantown, WV. From Philipsburg, PA; to Stonyfork, PA.

V–36 [Removed]

* * * * *

V–147 [Amended]

From Yardley, PA; INT Yardley 294° and East Texas, PA, 124° radials; East Texas; to Wilkes-Barre, PA. From Geneseo, NY; to Rochester, NY.

* * * * *

V–270 [Amended]

From Binghamton, NY; INT Binghamton 088° and Sparta, NJ, 344° radials; Chester, MA; INT Chester 091° and Boston, MA, 262° radials; to Boston.

* * * * *

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–440 STUBN, NY to TALLI, PA [Amended]

STUBN, NY	WP	(Lat. 42°05′38.58″ N, long. 077°01′28.68″ W)
WLKES, PA	WP	(Lat. 41°16′22.57″ N, long. 075°41′21.60″ W)
TALLI, PA	FIX	(Lat. 41°19′01.60″ N, long. 075°06′43.17″ W)

* * * * *

T–445 Harrisburg, PA (HAR) to AIRCO, NY [Amended]

Harrisburg, PA (HAR)	VORTAC	(Lat. 40°18′08.06″ N, long. 077°04′10.41″ W)
Selinsgrove, PA (SEG)	VOR/DME	(Lat. 40°47′27.09″ N, long. 076°53′02.55″ W)
LYKOM, PA	WP	(Lat. 41°20′18.75″ N, long. 076°46′30.30″ W)
STUBN, NY	WP	(Lat. 42°05′38.58″ N, long. 077°01′28.68″ W)
BEEPS, NY	FIX	(Lat. 42°49′13.26″ N, long. 076°59′04.84″ W)
Rochester, NY (ROC)	VOR/DME	(Lat. 43°07′04.65″ N, long. 077°40′22.06″ W)
AIRCO, NY	FIX	(Lat. 43°12′36.66″ N, long. 078°28′57.00″ W)

* * * * *

Issued in Washington, DC, on June 26, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024–14486 Filed 7–3–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2198; Airspace Docket No. 23–AEA–12]

RIN 2120–AA66

Establishment and Amendment of United States Area Navigation (RNAV) Routes; Eastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes three United States Area Navigation (RNAV) Routes T–434, T–454, and T–458; and amends three United States RNAV Routes T–291, T–314, and T–634 in the eastern United States. This action supports Next Generation Air Transportation System (NextGen) which provides a modern RNAV route structure to improve the efficiency of the National Airspace System (NAS).

DATES: Effective date 0901 UTC, September 5, 2024. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at *www.regulations.gov* using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Brian Vidis, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the Air Traffic Service (ATS) route structure as necessary to preserve the safe and efficient flow of air traffic within the NAS.

History

The FAA published a NPRM for Docket No. FAA 2023–2198 in the **Federal Register** (88 FR 87377; December 18, 2023), proposing to establish three RNAV routes and amend three RNAV routes in the eastern United States. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Differences From the NPRM

Subsequent to publication of the NPRM, the FAA identified that the HYATT, PA route point was incorrectly listed as a Fix. The HYATT route point is identified as a waypoint (WP) in the NASR database and charted as a WP accordingly.

Additionally, the PAGER, NY, WP is removed from the route description of RNAV Route T–634 as it is a turn of less than one degree. The removal of the PAGER WP does not substantively alter the route. This final rule corrects these errors.

Incorporation by Reference

United States Area Navigation Routes are published in paragraph 6011 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. FAA Order JO 7400.11H is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by establishing RNAV Routes T–434, T–454, and T–458, and amending RNAV Routes T–291, T–314, and T–634 in the eastern United States. This action supports NextGen which provides a modern RNAV route structure to improve the efficiency of the NAS. The amendments are described below.

T–291: Prior to this final rule, T–291 extended between the Harcum, VA (HCM), Very High Frequency Omnidirectional Range/Tactical Air Navigation (VORTAC) and the Albany, NY (ALB), VORTAC. The route is amended by extending T–291 to the south between the Harcum VORTAC and the Tar River, NC (TYI), VORTAC. The route overlays a portion of VOR Federal Airway V–189 between the Tar River VORTAC and the Franklin, PA (FKN), VORTAC. Additionally, the HYATT, PA, WP replaces the Milton, PA (MIP), VORTAC; and the DANZI, NY, WP replaces the Delancey, NY (DNY), VOR/Distance Measuring Equipment (VOR/DME). As amended, the route extends between the Tar River VORTAC and the Albany VORTAC.

T–314: Prior to this final rule, T–314 extended between the Barnes, MA (BAF), VORTAC and the Kennebunk, ME (ENE), VOR/DME. The route is amended by extending T–314 to the southwest between the Barnes VORTAC and the Kingston, NY (IGN), VOR/DME. The route overlays a portion of VOR Federal Airway V–93 between the Kingston VOR/DME and the SASHA, MA, Fix, and a portion of VOR Federal Airway V–292 between the SASHA Fix and the Barnes VORTAC. Additionally, the FAA removes route points from the route description for segments that contain turns of less than one degree. The following are the route points that are removed: FAIDS, MA, Fix; PUDGY, MA, Fix; LAPEL, MA, Fix; JOHNZ, NH, Fix; MANCH, NH, WP; KHRIS, NH, Fix; RAYMY, NH, Fix; and YUKES, ME, Fix. As amended, the route extends between the Kingston VOR/DME and the Kennebunk VOR/DME.

T–434: T–434 is a new route that extends between the SCAAM, PA, Fix and the NECCK, NJ, Fix. The route overlays a portion of VOR Federal Airway V–232 between the Keating, PA (ETG), VORTAC and the Colts Neck, NJ (COL), VOR/DME.

T–454: T–454 is a new route that extends between the SCAAM, PA, Fix and the NWTON, NJ, Fix. The route overlays a portion of VOR Federal Airway V–226 between the Keating, PA (ETG), VORTAC and the Stillwater, PA (STW), VOR/DME.

T–458: T–458 is a new route that extends between the STUBN, NY, WP and the Boston, MA (BOS), VOR/DME. The route overlays a portion of VOR Federal Airway V–270 between the Elmira, NY (ULW), VOR/DME and the Boston, MA (BOS), VOR/DME.

T–634: Prior to this final rule, T–634 extended between the VIBRU, NY, WP and the Syracuse, NY (SYR), VORTAC. The route is amended by extending T–634 to the southeast between the Syracuse VORTAC and the Sandy Point, RI (SEY), VOR/DME. The route overlays a portion of VOR Federal Airway V–483 between the Syracuse VORTAC and the Carmel, NY (CMK), VOR/DME; VOR Federal Airway V–374 between the Carmel VOR/DME and the CREAM, NY, Fix; and VOR Federal Airway V–34 between the CREAM Fix and the Sandy Point VOR/DME. Additionally, the BRUIN, NY, WP and the PAGER, NY WP are removed from the route description as they are a turn of less than one degree. As amended, the route extends between the VIBRU WP and the Sandy Point VOR/DME.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial

number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action of establishing RNAV Routes T–434, T–454, and T–458, and amending RNAV Routes T–291, T–314, and T–634 in the eastern United States, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and paragraph 5–6.5b, which categorically excludes from further environmental impact review ''Actions regarding establishment of jet routes and Federal airways (see 14 CFR 71.15, *Designation of jet routes and VOR Federal airways*) . . .''. As such, this airspace action is not expected to cause any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact statement.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–291 Tar River, NC (TYI) to Albany, NY (ALB) [Amended]

Tar River, NC (TYI)	VORTAC	(Lat. 35°58′36.21″ N, long. 077°42′13.43″ W)
COUPN, VA	WP	(Lat. 36°42′50.83″ N, long. 077°00′44.04″ W)
Harcum, VA (HCM)	VORTAC	(Lat. 37°26′55.18″ N, long. 076°42′40.87″ W)
COLIN, VA	FIX	(Lat. 38°05′59.23″ N, long. 076°39′50.85″ W)
SHLBK, MD	WP	(Lat. 38°20′16.21″ N, long. 076°26′10.51″ W)
LOUIE, MD	WP	(Lat. 38°36′44.33″ N, long. 076°18′04.37″ W)
GRACO, MD	FIX	(Lat. 38°56′29.81″ N, long. 076°11′59.22″ W)
BAABS, MD	WP	(Lat. 39°22′01.36″ N, long. 076°27′31.21″ W)
VINNY, PA	FIX	(Lat. 39°45′16.64″ N, long. 076°36′30.16″ W)
Harrisburg, PA (HAR)	VORTAC	(Lat. 40°18′08.06″ N, long. 077°04′10.41″ W)
Selinsgrove, PA (SEG)	VOR/DME	(Lat. 40°47′27.09″ N, long. 076°53′02.55″ W)
HYATT, PA	WP	(Lat. 41°01′24.47″ N, long. 076°39′54.34″ W)
MEGSS, PA	FIX	(Lat. 41°11′13.28″ N, long. 076°12′41.02″ W)
LAAYK, PA	FIX	(Lat. 41°28′32.64″ N, long. 075°28′57.31″ W)
DANZI, NY	WP	(Lat. 42°10′41.86″ N, long. 074°57′24.19″ W)
Albany, NY (ALB)	VORTAC	(Lat. 42°44′50.21″ N, long. 073°48′11.46″ W)

* * * * *

T–314 Kingston, NY (IGN) to Kennebunk, ME (ENE) [Amended]

Kingston, NY (IGN)	VOR/DME	(Lat. 41°39′55.63″ N, long. 073°49′20.06″ W)
PAWLN, NY	FIX	(Lat. 41°46′11.51″ N, long. 073°36′02.64″ W)
SASHA, MA	FIX	(Lat. 42°07′58.70″ N, long. 073°08′55.39″ W)
Barnes, MA (BAF)	VORTAC	(Lat. 42°09′43.05″ N, long. 072°42′58.32″ W)
Gardner, MA (GDM)	VOR/DME	(Lat. 42°32′45.32″ N, long. 072°03′29.48″ W)
Kennebunk, ME (ENE)	VOR/DME	(Lat. 43°25′32.42″ N, long. 070°36′48.69″ W)

* * * * *

T–434 SCAAM, PA to NECCK, NJ [New]

SCAAM, PA	FIX	(Lat. 41°11′37.46″ N, long. 077°58′15.20″ W)
HYATT, PA	WP	(Lat. 41°01′24.47″ N, long. 076°39′54.34″ W)
BEERS, PA	FIX	(Lat. 40°52′47.50″ N, long. 075°27′37.36″ W)
Solberg, NJ (SBJ)	VOR/DME	(Lat. 40°34′58.96″ N, long. 074°44′30.45″ W)
TYKES, NJ	FIX	(Lat. 40°17′22.38″ N, long. 074°23′06.13″ W)
NECCK, NJ	FIX	(Lat. 40°18′41.79″ N, long. 074°09′35.79″ W)

* * * * *

T–454 SCAAM, PA to NWTON, NJ [New]

SCAAM, PA	FIX	(Lat. 41°11′37.46″ N, long. 077°58′15.20″ W)
FAVUM, PA	FIX	(Lat. 41°15′59.17″ N, long. 077°35′42.32″ W)
Williamsport, PA (FQM)	VOR/DME	(Lat. 41°20′18.81″ N, long. 076°46′29.52″ W)
Wilkes-Barre, PA (LVZ)	VORTAC	(Lat. 41°16′22.08″ N, long. 075°41′22.08″ W)
NWTON, NJ	FIX	(Lat. 40°59′45.19″ N, long. 074°52′09.21″ W)

* * * * *

T–458 STUBN, NY to Boston, MA (BOS) [New]

STUBN, NY	WP	(Lat. 42°05′38.58″ N, long. 077°01′28.68″ W)
Binghamton, NY (CFB)	VOR/DME	(Lat. 42°09′26.97″ N, long. 076°08′11.30″ W)
DANZI, NY	WP	(Lat. 42°10′41.86″ N, long. 074°57′24.19″ W)
Chester, MA (CTR)	VOR/DME	(Lat. 42°17′28.75″ N, long. 072°56′57.82″ W)

SPENO, MA	FIX	(Lat. 42°16′48.55″ N, long. 072°09′14.70″ W)
GLYDE, MA	FIX	(Lat. 42°16′03.84″ N, long. 071°48′42.76″ W)
Boston, MA (BOS)	VOR/DME	(Lat. 42°21′26.82″ N, long. 070°59′22.37″ W)

* * * * *

T–634 VIBRU, NY to Sandy Point, RI (SEY) [Amended]

VIBRU, NY	WP	(Lat. 44°20′21.30″ N, long. 076°01′19.96″ W)
Watertown, NY (ART)	VORTAC	(Lat. 43°57′07.67″ N, long. 076°03′52.66″ W)
Syracuse, NY (SYR)	VORTAC	(Lat. 43°09′37.87″ N, long. 076°12′16.41″ W)
STODA, NY	FIX	(Lat. 43°07′00.20″ N, long. 075°51′21.23″ W)
RAHKS, NY	FIX	(Lat. 42°27′59.28″ N, long. 075°14′21.68″ W)
DANZI, NY	WP	(Lat. 42°10′41.86″ N, long. 074°57′24.19″ W)
WEETS, NY	FIX	(Lat. 41°51′26.98″ N, long. 074°11′51.51″ W)
Kingston, NY (IGN)	VOR/DME	(Lat. 41°39′55.63″ N, long. 073°49′20.06″ W)
CASSH, NY	FIX	(Lat. 41°35′38.16″ N, long. 073°42′17.07″ W)
Carmel, NY (CMK)	VOR/DME	(Lat. 41°16′48.32″ N, long. 073°34′52.78″ W)
CREAM, NY	FIX	(Lat. 41°08′55.85″ N, long. 072°31′18.32″ W)
Sandy Point, RI (SEY)	VOR/DME	(Lat. 41°10′02.77″ N, long. 071°34′33.91″ W)

* * * * *

Issued in Washington, DC, on June 25, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024–14345 Filed 7–3–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No. FAA–2023–1415; Amdt. No. 91–369A]

RIN 2120–AL99

Prohibition Against Certain Flights in the Kabul Flight Information Region (FIR) (OAKX)

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The Federal Aviation Administration (FAA) is issuing this final rule to permit all: U.S. air carriers; U.S. commercial operators; persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except when the operator of such aircraft is a foreign air carrier, to operate transiting overflights of the Kabul Flight Information Region (FIR) (OAKX) on jet routes P500–G500 at altitudes at and above Flight Level (FL) 300, subject to the approval of, and in accordance with the conditions established by, the appropriate authorities of Afghanistan. The FAA became aware that certain U.S. operators were having difficulty using jet routes P500–G500 in the Kabul FIR (OAKX) at altitudes at and above FL320 due to aircraft performance issues under certain meteorological conditions. After consideration of Afghanistan's practice of publishing Notices to Air Missions (NOTAMs) regarding overflights on these jet routes, the lack of any reported security incidents posing safety-of-flight risks to civil aircraft overflights on these jet routes since the FAA issued this Special Federal Aviation Regulation (SFAR) in July 2023 or while the FAA flight prohibition NOTAM that preceded it was in effect, and the very brief period of time U.S. civil aviation overflights on these jet routes would be in the Kabul FIR (OAKX), the FAA has determined transiting U.S. civil aviation overflights operating on jet routes P500–G500 in the Kabul FIR (OAKX) at altitudes at and above FL300 present a low risk. The FAA continues to prohibit U.S. civil aviation operations in the remainder of the Kabul FIR (OAKX) at altitudes below FL320 due to hazards to persons and aircraft engaged in operations at those altitudes due to the risk posed by violent extremist and militant activity and the lack of adequate risk mitigation capabilities to counter such activity.

DATES: This final rule is effective on July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Bill Petrak, Flight Standards Service, through the Washington Operations Center, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–3203; email *9-FAA-OverseasFlightProhibitions@faa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

This action amends Special Federal Aviation Regulation (SFAR) No. 119, 14 CFR 91.1619, to permit U.S. civil aviation airmen and operators to conduct transiting overflights of the Kabul FIR (OAKX) on jet routes P500–G500 at altitudes at and above FL300, subject to the approval of, and in accordance with the conditions established by, the appropriate authorities of Afghanistan.

On July 25, 2023, the Federal Aviation Administration (FAA) published a final rule in the **Federal Register** to prohibit certain flight operations in the Kabul FIR (OAKX) at altitudes below FL320 by all: U.S. air carriers; U.S. commercial operators; persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except when the operator of such aircraft is a foreign air carrier. In that final rule, the FAA determined that U.S. civil aviation overflights of the Kabul FIR (OAKX) at altitudes at and above FL320 could resume due to diminished risks to U.S. civil aviation operations at those altitudes.

Subsequently, the FAA became aware that certain U.S. operators were having difficulty using jet routes P500–G500 in the Kabul FIR (OAKX) at altitudes at and above FL320 due to aircraft performance issues under certain meteorological conditions. After consideration of Afghanistan's practice of publishing NOTAMs regarding overflights on these jet routes, the lack of any reported security incidents posing safety-of-flight risks to civil aircraft overflights on these jet routes since the FAA issued SFAR No. 119, 14 CFR 91.1619, in July 2023 or while the FAA flight prohibition NOTAM that preceded it was in effect, and the very brief period of time U.S. civil aviation overflights on these jet routes, on which the minimum en route altitude is FL300, would be in the Kabul FIR (OAKX), the FAA assesses the risk to the safety of transiting U.S. civil aviation overflights operating on jet routes P500–G500 in the Kabul FIR (OAKX) at altitudes at and above FL300 is low. Under the FAA flight prohibition NOTAM preceding the July 2023 final rule, the FAA had previously permitted U.S. civil aviation to conduct transiting overflight operations in the Kabul FIR (OAKX) on jet routes P500–G500. The FAA

continues to prohibit U.S. civil aviation operations in the remainder of the Kabul FIR (OAKX) at altitudes below FL320 due to hazards to persons and aircraft engaged in operations at those altitudes due to the risk posed by violent extremist and militant activity and the lack of adequate risk mitigation capabilities to counter such activity.

Therefore, the FAA is issuing this final rule to permit U.S. civil aviation to operate transiting overflights of the Kabul FIR (OAKX) on jet routes P500–G500 at altitudes at and above FL300, subject to the approval of, and in accordance with the conditions established by, the appropriate authorities of Afghanistan.

II. Authority and Good Cause

A. Authority

The FAA is responsible for the safety of flight in the U.S. and for the safety of U.S. civil operators, U.S.-registered civil aircraft, and U.S.-certificated airmen throughout the world. Sections 106(f) and (g) of title 49, U.S. Code (U.S.C.), subtitle I, establish the FAA Administrator's authority to issue rules on aviation safety. Subtitle VII of title 49, Aviation Programs, describes in more detail the scope of the agency's authority. Section 40101(d)(1) provides that the Administrator shall consider in the public interest, among other matters, assigning, maintaining, and enhancing safety and security as the highest priorities in air commerce. Section 40105(b)(1)(A) requires the Administrator to exercise this authority consistently with the obligations of the U.S. Government under international agreements.

The FAA is promulgating this rule under the authority described in 49 U.S.C. 44701, General requirements. Under that section, the FAA is charged broadly with promoting safe flight of civil aircraft in air commerce by prescribing, among other things, regulations and minimum standards for practices, methods, and procedures that the Administrator finds necessary for safety in air commerce and national security. This regulation is within the scope of the FAA's authority because it provides relief to U.S. civil aviation operators and airmen conducting transiting overflights of the Kabul FIR (OAKX) on jet routes P500–G500, permitting those persons to operate at altitudes at and above FL300, instead of at altitudes at and above FL320, as is required for operations conducted in the rest of the Kabul FIR (OAKX).

B. Good Cause for Immediate Adoption

Section 553(b)(B) of title 5, U.S. Code, authorizes agencies to dispense with notice and comment procedures for rules when the agency for ''good cause'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Also, section 553(d) permits agencies, upon a finding of good cause, to issue rules with an effective date less than 30 days from the date of publication. In this instance, the FAA finds good cause to forgo notice and comment and the delayed effective date because they would be impracticable and contrary to the public interest.

Providing notice and the opportunity for the public to comment here would be impracticable. The FAA's flight prohibitions, and any amendments thereto, need to include appropriate boundaries that reflect the agency's current understanding of the risk environment for U.S. civil aviation. This allows the FAA to protect the safety of U.S. operators' aircraft and the lives of their passengers and crews without over-restricting or under-restricting U.S. operators' routing options. However, the risk environment for U.S. civil aviation in airspace managed by other countries with respect to safety of flight is fluid in circumstances involving fighting, violent extremist and militant activity, or periods of heightened tensions, particularly where weapons capable of targeting or otherwise negatively affecting U.S. civil aviation are or may be present. This fluidity, and the potential for rapid changes in the risks to U.S. civil aviation, significantly limits how far in advance of a new or amended flight prohibition the FAA can usefully assess the risk environment. The delay that would be occasioned by providing an opportunity to comment on this action would significantly increase the risk that the resulting final action would not accurately reflect the current risks to U.S. civil aviation associated with the situation and thus would not establish boundaries for the flight prohibition commensurate with those risks.

While the FAA sought and responded to public comments, the boundaries of the area in which unacceptable risks to the safety of U.S. civil aviation existed might change due to: evolving military or political circumstances; violent extremist and militant group activity; the introduction, removal, or repositioning of more advanced anti-aircraft weapon systems; or other factors. As a result, if the situation improved while the FAA sought and responded to public comments, the rule the FAA finalized might be over-restrictive, unnecessarily limiting U.S. operators' routing options and potentially causing them to incur unnecessary additional fuel and operations-related costs, as well as potentially causing passengers to incur unnecessarily some costs attributed to their time. Conversely, if the situation deteriorated while the FAA sought and responded to public comments, the rule the FAA finalized might be under-restrictive, allowing U.S. civil aviation to continue operating in areas where unacceptable risks to their safety had developed. Such an outcome would endanger the safety of these aircraft, as well as their passengers and crews, exposing them to unacceptable risks of death, injury, and property damage that could occur if a U.S. operator's aircraft were shot down (or otherwise damaged) while operating in the Kabul FIR (OAKX).

Alternatively, if the FAA made changes to the area in which U.S. civil aviation operations would be prohibited between a notice of proposed rulemaking and a final rule due to changed conditions, the version of the rule the public commented on would no longer reflect the FAA's current assessment of the risk environment for U.S. civil aviation.

In addition, seeking comment would be contrary to the public interest because some of the rational basis for the rulemaking is based upon classified information and controlled unclassified information not authorized for public release. In order to meaningfully provide comment on a proposal, the public would need access to the basis for the agency's decision-making, which the FAA cannot provide. Disclosing classified or controlled unclassified information in order to seek meaningful comment on the proposal would harm the public interest. Accordingly, the FAA meaningfully seeking comment on the proposal is contrary to the public interest.

Therefore, providing notice and the opportunity for comment would be impracticable as it would hinder the FAA's ability to maintain appropriate flight prohibitions based on up-to-date assessments of the risks to the safety of U.S. civil aviation operations in airspace managed by other countries and contrary to the public interest as the FAA cannot protect classified and controlled unclassified information and meaningfully seek public comment.

For the same reasons discussed above, the potential safety impacts and the need for prompt action on up-to-date information that is not public would make delaying the effective date impracticable and contrary to the public

interest. Additionally, for transiting overflights of the Kabul FIR (OAKX) on jet routes P500–G500 at altitudes at and above FL300, any delay in the effective date of the rule would continue a prohibition on U.S. civil aviation operations on these jet routes at altitudes at and above FL300 that the FAA has determined is no longer needed for the safety of U.S. civil aviation and would thus unnecessarily restrict U.S. operators' routing options at those altitudes on those jet routes.

Accordingly, the FAA finds good cause exists to forgo notice and comment and any delay in the effective date for this rule.

III. Background and Discussion of the Final Rule

On August 30, 2021, the FAA issued NOTAM KICZ A0029/21 to address the then-existing unacceptable risks to the safety of U.S. civil aviation operations in the Kabul FIR (OAKX) at all altitudes, except for transiting overflight operations on jet routes P500–G500. This NOTAM prohibited, with certain limited exceptions, U.S. civil aviation operations in the Kabul FIR (OAKX) at all altitudes by all: U.S. air carriers; U.S. commercial operators; persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and all operators of U.S.-registered civil aircraft, except when the operator of such aircraft is a foreign air carrier, due to the risk posed by violent extremist and militant activity, lack of adequate risk mitigation capabilities, and disruption to air traffic services. The NOTAM allowed U.S. civil aviation overflights to transit the Kabul FIR (OAKX) on jet routes P500–G500, as such operations are only in the Kabul FIR (OAKX) very briefly.

Following the Taliban takeover of Afghanistan, the International Civil Aviation Organization (ICAO) Asia-Pacific Office made contact with Afghanistan's civil aviation authority and stood up a contingency coordination team (CCT) composed of Afghanistan and neighboring air navigation service providers, as well as International Air Transport Association (IATA) representation. Afghanistan's civil aviation authority and the CCT worked with neighboring air navigation service providers to establish a contingency plan for the safe resumption of civil overflights in the Kabul FIR (OAKX).

Subsequently, Afghanistan issued a series of NOTAMs delineating overflight procedures and established altitude blocks for specific categories of flight operations across various regions. The overflight procedures rely upon internationally-recognized traffic information broadcasts by aircraft (TIBA) procedures, which pilots use in areas around the world where air traffic services are very limited or unavailable to maintain safe separation between aircraft. Consequently, the FAA determined that U.S. civil aviation operations throughout the Kabul FIR (OAKX) could resume at altitudes at and above FL320 due to diminished risks to U.S. civil aviation operations at those altitudes. On July 25, 2023, the FAA published in the **Federal Register** a final rule, Prohibition Against Certain Flights in the Kabul Flight Information Region (FIR) (OAKX), allowing U.S. civil overflights of the Kabul FIR (OAKX) to resume at altitudes at and above FL320.[1] However, as described in more detail in the preamble to the July 2023 final rule, the FAA continued to assess the situation in the Kabul FIR (OAKX) at altitudes below FL320 as being hazardous for U.S. civil aviation and prohibited U.S. civil aviation operations at those altitudes.

Although the FAA did not identify or assess that there existed any increased safety-of-flight risks to transiting U.S. civil aviation overflights operating on jet routes P500–G500 due to violent extremist or militant activity, the FAA prohibited operations on those routes at altitudes below FL320 in the July 2023 final rule because the Kabul FIR Air Traffic Management Contingency Plan indicates that, as necessary, FL300 may be reserved for military operations by NOTAM. Consequently, the FAA decided to establish a minimum allowed overflight level of FL320 for U.S. civil aviation operations in the entirety of the Kabul FIR (OAKX) to help ensure aircraft separation between any military operations being conducted in the Kabul FIR (OAKX) at FL300 and U.S. civil aviation overflights.

Since it issued the July 2023 final rule, the FAA has received two petitions for exemption from SFAR No. 119, § 91.1619, from U.S. air carriers requesting to operate on jet routes P500–G500 at altitudes at and above FL300 instead of at altitudes at and above FL320 as required by SFAR No. 119, § 91.1619, due to aircraft performance issues under certain meteorological conditions.[2] [3]

Since the publication of the Kabul FIR Air Traffic Management Contingency Plan and continuing since the FAA issued the July 2023 final rule, Afghanistan has issued a series of NOTAMs permitting overflight operations between waypoints FIRUZ and MOTMO on jet routes P500–G500 at altitudes between FL300–FL510. The FAA is not aware of any safety or security incidents experienced by civil aircraft operating on jet routes P500–G500 in the Kabul FIR (OAKX) at altitudes at or above FL300 due to military flight operations while FAA NOTAM KICZ A0029/21, which permitted U.S. civil aviation operations on that route, was in effect or since the July 2023 final rule. In addition, the FAA is not aware of any active threats to U.S. civil aviation operations on jet routes P500–G500 in the Kabul FIR (OAKX) from violent extremist and militant activity and is not aware of any reports of security incidents involving violent extremist and militant activity posing safety-of-flight risks to civil aircraft overflights using these jet routes at altitudes at or above FL300 in the Kabul FIR (OAKX), either while FAA NOTAM KICZ A0029/21 was in effect or since the issuance of the July 2023 final rule. The very limited flight time in the Kabul FIR (OAKX) minimizes both potential exposure to any military operations in the Kabul FIR (OAKX) that might be operating at FL300 and to potential opportunistic threats should a violent extremist observe or hear an overflying aircraft. Specifically, the flight distance between waypoints FIRUZ and MOTMO on jet routes P500–G500 is approximately 12 nautical miles, which takes approximately 95 seconds at cruising speeds.

Consequently, the FAA has determined that U.S. civil aviation overflights of the Kabul FIR (OAKX) at altitudes at and above FL300 on jet routes P500–G500 present a low risk. Although violent extremists and militants have access to weapons posing risks up to 25,000 feet, and there is high terrain in the vicinity of jet routes P500–G500, the FAA did not see such weapons used against civil aviation overflights on these jet routes during approximately 20 years of U.S. military presence in Afghanistan or since the coalition withdrawal in August of 2021.

Therefore, consistent with the foregoing, the FAA is amending SFAR No. 119, § 91.1619, to permit U.S. civil

[1] *Prohibition Against Certain Flights in the Kabul Flight Information Region (FIR) (OAKX)* final rule, 88 FR 47765 (Jul. 25, 2023). The FAA had prohibited U.S. civil flight operations at all altitudes in the Kabul FIR (OAKX) in NOTAM KICZ A0029/21, except for transiting overflights on jet routes P500–G500. With the publication of the July 2023 final rule, the FAA rescinded NOTAM KICZ A0029/21.

[2] American Airlines, docket FAA–2023–1985.

[3] United Parcel Service, Co., docket FAA–2023–2065.

aviation to conduct transiting overflights of the Kabul FIR (OAKX) on jet routes P500–G500 at altitudes at and above FL300, subject to the approval of, and in accordance with the conditions established by, the appropriate authorities of Afghanistan.

However, this final rule continues to prohibit U.S. civil flight operations at altitudes below FL320 throughout the rest of the Kabul FIR (OAKX). Violent extremist and militant activities continue to pose safety-of-flight risks to U.S. civil aviation at altitudes below FL320 throughout the rest of Afghanistan. Violent extremists and militants are primarily armed with small arms, crew-served weapons, and field rockets and may have access to legacy man-portable air defense systems (MANPADS). Some MANPADS may be capable of reaching a maximum altitude of up to 25,000 feet above ground level; however, in the context of Afghanistan, the FAA must also account for the high altitude of some of the country's terrain. Allowing U.S. civil aviation operations in the Kabul FIR (OAKX) only at altitudes at or above FL320, other than on jet routes P500–G500, accounts for risks associated with the capabilities of weapons systems potentially available to violent extremist organizations and the terrain under other established international air routes in the Kabul FIR (OAKX).[4]

Further amendments to SFAR No. 119, § 91.1619, might be appropriate if the risk to U.S. civil aviation safety and security changes. In this regard, the FAA will continue to monitor the situation and evaluate the extent to which persons described in paragraph (a) of this rule might be able to operate safely in the Kabul FIR (OAKX).

The FAA also republishes the details concerning the approval and exemption processes in sections V and VI of this preamble, consistent with other recently published flight prohibition SFARs to enable interested persons to refer to this final rule for comprehensive information about requesting relief from the FAA from the provisions of SFAR No. 119, § 91.1619.

V. Approval Process Based on a Request From a Department, Agency, or Instrumentality of the United States Government

A. Approval Process Based on an Authorization Request From a Department, Agency, or Instrumentality of the United States Government

In some instances, U.S. Government departments, agencies, or instrumentalities may need to engage U.S. civil aviation to support their activities in the Kabul FIR (OAKX). If a department, agency, or instrumentality of the U.S. Government determines that it has a critical need to engage any person described in paragraph (a) of SFAR No. 119, § 91.1619, including a U.S. air carrier or commercial operator, to transport civilian or military passengers or cargo or conduct other operations in the Kabul FIR (OAKX), except for transiting overflights on jet routes P500–G500 at altitudes at and above FL300, that department, agency, or instrumentality may request the FAA to approve persons described in paragraph (a) of SFAR No. 119, § 91.1619, to conduct such operations.

The requesting U.S. Government department, agency, or instrumentality must submit the request for approval to the FAA's Associate Administrator for Aviation Safety in a letter signed by an appropriate senior official of the requesting department, agency, or instrumentality.[5] The FAA will not accept or consider requests for approval from anyone other than the requesting U.S. Government department, agency, or instrumentality. In addition, the senior official signing the letter requesting FAA approval must be sufficiently positioned within the requesting department, agency, or instrumentality to demonstrate that the organization's senior leadership supports the request for approval and is committed to taking all necessary steps to minimize aviation safety and security risks to the proposed flights. The senior official must also be in a position to: (1) attest to the accuracy of all representations made to the FAA in the request for approval, and (2) ensure that any support from the requesting U.S. Government department, agency, or instrumentality described in the request for approval is in fact brought to bear and is maintained over time. Unless justified by exigent circumstances, requesting U.S. Government departments, agencies, or instrumentalities must submit requests for approval to the FAA no less than 30 calendar days before the date on which the requesting department, agency, or instrumentality wishes the operator(s) to commence the proposed operation(s).

The requestor must send the request to the Associate Administrator for Aviation Safety, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591. Electronic submissions are acceptable, and the requesting entity may request that the FAA notify it electronically as to whether the FAA grants the request for approval. If a requestor wishes to make an electronic submission to the FAA, the requestor should contact the Washington Operations Center by telephone at (202) 267–3203 or by email at *9-FAA-OverseasFlightProhibitions@faa.gov* for submission instructions. The requestor must not submit its letter requesting FAA approval or related supporting documentation to the Washington Operations Center. Rather, the Washington Operations Center will refer the requestor to an appropriate staff member of the Flight Standards Service for further assistance.

A single letter may request approval from the FAA for multiple persons described in SFAR No. 119, § 91.1619, or for multiple flight operations. To the extent known, the letter must identify the person(s) the requester expects the SFAR to cover on whose behalf the U.S. Government department, agency, or instrumentality seeks FAA approval, and it must describe—

- The proposed operation(s), including the nature of the mission being supported;
- The service the person(s) covered by the SFAR will provide;
- To the extent known, the specific locations in the Kabul FIR (OAKX) where the proposed operation(s) will occur, including, but not limited to, the flight path and altitude of the aircraft while it is operating in the Kabul FIR (OAKX) and the airports, airfields, or landing zones at which the aircraft will take off and land; and
- The method by which the requesting department, agency, or instrumentality will provide, or how the operator will otherwise obtain, current threat information and an explanation of how the operator will integrate this information into all phases of the proposed operations (*i.e.,* the pre-mission planning and briefing, in-flight, and post-flight phases).

The request for approval must also include a list of operators with whom

[4] As defined in 14 CFR 1.1, ''Flight level means a level of constant atmospheric pressure related to a reference datum of 29.92 inches of mercury.'' Flight level, in this context, is differentiated from above-ground-level (AGL), which is altitude expressed in feet measured above ground level.

[5] This approval procedure applies to U.S. Government departments, agencies, or instrumentalities; it does not apply to the public. The FAA describes this procedure in the interest of providing transparency with respect to the FAA's process for interacting with U.S. Government departments, agencies, or instrumentalities that seek to engage U.S. civil aviation to operate in the area in which this SFAR would prohibit their operations in the absence of specific FAA approval.

the U.S. Government department, agency, or instrumentality requesting FAA approval has a current contract(s), grant(s), or cooperative agreement(s) (or its prime contractor has a subcontract(s)) for specific flight operations in the Kabul FIR (OAKX), except for operations in the Kabul FIR (OAKX) limited to transiting overflights on jet routes P500–G500 at altitudes at and above FL300. The requestor may identify additional operators to the FAA at any time after the FAA issues its approval. Neither the operators listed in the original request, nor any operators the requestor subsequently seeks to add to the approval, may commence operations under the approval until the FAA issues them an Operations Specification (OpSpec) or Letter of Authorization (LOA), as appropriate, for operations in the Kabul FIR (OAKX) at altitudes below FL320 and/or at altitudes below FL300 on jet routes P500–G500, as applicable. The approval conditions discussed below apply to all operators. Requestors should contact the Washington Operations Center by telephone at (202) 267–3203 or by email at *9-FAA-OverseasFlightProhibitions@faa.gov* for instructions on how to submit the names of additional operators the requestor wishes to add to an existing approval to the FAA. The requestor must not submit the names of additional operators it wishes to add to an existing approval to the Washington Operations Center. Rather, the Washington Operations Center will refer the requestor to an appropriate staff member of the Flight Standards Service for further assistance.

If an approval request includes classified information or controlled unclassified information not authorized for public release, requestors may contact the Washington Operations Center for instructions on submitting it to the FAA. The Washington Operations Center's contact information appears in the **FOR FURTHER INFORMATION CONTACT** section of this final rule.

FAA approval of an operation under SFAR No. 119, § 91.1619, does not relieve persons subject to this SFAR of the responsibility to comply with all other applicable FAA rules and regulations. Operators of civil aircraft must comply with the conditions of their certificates, OpSpecs, and LOAs, as applicable. Operators must also comply with all rules and regulations of other U.S. Government departments, agencies, or instrumentalities that may apply to the proposed operation(s), including, but not limited to, regulations issued by the Transportation Security Administration.

B. Approval Conditions

If the FAA approves the request, the FAA's Aviation Safety organization will send an approval letter to the requesting U.S. Government department, agency, or instrumentality informing it that the FAA's approval is subject to all of the following conditions:

(1) The approval will stipulate those procedures and conditions that limit, to the greatest degree possible, the risk to the operator while still allowing the operator to achieve its operational objectives.

(2) Before any approval takes effect, the operator must submit to the FAA:

(a) A written release of the U.S. Government from all damages, claims, and liabilities, including without limitation legal fees and expenses, relating to any event arising out of or related to the approved operations in the Kabul FIR (OAKX); and

(b) The operator's written agreement to indemnify the U.S. Government with respect to any and all third-party damages, claims, and liabilities, including without limitation legal fees and expenses, relating to any event arising out of or related to the approved operations in the Kabul FIR (OAKX).

(3) Other conditions the FAA may specify, including those the FAA might impose in OpSpecs or LOAs, as applicable.

The release and agreement to indemnify do not preclude an operator from raising a claim under an applicable non-premium war risk insurance policy the FAA issues under chapter 443 of title 49, U.S. Code.

If the FAA approves the proposed operation(s), the FAA will issue an OpSpec or LOA, as applicable, to the operator(s) identified in the original request and any operators the requestor subsequently adds to the approval, authorizing them to conduct the approved operation(s). In addition, as stated in paragraph (3) of this section V.B., the FAA notes that it may include additional conditions beyond those contained in the approval letter in any OpSpec or LOA associated with a particular operator operating under this approval, as necessary in the interests of aviation safety. U.S. Government departments, agencies, and instrumentalities requesting FAA approval on behalf of entities with which they have a contract or subcontract, grant, or cooperative agreement should request a copy of the relevant OpSpec or LOA directly from the entity with which they have any of the foregoing types of arrangements, if desired.

VI. Information Regarding Petitions for Exemption

Any operations not conducted under an approval the FAA issues through the approval process set forth previously may only occur in accordance with an exemption from SFAR No. 119, § 91.1619. A petition for exemption must comply with 14 CFR part 11. The FAA will consider whether exceptional circumstances exist beyond those described in the approval process in the previous section. To determine whether a petition for exemption from the prohibition this SFAR establishes fulfills the standards described in 14 CFR 11.81, the FAA consistently finds necessary the following information:

- The proposed operation(s), including the nature of the operation;
- The service the person(s) covered by the SFAR will provide;
- The specific locations in the Kabul FIR (OAKX) where the proposed operation(s) will occur, including, but not limited to, the flight path and altitude of the aircraft while it is operating in the Kabul FIR (OAKX) and the airports, airfields, or landing zones at which the aircraft will take off and land;
- The method by which the operator will obtain current threat information and an explanation of how the operator will integrate this information into all phases of its proposed operations (*i.e.,* the pre-mission planning and briefing, in-flight, and post-flight phases); and
- The plans and procedures the operator will use to minimize the risks identified in this preamble to the proposed operations, to support the relief sought, and demonstrate that granting such relief would not adversely affect safety or would provide a level of safety at least equal to that provided by this SFAR. The FAA has found comprehensive, organized plans and procedures of this nature to be helpful in facilitating the agency's safety evaluation of petitions for exemption from flight prohibition SFARs.

The FAA includes, as a condition of each such exemption it issues, a release and agreement to indemnify, as described previously.

The FAA recognizes that, with the support of the U.S. Government, the governments of other countries could plan operations that may be affected by SFAR No. 119, § 91.1619. While the FAA will not permit these operations through the approval process, the FAA will consider exemption requests for such operations on an expedited basis and in accordance with the order of preference set forth in paragraph (c) of SFAR No. 119, § 91.1619.

If a petition for exemption includes information that is sensitive for security reasons or proprietary information, requestors may contact the Washington Operations Center for instructions on submitting it to the FAA. The Washington Operations Center's contact information is listed in the **FOR FURTHER INFORMATION CONTACT** section of this final rule. Requestors must not submit their petitions for exemption or related supporting documentation to the Washington Operations Center. Rather, the Washington Operations Center will refer the requestor to the appropriate staff member of the Air Transportation Division, Flight Standards Service, or the Office of Rulemaking for further assistance.

VII. Severability

Congress authorized the FAA by statute to promote safe flight of civil aircraft in air commerce by prescribing, among other things, regulations and minimum standards for practices, methods, and procedures the Administrator finds necessary for safety in air commerce and national security. 49 U.S.C. 44701. Consistent with that mandate, the FAA is prohibiting certain persons from conducting flight operations in the Kabul FIR (OAKX) below certain altitudes due to the continuing hazards to the safety of U.S. civil flight operations at those altitudes. The purpose of this rule is to operate holistically in addressing a range of hazards and needs in the Kabul FIR (OAKX). However, the FAA recognizes that certain provisions focus on unique factors. Therefore, the FAA finds that the various provisions of this final rule are severable and able to operate functionally if severed from each other. In the event a court were to invalidate one or more of this final rule's unique provisions, the remaining provisions should stand, thus allowing the FAA to continue to fulfill its Congressionally authorized role of promoting safe flight of civil aircraft in air commerce.

VIII. Regulatory Notices and Analyses

Federal agencies consider impacts of regulatory actions under a variety of Executive orders and other requirements. First, Executive Orders 12866 and 13563, as amended by Executive Order 14094 (''Modernizing Regulatory Review''), direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), as codified in 5 U.S.C. 603 *et seq.,* requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act of 1979 (Pub. L. 96–39), as codified in 19 U.S.C. chapter 13, prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Agreements Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as codified in 2 U.S.C. chapter 25, requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

In conducting these analyses, the FAA has determined this final rule has benefits that justify its costs. This rule is a significant regulatory action, as defined in section 3(f)(4) of Executive Order 12866 as amended by Executive Order 14094. As 5 U.S.C. 553 does not require notice and comment for this final rule, 5 U.S.C. 603 and 604 do not require regulatory flexibility analyses regarding impacts on small entities. This rule will not create unnecessary obstacles to the foreign commerce of the United States. This rule will not impose an unfunded mandate on State, local, or Tribal governments, or on the private sector, by exceeding the threshold identified previously.

A. Regulatory Evaluation

This rule continues to prohibit U.S. civil flights in the Kabul FIR (OAKX) at altitudes below FL320, except for transiting overflights on jet routes P500–G500, due to the significant hazards to U.S. civil aviation described in this preamble. The alternative flight routes result in some additional fuel and operations costs to the affected operators, as well as some costs attributed to passenger time. However, this amendment of the SFAR provides relief to U.S. civil operators and airmen wishing to conduct transiting overflight operations on jet routes P500–G500 at altitudes at and above FL300, instead of requiring them to operate at altitudes at and above FL320, as the SFAR previously did.

For the reasons described in the Background and Discussion of the Final Rule section of this preamble, the FAA has determined that U.S. civil aviation overflights of the Kabul FIR (OAKX) at altitudes at and above FL300 on jet routes P500–G500 present a low risk and that U.S. operators and airmen may conduct such flights. However, as described in more detail in the Background and Discussion of the Final Rule section of this preamble, the FAA has also determined that U.S. civil aviation operations in the remainder of the Kabul FIR (OAKX) at altitudes below FL320 continue to pose unacceptable risks to the safety of U.S. civil aviation due to the risks to such operations posed by violent extremist and militant activity and the lack of adequate risk mitigation capabilities to counter such activity. The rule allows for a lower minimum flight level of FL300 on jet routes P500–G500, providing relief and reducing the cost for overflights transiting P500–G500 while continuing to prohibit unsafe flights in the remainder of the Kabul FIR (OAKX) at altitudes below FL320.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), in 5 U.S.C. 603, requires an agency to prepare an initial regulatory flexibility analysis describing impacts on small entities whenever 5 U.S.C. 553 or any other law requires an agency to publish a general notice of proposed rulemaking for any proposed rule. Similarly, 5 U.S.C. 604 requires an agency to prepare a final regulatory flexibility analysis when an agency issues a final rule under 5 U.S.C. 553 after that section or any other law requires publication of a general notice of proposed rulemaking. The FAA concludes good cause exists to forgo notice and comment and to not delay the effective date for this rule. As 5 U.S.C. 553 does not require notice and comment in this situation, 5 U.S.C. 603 and 604 similarly do not require regulatory flexibility analyses.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39) prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to this Act, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where

appropriate, that they be the basis for U.S. standards.

The FAA has assessed the potential effect of this final rule and determined that its purpose is to protect the safety of U.S. civil aviation from risks to their operations in the Kabul FIR (OAKX), a location outside the U.S. Therefore, the rule complies with the Trade Agreements Act of 1979.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $183 million in lieu of $100 million.

This final rule does not contain such a mandate. Therefore, the requirements of title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires the FAA to consider the impact of paperwork and other information collection burdens it imposes on the public. The FAA has determined no new requirement for information collection is associated with this final rule.

F. International Compatibility and Cooperation

In keeping with U.S. obligations under the Convention on International Civil Aviation, the FAA's policy is to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined no ICAO Standards and Recommended Practices correspond to this regulation. The FAA finds this action is fully consistent with the obligations under 49 U.S.C. 40105(b)(1)(A) to ensure the FAA exercises its duties consistently with the obligations of the United States under international agreements.

While the FAA's flight prohibition does not apply to foreign air carriers, DOT codeshare authorizations prohibit foreign air carriers from carrying a U.S. codeshare partner's code on a flight segment that operates in airspace for which the FAA has issued a flight prohibition for U.S. civil aviation. In addition, foreign air carriers and other foreign operators may choose to avoid, or be advised or directed by their civil aviation authorities to avoid, airspace for which the FAA has issued a flight prohibition for U.S. civil aviation.

G. Environmental Analysis

The FAA has analyzed this action under Executive Order 12114, Environmental Effects Abroad of Major Federal Actions, and DOT Order 5610.1C, Paragraph 16. Executive Order 12114 requires the FAA to be informed of environmental considerations and take those considerations into account when making decisions on major Federal actions that could have environmental impacts anywhere beyond the borders of the United States. The FAA has determined this action is exempt pursuant to section 2–5(a)(i) of Executive Order 12114 because it does not have the potential for a significant effect on the environment outside the United States.

In accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 8–6(c), the FAA has prepared a memorandum for the record stating the reason(s) for this determination and has placed it in the docket for this rulemaking.

IX. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this rule under the principles and criteria of Executive Order 13132. The agency has determined this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, this rule will not have federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this rule under Executive Order 13211. The agency has determined it is not a ''significant energy action'' under the Executive order and will not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

C. Executive Order 13609, Promoting International Regulatory Cooperation

Executive Order 13609 promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609 and has determined that this action will have no effect on international regulatory cooperation.

X. Additional Information

A. Electronic Access

Except for classified and controlled unclassified material not authorized for public release, all documents the FAA considered in developing this rule, including economic analyses and technical reports, may be accessed from the internet through the docket for this rulemaking.

Those documents may be viewed online at *https://www.regulations.gov* using the docket number listed above. A copy of this rule will be placed in the docket. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *https://www.federalregister.gov* and the Government Publishing Office's website at *https://www.govinfo.gov.* A copy may also be found at the FAA's Regulations and Policies website at *https://www.faa.gov/regulations_policies.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677.

B. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121) (set forth as a note to 5 U.S.C. 601) requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official or the persons listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit *https://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 91

Afghanistan, Air traffic control, Aircraft, Airmen, Airports, Aviation safety, Freight.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations, as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, 47534, Pub. L. 114–190, 130 Stat. 615 (49 U.S.C. 44703 note); articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180), (126 Stat. 11).

■ 2. Amend § 91.1619 by revising paragraph (c) to read as follows:

§ 91.1619 Special Federal Aviation Regulation No. 119—Prohibition Against Certain Flights in the Kabul Flight Information Region (FIR) (OAKX).

* * * * *

(c) *Permitted operations.* This section does not prohibit persons described in paragraph (a) of this section from conducting flight operations in the Kabul Flight Information Region (FIR) (OAKX) under the following circumstances:

(1) *Permitted operations that do not require an approval or exemption from the FAA.* (i) Overflights of the Kabul Flight Information Region (FIR) (OAKX) may be conducted at altitudes at and above Flight Level (FL) 320, subject to the approval of, and in accordance with the conditions established by, the appropriate authorities of Afghanistan.

(ii) Transiting overflights of the Kabul Flight Information Region (FIR) (OAKX) may be conducted on jet routes P500–G500 at altitudes at and above FL300, subject to the approval of, and in accordance with the conditions established by, the appropriate authorities of Afghanistan.

(2) *Operations permitted under an approval or exemption issued by the FAA.* Flight operations may be conducted in the Kabul Flight Information Region (FIR) (OAKX) at altitudes below FL320, provided that such flight operations occur under a contract, grant, or cooperative agreement with a department, agency, or instrumentality of the U.S. Government (or under a subcontract between the prime contractor of the U.S. Government department, agency, or instrumentality and the person described in paragraph (a) of this section) with the approval of the FAA or under an exemption issued by the FAA. The FAA will consider requests for approval or exemption in a timely manner, with the order of preference being: first, for those operations in support of U.S. Government-sponsored activities; second, for those operations in support of government-sponsored activities of a foreign country with the support of a U.S. Government department, agency, or instrumentality; and third, for all other operations.

* * * * *

Issued in Washington, DC, under the authority of 49 U.S.C. 106(f) and (g), 40101(d)(1), 40105(b)(1)(A), and 44701(a)(5).

Michael Gordon Whitaker,

Administrator.

[FR Doc. 2024–14708 Filed 7–3–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 40 and 47

[TD 10003]

RIN 1545–BQ93

Excise Tax on Designated Drugs; Procedural Requirements

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final rule.

SUMMARY: This document contains final regulations relating to the excise tax imposed on certain sales by manufacturers, producers, or importers of designated drugs. Specifically, the final regulations set forth procedural provisions relating to how taxpayers must report liability for such tax. The final regulations also except such tax from semimonthly deposit requirements. The final regulations affect manufacturers, producers, or importers of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare during certain statutory periods.

DATES:

Effective date: These regulations are effective on August 5, 2024.

Applicability dates: For dates of applicability, see §§ 40.0–1(e), 40.6011(a)–1(e), 40.6302(c)–1(f), and 47.5000D–1(b).

FOR FURTHER INFORMATION CONTACT: Jacob W. Peeples or James S. Williford at (202) 317–6855 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document amends the Excise Tax Procedural Regulations (26 CFR part 40) and adds new part 47 to 26 CFR chapter I to contain the ''Designated Drugs Excise Tax Regulations'' related to the excise tax imposed by section 5000D of the Internal Revenue Code (Code) on certain sales by manufacturers, producers, or importers of designated drugs (section 5000D tax).

Sections 1191 through 1198 of the Social Security Act (SSA), added by sections 11001 and 11002 of Public Law 117–169, 136 Stat. 1818 (August 16, 2022), commonly referred to as the Inflation Reduction Act of 2022 (IRA), require the Secretary of Health and Human Services to establish a Medicare prescription drug price negotiation program (Medicare Drug Price Negotiation Program) to negotiate maximum fair prices for certain high expenditure, single-source drugs covered under Medicare.

Section 5000D, added to new chapter 50A of the Code by section 11003 of the IRA, imposes an excise tax on certain sales by manufacturers, producers, or importers of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare during a day that falls within a period described in section 5000D(b). The periods described in section 5000D(b) relate to certain statutorily prescribed milestones in the Medicare Drug Price Negotiation Program. Because chapter 50A is a new chapter of the Code, the existing regulations that prescribe procedural rules applicable to most Federal excise taxes do not apply to chapter 50A.

Notice 2023–52 (2023–35 I.R.B. 650; August 28, 2023) announced that the Department of the Treasury (Treasury Department) and the IRS intended to propose regulations addressing substantive and procedural issues related to the section 5000D tax.

On October 2, 2023, a notice of proposed rulemaking (REG–115559–23) was published in the **Federal Register** (88 FR 67690) (proposed regulations). No public hearing was requested or held. The Treasury Department and the IRS received several comments in response to the proposed regulations. The comments addressing the proposed regulations are summarized in the Summary of Comments and Explanation of Revisions section of this preamble.

Summary of Comments and Explanation of Revisions

I. Overview

As noted in the Background section of this preamble, the Treasury Department and the IRS received several public comment submissions in response to the proposed regulations. The public comments fall into six general categories: timing of the publication of the proposed regulations; the quarterly filing requirement in the proposed regulations; the proposed regulations'

retroactive applicability dates; the constitutionality of the section 5000D tax; technical issues and questions relating to the implementation of the section 5000D tax itself; and comments on the Special Analyses provided in the proposed regulations. Each of these categories of comments is addressed in turn in parts II through VII of this Summary of Comments and Explanation of Revisions.

All public comments were considered and are available at *https://www.regulations.gov* or upon request. After full consideration of the public comments received in response to the proposed regulations, this Treasury decision adopts the proposed regulations with three non-substantive modifications. Specifically, the final regulations modify proposed §§ 40.0–1, 40.6011–1(d), and 40.6302(c)–1 by clarifying that the section 5000D tax is imposed on ''the sale of'' designated drugs. The language, as modified, more closely tracks the language of section 5000D(a).

II. Timing of the Publication of the Proposed Regulations

A commenter stated that the Treasury Department and the IRS acted prematurely when publishing proposed regulations related to procedural rules prior to publishing substantive rules for the section 5000D tax and requested that the Treasury Department and the IRS withdraw the proposed regulations until substantive rules are published.

The section 5000D tax is a self-executing tax—that is, the section 5000D tax is effective and applicable regardless of whether implementing regulations are published by the Treasury Department and the IRS. *See Sundance Helicopters, Inc.* v. *United States,* 104 Fed. Cl. 1, 11 (2012) (in determining whether the issuance of regulations is a precondition to the application of a statute, the court followed Tax Court precedent in *Estate of Neumann* v. *Comm'r,* 106 T.C. 216 (1996) (setting out the rule that ''a tax statute is self-executing if the regulation referred to in the statute deals only with how, not whether, the tax is to be applied.'')). Further, under section 5000D(b)(1), the first date that a manufacturer, producer, or importer could be liable for the section 5000D tax is October 2, 2023. As a result, publication of the proposed regulations was not premature because liability can arise under section 5000D in the absence of substantive regulatory guidance, and taxpayers needed this procedural guidance on how to meet their tax reporting and payment obligations for section 5000D tax liability incurred on and after October 2, 2023. Accordingly, the Treasury Department and the IRS are finalizing the proposed regulations without adopting this comment.

III. Quarterly Filing Requirement

A commenter expressed concern regarding the proposed regulations' quarterly filing and payment requirement. Specifically, the commenter stated that—in the absence of substantive guidance such as clarification of what sales are subject to the section 5000D tax—it is ''impossible'' for the IRS to determine that a ''quarterly cadence'' for filing returns and paying the section 5000D tax is rational. Further, the commenter stated that the quarterly filing requirement will be overly burdensome on taxpayers.

Generally, § 40.6011(a)–1(a)(2)(i) requires that taxpayers subject to Federal excise tax must file a Form 720, *Quarterly Federal Excise Tax Return,* beginning with the first calendar quarter during which their Federal excise tax liability arises. Once the first Form 720 is filed, a taxpayer is generally required to continue filing Forms 720 for every calendar quarter thereafter—regardless of whether additional Federal excise tax liabilities are incurred during a particular subsequent calendar quarter—until the taxpayer permanently ceases all operations with respect to which the Federal excise tax liability was incurred. *See* §§ 40.6011(a)–1(a)(2)(i) and 40.6011(a)–2(a)(1). Failure to file subsequent quarterly returns after filing the first Form 720 may result in the assessment of penalties under section 6651(a) of the Code.

In developing the proposed regulations, the Treasury Department and the IRS recognized that in the context of the section 5000D tax (under which a taxpayer may incur liability in a particular calendar quarter and then never incur liability again in subsequent calendar quarters), to require a taxpayer to continue to file Form 720 for every calendar quarter following the filing of its first Form 720 even if no tax liability is incurred in subsequent calendar quarters would be both unnecessary for tax administration and unduly burdensome on the taxpayer. As a result, the proposed regulations exempted taxpayers that incur a section 5000D tax liability (section 5000D taxpayers) and report that tax liability on a timely filed Form 720 from the general requirement to file subsequent Forms 720 if no section 5000D tax liability is incurred during a subsequent calendar quarter. Specifically, proposed § 40.6011(a)–1(d) required a taxpayer to file a subsequent Form 720 only if a new section 5000D tax liability arises during a particular calendar quarter.

Regarding the requirement to pay a section 5000D tax liability quarterly with the taxpayer's Form 720, generally, §§ 40.6071(a)–1(a) and 40.6151(a)–1 require that Form 720 filers must pay the tax shown on the return at the same time the return is filed. Providing a different rule for section 5000D taxpayers would introduce unnecessary complexity into the excise tax filing and payment regime. An increase in complexity could lead to taxpayer confusion and likely result in a greater burden on both taxpayers and the IRS with little to no benefit accruing to stakeholders. The Treasury Department and the IRS also note that proposed § 40.6302(c)–1 exempted the section 5000D tax from the semimonthly deposit requirements that apply to most other Federal excise taxpayers. By finalizing this proposed rule without this modification to the requirement to pay with the quarterly filing, the compliance burden on section 5000D taxpayers will be further reduced.

For these reasons, as well as for reasons similar to those discussed in part II of this Summary of Comments and Explanation of Revisions (related to the necessity to timely provide section 5000D taxpayers with procedural guidance on how to meet their tax reporting and payment obligations), the Treasury Department and the IRS are finalizing the proposed regulations without adopting this comment.

IV. Applicability Dates

The proposed regulations provided that the Treasury decision finalizing the proposed regulations will apply to calendar quarters beginning on or after October 1, 2023; in other words, the proposed regulations provided that this Treasury decision will not apply beginning on the date that it is published in the **Federal Register**, but rather it will retroactively apply as of the first day of the fourth calendar quarter of 2023. A commenter requested that the Treasury Department and the IRS reconsider the retroactive applicability dates provided in the proposed regulations because the section 5000D tax is new.

As discussed in part II of this Summary of Comments and Explanation of Revisions, the Treasury Department and the IRS prioritized providing section 5000D taxpayers with procedural guidance on how to meet their tax reporting and payment obligations by October 2, 2023, the first date when a taxpayer could incur a section 5000D tax liability. Because the

first date when a taxpayer could incur liability for the section 5000D tax is October 2, 2023, which falls within the fourth calendar quarter of 2023, it is appropriate for the final regulations that provide rules relating to filing and payment of the section 5000D tax to relate back to the beginning of the fourth calendar quarter of 2023 (that is, October 1, 2023), which in accordance with section 7805(b)(1)(B), would be the first taxable period ending after October 2, 2023 (that is, the date the proposed regulations were published in the **Federal Register**). As a result, the Treasury Department and IRS are finalizing the proposed applicability dates without adopting this comment.

V. Constitutionality

Some commenters stated that the Medicare Drug Price Negotiation Program generally, and the section 5000D tax specifically, may be unconstitutional. These comments are outside the scope of the proposed regulations, which set forth proposed rules for administering a duly enacted tax law. Therefore, it is not appropriate for the Treasury Department and the IRS to address these comments in the context of this rulemaking.

VI. Technical Comments

A commenter requested that the Treasury Department and the IRS consider providing sales-reporting and calculation ''safe harbors'' in these final regulations. Another commenter stated their belief that Notice 2023–52 requested clarification on how the Treasury Department and the IRS should define ''sales'' for purposes of the section 5000D tax. These comments are outside the scope of the proposed regulations, which related only to the procedures for reporting and paying the section 5000D tax.

VII. Comments on the Special Analyses

A. Paperwork Reduction Act

A commenter requested that the Treasury Department and the IRS reconsider the paperwork burden estimate in the Paperwork Reduction Act (44 U.S.C. 3507(d)) (PRA) section of the proposed regulations because the commenter believes that the number of estimated hours is too low. In this request, the commenter suggested that it is possible that no taxpayers will ever incur a section 5000D tax liability. The commenter accepted that the Treasury Department and the IRS do not have historical data on the number of compliance hours affected taxpayers may experience if a section 5000D tax liability is incurred and did not offer a specific estimated number of hours it views as more accurate than the estimate provided in the proposed regulations. Similarly, the commenter did not offer an alternative calculation methodology that the Treasury Department and the IRS could use to provide a better burden estimate.

The Treasury Department and the IRS calculated the estimated number of paperwork burden hours using the long-standing and established methodology outlined in Publication 5743, *Taxpayer Compliance Burden,* to arrive at the estimated total annual reporting burden of 1,380 hours stated in the proposed regulations. For these reasons, the Treasury Department and the IRS estimate that this Treasury decision will impose a total annual reporting burden of 1,380 hours, as discussed in part II of the Special Analyses section of this preamble. However, the Treasury Department and the IRS will regularly examine and, as necessary, update the estimated total annual reporting burden of this Treasury decision as required by the PRA.

B. Regulatory Flexibility Act

A commenter requested that the Treasury Department and the IRS conduct a Regulatory Flexibility Act (5 U.S.C. chapter 6) (RFA) analysis because the commenter is concerned that this Treasury decision may have an indirect effect on small entities. An agency may properly certify that no RFA analysis is needed when it determines that a rule will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the proposed rule. See *Mid-Tex Elec. Co-op., Inc.* v. *FERC,* 773 F.2d 327, 342 (D.C. Cir. 1985) (holding that Congress did not intend to require consideration of every indirect effect that any regulation might have on small businesses). Accordingly, as discussed in part III of the Special Analyses section of this preamble, the Treasury Department and the IRS continue to certify that this Treasury decision will not create additional obligations for, or impose a significant economic impact on, small entities, and as a result, a regulatory flexibility analysis under the RFA is not required.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

II. Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the PRA under control number 1545–0023.

The collections of information in these regulations relate to reporting and recordkeeping requirements that will allow taxpayers to meet their tax reporting obligations. The collections of information would generally be used by the IRS for tax compliance purposes and by taxpayers to facilitate proper tax reporting and compliance. The reporting and recordkeeping requirements are covered within the form and instructions for Form 720.

Because the section 5000D tax is a new tax that has never been reported to the IRS, the Treasury Department and the IRS do not have historical data on the number of affected taxpayers. The Centers for Medicare and Medicaid Services (CMS) has selected 10 drugs for price negotiation for initial price applicability year 2026. CMS will select for negotiation a limited number of drugs for each initial price applicability year after that, as outlined in the IRA. Further, manufacturers, producers, or importers of such drugs may or may not become subject to a section 5000D tax liability. Based on the foregoing, the IRS estimates that there will be between 0 and 50 taxpayers during the next 3 years.

If a taxpayer has a section 5000D tax liability, it would be required to file Form 720 to report such liability. Form 720 is a quarterly return. A taxpayer would only be required to file Form 720 during calendar quarters in which the taxpayer has a section 5000D tax liability. Therefore, a taxpayer that has a section 5000D tax liability in one calendar quarter but not in subsequent calendar quarters would only be required to file one Form 720.

The respondents with regard to the section 5000D tax are manufacturers, producers, or importers of certain drugs. The Treasury Department and the IRS estimate the annual burden of the collections of information as follows (these estimates, which are for PRA purposes only, are based on the high end of the range of possible taxpayers and the high end of the range of the frequency of responses, in which a taxpayer would have tax liability in all four calendar quarters):

Estimated frequency of responses: Quarterly.

Estimated number of responses: 50.

Estimated burden time per respondent: 6.9 hours.

Estimated total annual reporting burden: 1,380 hours.

A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by section 6103.

The Treasury Department and the IRS received a comment suggesting that the paperwork burden estimate provided in the proposed regulations was too low. However, for the reasons discussed in detail in the Summary of Comments and Explanation of Revisions section of this preamble and in this Special Analyses section, the Treasury Department and the IRS have not changed the estimates provided herein.

III. Regulatory Flexibility Act

For the reasons discussed in detail in the Summary of Comments and Explanation of Revisions section of this preamble and in this Special Analyses section, pursuant to the RFA, it is hereby certified that these final regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the section 5000D tax is imposed only on certain sales by manufacturers, producers, or importers of designated drugs during periods described in section 5000D(b). The periods described in section 5000D(b) relate to milestones in the Medicare Drug Price Negotiation Program, which involve only certain drugs with high Medicare expenditures. Drugs with high Medicare expenditures that are not already excluded from the Medicare Drug Price Negotiation Program under an exception such as the SSA's small biotech exception (sections 1192(b) and (d)(2) of the SSA) are likely to be manufactured, produced, or imported by large entities, so if any section 5000D tax liability arises, an insubstantial number of taxpayers will be small entities. As noted earlier, data is not available about the number of taxpayers affected, but the number is likely to be limited, in part due to the limited number of drugs selected for the Medicare Drug Price Negotiation Program in any particular year. In addition, these final regulations will assist taxpayers in meeting their tax reporting obligations by providing clarity on how to report section 5000D tax liability, which will make it easier for taxpayers to comply with section 5000D. Therefore, these final regulations will not create additional obligations for, or impose a significant economic impact on, small entities, and a regulatory flexibility analysis under the RFA is not required.

IV. Section 7805(f)

Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these final regulations was submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business. No comments were received from the Chief Counsel for the Office of Advocacy of the Small Business Administration.

V. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. These final regulations do not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector, in excess of that threshold.

VI. Executive Order 13132: Federalism

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

Statement of Availability of IRS Documents

The IRS Notice cited in this preamble is published in the Internal Revenue Bulletin and is available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *https://www.irs.gov.*

Drafting Information

The principal author of these regulations is Jacob W. Peeples of the Office of the Associate Chief Counsel (Passthroughs & Special Industries). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects

26 CFR Part 40

Excise taxes, Reporting and recordkeeping requirements.

26 CFR Part 47

Excise taxes.

Adoption of Amendments to the Regulations

Accordingly, the Treasury Department and the IRS amend 26 CFR chapter I, subchapter D, as follows:

PART 40—EXCISE TAX PROCEDURAL REGULATIONS

■ **Paragraph 1.** The authority citation for part 40 continues to read in part as follows:

Authority: 26 U.S.C. 7805.

* * * * *

■ **Par. 2.** Section 40.0–1 is amended by revising paragraphs (a) and (e) to read as follows:

§ 40.0–1 Introduction.

(a) *In general.* The regulations in this part are designated the *Excise Tax Procedural Regulations.* The regulations in this part set forth administrative provisions relating to the excise taxes imposed by chapters 31 through 34, 36, 38, 39, 49, and 50A of the Internal Revenue Code (Code) (except for the chapter 32 tax imposed by section 4181 (firearms tax) and the chapter 36 taxes imposed by sections 4461 (harbor maintenance tax) and 4481 (heavy vehicle use tax)), and to floor stocks taxes imposed on articles subject to any of these taxes. Chapter 31 relates to retail excise taxes; chapter 32 to manufacturers' excise taxes; chapter 33 to taxes imposed on communications services and air transportation services; chapter 34 to taxes imposed on certain insurance policies; chapter 36 to taxes imposed on transportation by water; chapter 38 to environmental taxes; chapter 39 to taxes imposed on registration-required obligations; chapter 49 to taxes imposed on indoor tanning services; and chapter 50A to taxes imposed on the sale of designated drugs. References in this part to taxes also include references to the fees imposed by sections 4375 and 4376 of the Code. *See* parts 43, 46 through 49,

and 52 of this chapter for regulations related to the imposition of tax.

* * * * *

(e) *Applicability dates*—(1) *Paragraph (a).* Paragraph (a) of this section applies to returns required to be filed under § 40.6011(a)–1 for calendar quarters beginning on or after October 1, 2023. For rules that apply before October 1, 2023, see 26 CFR part 40, revised as of April 1, 2024.

(2) *Paragraphs (b) and (c).* Paragraphs (b) and (c) of this section apply to returns for calendar quarters beginning after March 31, 2013. For rules that apply before March 31, 2013, see 26 CFR part 40, revised as of April 1, 2012.

(3) *Paragraph (d).* Paragraph (d) of this section applies to returns for calendar quarters beginning on or after January 19, 2021. For rules that apply before January 19, 2021, see 26 CFR part 40, revised as of April 1, 2020.

■ **Par. 3.** Section 40.6011(a)-1 is amended by:

■ 1. Revising the first sentence of paragraph (a)(2)(i).

■ 2. Adding paragraphs (d) and (e).

The revision and additions read as follows:

§ 40.6011(a)–1 Returns.

(a) * * *

(2) * * *

(i) * * * Except as provided in paragraphs (b) through (d) of this section, the return must be made for a period of one calendar quarter. * * *

* * * * *

(d) *Tax on the sale of designated drugs.* A return that reports liability imposed by section 5000D of the Internal Revenue Code must be made for a period of one calendar quarter. A return must be filed for each calendar quarter in which liability for the tax imposed by section 5000D is incurred. There is no requirement that a return be filed for a calendar quarter in which there is no liability imposed by section 5000D.

(e) *Applicability dates*—(1) *Paragraph (a)(2)(i).* Paragraph (a)(2)(i) of this section applies to returns filed for calendar quarters beginning on or after October 1, 2023. For rules that apply before October 1, 2023, see 26 CFR part 40, revised as of April 1, 2024.

(2) *Paragraph (c). See* paragraph (c)(2) of this section.

(3) *Paragraph (d).* Paragraph (d) of this section applies to returns filed for calendar quarters beginning on and after October 1, 2023.

■ **Par. 4.** Section 40.6302(c)–1 is amended by:

■ 1. Revising paragraphs (e)(1)(iv) and (v).

■ 2. Adding paragraph (e)(1)(vi).

■ 3. Revising paragraph (f).

The revisions and addition read as follows:

§ 40.6302(c)–1 Deposits.

* * * * *

(e) * * *

(1) * * *

(iv) Sections 4375 and 4376 (relating to fees on health insurance policies and self-insured insurance plans);

(v) Section 5000B (relating to indoor tanning services); and

(vi) Section 5000D (relating to the sale of designated drugs).

* * * * *

(f) *Applicability dates*—(1) *Paragraphs (a) through (d).* Paragraphs (a) through (d) of this section apply to deposits and payments made after March 31, 2013. For rules that apply before March 31, 2013, see 26 CFR part 40, revised as of April 1, 2013.

(2) *Paragraph (e).* Paragraph (e) of this section applies to calendar quarters beginning on or after October 1, 2023. For rules that apply before October 1, 2023, *see* 26 CFR part 40, revised as of April 1, 2024.

■ **Par. 5.** Add part 47 to read as follows:

PART 47—DESIGNATED DRUGS EXCISE TAX REGULATIONS

Sec.

Authority: 26 U.S.C. 7805.

Section 47.5000D–1 also issued under 26 U.S.C. 5000D.

§ 47.5000D–0 Table of contents.

This section lists the table of contents for §§ 47.5000D–1 through 47.5000D–4.

§§ 47.5000D–2—47.5000D–4 [Reserved]

§ 47.5000D–1 Introduction.

(a) *In general.* The regulations in this part are designated the *Designated Drugs Excise Tax Regulations.* The regulations in this part relate to the tax imposed by section 5000D of the Internal Revenue Code. See part 40 of this chapter for regulations relating to returns, payments, and other procedural rules applicable to this part.

(b) *Applicability date.* This section applies to returns filed for calendar quarters beginning on or after October 1, 2023.

§§ 47.5000D–2—47.5000D–4 [Reserved]

Douglas W. O'Donnell,

Deputy Commissioner.

Approved: June 24, 2024.

Aviva R. Aron-Dine,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2024–14706 Filed 7–3–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF JUSTICE

28 CFR Part 15

[Docket No. CIV 150; AG Order No. 5968–2024]

RIN 1105–AB37

Process for Determining That an Individual Shall Not Be Deemed an Employee of the Public Health Service

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: This rule sets forth a process by which the Attorney General or a designee may determine that an individual shall not be deemed an employee of the Public Health Service for purposes of medical malpractice coverage under the Public Health Service Act. The process described in this rule applies to individuals who are deemed to be Public Health Service employees, as well as any other individuals deemed to be Public Health Service employees under different statutory provisions to which the procedures set out in the Public Health Service Act have been made applicable.

DATES: This rule is effective on August 5, 2024.

FOR FURTHER INFORMATION CONTACT: James G. Touhey, Jr., Director, Torts Branch, Civil Division, Department of Justice, Washington, DC 20530, (202) 616–4400.

SUPPLEMENTARY INFORMATION: This rule finalizes, with some changes, a proposed rule that the Department of Justice (''Department'') published on this subject on March 6, 2015, at 80 FR 12104. In brief, the following changes were made to the text of the proposed rule:

In § 15.11, a sentence was added to clarify that an individual who is no longer ''deemed'' to be an employee of the Public Health Service pursuant to section 224(i) of the Public Health Service Act, 42 U.S.C. 233(i), is excluded from medical malpractice protections otherwise available to individuals ''deemed'' to be Public Health Service employees under the

statute that conferred the ''deemed'' employee status.

In § 15.12, the definition of ''Attorney General'' for purposes of the rule was deleted as vague and unnecessary in light of the more specifically defined roles and responsibilities of the initiating official, the adjudicating official, and the administrative law judge involved in proceedings under this subpart.

In § 15.13, a change was made to clarify that the initiating official's notice to an individual is intended to comply with the Administrative Procedure Act (''APA''), 5 U.S.C. 551, *et seq.,* by furnishing a statement of the factual allegations and law asserted in support of the proposed action.

In § 15.14, a change was made to clarify that the administrative law judge assigned to conduct a hearing under this subpart must, consistent with the APA, conduct proceedings in an impartial manner. In addition, § 15.14 now incorporates the grounds and procedure for seeking disqualification of an administrative law judge set forth in 5 U.S.C. 556(b).

In §§ 15.16 and 15.20, a change was made to clarify that the administrative law judge, consistent with the APA, must certify the record to the adjudicating official for a final determination.

A change was made to § 15.17 to clarify that the adjudicating official will consult with the Secretary of Health and Human Services (''Secretary'') in making a final determination. A subsection (d) was added to clarify that the Attorney General, consistent with the traditional authority of agency heads, possesses discretion to review any final determination within 30 days of its issuance.

In addition, minor clarifications were made to § 15.19 to make clear that final determinations, whether upholding or rejecting the initiating official's proposed action, will be distributed to the parties in the same way.

Changes were also made to the reinstatement procedures in § 15.20. Petitions for reinstatement must be submitted to the initiating official, who is responsible for forwarding the petition, along with a recommendation on whether the petition makes a prima facie case for reinstatement, to the adjudicating official. The adjudicating official is responsible for determining whether a prima facie case for reinstatement has been made. If the adjudicating official determines that a prima facie case has been made for reinstatement, an administrative law judge is appointed to conduct such proceedings as are deemed necessary to make a formal recommendation to the adjudicating official. This procedure was revised to avoid having the initiating official—who might be viewed as the adverse party in an original proceeding to de-deem an individual—exercise an unfettered gatekeeping role in determining whether that same individual's petition for reinstatement should receive a hearing.

Finally, the Department notes that since the date of publication of the proposed rule on March 6, 2015, the Supreme Court held in *Lucia* v. *SEC,* 138 S. Ct. 2044 (2018), that administrative law judges assigned by the Securities and Exchange Commission to preside over enforcement proceedings are inferior officers of the United States who must, consistent with Article II, sec. 2, cl. 2 of the United States Constitution, be appointed by the President, a court of law, or a department head. Administrative law judges appointed to preside over proceedings under this rule are to be appointed pursuant to 5 U.S.C. 3105, which authorizes each agency to appoint as many administrative law judges as are necessary for proceedings to be conducted in accordance with 5 U.S.C. 556 and 557. Administrative law judges appointed to preside over proceedings under this rule will be appointed in a manner consistent with *Lucia,* that is, appointed by an agency head.

Discussion

The Federally Supported Health Centers Assistance Acts of 1992 (Pub. L. 102–501) (''FSHCAA'') and 1995 (Pub. L. 104–73) amended section 224 of the Public Health Service Act (42 U.S.C. 233) to make the Federal Tort Claims Act (''FTCA'') (28 U.S.C. 1346(b), 2672) the exclusive remedy for medical malpractice claims for personal injury or death brought against qualifying federally supported health centers and certain statutorily identified categories of individuals, to the extent that the centers and these individuals, as the case may be, have been ''deemed'' by the Department of Health and Human Services to be eligible for FTCA coverage and the conditions for such coverage have been satisfied. 42 U.S.C. 233(g).

In 1996, the Health Insurance Portability and Accountability Act (Pub. L. 104–191) amended section 224 of the Public Health Service Act to provide that, subject to certain conditions, a ''free clinic health professional'' providing ''a qualifying health service'' for the free clinic may be ''deemed'' to be a Public Health Service employee eligible for FTCA coverage to the same extent as persons ''deemed'' to be Public Health Service employees under 42 U.S.C. 233(g). In 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) further amended section 224 of the Public Health Service Act to add ''an officer, governing board member, employee, or contractor of a free clinic . . . in providing services for the free clinic'' to the statutorily identified categories of eligible individuals for this purpose. 42 U.S.C. 233(o)(1).

And in 2016, the 21st Century Cures Act (Pub. L. 114–225) amended section 224 of the Public Health Service Act to provide that, subject to certain conditions, a ''health professional volunteer'' at an entity ''deemed'' to be a Public Health Service employee by virtue of 42 U.S.C. 233(g) may be ''deemed'' to be a Public Health Service employee eligible for FTCA coverage to the same extent as persons ''deemed'' to be Public Health Service employees under 42 U.S.C. 233(g). 42 U.S.C. 233(q).

This rule will apply to any individual ''deemed'' to be a Public Health Service employee, regardless of the statutory provision under which the deemed status is obtained, provided that Congress has made the individual's ''deemed'' Public Health Service employee status subject to the procedures set out in 42 U.S.C. 233(i).

Section 233(i) of title 42 provides that the Attorney General, in consultation with the Secretary, may, on the record, determine, after notice and an opportunity for a full and fair hearing, that an individual physician or other licensed or certified health care practitioner who is an officer, employee, or contractor of an entity described in 42 U.S.C. 233(g)(4) shall not be deemed to be an employee of the Public Health Service for purposes of 42 U.S.C. 233 if ''treating such individual as such an employee would expose the Government to an unreasonably high degree of risk of loss'' based on one or more of the following enumerated statutory criteria: (1) the individual does not comply with the policies and procedures that the entity has implemented pursuant to 42 U.S.C. 233(h)(1); (2) the individual has a history of claims filed against him or her as provided for under 42 U.S.C. 233 that is outside the norm for licensed or certified health care practitioners within the same specialty; (3) the individual refused to reasonably cooperate with the Attorney General in defending against any such claim; (4) the individual provided false information relevant to the individual's performance of his or her duties to the Secretary, the Attorney General, or an applicant for or recipient

of funds under chapter 6A of title 42; or (5) the individual was the subject of disciplinary action taken by a State medical licensing authority or a State or national professional society. 42 U.S.C. 233(i)(1).

A final determination by the Attorney General under 42 U.S.C. 233(i) that an individual physician or other licensed or certified health care professional shall not be deemed to be an employee of the Public Health Service is effective when the entity employing such individual receives notice of such determination, and the determination applies only to acts or omissions occurring after the date such notice is received. 42 U.S.C. 233(i)(2).

This rule establishes a process for creating the record and providing the full and fair hearing before the Attorney General makes a final determination under 42 U.S.C. 233(i).

The first step, pursuant to § 15.13(a), is a finding by the ''initiating official,'' in consultation with the Secretary, that treating an individual as an employee of the Public Health Service may expose the Government to an unreasonably high degree of risk of loss for one or more of the statutorily enumerated reasons in 42 U.S.C. 233(i). Under § 15.12(d), the initiating official is a Deputy Assistant Attorney General of the Department of Justice's Civil Division or a designee of a Deputy Assistant Attorney General.

Section 15.13(a) requires the initiating official to provide notice to the individual in question that an administrative hearing will be held to determine whether treating the individual as an employee of the Public Health Service would expose the Government to an unreasonably high degree of risk of loss based upon one or more of the statutory criteria enumerated in 42 U.S.C. 233(i). Following a period for discovery and depositions, to the extent determined appropriate by an administrative law judge under § 15.15, the hearing is then conducted by the administrative law judge in the manner prescribed in § 15.14. After the hearing is conducted and the record is closed, § 15.16 requires the administrative law judge to certify the record and submit written findings of fact, conclusions of law, and a recommended decision to the ''adjudicating official,'' who is the Assistant Attorney General for the Department of Justice's Civil Division or a designee of the Assistant Attorney General. Section 15.16 provides that copies of the findings of fact, conclusions of law, and recommended decision are made available to the parties and to the Secretary. Section 15.17(b) then gives the parties 30 days to submit certain additional materials, including exceptions to the administrative law judge's recommended decision, to the adjudicating official, who then must, in consultation with the Secretary, make a final determination whether treating the individual as an employee of the Public Health Service for purposes of 42 U.S.C. 233 would expose the Government to an unreasonably high degree of risk of loss based on one or more of the criteria specified in 42 U.S.C. 233(i). The Attorney General may exercise discretion to review any final determination within 30 days of its issuance.

Section 15.18 provides that an individual who is dissatisfied with the final determination may seek rehearing within 30 days after notice of the determination is sent, and § 15.20 allows individuals who have been determined to expose the United States to an unreasonably high degree of risk of loss to apply for reinstatement after a period of time. Consistent with 42 U.S.C. 1320a-7e(a) and 45 CFR 60.3, 60.5(h) and 60.16, the rule also provides that the Department will notify the National Practitioner Data Bank (''NPDB'') of the issuance of the Attorney General's final determination that an individual provider shall not be deemed to be an employee of the Public Health Service under this rule. The NPDB, which is maintained by the Health Resources and Services Administration within the Department of Health and Human Services, is a confidential information clearinghouse created by Congress with primary goals of improving health care quality and protecting the public.

Discussion of Comments

The Department received ten public comments on the proposed rule during the comment period, which closed on May 6, 2015. Several commenters generally supported the proposed rule as providing adequate notice and process to reach fair decisions on whether to de-deem individual practitioners who pose an unreasonably high degree of risk of loss to the Government. The Department is grateful for the feedback.

Several comments were received from membership organizations of federally supported health centers that receive Federal grant money under 42 U.S.C. 254b, as well as one federally supported health center that offered comments on its own behalf. These comments generally sought additional guidance on how the rules and criteria set forth in 42 U.S.C. 233(i)(1) would be applied. A few other commenters expressed more general concerns about the consequences of de-deeming determinations. Summaries of these comments and the Department's responses to them are set forth below.

1. Some commenters requested that the Department provide additional guidance on how the statutory criteria for determining whether treating an individual physician or certified health care provider as a Public Health Service employee exposes the Government to an ''unreasonably high degree of risk of loss'' will be applied. These commenters requested that clearer definitions be adopted and that specific examples be provided for how each of the criteria set forth in 42 U.S.C. 233(i)(A)–(E) will be weighed and considered.

Response: The Department does not adopt the changes suggested in these comments. The purpose of these regulations is procedural: to establish the process and procedures used to create a record and provide an individual medical provider the opportunity for the ''full and fair hearing'' required by section 233(i)(1) before the Attorney General makes a ''final determination'' that an individual ''shall not be deemed to be'' an employee of the Public Health Service for purposes of 42 U.S.C. 233. The Department is not undertaking, at this time, a regulatory effort to interpret or re-interpret the statutory criteria that Congress established more than 20 years ago to govern such determinations.

Section 233(i) requires a full and fair hearing to determine whether any one of these factors or combination of factors supports a determination that treating an individual physician or certified health care provider as a Public Health Service employee poses an ''unreasonably high degree of risk of loss'' to the Government.

The commenters recognized that ''strict definitions'' for these criteria would be impracticable. The Department agrees with the commenters. In addition to the impracticality of adopting strict definitions, the Department also observes that the application of the criteria set forth in the statute will necessarily depend on the specific facts and circumstances of each individual case.

2. Some commenters requested that the Department expand the scope of the regulations to specify the form and substance of the consultation that the Attorney General undertakes with the Secretary before finding that an individual should be provided notice of a hearing to determine whether treating

that individual as an employee of the Public Health Service poses an unreasonable risk of loss to the Government.

Response: The Department does not adopt the change suggested in these comments. The statute does not require that the Department's regulations specify the form and substance of the Attorney General's consultation with the Secretary. Moreover, a requirement for public disclosure of such consultations would not be warranted given the predecisional, deliberative nature of the consultation process between agencies.

3. Some commenters requested that the Department, when notifying an individual that a proceeding has been initiated under 42 U.S.C. 233(i), be required to provide both the specific information upon which the Department will rely and the standards that will apply for evaluating the criteria set forth in 42 U.S.C. 233(i). The commenters suggested that providing such information in the hearing notice would reduce discovery costs and increase efficiency of the hearing process.

Response: In response to these comments, the Department has added language in § 15.13(c) to clarify that the notice provided to individuals will set forth the factual allegations supporting the initiating official's proposed action, consistent with the requirements for notice under 5 U.S.C. 554(b). Thus, in addition to providing a statement of the nature and purpose of the hearing, the name of the administrative law judge who will preside, a statement of the nature of the action proposed to be taken, and a statement of the time, date, and location of the hearing for the individual to be heard, the notice will also provide a statement of the facts and, where appropriate, the law asserted in support of the proposed action. 28 CFR 15.13(c). The administrative law judge is vested with all powers necessary to reduce discovery costs and increase the efficiency of the process through exchanges of information and narrowing of issues. 28 CFR 15.14–.15. As for the further comment requesting additional information about the standards that will apply for evaluating the criteria set forth in 42 U.S.C. 233(i), the Department does not adopt the change requested in this comment for the reasons already expressed above.

4. One commenter requested that the Department state the period of time after which a de-deemed practitioner may apply for reinstatement.

Response: The final rule provides that a de-deemed practitioner may apply for reinstatement not sooner than five years after the time for seeking rehearing of the initial determination to de-deem a practitioner has expired. 28 CFR 15.20(a).

5. One commenter requested that the Department clarify the events and informational exchanges that will or could set into the motion the de-deeming process.

Response: The statute and final rule provide this information. When the Department's initiating official, in consultation with the Secretary, finds, based upon a review of available information, that treating an individual as an employee of the Public Health Service may expose the Government to an unreasonably high degree of risk of loss based on one or more of the criteria enumerated in 42 U.S.C. 233(i), the de-deeming process is initiated by issuing a notice for an administrative hearing to determine whether that individual should be de-deemed. 42 U.S.C. 233(i)(1); 28 CFR 15.13. The notice will set forth the facts, and where applicable, the law upon which the proposed action is based.

6. A few commenters expressed concern that the de-deeming process could be initiated to rescind FTCA coverage while a lawsuit was pending and requested that the rule allow only for prospective de-deeming. Another commenter suggested adoption of a ''safety period''—a designated period of time during which a ''deemed'' employee cannot be subject to ''de-deeming''—that would apply where litigation is anticipated involving acts or omissions of a practitioner who has been deemed to be an employee of the Public Health Service.

Response: The Department agrees that de-deeming should be prospective only (as the statute requires) but does not adopt the ''safety period'' suggestion. The statute provides that the Attorney General's decision to de-deem an individual shall apply only to acts or omissions occurring after the date that notice of the Attorney General's final determination that an individual not be deemed to be a Public Health Service employee is received. 42 U.S.C. 233(i)(2). The final regulations therefore provide in § 15.19(c) that a final agency determination that an individual provider shall not be deemed to be an employee of the Public Health Service shall apply to all acts or omissions of the individual occurring after the date the adverse final determination is received by the relevant entity or free clinic. The final regulations similarly provide in § 15.20(f) that a determination that an individual is reinstated pursuant to this section . . . shall apply only to acts or omissions of the individual occurring after the date of the final reinstatement determination. There is no need to adopt the suggested ''safety period.'' If a lawsuit is pending, or even anticipated, then the acts or omissions giving rise to that pending or anticipated suit will already have occurred. The Attorney General's ''de-deeming'' determination does not apply to acts or omissions that occurred before the de-deeming determination becomes final, and reinstatement determinations similarly apply only to acts or omissions that occur after reinstatement.

7. One commenter expressed concern that the proposed rule might have untoward consequences, such as difficulty in securing quality replacement personnel or loss of liability coverage while a lawsuit is pending.

Response: The Department does not adopt further changes in response to these comments. There should be no loss of liability coverage while a lawsuit is pending, as the Attorney General's final determination that a practitioner is de-deemed is effective only as to acts or omissions that occur after such a determination is received by the entity employing that practitioner. 42 U.S.C. 233(i)(2). Moreover, a final de-deeming determination is applicable only to the individual who was subject to the hearing and final determination.

The Attorney General's de-deeming determination does not require or compel a health center to terminate a practitioner. Entities may choose to employ ''de-deemed'' practitioners, but they can no longer rely on the protections of 42 U.S.C. 233(g) or similar statutes, as the case may be, as a substitute for medical malpractice liability coverage for that practitioner if that practitioner is subject to a medical malpractice claim for acts or omissions occurring after receipt of a final de-deeming determination, for so long as the final determination remains effective. Congress's decision to authorize the Attorney General to de-deem individual practitioners reflects a policy judgment that, if an individual practitioner exposes the Government to an unreasonably high degree of risk of loss based on any of the statutory criteria enumerated in 42 U.S.C. 233(i), insuring against that risk or finding a suitable replacement should fall upon the entity responsible for hiring and retaining the practitioners or the sponsoring free clinic, not the United States. Qualifying health centers that receive Federal grants pursuant to 42 U.S.C. 254b may purchase ''tail,'' ''gap,'' or ''wrap-around'' insurance to cover claims for which liability protections under 42 U.S.C. 233(g) or similar

statutes, as the case may be, are inapplicable.

8. One commenter expressed concern that final determinations are vested in the Attorney General or the Attorney General's designee and suggested that the recommendations of the presiding administrative law judge be binding or that three-judge panels be established for purposes of making final determinations.

Response: The Department does not adopt the changes requested in this comment. Under 42 U.S.C. 233(i), the ''final determination'' on whether to de-deem an individual ''under this subsection'' is vested in the ''Attorney General.'' The Department is not free to re-write the statute. Moreover, because section 233(i) provides that the Attorney General's final determination shall be made ''on the record'' ''after notice and an opportunity for a full and fair hearing,'' the provisions of sections 554, 556, and 557 of the APA are applicable to these hearings. *See* 5 U.S.C. 554(a), (c)(2) (section 554 applies ''in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing''; such hearings and decisions on contested issues are to be conducted ''in accordance with sections 556 and 557''). This rule provides for a hearing and recommended decision by an administrative law judge and a final determination by the agency, consistent with the foregoing provisions of the APA. Any review of the Attorney General's ''final determination'' is governed by the APA, so further review of that final determination by an Article III court is possible. The Department also declines to render the presiding administrative law judge's decision binding. Providing for a recommended decision that is further reviewed by the adjudicating official, with discretionary review by the Attorney General, adds further layers of review and therefore reduces the risk of an erroneous determination.

Regulatory Flexibility Act

The Attorney General, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), has reviewed this final rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities because it pertains to personnel and administrative matters affecting the Department. This rule merely sets forth the process for a hearing used to determine whether certain individual health care providers should no longer be ''deemed'' to be ''employees of the Public Health Service,'' thus excluding such individual health care providers from eligibility for the medical malpractice liability protections under 42 U.S.C. 233(g), (o), or (q). The rule does not adopt substantive standards and therefore will not have a significant impact on regulated parties.

Executive Orders 12866, 13563, and 14094: Regulatory Planning and Review

This final rule has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review,'' Executive Order 13563, ''Improving Regulation and Regulatory Review,'' and Executive Order 14094, ''Modernizing Regulatory Review.'' The Office of Management and Budget has determined that this final rule is a ''significant regulatory action'' under Executive Order 12866, section 3(f), and accordingly this final rule has been reviewed by the Office of Management and Budget. 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, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The Department has assessed the costs and benefits of this final rule and believes that its benefits justify its costs.

As an initial matter, this final rule only establishes a process for removing a statutorily conferred deemed status applicable to an individual provider who is determined to expose the Government to an unreasonably high degree of risk of loss for one or more statutorily enumerated reasons. As further explained below, Congress expressly granted the Attorney General the authority to de-deem certain individual physicians or other licensed or certified health care practitioners, provided that certain procedural safeguards were in place. This rule establishes those safeguards. The process will impose some costs on both the government and the individuals who are subject to proceedings under 42 U.S.C. 233(i). But the net benefit is to reduce the potential for incorrect de-deeming decisions, to ensure that a de-deeming decision is based upon a developed record, and to provide the individual provider an opportunity to participate in the process. On balance, the Department believes these benefits outweigh the costs and will contribute to just decisions.

Congress expressly provided the Attorney General with the authority to exclude individuals who expose the Government to an unreasonably high degree of risk of loss based upon one or more statutory criteria from the malpractice protections afforded under 42 U.S.C. 233(g) and similar statutes. A statutory provision granting the Attorney General authority to exclude an individual provider has existed since the FSHCAA was first enacted in 1992. This provision was specifically designed to ''assure that FTCA coverage is not extended to individual practitioners that do not provide care of acceptable quality'' when the Attorney General determines that such individuals ''expose the U.S. to an unreasonably high degree of risk of loss.'' H.R. Rep. No. 102–823, pt. 2, at 8 (1992).

When the FSHCAA was amended and extended in 1995, Congress continued to include the provision authorizing the Attorney General to exclude an individual provider, adding language to clarify that an individual provider's ''coverage'' under the FSHCAA would be removed only after receiving notice and an opportunity for a full and fair hearing, with all decisions to be made ''on the record.'' H.R. Rep. No. 104–398, at 13 (1995); Public Law 104–73, sec. 9, 109 Stat. 777, 781 (1995).

In light of the foregoing, this final rule assures the procedural protections Congress intended, without altering Congress's objective that certain individual providers be subject to exclusion from the malpractice liability protections under 42 U.S.C. 233 if they expose the Government to an unreasonably high degree of risk of loss based on the enumerated statutory criteria. Congress already has established that the benefits of excluding certain providers outweigh the costs if procedural protections are afforded and the final decision is supported by one or more of the criteria specified in 42 U.S.C. 233(i).

The Department does not expect that the process created by the final rule will have systemic or large-scale costs because it is only the rare individual provider who would be subject to the procedures under this rule based on the statutory criteria of 42 U.S.C. 233(i); proceedings against an individual provider under this rule are expected to be infrequent and will, therefore, affect only a small fraction of providers, health centers, or, potentially, their patients.

The majority of costs associated with the final rule, then, would come in the individual instances of its application, which are not feasible to predict. The

administrative process will impose some defense costs on the particular individual who is the subject of the hearing, but §§ 15.14 and 15.15 provide flexibility that may enable the parties and administrative law judges to avoid unduly burdensome costs when those costs are unnecessary.

While it is not feasible to estimate these costs with precision, the Department notes that the litigation costs incurred in defending medical malpractice suits in court frequently exceed $100,000 per case. The potential costs associated with a section 233(i) proceeding, by contrast, are expected to be a small fraction of the cost of litigating malpractice actions brought against individual providers. If even one provider is excluded from malpractice protections under 42 U.S.C. 233(g) or similar statutes, potentially resulting in at least one fewer malpractice action that the United States otherwise might have been required to defend, the potential cost savings to the United States will be tens of thousands of dollars on litigation expenses alone.

The Department also observes that losses in covered medical malpractice actions against deemed centers and their personnel are borne by the public fisc through the payment of judgments and settlements and other expenses. Each year, the Department transmits to the Secretary and Congress an estimate of the dollar amount of claims and litigation for which payments are expected to be made during the upcoming fiscal year, along with related fees and expenses. Although in 1996, it was estimated that only 14,234 individual providers were deemed to be Public Health Service employees for purposes of malpractice claims, that number has steadily risen, reaching in excess of 250,000 ''deemed'' providers as of April 2022.

In addition to the increasing numbers of providers eligible for malpractice protections under 42 U.S.C. 233(g) and similar statutes, the amount of money paid by the United States as a result of judgments and settlements and litigation expenses has steadily increased as well. Since fiscal year 2014, the average annual amount sought by claimants in malpractice losses against deemed providers has been approximately $35 billion. To be sure, the United States pays substantially less than the amount claimed in the majority of cases, but it still paid in excess of $100 million in fiscal years 2017, 2018, and 2019, respectively, including a then-record amount of $135,047,091 in 2019 alone. Fiscal years 2020 and 2021 saw a slight downturn in the number of claims paid, likely the result of delays in court proceedings during the COVID–19 pandemic and related restrictions. In fiscal year 2022, with restrictions largely lifted, the United States paid $158,338,182.79 in judgments and settlements, a new record amount.

Neither the criteria set forth in 42 U.S.C. 233(i) nor the final rule contemplates that an individual provider subjects the Government to an unreasonably high degree of risk of loss merely by subjecting the United States to suit on malpractice claims that result in losses. That is a potential basis for de-deeming only to the extent that a single provider's care has resulted in claims outside the norm for a licensed or certified practitioner in the same specialty. If a single provider, for example, exposed the United States to several meritorious claims, each costing the United States $1 million, and that provider's history of claims was outside the norm for a practitioner in the same specialty, then excluding that provider from the malpractice liability protections of 42 U.S.C. 233(g) or another statute, as the case may be, may result in substantial savings to the United States in the future. That is because de-deeming the provider will reduce the number of claims and the amount of losses the United States would otherwise have incurred as a result of that provider's care and treatment.

The Department further notes that, unlike with actual Federal employees, over whom Federal agencies exercise plenary control and have various means of addressing risk through disciplinary action or termination, individual providers deemed to be Public Health Service employees for purposes of covered malpractice claims remain under the exclusive control and supervision of the public or non-profit private entity that employs them. The Government has no role in the day-to-day operations of health centers or free clinics and no involvement in the employment or disciplinary decisions of such entities.

The Attorney General's authority to exclude an individual provider who poses an unreasonably high degree of risk of loss through a section 233(i) proceeding provides the United States some small measure of risk control. Moreover, the authority granted to the Attorney General under section 233(i) is, in practice, no different from the authority that a private insurance carrier could exercise to refuse to insure an individual provider who poses an unreasonably high degree of risk of loss. A section 233(i) proceeding to exclude an individual provider from coverage under 42 U.S.C. 233(g) or similar statutes, if it is determined that the individual provider poses an unreasonably high degree or risk of loss, is similar to the ability that a private insurer possesses to exclude from coverage individual providers for the same reasons.

In the event that treating an individual provider as a Public Health Service employee is ultimately determined to expose the United States to an unreasonably high degree of risk of loss, the Department acknowledges that there will be certain costs to that provider. An individual provider who is no longer deemed to be an employee of the Public Health Service for purposes of malpractice claims may, for example, be required to obtain personal medical malpractice insurance to continue practicing. The provider may also experience negative employment consequences as a result of the Attorney General's determination.

For several reasons, it is not feasible to estimate the costs to specific, individual providers of having to procure malpractice insurance in lieu of relying on deemed Public Health Service employee status for malpractice protection. Malpractice insurance rates vary greatly depending on factors like specialty and location, insurance provider, loss history, coverage requirements, policy limits, and policy type.[1] Even within States, coverage costs can vary from county to county depending on factors like population density and the density of the physician population in a given area.

For example, State-filed malpractice premiums, before applied insurer discounts, average between roughly $2,486 and $15,949 in Nebraska, but between roughly $10,560 and $161,942 in New York, with higher premiums for higher-risk specialties.[2] Compared to the average *loss* to the United States in malpractice actions brought under 42 U.S.C. 233(g) and related statutes, which in the first half of fiscal year 2022 averaged $1,064,767 per claim paid, the net benefit to the United States of excluding an individual provider who poses an unreasonably high degree of risk of loss to the United States justifies

[1] *See* Gallagher Healthcare, *How Much Does Medical Malpractice Insurance Cost?* (March 19, 2020), *https://www.gallaghermalpractice.com/blog/post/how-much-does-medical-malpractice-insurance-cost.*

[2] *Compare* Gallagher Health Care, *Nebraska Medical Malpractice Insurance, https://www.gallaghermalpractice.com/state-resources/nebraska-medical-malpractice-insurance* (last visited January 26, 2024), *with New York Medical Malpractice Insurance, www.gallaghermalpractice.com/state-resources/new-york-medical-malpractice-insurance* (last visited January 26, 2024).

the potential costs to that provider of procuring personal insurance.

The Department further observes that, while premiums may vary by location or specialty, an individual provider subject to a proceeding governed by this rule could come from any location or specialty; the only factor common to a provider subject to a proceeding under this rule will be a threshold finding, triggering the process under this rule, that the provider may expose the United States to an unreasonably high degree of risk of loss. Any provider who is excluded from coverage by a final determination made under 42 U.S.C. 233(i) would merely be placed in the position that provider would have occupied but for the existence of these statutes—that of a provider who must procure personal insurance. If a provider turns out to be uninsurable in the private insurance market, that provider's inability to procure insurance merely underscores that the provider poses an unreasonably high degree of risk of loss. Congress conferred upon the Attorney General the authority to de-deem certain individuals in order to protect against such an unreasonably high risk of loss. 42 U.S.C. 233(i); H.R. Rep. No. 102–823, pt. 2, at 8 (1992).

The Department acknowledges as well that if an individual provider is no longer deemed to be an employee of the Public Health Service and leaves the practice, the health center or free clinic may incur costs to find a new provider. Replacing providers, however, may occur even absent this final rule establishing a process for de-deeming individual providers, and the costs to entities of filling positions may not be readily traceable to the process established by this final rule.

In any event, the Department expects that substantial benefits will justify any costs incurred in finding replacements, as any individual who is replaced after being excluded from coverage following a proceeding under this rule will be one who has been determined to create an unreasonably high degree of risk of loss on claims for malpractice. It is anticipated that, in the usual case, the individual's replacement will provide reduced risk of loss for the United States and better care for patients. While there may be instances in which an individual who presented such a risk of loss cannot be replaced, the Department believes that these costs are justified by the benefits of implementing this rule to carry out Congress's stated objectives. Congress enacted 42 U.S.C. 233(i) ''to assure that FTCA coverage is not extended to individual practitioners that do not provide care of acceptable quality'' by providing a process whereby the Attorney General may exclude individuals based on a determination that such individuals ''expose the U.S. to an unreasonably high degree of risk of loss.'' H.R. Rep. No. 102–823, pt. 2, at 8 (1992). Implementing the process for section 233(i) proceedings through this final rule is a procedural step toward effectuating Congress's purpose in enacting section 233(i).

Based on the expectation that the process will be used sparingly and only for an individual provider who exposes the United States to an unreasonably high degree of risk of loss on medical malpractice claims for personal injury or death, the Department has concluded that the net benefits of improved patient care and reduced losses to the United States traceable to malpractice claims justify the potential costs of implementing a process to carry out 42 U.S.C. 233(i).

Executive Order 13132: Federalism

This final rule 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. Therefore, in accordance with Executive Order 13132, the Department of Justice has determined that this final rule will not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Executive Order 12988: Civil Justice Reform

This final rule meets the applicable standards provided in sections 3(a) and 3(b)(2) of Executive Order 12988.

Unfunded Mandates Reform Act of 1995

This final rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*

Small Business Regulatory Enforcement Fairness Act of 1996

This final rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 804. This final rule will not result in an annual effect on the economy of $100 million or more; a major increase in cost or prices; significant adverse effects on competition, employment, investment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

List of Subjects in 28 CFR Part 15

Claims, Government contracts, Government employees, Health care, Immunization, Nuclear energy.

For the reasons set forth in the preamble, the Attorney General amends part 15 of title 28 of the Code of Federal Regulations as follows:

PART 15—CERTIFICATIONS, DECERTIFICATIONS, AND NON-DEEMING DETERMINATIONS FOR PURPOSES OF THE FEDERAL TORT CLAIMS ACT

■ 1. The authority citation for part 15 is revised to read as follows:

Authority: 5 U.S.C. 301, 554, 556, 557, and 8477(e)(4); 10 U.S.C. 1054, 1089; 22 U.S.C. 2702, 28 U.S.C. 509, 510, and 2679; 38 U.S.C. 7316; 42 U.S.C. 233, 2212, 2458a, and 5055(f); and sec. 2, Pub. L. 94–380, 90 Stat. 1113 (1976).

■ 2. The heading for part 15 is revised to read as set forth above.

■ 3. Designate §§ 15.1 through 15.4 as subpart A under the following heading:

Subpart A—Certification and Decertification in Connection With Certain Suits Based Upon Acts or Omissions of Federal Employees and Other Persons

§§ 15.5 through 15.10 [Reserved]

■ 4. Add reserved §§ 15.5 through 15.10 to newly designated subpart A.

■ 5. Add subpart B to read as follows:

Subpart B—Determination of Individuals Deemed Not To Be Employees of the Public Health Service

Sec.

Subpart B—Determination of Individuals Deemed Not To Be Employees of the Public Health Service

§ 15.11 Purpose.

(a) The purpose of this subpart is to implement the notice and hearing

procedures applicable to a determination by the Attorney General or the Attorney General's designee under 42 U.S.C. 233(i) that an individual health care provider shall not be deemed an employee of the Public Health Service for purposes of 42 U.S.C. 233(g) or any other statute that confers deemed Public Health Service employee status to which 42 U.S.C. 233(i) has been made applicable. Under 42 U.S.C. 233(i), an individual health care provider who is no longer deemed to be an employee of the Public Health Service is excluded from any malpractice protections otherwise made statutorily available to individuals deemed to be Public Health Service employees.

(b) Section 233(i) of title 42 provides that the Attorney General, in consultation with the Secretary of Health and Human Services, may on the record determine, after notice and an opportunity for a full and fair hearing, that an individual physician or other licensed or certified health care practitioner who is an officer, employee, or contractor of an entity described in 42 U.S.C. 233(g)(4) shall not be deemed to be an employee of the Public Health Service for purposes of 42 U.S.C. 233 if treating such individual as such an employee would expose the Government to an unreasonably high degree of risk of loss.

§ 15.12 Definitions.

As used in this subpart:

Adjudicating official means the Assistant Attorney General for the Civil Division of the Department of Justice or a designee of the Assistant Attorney General.

Entity means an entity described in 42 U.S.C. 233(g)(4).

Individual means an individual physician or other licensed or certified health care practitioner who is or was an officer, employee, or contractor of an entity described in 42 U.S.C. 233(g)(4); a health professional, officer, employee, or contractor of a free clinic as described in 42 U.S.C. 233(o); or a health professional volunteer as described in 42 U.S.C. 233(q).

Initiating official means a Deputy Assistant Attorney General of the Civil Division of the Department of Justice or a designee of a Deputy Assistant Attorney General.

Parties means an individual, as defined in paragraph (c) of this section, and the initiating official, as defined in paragraph (d) of this section.

Public Health Service means the Public Health Service or an operating division or component of the Public Health Service.

Secretary means the Secretary of Health and Human Services or the Secretary's designee.

Unreasonably high degree of risk of loss is a determination based on consideration of one or more of the following statutory criteria—

(1) The individual does not comply with the policies and procedures that the entity or the sponsoring free clinic has implemented pursuant to 42 U.S.C. 233(h)(1);

(2) The individual has a history of claims filed against him or her as provided for under 42 U.S.C. 233 that is outside the norm for licensed or certified health care practitioners within the same specialty;

(3) The individual refused to reasonably cooperate with the Attorney General in defending against any such claim;

(4) The individual provided false information relevant to the individual's performance of his or her duties to the Secretary, the Attorney General, or an applicant for or recipient of funds under title 42, chapter 6A, United States Code; or

(5) The individual was the subject of disciplinary action taken by a State medical licensing authority or a State or national professional society.

§ 15.13 Notice of hearing.

(a) Whenever the initiating official, in consultation with the Secretary, finds, based upon available information gathered or provided, that treating an individual as an employee of the Public Health Service may expose the Government to an unreasonably high degree of risk of loss, the initiating official shall notify the individual that an administrative hearing will be conducted for the purpose of determining whether treating the individual as an employee of the Public Health Service for purposes of 42 U.S.C. 233 would expose the United States to an unreasonably high degree of risk of loss.

(b) The notice of hearing shall be in writing and shall be sent by registered or certified mail to the individual at the individual's last known address, or to the individual's attorney in the event the Attorney General has received written notice that the individual has retained counsel.

(c) The notice shall contain:

(1) A statement of the nature and purpose of the hearing;

(2) The factual allegations and, where appropriate, the law asserted in support of the proposed action;

(3) The name of the administrative law judge;

(4) A statement of the nature of the action proposed to be taken; and

(5) A statement of the time, date, and location of the hearing.

(d) The hearing shall be initiated not sooner than 60 days of the date on the written notice of hearing.

§ 15.14 Conduct of hearing.

(a) An administrative law judge appointed in accordance with 5 U.S.C. 3105 shall preside over the hearing.

(b) Pursuant to 5 U.S.C. 556(b), the administrative law judge is to conduct all proceedings in an impartial manner. The administrative law judge may disqualify himself at any time. An individual may move to disqualify the appointed administrative law judge only upon the filing, in good faith, of a timely and sufficient affidavit of personal bias or other ground for disqualification of the administrative law judge, such as conflict of interest or financial interest. If such affidavit is timely filed, the adjudicating official shall determine the matter as part of the record and final determination in the case.

(c) The administrative law judge shall have the following powers:

(1) Administer oaths and affirmations;

(2) Issue subpoenas authorized by law;

(3) Rule on offers of proof and receive relevant evidence;

(4) Take depositions or have depositions taken when the ends of justice would be served;

(5) Regulate the course of the hearing;

(6) Hold conferences for the settlement or simplification of the issues by consent of the parties or by the use of alternative means of dispute resolution;

(7) Inform the parties as to the availability of one or more alternative means of dispute resolution, and encourage use of such methods;

(8) Dispose of procedural requests or similar matters;

(9) Make or recommend decisions;

(10) Require and, in the discretion of the administrative law judge, adopt proposed findings of fact, conclusions of law, and orders;

(11) Take any other action that administrative law judges are authorized by statute to take; and

(12) All powers and duties reasonably necessary to perform the functions enumerated in paragraphs (c)(1) through (11) of this section.

(d) The administrative law judge may call upon the parties to consider:

(1) Simplification or clarification of the issues;

(2) Stipulations, admissions, agreements on documents, or other understandings that will expedite conduct of the hearing;

(3) Limitation of the number of witnesses and of cumulative evidence; and

(4) Such other matters as may aid in the disposition of the case.

(e) At the discretion of the administrative law judge, parties or witnesses may participate in hearings by video conference.

(f) All hearings under this subpart shall be public unless otherwise ordered by the administrative law judge.

(g) The hearing shall be conducted in conformity with 5 U.S.C. 554–557 (sections 5–8 of the Administrative Procedure Act).

(h) The initiating official shall have the burden of going forward with the evidence and shall generally present the Government's evidence first.

(i) Technical rules of evidence shall not apply to hearings conducted pursuant to this subpart, but rules designed to assure production of the most credible evidence available and to subject testimony to cross-examination shall be applied where reasonably necessary by the administrative law judge. The administrative law judge may exclude irrelevant, immaterial, or unduly repetitious evidence. All documents and other evidence offered or taken for the record shall be open to examination by the parties, and opportunity shall be given to refute facts and arguments advanced on either side of the issues. A transcript shall be made of the oral evidence except to the extent the substance thereof is stipulated for the record.

(j) During the time a proceeding is pending before an administrative law judge, all motions shall be addressed to the administrative law judge and, if within the administrative law judge's delegated authority, shall be ruled upon. Any motion upon which the administrative law judge has no authority to rule shall be certified to the adjudicating official with a recommendation. The opposing party may answer within such time as may be designated by the administrative law judge. The administrative law judge may permit further replies by both parties.

§ 15.15 Discovery.

(a) At any time after the initiation of the proceeding, the administrative law judge may order, by subpoena if necessary, the taking of a deposition and the production of relevant documents by the deponent. Such order may be entered upon a showing that the deposition is necessary for discovery purposes and that such discovery could not be accomplished by voluntary methods. Such an order may also be entered in extraordinary circumstances to preserve relevant evidence upon a showing that there is substantial reason to believe that such evidence could not be presented through a witness at the hearing. The decisive factors for a determination under this subsection, however, shall be fairness to all parties and the requirements of due process. A deposition may be taken orally or upon written questions before any person who has the power to administer oaths and shall not exceed one day of seven hours.

(b) Each deponent shall be duly sworn, and any adverse party shall have the right to cross-examine. Objections to questions or documents shall be in short form, stating the grounds upon which objections are made. The questions propounded and the answers thereto, together with all objections made (but not including argument or debate), shall be reduced to writing and certified by the person before whom the deposition was taken. Thereafter, the person taking the deposition shall forward the deposition and one copy thereof to the party at whose instance the deposition was taken and shall forward one copy to the representative of the other party.

(c) A deposition may be admitted into evidence as against any party who was present or represented at the taking of the deposition, or who had due notice thereof, if the administrative law judge finds that there are sufficient reasons for admission and that the admission of the evidence would be fair to all parties and comport with the requirements of due process.

§ 15.16 Recommended decision.

Within a reasonable time after the close of the record of the hearings conducted under § 15.14, the administrative law judge shall certify the record to the adjudicating official and shall submit to the adjudicating official written findings of fact, conclusions of law, and a recommended decision. The administrative law judge shall promptly make copies of the findings of fact, conclusions of law, and recommended decision available to the parties and the Secretary.

§ 15.17 Final determination.

(a) In hearings conducted under § 15.14, the adjudicating official shall, subject to subsection (d), make the final determination on the basis of the certified record, findings, conclusions, and recommendations presented by the administrative law judge.

(b) Prior to making a final determination, the adjudicating official shall give the parties an opportunity to submit the following, within thirty days after the submission of the administrative law judge's recommendations:

(1) Proposed findings and determinations;

(2) Exceptions to the recommendations of the administrative law judge;

(3) Supporting reasons for the exceptions or proposed findings or determinations; and

(4) Final briefs summarizing the arguments presented at the hearing.

(c) The adjudicating official shall, within a reasonable time after receiving the parties' submissions, consult with the Secretary and then make a final determination. Copies of the final determination shall be served upon each party to the proceeding. Subject to paragraph (d) of this section, the final determination made by the adjudicating official under this rule shall constitute the final agency action.

(d) Within 30 days of any final determination made by the adjudicating official, the Attorney General may exercise discretion to review the final determination. In the event the Attorney General exercises discretion to review a decision, the Attorney General's final determination shall constitute the final agency action.

§ 15.18 Rehearing.

(a) An individual dissatisfied with a final determination under § 15.17 may, within 30 days after the notice of the final determination is sent, request the adjudicating official to re-review the record.

(b) The adjudicating official may require that another oral hearing be held on one or more of the issues in controversy, or permit the dissatisfied party to present further evidence or argument in writing, if the adjudicating official finds that the individual has:

(1) Presented evidence or argument that is sufficiently significant to require the conduct of further proceedings; or

(2) Shown some defect in the conduct of the adjudication under this subpart sufficient to cause substantial unfairness or an erroneous finding in that adjudication.

(c) Any rehearing ordered by the adjudicating official shall be conducted pursuant to § § 15.14 through 15.16.

§ 15.19 Effective date of a final determination.

(a) A final determination under § 15.17 shall be provided to the Department of Health and Human Services and sent by certified or registered mail to the individual and to the entity employing or sponsoring such individual if the individual is currently

an officer, employee, contractor, or health professional volunteer of an entity described in 42 U.S.C. 233(g)(4) or a health professional, officer, employee, or contractor of a free clinic described in 42 U.S.C. 233(o). In the event the individual is no longer an officer, employee, contractor, or health professional volunteer of an entity described in 42 U.S.C. 233(g)(4), or a health professional, officer, employee, or contractor of a free clinic described in 42 U.S.C. 233(o), the determination shall be sent by certified or registered mail to the individual and to the last entity described in 42 U.S.C. 233(g)(4) or free clinic described in 42 U.S.C. 233(o) at which such individual was an officer, employee, contractor, health professional volunteer, or health professional.

(b) A final determination shall be effective upon the date the written determination is received by such entity or free clinic.

(c) A final determination that an individual provider shall not be deemed to be an employee of the Public Health Service shall apply to all acts or omissions of the individual occurring after the date the adverse final determination is received by such entity or free clinic.

(d) The Attorney General will inform the National Practitioner Data Bank of any final determination under § 15.17 that an individual shall not be deemed to be an employee of the Public Health Service for purposes of 42 U.S.C. 233.

§ 15.20 Reinstatement.

(a) Not sooner than five years after the time for rehearing has expired, and no more often than once every five years thereafter, an individual who has been the subject of a final determination under § 15.17 may petition the initiating official for reconsideration of that determination and for reinstatement. The individual bears the burden of proof and persuasion.

(b) In support of the petition for reinstatement, the individual shall submit relevant evidence relating to the period since the original proceedings under this subpart and a statement demonstrating and explaining why treating the individual as an employee of the Public Health Service for purposes of 42 U.S.C. 233 would no longer expose the United States to an unreasonably high degree of risk of loss.

(c) Upon receiving a petition for reinstatement, the initiating official shall forward the petition, together with an evaluation and recommendation on whether the petition makes a prima facie case for reinstatement, to the adjudicating official. The adjudicating official shall determine, in the adjudicating official's discretion, whether the petition makes a prima facie case that the individual provider no longer would expose the United States to an unreasonably high degree of risk of loss. The adjudicating official's determination that a petition does not make a prima facie case for reinstatement is not subject to further review.

(d) If the adjudicating official determines that a prima facie case has been made for reinstatement, an administrative law judge shall be appointed in accordance with 5 U.S.C. 3105 and shall conduct such proceedings pursuant to §§ 15.14 through 15.16 as the administrative law judge deems necessary, in the administrative law judge's discretion, to determine whether the individual has established that treating the individual as an employee of the Public Health Service for purposes of 42 U.S.C. 233 would no longer expose the United States to an unreasonably high degree of risk of loss. After conducting such proceedings as the administrative law judge deems necessary, the administrative law judge shall certify the record to the adjudicating official and shall submit written findings of fact, conclusions of law, and a recommended decision to the adjudicating official pursuant to § 15.16.

(e) Following proceedings conducted under paragraph (d) of this section, the adjudicating official shall make the final determination on the basis of the record, findings, conclusions, and recommendations presented by the administrative law judge, which shall include the record from the original determination and any petition for rehearing. Copies of the adjudicating official's final determination shall be furnished to the parties. The adjudicating official's final determination shall constitute the final agency action.

(f) A determination that an individual is reinstated pursuant to this section shall be distributed in the same manner as provided in § 15.19 and shall apply only to acts or omissions of the individual occurring after the date of the final reinstatement determination.

Dated: June 28, 2024.

Merrick B. Garland,

Attorney General.

[FR Doc. 2024–14696 Filed 7–3–24; 8:45 am]

BILLING CODE 4410–12–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1630

RIN 3046–AB33

Removal of ADA Appendix Sections Related to Removal of Final ADA Wellness Rule Vacated by Court

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final rule.

SUMMARY: The Equal Employment Opportunity Commission is issuing a final rule supplementing a final rule it published on December 20, 2018, entitled ''Removal of Final ADA Wellness Rule Vacated by Court,'' which removed the incentive section in ADA regulations. This rule removes the discussion about the incentive section from the ADA appendix.

DATES: This final rule is effective as of July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Sarah DeCosse, Assistant Legal Counsel, (202) 921–3240 (voice); (800) 669–6820 (TTY), Office of Legal Counsel, 131 M Street NE, Washington, DC 20507. Requests for this document in an alternative format should be made to the Office of Communications and Legislative Affairs at (202) 921–3191 (voice), (800) 669–6820 (TTY), or (844) 234–5122 (ASL).

SUPPLEMENTARY INFORMATION: On May 17, 2016, the Equal Employment Opportunity Commission (EEOC or Commission) published a final rule under the authority of title I of the Americans with Disabilities Act (ADA), 42 U.S.C. 12101–12117, ''provid[ing] guidance on the extent to which employers may use incentives to encourage employees to participate in wellness programs that ask them to respond to disability-related inquiries and/or undergo medical examinations.'' 81 FR 31126 (May 17, 2016). This 2016 rule also discussed the incentive provisions in the ADA appendix.

On October 24, 2016, AARP filed a complaint in the U.S. District Court for the District of Columbia challenging the incentive section of the ADA rule. On August 22, 2017, the District Court concluded that the Commission did not provide sufficient reasoning to justify the incentive limit adopted in the ADA rule and remanded the rule to the EEOC for reconsideration without vacating it. Following a motion by AARP to alter or amend the court's summary judgment order, the court issued an order vacating the incentive section of the rule, which was 29 CFR 1630.14(d)(3), effective

January 1, 2019. *AARP* v. *EEOC,* No. 16–2113 (D.D.C. December 20, 2017). Consistent with that decision, the EEOC published a final rule entitled ''Removal of Final ADA Wellness Rule Vacated by Court'' at 83 FR 65296 (December 20, 2018) to remove the incentive section of the ADA rule at 29 CFR 1630.14(d)(3). However, due to an oversight, this 2018 final rule did not remove the corresponding discussion of that section in the appendix to 29 CFR part 1630. The instant final rule serves to supplement 83 FR 65296 (December 20, 2018) and implement the court's ruling by removing the corresponding portions of the appendix to 29 CFR part 1630 in which 29 CFR 1630.14(d)(3) is discussed. Doing so will reflect the revisions to the ADA rule as amended by 83 FR 65296.

Like the 2018 rule, this supplemental rule is not subject to the requirement to provide an opportunity for public comment because it falls under the good cause exception at 5 U.S.C. 553(b)(4)(B). The good cause exception is satisfied when notice and comment is ''impracticable, unnecessary, or contrary to the public interest.'' *Id.* Just as the EEOC proceeded directly to a final rule for the original removal of the regulatory incentive text based on the ''good cause'' exception, here, too, this rule is an administrative measure that corrects an omitted step in 2018 and implements the court's order referenced above. Seeking public comment on this removal also is unnecessary because the Commission is acting to execute the court order.

Finally, because this rule implements a court order already in effect, the Commission has good cause to waive the 30-day effective date under 5 U.S.C. 553(d)(3).

Regulatory Procedures

Executive Order 12866 (as Amended by Executive Order 14094)

The Commission has complied with the principles in section 1(b) of Executive Order 12866, as amended by Executive Order 14094, Regulatory Planning and Review. This rule is not a ''significant regulatory action'' under section 3(f) of the Executive Order and does not require an assessment of potential costs and benefits under section 6(a)(3) of the Executive Order.

Paperwork Reduction Act

This regulation contains no new information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 604, requires a final regulatory flexibility analysis for final rules only ''after being required to publish a general notice of proposed rulemaking'' or for interpretive internal revenue laws. This rule is being promulgated without a notice of proposed rulemaking for the reasons described above. Further, it does not concern internal revenue matters. Therefore, a regulatory flexibility analysis is not required.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, in 1995 dollars, updated annually for inflation. In 2023, that threshold was approximately $177 million. It will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*

List of Subjects in 29 CFR Part 1630

Equal employment opportunity, Individuals with disabilities.

For the reasons set forth in the preamble, and under the authority of 42 U.S.C. 12116 and 12205a of the Americans with Disabilities Act, the Commission amends 29 CFR part 1630 as follows:

PART 1630—REGULATIONS TO IMPLEMENT THE EQUAL EMPLOYMENT PROVISIONS OF THE AMERICANS WITH DISABILITIES ACT

■ 1. The authority citation for part 1630 continues to read as follows:

Authority: 42 U.S.C. 12116 and 12205a of the Americans with Disabilities Act, as amended.

Appendix to Part 1630 [Amended]

■ 2. Amend the appendix to part 1630, under the heading ''Section 1630.14 Medical Examinations and Inquiries Specifically Permitted,'' by removing the entries for ''Section 1630.14(d)(3): Limitations on Incentives'' and ''Application of Section 1630.14(d)(3) to Smoking Cessation Programs''.

For the Commission.

Charlotte A. Burrows,

Chair.

[FR Doc. 2024–14606 Filed 7–3–24; 8:45 am]

BILLING CODE 6570–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA–HQ–OAR–2023–0072; EPA–HQ–OAR–2022–0730; FRL–12032–01–OAR]

RIN 2060–AV09; 2060–AV71

New Source Performance Standards; Incorporation by Reference; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The Environmental Protection Agency (EPA) finalized multiple actions with incorporation by reference (IBR) in separate final rules that amended the same centralized IBR section. The amendatory instructions for that section were drafted based on a different publication order than the ultimate publication order of the affected rules. This rule corrects the instructions allowing Office of the Federal Register (OFR) editors to codify the amendments from each rule.

DATES: The corrections in instructions 1 and 2 are effective July 8, 2024, and the corrections in instructions 3 and 4 are effective July 15, 2024.

FOR FURTHER INFORMATION CONTACT: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, P.O. Box 12055, Research Triangle Park, North Carolina, 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov.*

SUPPLEMENTARY INFORMATION: The EPA published two final rules, 89 FR 39798 (May 9, 2024) and 89 FR 42932 (May 16, 2024), that each amended 40 CFR 60.17, the centralized IBR section for 40 CFR part 60. The amendatory instructions were drafted with the assumption that the two rules would publish in the reverse order. Given the order in which they published, if OFR editors were to effectuate the instructions, the editors would revise paragraphs other than the ones intended on July 8, 2024 (the effective date of the first rule), and July 15, 2024 (the effective date of the second rule), and would be unable to carry out an instruction in the second rule. This rule corrects the instructions allowing OFR editors to codify the amendments from each rule.

Corrections

I. As of July 8, 2024, in FR Doc. 2024–09233 at 89 FR 39798 in the **Federal Register** of Thursday May 9, 2024, make the following corrections:

§ 60.17 [Corrected]

■ 1. On page 40027, in the second column, in amendment 2, correct the text of instruction 2.a. to read ''Revising paragraphs (d)(1), (g)(15) and (16), (h)(37), (42), (46), (143), (202), and (208), the introductory text of paragraph (i);''

■ 2. On page 40027, in the third column, in § 60.17(h):
■ a. Correct ''(38)'' to read ''(37)'';
■ b. Correct ''(43)'' to read ''(42)'';
■ c. Correct ''(47)'' to read ''(46)'';
■ d. Correct ''(145)'' to read ''(143)'';
■ e. Correct ''(206)'' to read ''(202)''; and
■ f. Correct ''(212)'' to read ''(208)''.

II. As of July 15, 2024, in FR Doc. 2024–07002 at 89 FR 42932 in the **Federal Register** of Thursday May 16, 2024, make the following corrections:

§ 60.17 [Corrected]

■ 3. On page 43067, in the second column, in amendment 2:
■ a. Correct instruction 2.c. to read ''Revising and republishing paragraph (k).''; and
■ b. Remove instruction 2.d.

■ 4. On page 43068, in the first column, in § 60.17, correct ''(j)'' to read ''(k)''.

Joseph Goffman,

Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2024–14407 Filed 7–3–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60 and 63

[EPA–HQ–OAR–2020–0371; EPA–HQ–OAR–2022–0730; FRL–12066–01–OAR]

RIN 2060–AU97; 2060–AV71

New Source Performance Standards (NSPS) for the Synthetic Organic Chemical Manufacturing Industry (SOCMI) and National Emission Standards for Hazardous Air Pollutants (NESHAP) for the SOCMI and Group I & II Polymers and Resins Industry and NESHAP: Gasoline Distribution Technology Reviews and NSPS Review for Bulk Gasoline Terminals; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule, correction.

SUMMARY: The Environmental Protection Agency (EPA) is correcting final rules that appeared in the **Federal Register** on May 8, 2024, and May 16, 2024. This action corrects instructions allowing Office of **Federal Register** editors to codify the amendments from the rules. This action also includes express instructions to lift the stay of provisions granted on June 2, 2008 (73 FR 31372). The corrections to instructions in this document do not alter or change the content or text of any regulatory provision.

DATES: The correction to 40 CFR 63.11099, at instruction 6, is effective July 8, 2024. The corrections to 40 CFR 60.481, 60.482–1, 60.481a, 60.482–1a, and 60.482–11a, at instructions 1 through 5, are effective July 15, 2024.

FOR FURTHER INFORMATION CONTACT: For the Gasoline Distribution rules, contact U.S. EPA, Attn: Ms. Jennifer Caparoso, Mail Drop: E143–01, 109 T.W. Alexander Drive, P.O. Box 12055, RTP, NC 27711; telephone number: (919) 541–4063; and email address: *caparoso.jennifer@epa.gov.* For the Synthetic Organic Chemical Manufacturing Industry rules, contact U.S. EPA, Attn: Mr. Andrew Bouchard, Mail Drop: E143–01, 109 T.W. Alexander Drive, P.O. Box 12055, RTP, North Carolina 27711; telephone number: (919) 541–4036; and email address: *bouchard.andrew@epa.gov.*

SUPPLEMENTARY INFORMATION: The EPA published two final actions, 89 FR 39304 (May 8, 2024) and 89 FR 42932 (May 16, 2024), that amended 40 CFR part 63, subpart BBBBBB, and 40 CFR part 60, subparts VV and VVa, respectively. The Office of **Federal Register** (OFR) editor is unable to carry out certain instructions of the rules as currently written. This action corrects the instructions allowing OFR editors to codify the amendments from each rule. Additionally, this action includes express instructions in the amendatory text to lift the stay of the definition of ''Process unit'' and the method of allocating shared storage vessels in 40 CFR part 60, subpart VV, as well as the stay of the definitions of ''Process unit'' and ''Capital expenditure'' and the method of allocating shared storage vessels in 40 CFR part 60, subpart VVa.

Corrections

In FR Doc. 2024–07002, appearing in page 42932 in the **Federal Register** of Thursday, May 16, 2024, the following corrections are made:

§ 60.481 [Corrected]

■ 1. Effective July 15, 2024, on page 43068, in the second column, in part 60, amendatory instruction 4 is corrected to read as follows:

''■ 4. Amend § 60.481 by lifting the stay on the definition of ''Process unit'' and revising the definition of ''Process unit''.

The revision reads as follows:''

§ 60.482–1 [Corrected]

■ 2. Effective July 15, 2024, on page 43068, in the second column, in part 60, amendatory instruction 5 is corrected to read as follows:

''■ 5. Amend § 60.482–1 by lifting the stay on paragraph (g) and removing paragraph (g).''

§ 60.481a [Corrected]

■ 3. Effective July 15, 2024, on page 43070, in the second column, in part 60, amendatory instruction 11 is corrected to read as follows:

''■ 11. Amend § 60.481a by lifting the stay on the definitions of ''Capital expenditure'' and ''Process unit'' and revising the definitions to read as follows:''

§ 60.482–1a [Corrected]

■ 4. Effective July 15, 2024, on page 43070, in the first column, in part 60, amendatory instruction 12 is corrected to read as follows:

''■ 12. Amend § 60.482–1a by:

■ a. Revising paragraph (e); and

■ b. Lifting the stay on paragraph (g) and removing paragraph (g).

The revisions read as follows:''

§ 60.482–11a [Corrected]

■ 5. Effective July 15, 2024, on page 43070, in the second column, in part 60, amendatory instruction 13 is corrected to read as follows:

''■ 13. Amend § 60.482–11a by lifting the stay and removing the section.''

In FR Doc. 2024–04629, appearing on page 39304 in the **Federal Register** on Wednesday, May 8, 2024, the following correction is made:

§ 63.11099 [Corrected]

■ 6. Effective July 8, 2024, on page 39383, in the third column, in part 63, amendatory instruction 29 is corrected to read as follows:

''■ 29. Section 63.11099 is amended by revising paragraph (c) introductory text and adding paragraph (c)(5) to read as follows:''

Joseph Goffman,

Assistant Administrator.

[FR Doc. 2024–14678 Filed 7–3–24; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

48 CFR Part 502

[GSAR Case 2022–G517, Docket No. GSA–GSAR–2023–0028; Sequence No. 1]

RIN 3090–AK60

General Services Administration Acquisition Regulation; Reduction of Single-Use Plastic Packaging; Correction

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Final rule; correction.

SUMMARY: GSA is issuing a correction to GSAR Case 2022–G517, ''Reduction of Single-use Plastic Packaging,'' which published in the **Federal Register** on June 6, 2024. This correction makes an update to the definition ''Packaging''.

DATES: Effective July 8, 2024.

FOR FURTHER INFORMATION CONTACT: Adina Torberntsson, *adina.torberntsson@gsa.gov* or call (720) 475–0568. Please cite GSAR Case 2022–G517; Correction.

SUPPLEMENTARY INFORMATION:

Correction

■ In rule FR Doc. 2024–12192, published in the **Federal Register** at 89 FR 48330, on June 6, 2024, on page 48336, in the second column, amendatory instruction 2, section 502.101, correct paragraph 3 of the definition of *Packaging* to read as follows:

502.101 [Corrected]

* * * * *

Packaging * * *

(3) Shipping packaging means packaging that serves as protection for the goods to ensure safe transport to the end customer, including:

(i) Ancillary packaging or transport packaging or tertiary packaging means packaging intended to secure the product, such as packing peanuts, wrapping materials, or molded materials. Ancillary packaging (or all shipping packaging) is typically outside of brand packaging.

(ii) Redundant packaging or unnecessary packaging means packaging that does not add any measurable protection to the supply being shipped, such as multiple layers of bubble wrap to an already durable product that is encased in a cardboard box. An example of this is a home testing kit with all plastic components already packaged in a cardboard box with cardboard inserts to absorb shock, that is then shipped in multiple layers of bubble wrap. In this example the bubble wrap is the redundant single-use plastic packaging.

* * * * *

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy, General Services Administration.

[FR Doc. 2024–14683 Filed 7–3–24; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 240624–0175]

RIN 0648–BN14

Taking of Marine Mammals Incidental to Commercial Fishing Operations; Amendment to the Atlantic Pelagic Longline Take Reduction Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule; delay of effective date.

SUMMARY: We, NMFS, are delaying the effective date of terminal gear requirements that amend the Pelagic Longline Take Reduction Plan (PLTRP) regulations in a final rule that published on June 6, 2023.

DATES: The effective date of the regulatory requirements contained in 50 CFR 229.36(d) that was published in a final rule at 88 FR 36965 on June 6, 2023, is delayed until January 1, 2025.

FOR FURTHER INFORMATION CONTACT: Erin Fougères, NMFS, Southeast Region, at 727–824–5312 or *erin.fougeres@noaa.gov,* or Kristy Long, NMFS, Office of Protected Resources at 206–526–4792 or *kristy.long@noaa.gov.* Individuals who use telecommunications devices for the deaf (TDD) may call the Federal Information Relay Service at 1–800–877–8339 between 8 a.m. and 4 p.m. eastern time, Monday through Friday, excluding Federal holidays.

SUPPLEMENTARY INFORMATION: On June 6, 2023, we published a final rule to amend the PLTRP (88 FR 36965). The PLTRP is required under section 118 of the Marine Mammal Protection Act (MMPA) to reduce mortality and serious injury (M/SI) of short-finned pilot whales (*Globicephala macrorhynchus*) incidental to the Atlantic portion of the Category I Atlantic Ocean, Caribbean, Gulf of Mexico large pelagics longline fishery. Regulatory requirements in the amended PLTRP were effective on July 6, 2023, except for the requirements contained in 50 CFR 229.36(d), implementing terminal gear restrictions, which were to become effective on July 8, 2024 (88 FR 36965).

The terminal gear requirements contained in 50 CFR 229.36(d) require: (1) circle hooks must have a round wire diameter not to exceed 4.05 millimeters (mm; 0.159 inches (in)) if the hooks are size 16/0, or 4.40 mm (0.173 in) if the hooks are size 18/0, and must have a straightening force not to exceed 300 pounds (lb; 136.08 kilograms (kg)); and (2) monofilament leaders and branch lines (*i.e.,* gangions) must have a minimum diameter of 1.8 mm (0.071 in) and a breaking strength of at least 300 lb (136.08 kg). These requirements apply to the U.S. exclusive economic zone (EEZ) portions of the Northeast Coastal (NEC), Mid-Atlantic Bight (MAB), South Atlantic Bight (SAB), and Florida East Coast (FEC) pelagic longline statistical areas, which together compose the entirety of the U.S. Atlantic EEZ (east of the line of demarcation between the Atlantic Ocean and the Gulf of Mexico as defined in 50 CFR 600.105(c)).

In the proposed rule to amend the PLTRP, we sought comments on the length of time necessary for manufacturers and industry to implement the new terminal gear regulations. Two commenters noted that manufacturers may need time to produce new hooks, but were concerned about additional delays to implementing regulations. Two additional commenters suggested that at least 1 full year was needed to plan and implement the hook design and allow fishermen time to work through existing inventories of hooks that would not meet the new regulatory requirements. These same commenters recommended that the fishery be given no less than 18 months following the publication of the final rule to implement the new hook requirements. In an effort to balance the conservation needs for the species and the practical and economic needs of the pelagic longline industry, we decided to delay the implementation of these terminal gear requirements by 12 months. Our final rule, which was published on June 6, 2023, and became effective on July 6, 2023, specified an effective date for the new terminal gear requirements of July 8, 2024.

Currently, some hooks that meet the specifications contained in 50 CFR 229.36(d) are available, although they are available in limited quantities and are not preferred broadly across the fishery. A primary hook manufacturer for the Atlantic pelagic longline fishing

industry, did not have a 16/0 or 18/0 circle hook that met the hook regulations required by the PLTRP amendments and, thus, needed to design, test, and manufacture new, compliant hooks. Although that process began at the time of publication of the final rule, as of May 31, 2024, those new, compliant hooks remain unavailable for purchase due to manufacturing delays. Compliant hooks are projected to be available for sale in sufficient quantities to meet the Atlantic pelagic longline fishery's needs shortly prior to the original July 8, 2024 effective date. However, we have determined that fishermen will not have sufficient time to phase out old hooks and implement new hooks before July 8, 2024, as intended by the final rule. Fishermen could purchase the new, compliant hooks if they become available before July 8, 2024, but changing them over and replacing non-compliant hooks would be labor intensive and costly. Therefore, we are delaying the effective date of the terminal gear requirements contained in 50 CFR part 229.36(d) until January 1, 2025, to allow fishermen to purchase new, compliant hooks, once they become available, and to phase in their use as older hooks need to be replaced, as originally intended by the final rule.

We expect that the impact of delaying the marine mammal protections afforded by the terminal gear requirements until January 1, 2025, will be minor. Based on data from 2015 through 2019, the Potential Biological Removal (PBR) for the western North Atlantic stock of short-finned pilot whales is 236 and the average annual M/SI incidental to the Atlantic pelagic longline fishery was 136 animals (Hayes *et al.,* 2022). Therefore, the western North Atlantic stock is not a strategic stock under the MMPA because the mean annual human-caused M/SI does not exceed PBR. More recently, NMFS confirmed that there were 15 observed hooked or entangled short-finned pilot whales in the Atlantic pelagic longline fishery in 2022, and 17 observed hooked or entangled short-finned pilot whale in 2023. Serious injury determinations for these have not been completed or been extrapolated to overall bycatch estimates yet; however, they are lower than the observed hooked or entangled short-finned pilot whales in 2021 and 2020, despite consistent observer coverage in 2022 and 2023. Therefore, although delaying the effective date of the terminal gear requirements by an additional 6 months will delay protections afforded by the regulations, M/SI of the western north Atlantic short-finned pilot whale stock is not expected to exceed PBR and is not expected to suffer serious adverse effects. In addition, although the effective date will be delayed by approximately 6 months until January 1, 2025, we anticipate that fishermen will begin to purchase and utilize the new hooks once they become available, to replace older hooks that are lost, bent or broken. Therefore, some of the protections afforded by the regulations to short-finned pilot whales are likely to occur before January 1, 2025.

In summary, we are delaying the effective date for the terminal gear requirements contained in 50 CFR part 229.36(d) in the amended PLTRP published on June 6, 2023 (88 FR 36965) for 6 months, until January 1, 2025, due to hook manufacturing delays. This delay in effective date will allow pelagic longline fishermen to purchase compliant hooks, once available, and to phase in their use. Although delaying the effective date will delay marine mammal protections afforded by the regulation, the impact is expected to be minor. We intend to provide no further extensions of the effective date beyond January 1, 2025.

Administrative Procedure Act

The Assistant Administrator for Fisheries (AA) finds that there is good cause to waive the requirements to provide prior notice and opportunity for public comment pursuant to the authority set forth in 5 U.S.C. 553(b)(B), because prior notice and opportunity for public comment on this temporary delay is unnecessary and contrary to the public interest. Such procedures are unnecessary because the rule that published at 88 FR 36965 on June 6, 2023, has already been subject to notice and comment, and all that remains is to notify the public of this delay in the effective date of the previously noticed regulations. Providing additional prior notice and opportunity for public comment is contrary to the public interest because there is a need to immediately implement this action to delay the July 8, 2024, the effective date of the terminal gear requirements contained in 50 CFR 229.36(d) and to provide notice of the delay to affected fishery participants. Failure to extend the effective date risks inflicting potentially serious economic costs on the fishing industry, which were not intended or analyzed when the final rule was published, in the form of missed fishing opportunities and higher gear transition costs. We are temporarily delaying the effective date (see **DATES** section) of the regulatory requirements contained in 50 CFR 229.36(d) to provide fishers with additional time to obtain and incorporate newly manufactured hooks that meet the regulatory specifications.

For these same reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

References

Hayes, S.A., Josephson, E., Maze-Foley, K., Rosel, P.E., and Wallace, J. 2022. U.S. Atlantic and Gulf of Mexico Marine Mammal Stock Assessments 2021. NOAA Technical Memorandum NMFS–NE–288.

Authority: 16 U.S.C. 1361 *et seq.*

Dated: June 25, 2024.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2024–14279 Filed 7–3–24; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 89, No. 129
Friday, July 5, 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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1696; Project Identifier MCAI–2023–01234–A]

RIN 2120–AA64

Airworthiness Directives; Diamond Aircraft Industries Inc. (Type Certificate Previously Held by Diamond Aircraft Industries GmbH) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2009–10–04, which applies to certain Diamond Aircraft Industries GmbH (type certificate now held by Diamond Aircraft Industries Inc.) Model DA 40 and DA 40 F airplanes. AD 2009–10–04 requires repetitively inspecting the nose landing gear (NLG) leg for cracks and replacing the NLG leg if cracks are found. Since the FAA issued AD 2009–10–04, Transport Canada updated mandatory continuing airworthiness information (MCAI) to correct this unsafe condition on these products. This proposed AD results from changes made to the part replacement options and the repetitive inspections. This proposed AD would require doing repetitive detailed inspections of the NLG leg pivot axle for cracking and if cracking is found replacing that part with a serviceable part. This proposed AD would also require eventually replacing all NLG legs having certain part numbers with serviceable parts, if not already done, and prohibit installing affected parts. Replacing affected parts with serviceable parts would be terminating action for the repetitive inspections specified in this proposed AD. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by August 19, 2024.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–1696; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the MCAI, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For Diamond Aircraft Industries material, contact Diamond Aircraft Industries Inc., 1560 Crumlin Sideroad, London, ON, Canada, N5V 1S2; phone: (519) 457–4041; email: *support-canada@diamondaircraft.com;* website: *diamondaircraft.com*.
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

FOR FURTHER INFORMATION CONTACT: Gabriel Kim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7300; email: *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2024–1696; Project Identifier MCAI–2023–01234–A'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this 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 this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Gabriel Kim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2009–10–04, Amendment 39–15899 (74 FR 22435, May 13, 2009) (AD 2009–10–04), for certain Diamond Aircraft Industries GmbH (type certificate now held by Diamond Aircraft Industries Inc.) Model DA 40 and DA 40 F airplanes. AD 2009–10–04 was prompted by MCAI originated by the European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union. EASA issued AD 2009–0016, dated January 22, 2009 (EASA AD 2009–0016), to address fatigue cracking of the NLG leg part number (P/N) D41–3223–10–00 at the pivot axle.

AD 2009–10–04 superseded and maintains the requirements of AD 2007–17–06, Amendment 39–15164 (72 FR 46549, August 21, 2007), which required repetitively inspecting the NLG leg for cracks and replacing the NLG leg if cracks are found. The FAA issued AD 2009–10–04 to exclude from the applicability any airplanes that have the improved NLG leg installed.

Actions Since AD 2009–10–04 Was Issued

Effective November 15, 2017, the design and oversight responsibilities for the Model DA 40, DA 40 F, and DA 40 D airplanes were transferred from Diamond Aircraft Industries GmbH of Austria as the design approval holder, and EASA as the civil aviation authority, to Diamond Aircraft Industries Inc. (Diamond), of Canada as the new design approval holder, and Transport Canada as the civil aviation authority. After that transition, Transport Canada received several in-service reports of P/N D41–3223–10–00_1 cracking at the pivot axle and in some cases, fracture of the NLG leg. Investigation revealed that the failures were the result of fatigue cracking.

Since the FAA issued AD 2009–10–04, Transport Canada superseded EASA AD 2009–0016 and issued Transport Canada AD CF–2023–50, dated July 10, 2023 (Transport Canada AD CF–2023–50), to address failure of the NLG leg at the pivot axle by requiring initial and repetitive detailed inspections of NLG leg P/N D41–3223–10–00 and P/N D41–3223–10–00_1 to detect cracking, replacing a NLG leg, as required, with a serviceable part, and prohibiting the installation of NLG leg P/N D41–3223–10–00 or P/N D41–3223–10–00_1 as a replacement part.

Transport Canada AD CF–2023–20 differed from the Diamond material because Transport Canada AD CF–2023–20 required a detailed inspection of the pivot axle of the NLG leg P/N D41–3223–10–00 and P/N D41–3223–10–00_1 using a bright light and 10X magnifying glass instead of Type II visible dye for the inspection of the pivot axle. After Transport Canada AD CF–2023–50 was issued, the repetitive inspection interval was increased from 100 hours air time to 110 hours air time to align with the scheduled 100-hour inspection in chapter 5 of the DA 40 series Airplane Maintenance Manual. To require the change to Transport Canada AD CF–2023–50, Transport Canada issued AD CF–2023–50R1, dated November 29, 2023 (also referred to as the MCAI). The MCAI was published to address the time interval change of the repetitive inspection from 100-hour intervals to 110-hour intervals.

You may examine the MCAI in the AD docket at regulations.gov under Docket No. FAA–2024–1696.

Related Material Under 1 CFR Part 51

The FAA reviewed Diamond Mandatory Service Bulletin MSB 40–091 Rev. 0, dated January 18, 2021, published with Diamond Aircraft Industries Work Instruction WI–MSB 40–091 Rev. 0, dated January 18, 2021 (issued as one document). This material specifies procedures for doing repetitive dye penetrant inspections of the NLG leg pivot axle for cracking and replacing the NLG for Model DA 40 airplanes.

The FAA also reviewed Diamond Mandatory Service Bulletin MSB F4–038 Rev. 0, dated January 18, 2021, published with Diamond Aircraft Industries Work Instruction WI–MSB F4–038 Rev. 0, dated January 18, 2021 (issued as one document). This material specifies procedures for doing repetitive dye penetrant detailed inspections of the NLG leg pivot axle for cracking and replacing the NLG for Model DA 40 F airplanes.

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and material referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain none of the requirements of AD 2009–10–04. This proposed AD would require doing repetitive detailed inspections of the NLG leg pivot axle for cracking and if cracking is found replacing that part with a serviceable part. This proposed AD would require eventually replacing all NLG legs having certain part numbers with serviceable parts, if not already done, and prohibiting installing affected parts. Replacing affected parts with serviceable parts would be terminating action for the repetitive inspections that would be required by this proposed AD.

Differences Between This Proposed AD, the MCAI, and the Material

The MCAI applies to Model DA 40 D airplanes, however, this proposed AD would not because that model does not have an FAA type certificate.

Although the Diamond material specifies to do dye penetrant inspections, the MCAI requires, and this proposed AD would require, using a bright light (minimum of 100 foot-candles) and 10X magnifying glass instead of dye penetrant.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 693 airplanes of U.S. registry.

The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per airplane	Cost on U.S. operators
Inspect NLG leg pivot axle.	1 work-hour × $85 per hour = $85 per inspection cycle.	$50 per inspection cycle.	$135 per inspection cycle.	Up to $93,555 per inspection cycle.
Replace NLG leg	2 work-hours × $85 per hour = $170	$3,900	$4,070	Up to $2,820,510.

The costs of the proposed inspection and replacement of the NLG leg are based on all airplanes having an affected NLG installed. The FAA has no way of determining the number of airplanes that have the affected NLG installed, and those that do not have one installed would only be affected by the installation prohibition.

The FAA has included all known costs in its cost estimate. According to

the manufacturer, however, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have 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.

For the reasons discussed above, I certify that the proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2009–10–04, Amendment 39–15899 (74 FR 22435, May 13, 2009); and

■ b. Adding the following new airworthiness directive:

Diamond Aircraft Industries Inc. (Type Certificate Previously Held by Diamond Aircraft Industries GmbH): Docket No. FAA–2024–1696; Project Identifier MCAI–2023–01234–A.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by August 19, 2024.

(b) Affected ADs

This AD replaces AD 2009–10–04, Amendment 39–15899 (74 FR 22435, May 13, 2009) (AD 2009–10–04).

(c) Applicability

This AD applies to Diamond Aircraft Industries Inc. (type certificate previously held by Diamond Aircraft Industries GmbH) Model DA 40 and DA 40F airplanes, all serial numbers, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 3220, Nose/Tail Landing Gear.

(e) Unsafe Condition

This AD was prompted by failure of a NLG in the area of the pivot axle. The unsafe condition, if not addressed, could lead to damage to the airplane and injury to occupants.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Definitions

For the purposes of this AD the definitions in paragraphs (g)(1) through (3) of this AD apply:

(1) An ''affected part'' is an NLG leg having either P/N D41–3223–10–00 or P/N D41–3223–10–00_1.

(2) A ''serviceable part'' is an NLG leg that is not an affected part. NLG legs having P/N D41–3223–10–00_2 or P/N D41–3223–10–00_3 are considered serviceable parts.

(3) The ''applicable mandatory service bulletin (MSB) for your airplane'' is:

(i) For Model DA 40 airplanes: Diamond Aircraft Industries Mandatory Service Bulletin MSB 40–091 Rev. 0, dated January 18, 2021, published with Diamond Aircraft Industries Work Instruction WI–MSB 40–091 Rev. 0, dated January 18, 2021 (issued as one document).

(ii) For Model DA 40 F airplanes: Diamond Aircraft Industries Mandatory Service Bulletin MSB F4–038 Rev. 0, dated January 18, 2021, published with Diamond Aircraft Industries Work Instruction WI–MSB F4–038 Rev. 0, dated January 18, 2021 (issued as one document).

(h) Required Actions

For all airplanes with an affected part installed, do the applicable actions specified in paragraphs (h)(1) and (2) of this AD.

(1) Within 25 hours time-in-service (TIS) or 30 days after the effective date of this AD, whichever occurs first, and thereafter at intervals not to exceed 110 hours TIS, perform the actions required by paragraphs (h)(1)(i) through (v) of this AD:

(i) Prepare the airplane for inspection of the pivot axle of the affected part in accordance with Section III, Paragraphs 1 through 4, of the Work Instruction of the applicable MSB for your airplane.

(ii) Clean the pivot axle of the affected part ensuring that any visible dye inspection residue is removed.

Note 1 to paragraph (h)(1)(ii): Paragraph 5–63, Cleaners and Applicators, of Chapter 5, Nondestructive Inspection (NDI), Section 5, Penetrant Inspection, of FAA Advisory Circular 43.13–1B, ''Acceptable Methods, Techniques, and Practices—Aircraft Inspection and Repair,'' Change 1, dated September 8, 1998, provides guidance regarding an approved cleaning method.

(iii) Perform a detailed inspection of the pivot axle of the affected part using a bright light (minimum of 100 foot-candles) and 10X magnifying glass to detect cracking, paying special attention to the radius at the top of the pivot axle as shown in Figure 1 of the Work Instruction of the applicable MSB for your airplane, except where Figure 1 refers to a ''dye penetrant inspection'' this AD does not require that type of inspection.

(iv) If any cracking is found during any inspection required by paragraph (h)(1)(iii) of this AD, before further flight, replace the affected part with a serviceable part, and reinstall the nose wheel fork in accordance with Section III, Paragraphs 8 through 12 of the Work Instruction of the applicable MSB for your airplane.

(v) If no cracking is found during any inspection required by paragraph (h)(1)(iii) of this AD and the compliance time specified in paragraph (h)(2) of this AD has not been exceeded, the affected part can remain installed until the compliance time specified in paragraph (h)(2) of this AD is reached. Reinstall the nose wheel fork in accordance with Section III, Paragraphs 8 through 12, of the Work Instruction of the applicable MSB for your airplane.

(2) Within 2,500 hours TIS or 24 months after the effective date of this AD, whichever occurs first, replace an affected part with a serviceable part. This part replacement is terminating action for the repetitive inspections required by paragraph (h)(1) of this AD.

(i) Parts Installation Prohibition

As of the effective date of this AD, do not install an affected part on any airplane.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local

Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (k)(1) of this AD or email to: *9-AVS-AIR-730-AMOC@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local Flight Standards District Office/certificate holding district office.

(k) Additional Information

(1) For more information about this AD, contact Gabriel Kim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7300; email: *9-avs-nyaco-cos@faa.gov.*

(2) FAA Advisory Circular 43.13–1B, ''Acceptable Methods, Techniques, and Practices—Aircraft Inspection and Repair,'' Change 1, dated September 8, 1998, may be found at *drs.faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Diamond Aircraft Industries Mandatory Service Bulletin MSB 40–091 Rev. 0, dated January 18, 2021, published with Diamond Aircraft Industries Work Instruction WI–MSB 40–091 Rev. 0, dated January 18, 2021 (issued as one document).

(ii) Diamond Aircraft Industries Mandatory Service Bulletin MSB F4–038 Rev.0, dated January 18, 2021, published with Diamond Aircraft Industries Work Instruction WI–MSB F4–038 Rev. 0, dated January 18, 2021 (issued as one document).

(3) For Diamond Aircraft Industries material contact Diamond Aircraft Industries Inc., 1560 Crumlin Sideroad, London, ON, Canada, N5V 1S2; phone: (519) 457–4041; email: *support-canada@diamondaircraft.com;* website: *diamondaircraft.com.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on June 21, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–14140 Filed 7–3–24; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 40

RIN 3038–AF14

Event Contracts

AGENCY: Commodity Futures Trading Commission.

ACTION: Extension of comment period.

SUMMARY: On May 10, 2024, the Commodity Futures Trading Commission (''Commission'' or ''CFTC'') issued a notice of proposed rulemaking (''NPRM'') titled Event Contracts. The comment period for the NPRM was scheduled to close on July 9, 2024. The Commission is extending the comment period for the NPRM by an additional thirty days.

DATES: The comment period for the NPRM titled Event Contracts is extended through August 8, 2024.

ADDRESSES: You may submit comments, identified by ''Event Contracts, RIN 3038–AF14,'' by any of the following methods:

- *CFTC Comments Portal: https://comments.cftc.gov/.* Select the ''Submit Comments'' link for this rulemaking and follow the instructions on the Public Comment Form.
- *Mail:* Send to Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Follow the same instructions as for Mail, above.

Please submit your comments using only one of these methods. To avoid possible delays with mail or in-person deliveries, submissions through the CFTC Comments Portal are encouraged.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *https://comments.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act (''FOIA''), a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations. *See* 17 CFR 145.9.

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse, or remove any or all of your submission from *https://comments.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the FOIA.

FOR FURTHER INFORMATION CONTACT: Nora Flood, Chief Counsel, Division of Market Oversight, Commodity Futures Trading Commission, (202) 418–6059, *nflood@cftc.gov,* Three Lafayette Centre, 1151 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION: On May 10, 2024, the Commission approved proposed amendments to its rules concerning event contracts in certain excluded commodities.[1] The proposed amendments would further specify types of event contracts that fall within the scope of section 5c(c)(5)(C) of the Commodity Exchange Act (''CEA'') and are contrary to the public interest, such that they may not be listed for trading or accepted for clearing on or through a CFTC-registered entity. Among other things, the proposed amendments would further specify the types of event contracts that involve ''gaming.'' In addition, the proposed amendments would further align the language of the Commission's event contract rules with the statutory text of CEA section 5c(c)(5)(C), and make certain technical changes to the rules in order to enhance clarity and organization.

The NPRM was published on the Commission's website on May 10, 2024, and was made available for public comment through July 9, 2024, for a total comment period of 60 days.[2] The NPRM was subsequently published in the **Federal Register** on June 10, 2024.[3] The Commission is extending the comment period by an additional thirty days, until August 8, 2024, in order to allow interested persons additional time to analyze the proposal and prepare their comments.

Issued in Washington, DC, on June 27, 2024, by the Commission.

Christopher Kirkpatrick,

Secretary of the Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

[1] *See* ''CFTC to Hold a Commission Open Meeting May 10,'' CFTC Rel. No. 8906–24, *available at https://www.cftc.gov/PressRoom/PressReleases/8906-24.*

[2] *See* ''CFTC Issues Proposal on Event Contracts,'' CFTC Rel. No. 8907–24, *available at https://www.cftc.gov/PressRoom/PressReleases/8907-24.*

[3] *See* Event Contracts, 89 FR 48968 (June 10, 2024).

Appendix to Event Contracts (Extension of Comment Period)—Commission Voting Summary

On this matter, Chairman Behnam and Commissioners Johnson, Goldsmith Romero, Mersinger, and Pham voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2024–14610 Filed 7–3–24; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 39

[Docket No. RM21–12–000]

Electric Reliability Organization Performance Assessments; Withdrawal

AGENCY: Federal Energy Regulatory Commission.

ACTION: Withdrawal of notice of proposed rulemaking and termination of rulemaking proceeding.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is withdrawing a notice of proposed rulemaking, which proposed to amend its regulations pursuant to section 215 of the Federal Power Act to require the Commission-certified Electric Reliability Organization (ERO) to submit performance assessments every three years; to include in its performance assessment a detailed discussion of any areas of the ERO's responsibilities and activities, or a Regional Entity's delegated functions, beyond those required by the Commission's regulations, that the Commission has identified at least 90 days prior to the expected performance assessment submission date; and to formalize the method for the ERO and Regional Entities to receive and respond to recommendations by the users, owners, and operators of the Bulk-Power System, and other interested parties for improvement of the ERO's operations, activities, oversight, and procedures.

DATES: The notice of proposed rulemaking published in the **Federal Register** at 86 FR 7518 on January 29, 2021, is withdrawn as of July 5, 2024.

FOR FURTHER INFORMATION CONTACT:

Michael Gildea (Technical Information), Office of Electric Reliability, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8420, *michael.gildea@ferc.gov*

Leigh Anne Faugust (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6396, *leigh.faugust@ferc.gov*

SUPPLEMENTARY INFORMATION:

Withdrawal of Notice of Proposed Rulemaking and Termination of Rulemaking Proceeding

1. On January 19, 2021, the Commission issued a notice of proposed rulemaking (NOPR) proposing to revise its regulations regarding the Electric Reliability Organization's (ERO) performance assessments pursuant to section 215 of the Federal Power Act (FPA).[1] The Commission received seven comments in response to the NOPR.[2] After reviewing the comments received, the Commission has decided to retain its existing regulations regarding the ERO's performance assessments. For the reasons set forth below, we are exercising our discretion to withdraw the NOPR and terminate this rulemaking proceeding.

I. Background

A. Commission Regulations on the ERO Performance Assessment

2. Section 215 of the FPA requires the Commission to issue regulations that, among other things, provide for the certification of an entity as the ERO if it meets certain criteria.[3] On February 3, 2006, the Commission issued Order No. 672, which amended the Commission's regulations to implement the requirements of FPA section 215.[4] The specific requirements for the ERO performance assessments are set out in the Commission's regulations in § 39.3(c).[5] On July 20, 2006, the Commission certified NERC as the ERO.[6]

B. NOPR

3. In its NOPR, the Commission proposed to amend its regulations regarding the ERO performance assessments. First, the Commission proposed to require the ERO to submit assessments of its performance every three years instead of every five years. Second, the Commission proposed to add a requirement for the ERO to include in its performance assessment a detailed discussion of any areas of the ERO's responsibilities and activities, or a Regional Entity's delegated functions, beyond those required by the Commission's regulations, that the Commission has identified at least 90 days prior to the expected performance assessment submission date. Finally, the Commission proposed to formalize the method for the ERO and Regional Entities to receive and respond to recommendations by the users, owners, and operators of the Bulk-Power System, and other interested parties for improvement of the ERO's operations, activities, oversight, and procedures.

4. The Commission explained in the NOPR that it believed that the proposals would provide better continuity in its review of the ERO's operations, activities, oversight, procedures, and evaluation of the effectiveness of each Regional Entity in the performance of delegated functions. Further, the Commission explained that shorter performance assessment cycles could provide an opportunity for timelier identification and implementation of potential improvements to ERO performance and improve the efficiency of the overall performance assessment process.[7]

5. Notice of the NOPR was published in the **Federal Register**, 86 FR 7518 (Jan. 29, 2021), with comments due by March 1, 2021.

C. Comments

6. In their joint comments, NERC and the Regional Entities oppose all proposed modifications. They assert that the proposed changes would place undue burden on ERO staff by directing their focus away from key activities that ''would outweigh any potential benefits.'' [8] They explain that the existing five-year performance assessment cycle provides ''greater opportunity to demonstrate evolution of

[1] *Revisions to Regulations on Elec. Reliability Org. Performance Assessments,* Notice of Proposed Rulemaking, 86 FR 7518 (Jan. 29, 2021), 174 FERC ¶ 61,031 (2021).

[2] The North American Electric Reliability Corporation (NERC) and Regional Entities, jointly; the Western Interconnection Regional Advisory Body (WIRAB); the ISO/RTO Council; the American Public Power Association, Edison Electric Institute, Electric Power Supply Association, the Large Public Power Council, National Rural Electric Cooperative Association, and Transmission Access Policy Study Group, jointly (Joint Trade Associations); Public Citizen, Inc. (Public Citizen); and the Foundation for Resilient Societies (Resilient Societies).

[3] 16 U.S.C. 824o.

[4] *Rules Concerning Certification of the Elec. Reliability Org.; and Procedures for the Establishment, Approval, and Enforcement of Elec. Reliability Standards,* Order No. 672, 71 FR 8662 (Feb. 17, 2006), 114 FERC ¶ 61,104, at P 186, *order on reh'g,* Order No. 672–A, 114 FERC ¶ 61,328 (2006).

[5] 18 CFR 39.3(c) (2023).

[6] *N. Am. Elec. Reliability Corp.,* 116 FERC ¶ 61,062, *order on reh'g and compliance,* 117 FERC ¶ 61,126 (2006), *aff'd sub nom. Alcoa Inc.* v. *FERC,* 564 F.3d 1342 (D.C. Cir. 2009) (ERO Certification Order) (certifying NERC as the ERO responsible for the development and enforcement of mandatory Reliability Standards).

[7] NOPR, 174 FERC ¶ 61,031 at P 1.

[8] NERC and Regional Entities Joint Comments at 2.

the ERO than a three-year cycle'' [9] and allows NERC initiatives to come to fruition and be evaluated.[10] NERC and the Regional Entities explain that, due to the time it takes to coordinate with the Regional Entities, incorporate stakeholder feedback, present the draft to the NERC Board of Trustees for approval, and meet with Commission staff on specific questions, a three-year cycle would mean the process would begin two years after the prior assessment ends.[11]

7. Regarding the proposed 90-day advance notice of Commission requested information, NERC and the Regional Entities believe that the NOPR proposal does not consider ''numerous, existing opportunities for coordination and timely feedback from industry, FERC Commissioners, and Commission staff.'' [12] They re-affirm their commitment to the existing oversight process to provide the Commission with ''all information necessary for [the Commission's] evaluation'' of the ERO's ongoing compliance with its certification criteria through the performance assessments.[13]

8. Finally, NERC and the Regional Entities oppose a formal solicitation of stakeholder feedback and recommendations. They say they already provide ''extensive opportunities for stakeholder feedback on ERO operations, activities, oversight, and procedures, including areas for improvement.'' [14] NERC and the Regional Entities explain that they solicit public comment on the draft performance assessment two to three months prior to its filing—asserting that the draft performance assessment is the ''best vehicle to solicit comments . . . because such a posting ensures that comments are grounded in specific activities and issues material to ERO certification and effectiveness.'' [15]

9. WIRAB, Joint Trade Associations, Public Citizen, and Resilient Societies support the proposed changes to the Commission's regulations.[16] The ISO/RTO Council supports the formal solicitation of public feedback.[17] Commenters generally agree that the proposed changes would support the early identification of emerging trends, challenges, and opportunities regarding the ERO's assurance of Bulk-Power System reliability and allow necessary changes to be made in a timelier manner.[18]

II. Discussion

10. The Commission withdraws the NOPR and terminates this proceeding. We appreciate the feedback that the Commission received in response to the NOPR. Considering NERC and the Regional Entities' concerns regarding the scope and implementation of the proposal and the increased burden on the ERO, that NERC will need to expend significant resources to address multiple Commission directives, and that the Commission will need to expend significant resources considering those responsive proposals,[19] we do not believe that modifying the periodicity or procedural requirements for the ERO performance assessments is an efficient use of ERO or Commission resources.

11. Therefore, we exercise our discretion to withdraw the NOPR and terminate this rulemaking proceeding.[20]

The Commission orders: The NOPR is hereby withdrawn and Docket No. RM21–12–000 is hereby terminated.

By the Commission. Commissioner Rosner is not participating.

Issued: June 27, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–14667 Filed 7–3–24; 8:45 am]

BILLING CODE 6717–01–P

[9] *Id.* at 6.

[10] *Id.* at 8.

[11] *Id.* at 11.

[12] *Id.* (referencing NERC and Regional Entities Joint Comments, App. A listing such opportunities (*e.g.,* board meetings, stakeholder meetings, and technical and Reliability Standards working groups)).

[13] *Id.* at 2.

[14] *Id.* at 13.

[15] *Id.* at 14.

[16] *See* WIRAB Comments at 3; Joint Trade Associations Comments at 3–4; Public Citizen Comments at 2–3; and Resilient Societies Comments at 1.

[17] ISO/RTO Council Comments at 2.

[18] *See, e.g.,* WIRAB Comments at 3; Resilient Societies Comments at 4–5; Joint Trade Associations Comments at 3–4.

[19] *See, e.g., Reliability Standards to Address Inverter-Based Resources,* Order No. 901, 88 FR 74250 (Oct. 30, 2023), 185 FERC ¶ 61,042 (2023), (directing revisions to Reliability Standards for inverter-based resources); *Transmission Sys. Planning Performance Requirements for Extreme Weather,* Order No. 896, 88 FR 41262 (June 23, 2023), 183 FERC ¶ 61,191 (2023) (directing revisions to Reliability Standards for transmission system planning); *N. Am. Elec. Reliability Corp.,* 187 FERC ¶ 61,196 (2024) (directing revisions to Reliability Standards to address generator cold weather preparedness).

[20] *See, e.g., Revised Public Utility Filing Requirements for Elec. Quarterly Reports,*169 FERC ¶ 61,236 (2019) (order withdrawing NOPR and terminating rulemaking proceeding); *see also, e.g., Fast-Start Pricing in Markets Operated by Reg'l Transmission Org. and Indep. Sys. Operators,* 161 FERC ¶ 61,293 (2017) (order withdrawing NOPR and terminating rulemaking proceeding).

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 2

[ET Docket No. 24–136; FR ID 228432]

Promoting the Integrity and Security of Telecommunications Certification Bodies, Measurement Facilities, and the Equipment Authorization Program

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) proposes to strengthen requirements and oversight relating to telecommunications certification bodies and measurement facilities to help ensure the integrity of these entities for purposes of the equipment authorization, to better protect national security, and to advance the Commission's comprehensive strategy to build a more secure and resilient communications supply chain.

DATES: Comments are due on or before September 3, 2024 and reply comments are due on or before October 3, 2024.

ADDRESSES: You may submit comments, identified by ET Docket No. 24–136, by any of the following methods:

Federal Communications Commission's Website: https://www.fcc.gov/ecfs/. Follow the instructions for submitting comments. *See Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (1988).*

- *Mail:* Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although the Commission continues to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- *People with Disabilities:* Contact the Commission to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Jamie Coleman of the Office of Engineering and Technology, at *Jamie.Coleman@fcc.gov* or 202–418–2705.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking,* ET Docket No. 24–136; FCC 24–58, adopted on May 23, 2024, and released on May 24, 2024. The full text of this document is available for public inspection and can be downloaded at *https://docs.fcc.gov/public/attachments/FCC-24-58A1.pdf.* Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format) by sending an email to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Comment Period and Filing Procedures. Pursuant to sections 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 provided in the **DATES** section of this document. Comments must be filed in ET Docket No. 24–136. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the 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. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.
  - Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
  - U.S. Postal Service first-class, Express, and Priority mail must be addressed to 45 L Street NE, Washington, DC 20554.

Ex Parte Presentations. These proceedings shall be treated as ''permit-but-disclose'' proceedings 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). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Procedural Matters

Regulatory Flexibility Act. The Regulatory Flexibility Act of 1980, as amended (RFA), requires that an agency prepare a regulatory flexibility analysis for notice and comment rulemakings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' 5 U.S.C. 603, 605(b). The RFA, 5 U.S.C. 601–612, was amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, Title II, 110 Stat. 857 (1996). Accordingly, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) concerning the possible/potential impact of the rule and policy changes contained in this document. The IRFA is found in Appendix B of the FCC document, *https://docs.fcc.gov/public/attachments/FCC-24-58A1.pdf.* The Commission invites the general public, in particular small businesses, to comment on the IRFA. Comments must have a separate and distinct heading designating them as responses to the IRFA and must be filed by the deadlines for comments on the Notice of Proposed Rulemaking indicated in the **DATES** section of this document.

Paperwork Reduction Act: This document may contain proposed or modified information collection requirements. Therefore, the Commission seeks comment on potential new or revised information collections subject to the Paperwork Reduction Act of 1995. If the Commission adopts any new or revised information collection requirements, the Commission will publish a notice in the **Federal Register** inviting the general public and the Office of Management and Budget to comment on the information collection requirements, 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 comments on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

Accessing Materials

Providing Accountability Through Transparency Act: Consistent with the Providing Accountability Through Transparency Act, Public Law 1189–9, a summary of the Notice of Proposed Rulemaking will be available at *https://www.fcc.gov/proposed-rulemakings.*

OPEN Government Data Act. The OPEN Government Data Act, requires agencies to make ''public data assets'' available under an open license and as ''open Government data assets,'' *i.e.,* in machine-readable, open format, unencumbered by use restrictions other than intellectual property rights, and based on an open standard that is maintained by a standards organization. 44 U.S.C. 3502(20), (22), 3506(b)(6)(B). This requirement is to be implemented ''in accordance with guidance by the Director'' of the OMB. (OMB has not yet issued final guidance. The term ''public data asset'' means ''a data asset, or part thereof, maintained by the Federal Government that has been, or may be, released to the public, including any data asset, or part thereof, subject to disclosure under [the Freedom of Information Act (FOIA)].'' 44 U.S.C. 3502(22). A ''data asset'' is ''a collection of data elements or data sets that may be grouped together,'' and ''data'' is ''recorded information, regardless of form or the media on which the data is recorded.'' 44 U.S.C. 3502(17), (16).

Synopsis

I. Introduction

1. From 5G networks and Wi-Fi routers to baby monitors and fitness trackers, a wide array of radio-frequency (RF) devices are ubiquitous in Americans' daily lives and across our economy. The FCC's equipment authorization program is tasked with ensuring that all of these devices available to American businesses and consumers comply with our rules regarding, among other things, interference, radio-frequency (RF) emissions, and hearing aid compatibility. To ensure the efficient and effective review of tens of thousands of equipment authorizations annually, the Commission delegates certain important responsibilities to telecommunications certification bodies (TCBs) and measurement facilities (test labs) with regard to implementing our equipment authorization program. Now, as part of ongoing efforts to promote national security and protect our nation's communications equipment supply chain, the Commission has placed significant new national security related responsibilities on TCBs and test labs. By establishing new equipment authorization program rules that prohibit authorization of communications equipment that has been determined to pose an unacceptable risk to the national security of the United States or the security and safety of United States persons, these entities now must help ensure that such prohibited equipment is kept out of our nation's supply chain. Further, these entities are entrusted with receiving and maintaining sensitive and proprietary information regarding communications equipment. In light of these new and ongoing responsibilities and the persistent and evolving threats posed by untrustworthy actors seeking, among other things, to compromise our networks and supply chains, today the Commission seeks to strengthen its requirements for and oversight of TCBs and test labs by proposing new rules that would help ensure the integrity of these entities for purposes of the equipment authorization program, better protect national security, and advance the Commission's comprehensive strategy to build a more secure and resilient communications supply chain. It is vital for the Commission to ensure that these entities are not subject to influence or control by foreign adversaries or other untrustworthy actors that pose a risk to national security.

2. Specifically, the Commission proposes to prohibit from recognition by the FCC and participation in its equipment authorization program, any TCB or test lab in which an entity identified on the Covered List has direct or indirect ownership or control, and prohibit reliance on or use of, for purposes of equipment authorization, any TCB or test lab that is directly or indirectly owned or controlled by any entity on the Covered List or by any third party in which an entity identified on the Covered List has any direct or indirect ownership or control. Considering the national security concerns about entities identified on the Covered List, the Commission also directs the Office of Engineering and Technology (OET) to take swift action to suspend the recognition of any TCB or test lab directly or indirectly owned or controlled by entities identified on the Covered List, thereby preventing such entities from using their owned or controlled labs to undermine its current prohibition on Covered Equipment. Next, the Commission seeks comment on prohibiting recognition of any TCB or test lab directly or indirectly owned or controlled by a foreign adversary or any other entity that has been found to pose a risk to national security. To that end, and consistent with Commission action in other recent national security proceedings, the Commission seeks comment on whether and how it should consider national security determinations made in other Executive Branch agency lists in establishing eligibility qualifications for FCC recognition of a TCB or a test lab in its equipment authorization program. In addition, the Commission proposes that the prohibition would be triggered by direct or indirect ownership or control of 10% or more and, to help ensure that it has the information to enforce this requirement, TCBs and test labs would be required to report direct or indirect equity and/or voting interest of 5% or greater by any entity. Further, to implement the proposed national security prohibition, to ensure the integrity of the equipment authorization program and the impartiality of the TCBs and test labs within it, the Commission proposes to collect additional ownership and control information from TCBs and test labs. The Commission also seeks comment on other revisions concerning TCBs and test labs as the Commission seeks to address these issues.

II. Background

3. The Commission's equipment authorization program, codified in the Commission's part 2 rules, plays a critical role in enabling the Commission to carry out its responsibilities under the Communications Act. Under section 302 of the Communications Act, the Commission is authorized to make reasonable regulations governing the interference potential of equipment that emit radiofrequency (RF) energy and that can cause harmful interference to radio communications, which are implemented through the equipment authorization program. In addition, the equipment authorization program helps ensure that communications equipment comply with certain other policy objectives—which include protecting the communications networks and supply chain from equipment that poses an unacceptable risk to national security.

4. Communications equipment must comply with the requirements under part 2 before they can be marketed in or imported to the United States. Under 47 U.S.C. 302a(e), the Commission has delegated certain important responsibilities to TCBs and test labs with regard to implementing the Commission's equipment authorization program.

A. Telecommunications Certification Bodies and Test Labs

5. *Telecommunications Certification Bodies (TCBs).* The Commission's rules specify the qualification criteria for TCBs and assign TCBs responsibility for issuing equipment certifications under Commission direction and oversight. In authorizing the use of TCBs, the Commission sought to speed the process for bringing new technologies to market while also adopting an oversight framework to ensure that the TCBs act impartially and consistent with their responsibilities. The creation and use of TCBs in the equipment authorization process allowed the Commission to implement Mutual Recognition Agreements (MRAs) with the European Union, the Asia-Pacific Economic Cooperation, and other foreign trade partners.

6. TCBs are responsible for reviewing and evaluating applications for equipment certification for compliance with the Commission's applicable requirements (including technical compliance testing and other requirements) and determining whether to grant or to dismiss the application based on whether it is in accord with Commission requirements. TCBs must meet all the appropriate specifications in the ISO/IEC 17065 standard, which include requirements to ensure that TCBs carry out their responsibilities in a ''competent, consistent, and impartial manner.'' Commission rules also impose certain obligations on each TCB to perform post-market surveillance, based

on ''type testing a certain number of samples of the total number of product types'' that the TCB has certified.

7. To carry out their prescribed equipment certification responsibilities, under current rules TCBs must be accredited based on determinations made by a Commission-recognized accreditation body and recognized by the Commission before they are authorized to evaluate applications for equipment authorization. Under Commission rules, TCBs must be located in the United States or in countries that have entered into applicable Mutual Recognition Agreements (MRAs) with the United States.

8. For TCBs located outside of the United States, designation is authorized in accordance with the terms of an effective bilateral or multilateral MRA to which the United States is a party. Pursuant to each MRA, participating countries agree to accept the equipment authorizations performed by the TCB-equivalent conformity assessment body of the other country. There are 15 FCC-recognized Designating Authorities in MRA-partnered countries. These Designating Authorities are governmental organizations associated with MRA-partnered economies. Currently there are 40 FCC-recognized TCBs, the majority of which are located in the United States and the rest are located in nine MRA-partnered countries.

9. Finally, the Commission will withdraw recognition of a TCB if the TCB's designation or accreditation is withdrawn, the Commission determines that there is ''just cause,'' or the TCB requests that it no longer hold a recognition. The Commission's rules also set forth specific procedures, including notification requirements, that the Commission will follow if it intends to withdraw its recognition of a TCB.

10. *Test labs.* Test labs ensure that subject equipment complies with the Commission's applicable technical rules to minimize the risk of harmful interference, promote efficient use of spectrum, and advance other policy goals, such as ensuring hearing aid compatibility and controlling the environmental effects of RF radiation. The role and responsibilities of test labs specifically concern the development of technical reports on testing equipment for which authorization is sought for compliance with the Commission's applicable technical requirements. Applicants for equipment certification provide the testing data to a TCB to show compliance with the FCC requirements.

11. For all granted applications, the TCBs must send to the FCC any test lab data and other information relied upon by the TCB. This information is made publicly available on the FCC website upon grant of the equipment authorization. Under the Commission's rules, test labs do not have any role or responsibility for making any certification decision on whether the equipment would be in compliance, nor do they have any role with respect to any other certification determination, including on whether the equipment constitutes ''covered'' equipment; all certification activities (evaluation, review, and decisional determinations) are reserved for TCBs.

12. Under Commission rules, testing for equipment certification can only be performed by a test lab that has been accredited by an FCC-recognized accreditation body and recognized by the Commission. Applicable rules require that these test labs be accredited based on ISO/IEC 17025. The Commission's rules require that entities wishing to become a recognized laboratory accreditation body must submit a written request to the Chief of OET and submit evidence concerning their credentials and qualifications to perform accreditation of laboratories that test equipment to Commission requirements, consistent with the technical requirements set forth under section 2.948(e). Applicants must successfully complete and submit a peer review. Under the ISO/IEC 17011 standard, accreditation body applicants must meet specified impartiality, management, and accreditation requirements, and otherwise meet accreditation body responsibilities. OET publishes its findings and maintains a web page on FCC-recognized accreditation bodies.

13. The Commission notes, however, that its rules do not currently require accreditation and FCC recognition of test labs that are relied upon as part of the Supplier's Declaration of Conformity (SDoC) process for obtaining an equipment authorization. In 2017, the Commission revised its rules to no longer require testing by accredited and FCC-recognized test labs for equipment with a reduced potential to cause harmful interference authorized in the SDoC process. The SDOC process applies, generally, to equipment that does not contain a radio transmitter and contains only digital circuitry—such as computer peripherals, microwave ovens, ISM equipment, switching power supplies, LED light bulbs, radio receivers, and TV interface devices.

14. The Commission recognizes four accreditation bodies in the U.S. that can designate test labs that operate in the United States. As for accreditation of test labs outside of the United States in countries that have entered into an MRA, § 2.948(f)(1) provides that test lab accreditation will be acceptable if the accredited laboratory has been designated by a foreign designating authority and recognized by the Commission under the terms of an MRA. Currently there are 24 such FCC-recognized test lab accreditation bodies outside the United States, located in 23 different MRA-partnered countries.

15. The Commission has a separate rule provision concerning the accreditation bodies that are permitted to accredit test labs in countries that do not have an MRA with the United States. If the test lab is located in a country that does not have an MRA with the United States, then the test lab must be accredited by an organization recognized by the Commission to perform accreditations in non-MRA countries. Currently, the Commission has recognized three such accrediting bodies. In response to requests from industry for clarifying the process by which test labs are accredited in non-MRA countries, the Commission in 2016 directed OET to provided clearer guidance on accreditation of test labs in non-MRA-partnered countries. Current rules do not preclude an accreditation body that is not in an MRA-partnered country from submitting a request to be recognized, but, to date, no accreditation body outside of an MRA-partnered economy has submitted a request for FCC recognition.

16. Under the Commission rules, if a test lab has been accredited for the appropriate scope for the types of equipment that it will test, then it ''shall be deemed competent to test and submit test data for equipment subject to certification.'' Test labs must be reassessed at least every two years. Under current procedures, if the accreditation body re-assesses the test lab and concludes that it continues to meet the requirements set forth under ISO/IEC 17025, the accreditation body will update the expiration date for the test lab's accreditation in the FCC's Equipment Authorization Electronic System (EAS) for a period of up to two years. While the Commission's rules currently provide procedures for FCC recognition of test lab accreditation bodies, its rules do not currently include specific Commission rules or procedures for withdrawing recognition of a test lab accreditation body.

17. The Commission maintains a list of FCC-recognized accredited test labs on its website, which currently lists nearly 640 test labs. Currently, MRA-

partnered economies have the most FCC-recognized test labs, while there are also are many test labs in countries in economies that have not entered an MRA with the United States.

B. Recent Commission Actions

18. *The EA Security R&O and FNPRM.* On November 11, 2022, the Commission adopted the *EA Security Report and Order, Order, and Further Notice of Proposed Rulemaking.* (*Final Rule,* 88 FR 7592 (February 6, 2023); *Notice of Proposed Rulemaking,* 88 FR 14312 (March 8, 2023)). Specifically, the Commission established several new rules to prohibit authorization of communications equipment identified on the Commission's Covered List (''covered'' equipment) developed pursuant to the Secure Networks Act. The Covered List identifies certain types of communications equipment produced by particular entities—currently, Huawei, ZTE, Hytera, Hikvision, and Dahua (and their respective subsidiaries and affiliates), as well as certain services provided by particular entities. This list is derived from specific determinations made by enumerated sources, including certain Executive Branch agencies and Congress, under the Secure Network Act, that certain equipment poses an unacceptable risk to national security. *The EA Security R&O* revised part 2 of the Commission's rules concerning equipment authorization requirements and processes. To help implement the prohibition on authorization of any ''covered'' equipment, applicants seeking equipment authorization are required to make certain attestations (in the form of certifications) about the equipment for which they seek authorization. These include attesting that the equipment is not prohibited from receiving authorization and whether the applicant is an entity identified on the Covered List as an entity producing ''covered'' communications equipment. TCBs, pursuant to their responsibilities as part of the Commission's equipment authorization program, review the applications and must ensure that only applications that meet all of the Commission's applicable technical and non-technical requirements are ultimately granted, and that none of these grants are for prohibited equipment.

19. In affirming in the *EA Security R&O* its authority to prohibit authorization of communications equipment that had been placed on the Covered List, the Commission also noted that it has broad statutory authority, predating the Secure Networks Act and the Secure Equipment Act, under sections 302 and 303(e) of the Communications Act and other statutory provisions, to take into account national security concerns when promoting the public interest.

20. *Other Recent Commission Actions.* Since adoption of the *EA Security R&O, Order, and FNPRM* in November 2022, the Commission has taken several additional steps to address evolving national security concerns to protect the security of America's critical communications networks and supply chains. In April 2023, in the *Evolving Risks Order and NPRM* (*Final Rule,* 88 FR 85514 (December 8. 2023), *Proposed Rule,* 88 FR 50486 (August 1, 2023)), the Commission took additional steps to protect the nation's telecommunications infrastructure from threats in an evolving national security and law enforcement landscape by proposing comprehensive changes to the Commission's rules that allow carriers to provide international telecommunications service pursuant to section 214 of the Communications Act. The Commission proposed, among other things, to adopt a renewal framework or, in the alternative, a formalized periodic review process for all international section 214 authorization holders. The Commission stated that, in view of the evolving national security and law enforcement concerns identified in its recent proceedings revoking the section 214 authorizations of certain providers controlled by the Chinese government, it believes that a formalized system of periodically reassessing international section 214 authorizations would better ensure that international section 214 authorizations, once granted, continue to serve the public interest. In the *Evolving Risks Order,* the Commission required all international section 214 authorization holders to respond to a one-time collection to update the Commission's records regarding their foreign ownership, noting that ''the information will assist the Commission in developing a timely and effective process for prioritizing the review of international section 214 authorizations that are most likely to raise national security, law enforcement, foreign policy, and/or trade policy concerns.'' In the *Evolving Risks NPRM,* the Commission proposed, among other things, to prioritize the renewal applications or any periodic review filings and deadlines based on, for example, ''reportable foreign ownership, including any reportable foreign interest holder that is a citizen of a foreign adversary country,'' as defined in the Commerce Department's rule, 15 CFR 7.4. The Commission also sought comment on whether to revise its ownership reporting threshold, currently set at 10% or greater direct and indirect equity and/or voting interests, to 5%, noting that the current 10% threshold may not capture all of the foreign interests that may present national security, law enforcement foreign policy, and/or trade policy concerns in today's national security and law enforcement environment. The Commission also proposed, among other things, to require applicants to certify in their application whether or not they use equipment or services identified in the Commission's Covered List. The Commission stated that it intends to continue to collaborate with the relevant Executive Branch agencies and refer matters to the Executive Branch agencies where warranted.

21. On March 14, 2024, the Commission adopted the *Cybersecurity IoT Labeling R&O* to strengthen the nation's cybersecurity protections by adopting a voluntary cybersecurity labeling program for wireless Internet of Things (IoT) products. Through this IoT Labeling Program, the Commission will provide consumers with an FCC IoT label that includes the U.S. government certification mark (referred to as the Cyber Trust Mark) that provides assurances that an IoT product that bears the FCC IoT Label meets certain minimum cybersecurity standards and strengthens the chain of connected IoT products in their own homes and as part of a larger national IoT ecosystem. The Order established a new administrative framework and regulatory structure to implement this voluntary program, with the Commission having program oversight while delegating certain responsibilities to new Cybersecurity Labeling Administrators and FCC-recognized testing labs (*e.g.,* Cybersecurity Testing Labs) to evaluate whether particular IoT devices and products meet the prescribed criteria for obtaining the Cyber Trust Mark. Among other things, the Commission also determined that entities that are owned, controlled by, or affiliated with ''foreign adversaries,'' as defined by the Department of Commerce, should be ineligible for purposes of the Commission's voluntary IoT Labeling Program. The Commission also generally prohibited entities that produce equipment on the Covered List, as well as entities named on the DOD's list of Chinese military companies or the Department of Commerce's Entity List, from any participation in the IoT Labeling Program. Also, the Commission specifically prohibited any

of these entities from serving as a Cybersecurity Label Administrator or serving as an FCC-recognized test lab for testing products for compliance with forthcoming cybersecurity technical standards. The Commission concluded that these lists represent the determination of relevant Federal agencies that entities on these lists may pose a national security threat within their respective areas, and that it is not in the public interest to permit these entities to provide assurance to the public that their products meet the new cybersecurity standards for obtaining a Cyber Trust Mark.

III. Discussion

22. In this NPRM, the Commission proposes and seeks comment on potential revisions to the Commission's rules designed to promote the integrity of its equipment authorization program and ensure that it serves the Commission's goals in protecting the communications equipment supply chain from entities posing unacceptable national security concerns. First, the Commission proposes to prohibit from recognition by the FCC and participation in the equipment authorization program, any TCB or test lab in which an entity identified on the Covered List (*i.e.,* any named entity or any of its subsidiaries or affiliates) has direct or indirect ownership or control. Second, the Commission seeks comment on the extent to which it should impose eligibility restrictions for TCBs and test labs based on lists developed by Executive Branch agencies that reflect expert determinations about entities that pose national security risks. Third, the Commission proposes and seeks comment on collecting various ownership information from TCBs and test labs to strengthen our oversight and implement any affiliation prohibitions that may be adopted. Fourth, the Commission seeks comment on other aspects associated with implementation of its proposals as well as other considerations to strengthen the Commission's oversight of TCBs and test labs. These include clarification of current rules and applicable standards to ensure the impartiality and integrity of TCBs.

A. Prohibiting Recognition of TCBs and Test Labs in Which Entities Identified on the Covered List Have Direct or Indirect Ownership or Control

23. In 2022 in the *EA Security R&O* the Commission adopted rules to prohibit authorization of certain equipment produced by entities named on the Covered List and adopted supply chain protections that include new informational requirements that seek to ensure that these untrustworthy entities do not adversely influence certification of equipment that poses unacceptable national security risks. The Covered List is derived from specific determinations made by certain enumerated sources (particular Executive Branch agencies with national security expertise and Congress) under the Secure Networks Act that certain equipment poses an unacceptable risk to national security. Congress has also made determinations in the Secure Networks Act that certain of these entities and their equipment pose an unacceptable risk to national security. In the future, Executive Branch agencies may add to the Covered List. Even before the Secure Networks Act, the Commission designated Huawei and ZTE (along with their parents, affiliates, and subsidiaries) as ''covered companies'' that pose a unique threat to the security and integrity of the nation's communications networks and supply chains because of their close ties to the Chinese government and military, and the security flaws in their equipment.

24. In light of these determinations from expert Executive Branch agencies and Congress about the serious national security risks posed by entities with equipment on the Covered List, the Commission tentatively conclude that the Commission should not recognize or permit reliance on TCBs, test labs, or their accrediting bodies, or permit them to have any role in the Commission's equipment authorization program, if they have sufficiently close ties with Covered List entities. Accordingly, the Commission proposes to restrict the eligibility of entities that may serve as TCBs or test labs based on, at a minimum, the Covered List. Specifically, the Commission proposes to prohibit from recognition by the Commission and participation in its equipment authorization program, any TCB or test lab in which an entity identified on the Covered List (*i.e.,* any named entity or any of its subsidiaries or affiliates) has direct or indirect ownership or control. The Commission's proposed prohibition would preclude the use of such TCBs and test labs, as part of any equipment authorization-related reliance or testing, not only with regard to certification of equipment, but also authorization of equipment pursuant to SDoC procedures. The Commission seeks comment on this proposal.

25. Further, in the interest of national security, and out of an abundance of caution, the Commission finds that it is imperative that it not allow entities identified on its Covered List to use test labs they own or control to circumvent or otherwise undermine the Commission's prohibition on authorization of equipment identified on the Covered List or undermine the integrity of its supply chain. To that end, the Commission notes that OET has taken action to deny the re-recognition of a test lab apparently owned by an entity on the Covered List—Global Compliance and Testing Center of Huawei Technologies—while allowing this test lab to provide additional information on whether it is owned or controlled by Huawei Technologies Company or any other entity on the Covered List, and to show cause why it should be allowed re-recognition. Accordingly, the Commission directs OET to suspend, pending the outcome of this proceeding, recognition of any TCB or test lab for which there is sufficient evidence to conclude such TCB or test lab is owned or controlled by an entity identified on the Covered List, while allowing such TCB or test lab thirty days from the date of such suspension to certify, and provide supporting documentation, that no entity identified on the Covered List holds a 10% or more direct or indirect ownership interest or controlling interest in the TCB or test lab. The Commission believes this action is necessary to protect against additional national security risks to its equipment authorization program and supply chain, including protecting existing manufacturers from unknowing reliance on untrustworthy entities, pending the implementation of the additional ownership disclosures and transparency requirements the Commission proposes in this proceeding. Any burden on existing recognized TCBs or test labs should be minimal, as only those entities for whom OET has reason to question their ownership or control by an entity or entities identified on the Covered List will be impacted, and those TCBs or test labs will be given an opportunity to show cause why their FCC recognition should not be revoked for just cause. As the Commission weighs the importance of its national security against these minimal measures to prevent entities on the Covered List from owning or controlling FCC-recognized TCBs or test labs, the Commission finds that the compelling interest outweighs any burden imposed by such temporary suspension.

B. Prohibiting Recognition of TCBs and Test Labs in Which Other Entities That Raise National Security Concerns Have Direct or Indirect Ownership or Control

26. The Commission also seeks comment on whether there are other types of direct or indirect ownership or

control, or other types of influences beyond the Covered List determinations that potentially could adversely affect a TCB's or test lab's trustworthiness, or otherwise undermine the public's confidence. In recognition that TCBs and test labs have access to proprietary, sometimes sensitive information about suppliers and their devices, the Commission seeks comment on whether, and to what extent, the Commission should apply other lists developed by Executive Branch agencies that reflect expert determinations about entities that pose national security concerns.

27. The Covered List is only one source that identifies entities that raise national security concerns that potentially affect the communications equipment supply chain. Several Executive Branch agencies with particular national security responsibilities, and based upon specific statutory authorities, have recently developed or updated lists that identify entities, technologies, or services that they have determined raise national security concerns.

28. For example, the Department of Commerce maintains a list of ''foreign adversary'' countries that identifies any foreign government or foreign non-government person that the Secretary of Commerce has determined to have engaged in a ''long-term pattern or serious instances of conduct significantly adverse to the national security interest of the United States or security and safety of United States persons.'' The Department of Commerce's list of foreign adversaries currently includes several foreign governments and foreign non-government persons, including China (including Hong Kong), Cuba, Iran, and Russia. As discussed above, the Commission has recently relied in part on this foreign adversary list (as well as the Covered List) in both the *Evolving Risks Order and NPRM* and the *Cybersecurity IoT Labeling R&O,* when making proposals and taking particular actions, respectively, that serve to promote the Commission's national security goals in those proceedings.

29. The Department of Defense (DOD), pursuant to section 1260H of the NDAA of 2021, has identified each entity that the Secretary of Defense has determined is a ''Chinese military company'' that is ''operating directly or indirectly in the United States'' and is ''engaged in providing commercial services, manufacturing, producing, or exporting.'' This DOD list (1260H List) currently includes 73 entities, including three of the five equipment manufacturers listed on the Covered List. Beginning in 2026, pursuant to other statutes, the DOD is prohibited from procurement from companies identified on the 1260H list.

30. Meanwhile, the Department of Commerce's Entity List identifies entities that are reasonably believed to be involved in, or to pose a significant risk of being or becoming involved in, activities contrary to U.S. national security or foreign policy interests. Among other things, the Entity List seeks to ensure that sensitive technologies do not fall into the hands of known threats. As discussed above, in its *Cybersecurity IoT Labeling R&O* the Commission prohibited entities named on DOD's 1260H List or the Department of Commerce's Entity List (as well as entities producing equipment on the Covered List) from any participation in the Commission's IoT Labeling Program.

31. Further, there are various other Executive Branch agency lists that address national security concerns in addition to those above. For instance, the Commerce Department also publishes a Military End User List, which identifies foreign parties that pursuant to the Export Administration Regulations (EAR) are prohibited from receiving particular items, including certain telecommunications equipment and software, unless the exporter secures a license. These parties have been determined by the U.S. Government to be ''military end users,'' and represent an unacceptable risk of use in or diversion to a ''military end use'' or ''military end user'' in China, Russia, or Venezuela. The Department of Treasury's Office of Foreign Assets Control, in coordination with the Department of State and DOD, administers various sanctions programs, including the Non-Specially Designated Nationals Chinese Military-Industrial Complex Companies List (CMIC List), which identifies individuals and companies as operating or having operated in the defense or surveillance technology sector of the People's Republic of China and from which U.S. persons are generally prohibited from purchasing or selling publicly traded securities. In section 5949 of the NDAA for FY 2023, Congress prohibited executive agencies from procuring, obtaining, or contracting with entities to obtain any electronic parts, products, or services that include ''covered semiconductor chips'' produced by three Chinese companies (and their subsidiaries or affiliates). The legislation authorizes DOD and the Commerce Department to designate other ''covered products or services'' if they determine them to be owned, controlled by, or connected to the government of a foreign country of concern, including China, Russia, North Korea, and Iran.

32. The Commission seeks comment on whether, and if so, the extent to which, the Commission should rely upon any of the various lists developed by the Executive Branch agencies that involve particular determinations relating to national security as a source to identify entities that raise national security concerns warranting a prohibition on participation in the Commission's equipment authorization program. While each list is designed to support specific prohibitions or agency objectives, the national security objectives common throughout each may warrant that the Commission take a cautious approach, especially with respect to those products for which relevant Federal agencies have expressed other security concerns. Are any such lists particularly suitable, or ill-fitting, for the equipment authorization context? The Commission also seeks comment on whether it should consider any other Executive Branch agency lists to rely upon as a source to identify entities that raise national security concerns and to restrict participation of those entities in the Commission's equipment authorization program. What other lists or sources of information should the Commission consider?

33. The Commission notes that it has a longstanding policy of according deference to the Executive Branch agencies' expertise in identifying risks to national security and law enforcement interests. With regard to each of these lists, to the extent that commenters recommend consideration of any of these lists with regard to eligibility for recognition of a TCB or test lab, the Commission asks that commenters explain why such eligibility should be restricted based on the list, as well as any other considerations the Commission should take into account in implementing such a restriction. The Commission invites comment on any other issues concerning consideration of any of these lists of Executive Branch determinations.

34. Further, the Commission seeks comment on other determinations on which it should rely to prohibit participation in its equipment authorization program. Specifically, should any ''foreign entity of concern'' as defined by the CHIPS Act be prohibited from participation? What about entities subject to exploitation, influence, or control by the government of a foreign adversary, such as foreign adversary state-owned enterprises,

including their U.S.-based subsidiaries, or entities that conduct research, development, testing, and evaluation in support of the military or intelligence apparatus of a foreign adversary (*i.e.* defense contractors)? What about entities with ownership interests by municipal, state, or other governmental entities within a foreign adversarial country? Are there any other determinations reflecting national security risks and/or practices contrary to U.S. interests, such as entities with documented evidence of human rights abuses, forced labor, and similar practices, including entities who meet the criteria established by the Uyghur Forced Labor Prevention Act? Are there any other determinations the Commission should consider that would indicate the untrustworthiness of an entity in terms of its equipment authorization program?

C. Ownership, Control, or Influence by Entities That Pose an Unacceptable Risk to National Security

35. To further protect the nation's telecommunications infrastructure and communications equipment supply chain from threats in an evolving national security landscape and to ensure the integrity of the equipment authorization program, the Commission proposes and seeks comment on collecting various ownership and control information from TCBs and test labs.

36. The Commission notes that, outside the context of the equipment authorization program, the Commission and other government agencies have routinely adopted rules to identify direct or indirect ownership or control of entities by third parties in order to address national security, competition, or other concerns. The Commission in many cases has required regulated entities to disclose information regarding related parties, whether those other parties control the entity, or have an ownership interest in it, or have some other relationship with the entity that is relevant to the public interest. For example, applicants seeking a new FCC satellite license, a modification of a satellite license, or the assignment or transfer of a satellite license, must disclose certain information both about foreign ownership and corporate ownership. The Commission's rules also require the disclosure of ownership information and corporate ownership information that would assist the Commission's public interest review of applications for international section 214 authority. The Commission notes that in the recent *Evolving Risks Order and NPRM,* the Commission sought comment on revising its ownership reporting threshold, currently set at 10% or greater direct and indirect equity and/or voting interests, to 5%, noting that the current 10% threshold may not capture all of the foreign interests that may present national security, law enforcement foreign policy, and/or trade policy concerns in today's national security and law enforcement environment. With respect to wireless licenses, there are a number of rules requiring applicants and/or licensees to disclose certain information on ownership and control. Similarly, with respect to radio and local television licenses, the Commission's media ownership rules require extensive disclosure of information. The Commission likewise requires that entities seeking small business bidding credits in Commission spectrum license auctions have attributed to them revenues of parties with controlling interests in the entity, as well as other entities that those parties control and other entities within its own control. In addition, such entities will have the revenues of parties with an interest in their spectrum licenses beyond a specified threshold attributed to them as well, to assure that those other parties are not using the entities as a conduit for spectrum access obtained with a bidding credit. In order to enforce these ownership rules, the Commission requires applicants for such licenses to supply certain information.

37. Additionally, the Commission notes that other Executive Branch agencies also require entities to supply information on ownership and control so that the agencies can carry out their statutory responsibilities. For example, in the *2021 Standard Questions Order,* 86 FR 68428 (December 2, 2021), the Commission adopted a set of standardized national security and law enforcement questions (Standard Questions) that certain applicants and petitioners with reportable foreign ownership will be required to answer as part of the Executive Branch review process of their applications and petitions. With respect to such applications or petitions that the Commission accepts for filing and refers to the relevant Executive Branch agencies for their review of any national security, law enforcement, and other concerns related to the foreign ownership, as part of the Commission's public interest review of the application or petition, the applicants and petitioners will be required to provide to the Committee information regarding all entities that hold or will hold an ownership interest of five percent or more in the applicant or petitioner in question. The Commission has noted that this information is important to the Committee's review of applications and petitions referred by the Commission for national security and law enforcement concerns and will assist the Committee's determination whether to recommend to the Commission that grant of the application or petition is consistent with U.S. national security and law enforcement interests. Similarly, the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR) requires certain companies to file premerger notifications with the Federal Trade Commission and the Antitrust Division of the Department of Justice. Companies required to submit a HSR pre-merger notification must supply certain information, including, *inter alia,* information on subsidiaries of the filing entity and minority shareholders of the filing entity and its ultimate parent entity.

38. *TCB and test lab ownership and control reporting requirements.* In order to more effectively protect the Commission's equipment authorization program from the direction or influence of untrustworthy entities and ensure the integrity of the program, the Commission proposes to require any entity seeking to become an FCC-recognized TCB or test lab to submit to the Commission sufficient information for the Commission to determine the TCB's or test lab's ownership and control, consistent with any threshold determinations the Commission may adopt, as proposed in this proceeding.

39. The Commission believes that collection of certain general ownership and control information places the Commission in the best position to evaluate any ownership interest concerns that potentially may be raised regarding an entity's impartiality or trustworthiness, particularly with regard to potential influence by entities that raise national security concerns. Further, the Commission also believes that such ownership information could be relevant to establishing appropriate ''qualifications and standards'' under section 302(e) regarding private entities to which the Commission has delegated and entrusted certain responsibilities as part of its equipment authorization program. The Commission has broad authority under section 302, when delegating certification responsibilities to private organizations such as TCBs and test labs, to ''establish such qualifications and standards as it deems appropriate'' for certification and testing activities. In particular, such data can be instructive in efforts to bolster the integrity of the equipment authorization

program, such as ensuring that TCBs are complying with applicable impartiality requirements and rules targeted at ensuring they are not owned or controlled by a manufacturer whose equipment they must examine.

40. The Commission proposes that each TCB or test lab be required to report direct or indirect equity and/or voting interest in the TCB or test lab of 5% or greater. In other similar information collections, the Commission has agreed with Executive Branch determinations that a 5% threshold is appropriate because in some instances less-than-ten percent foreign ownership interest—or a collection of such interests—may pose a national security or law enforcement risk. The Commission seeks comment on this proposal. Alternatively, the Commission seeks comment on other levels and on whether it should raise or lower the ownership threshold for purposes of disclosure. If the Commission were to require submission of any such ownership information, how should such information be collected (*e.g.,* what particular information in what kind of submissions) and how frequently should this information be reported to the Commission? Should there be a distinction between foreign private ownership vs. foreign governmental ownership? The Commission also seeks comment on evolving ownership and how to ensure that the Commission is timely informed of changes in ownership of TCBs and test labs. Should additional reporting requirements apply to changes in ownership? If so, what thresholds of change should trigger such reporting? The Commission seeks comment on relevant aspects to the information that should be collected.

41. Further, to implement the proposed prohibition of Covered List entities discussed above and align the prohibition with the Commission's equipment authorization program rules regarding prohibited equipment, the Commission proposes to prohibit from recognition by the FCC and participation in its equipment authorization program any TCB or test lab in which an entity identified on the Covered List controls or holds a 10% or more direct or indirect ownership interest. The Commission seeks comment on this proposal. The Commission also invites comment on any other threshold interest level that commenters may believe appropriate, and requests that they provide support for their views. The Commission makes this proposal while noting that, in the *EA Security R&O,* the Commission prohibited authorization of equipment produced by ''affiliates'' of entities named on the Covered List and defined an ''affiliate'' as ''an entity that (directly or indirectly) own or controls, is owned or controlled by, or is under common ownership or control with another entity,'' and defined the term 'own' in this context as to ''have, possess, or otherwise control an equity interest (or the equivalent thereof) of more than 10 percent.'' The Commission therefore proposes to revise the term ''own'' in this context to reflect ten percent or more, rather than more than 10 percent. The Commission seeks comment on this proposal. The Commission further proposes to require that TCBs and test labs that are currently recognized by the FCC must: (1) no later than 30 days after the effective date of any final rules adopted in this proceeding, certify that no entity identified on the Covered List or otherwise specified in the Commission's final rules has direct or indirect ownership or control of the relevant TCB or test lab, and (2) no later than 90 days after the effective date of any final rules adopted in this proceeding identify any entity (including the ultimate parent of such entities) that holds such ownership or control interest as the Commission's final rules require, currently proposed as 5% or more ownership, as discussed above. The Commission proposes to adopt the definition of ''ultimate parent entity'' used in the rules governing pre-merger notifications under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, which defines the ultimate parent entity as ''an entity which is not controlled by any other entity.'' The Commission seeks comment on this proposal. In keeping with this proposal, the Commission also proposes to clarify the requirement that every entity specifically named on the Covered List must provide to the Commission, pursuant to § 2.903(b), information regarding all of its subsidiaries and affiliates, not merely those that produce ''covered'' equipment. Further, the Commission proposes that, if a relevant TCB or test lab does not so certify, or provides a false or inaccurate certification, the Commission would suspend the recognition of any such TCB or test lab and commence action to withdraw FCC recognition under applicable withdrawal procedures, as discussed further below. The Commission seeks any additional comment on these proposals and their implementation.

D. Rule Revisions Concerning TCBs and Test Labs

1. Telecommunications Certification Bodies

42. As discussed above, the Commission proposes to prohibit from recognition by the FCC and participation in its equipment authorization program, any TCB or test lab in which an entity identified on the Covered List controls or holds a 10% or more direct or indirect ownership interest and seeks comment on a similar prohibition with regard to other entities that raise national security concerns. The Commission also proposes to collect certain ownership information from TCBs and test labs. In this section, the Commission proposes and seeks comment on additional issues regarding implementation of its proposed prohibition as well as any other revisions the Commission may adopt in this rulemaking.

43. *Post-market surveillance.* The Commission invites comment on whether it should revise the post-market surveillance rules, policies, or guidance to expressly require such surveillance of granted authorizations, not only with respect to compliance with technical and attestation requirements, but also regarding compliance relating to the prohibition on authorization of ''covered'' equipment. The Commission seeks comment on reasonable practices TCBs could implement to identify erroneous authorizations of ''covered'' equipment. Are there best practices or analogous legal frameworks that could be leveraged here? Should the Commission change the post-market surveillance requirements to require that TCBs review certification grants by other TCBs? Should the Commission require that any post-market surveillance testing be done only by FCC-recognized labs in the United States and/or MRA countries? What other measures should the Commission take to strengthen the integrity of the post-market surveillance process to ensure that prohibited equipment has not been erroneously authorized? The Commission also invites comment on any other revisions that it should consider in light of any revisions that the Commission adopts in this proceeding.

44. *TCB accrediting bodies.* In order for a TCB that is recognized by the FCC to remain so recognized, the TCB's accreditation body must perform an assessment at least every two years to determine that the TCB remains competent to perform the work for the scopes for which it has been recognized. Upon successful completion of the re-

assessment by the accreditation body, the information is sent to the TCB's designating authority, which then updates this continued accreditation in the FCC's EAS database. Neither the ISO/IEC standards nor Commission rules include any specific restrictions on the ownership or control of an accreditation body. MRAs generally focus on the capability of accreditation bodies, and do not include specific provisions or restrictions on ownership other than impartiality.

45. The Commission seeks comment on potential revisions concerning its rules and procedures for recognition and re-recognition of TCB accrediting bodies in light of any revisions that the Commission may adopt in this proceeding. What revisions are needed, if any, to ensure that the accreditation body's assessment of entities seeking to become TCBs includes a review of the TCB's ownership and compliance with any requirements the Commission may adopt in this proceeding?

46. *Accreditation and reassessment of TCBs.* The Commission seeks comment on whether it should clarify or revise its rules or procedures concerning the accreditation of TCBs to ensure that the TCBs can meet their responsibilities. The Commission seeks comment on what particular steps or procedures in the accreditation process could be implemented to examine how TCBs are structured, owned, or managed to safeguard impartiality and otherwise ensure that commercial, financial, or other pressures do not compromise impartiality on certification activities concerning prohibited equipment authorization. Under the Commission's rules, each TCB must be reassessed for continued accreditation at least every two years. If the Commission were to decide to revise any rules or procedures to address impartiality or untrustworthiness concerns along the lines indicated above, the Commission similarly proposes to require any reassessment for continued accreditation to take those issues into account. Accordingly, the Commission seeks comment on the potential clarifications or revisions to the process for the periodic reassessment of TCBs for continued recognition by the Commission. Should, for instance, the Commission provide additional clarity on the reassessment process for submitting the request for reassessment or the review by the accrediting body? Are there other requirements that the Commission should adopt consistent with the issues raised above and the Commission goals in this proceeding?

47. The Commission also seeks comment on whether any clarifications or revision of rules or procedures, either for a new accreditation or a continued accreditation, may implicate or affect U.S. international agreements such as MRAs concerning TCBs and TCB accreditation. Finally, to the extent any commenter proposes further clarification or revisions, the Commission asks that they address any implications under the existing MRAs and whether and how to implement any suggested changes.

48. *FCC recognition of TCBs.* Considering the proposals and approaches the Commission discusses above, the Commission seeks comment on whether it should consider potential revisions to the rules or processes by which the Commission recognizes a TCB following its initial accreditation, and/or the process by which accreditation is subsequently extended on a periodic basis, including any further review the FCC would do to continue to recognize an accredited TCB. Under the Commission's current rules, it will recognize as a TCB any organization in the United States that meets the qualification criteria and is accredited and designated by NIST or NIST's recognized accreditor. Additionally, the Commission will recognize as a TCB any organization outside the United States that meets the qualification criteria and is designated pursuant to the applicable bilateral or multilateral MRA. The Commission seeks comment on whether it should consider making any clarifications or changes to the FCC recognition process to better ensure that TCBs have the capacity and procedures to meet their obligations under Commission rules, including any requirements the Commission adopts in this proceeding. The Commission invites comment on its rules and procedures regarding recognition of TCBs as qualified for authorizing equipment. Are there any changes that should be considered, either to the rules or procedures concerning the FCC's initial recognition of a TCB, or its continued recognition following any periodic reassessment or reaccreditation of TCBs? To the extent that commenters suggest any changes to the rules or procedures, the Commission asks that they address any implications for MRAs applicable to equipment certification.

49. *Withdrawal of FCC recognition.* In addition, the Commission seeks comment on tits rules and policies regarding withdrawal of FCC recognition of a TCB. Under the Commission's rules it will withdraw recognition of a TCB if its designation or accreditation is withdrawn, if the Commission determines that there is ''just cause'' for withdrawing the recognition, or if the TCB requests that it no longer be designated or recognized.

50. The Commission invites comment on the procedures by which it would withdraw recognition of a TCB. The Commission's rules require that it notify a TCB in writing when it has concerns or evidence that the TCB is not certifying equipment in accordance with the Commission rules and policies, and request that the TCB explain and correct any deficiencies. The rules also provide particular procedures for withdrawal, including notification requirements such as providing TCBs at least 60 days to respond. To the extent the TCB was designated and recognized pursuant to an MRA, the Commission must consult with the U.S. Trade Representative, as necessary, concerning any disputes involving the Telecommunications Trade Act of 1988. In light of the Commission's proposals and issues raised above, the Commission invites comment on whether it should consider clarifications or revisions to the Commission's rules or policies, including the current notification requirements and procedures, and if so whether and to what extent such changes would affect the MRAs.

2. Measurement Facilities (Test Labs)

51. In this section, the Commission proposes and seeks comment on additional issues regarding implementation of its proposed prohibition, as well as any other revisions the Commission may adopt in this rulemaking, concerning test labs.

52. *Transparency.* With the existing transparency requirements and public availability requirements regarding any test lab data and information that TCBs rely upon, are there additional transparency requirements that would be necessary or appropriate in light of the proposal above? The Commission asks that commenters recommending any particular changes address the implications of such changes for existing Commission rules and policies, including the consistency of such changes with ISO/IEC 17025, as well as any potential MRA-related implications.

53. *Test lab accrediting bodies.* The Commission also invites comment on whether additional clarifications or modifications to the current processes regarding the accreditation of test labs are appropriate in light of the Commission proposals and discussion above and its goals in this proceeding. The Commission asks that commenters discuss what changes may be needed with regard to the accreditation body's expertise were the Commission to adopt its proposals to preclude the

accreditation of any test labs associated with entities identified on the Covered List, as well as what changes may be needed in the event that the Commission concludes that other indicia about test labs affect their eligibility. Commenters should address the specific reasons for making changes that are not already addressed by Commission rules and policies. Finally, the Commission asks that commenters address any other implications of their suggestions, including the extent to which MRAs may be affected.

54. Also, in light of evolving national security risks, such as those that may be reflected in the Commerce Department's ''foreign adversaries'' list, the Commission proposes to preclude accreditation bodies associated with any such foreign adversary and seeks comment. How would such association be determined? The Commission also seeks comment on whether test lab accreditation bodies should be located only in the United States or other MRA-partnered countries.

55. *Accreditation of test labs.* The Commission also seeks comment on the responsibilities and procedures by which FCC-recognized accreditation bodies conduct their assessment of prospective test labs and determine whether to accredit particular test labs. Should the Commission clarify its recognition requirements with regard to any of the ISO/IEC 17025 standards into its rules and procedures to ensure that the accreditation process for test labs is sufficiently robust to ensure that the requirements that labs be competent and impartial, are managed to safeguard impartiality, and generate valid test results, and that effective procedures are in place include ensuring that labs meet the ownership and control requirements adopted in the proceeding?

56. The Commission also requests comment on whether any of these Commission rules or policies concerning reassessment of test lab accreditation every two years should be clarified or revised in order to help ensure that untrustworthy labs are not recognized and do not be continued to be recognized by the Commission. The Commission notes that if it were to adopt clarifications of any ISO/IEC 17025 principles (*e.g.,* on personnel, training, or effective management) to ensure that test labs conduct testing in a competent and impartial manner, the Commission proposes to require that the accreditation bodies reassess test labs under the new requirements or procedures. Should OET establish additional specific procedures for reassessment and FCC re-recognition of test labs? The Commission seeks comment on other potential revisions of its procedures for reassessment of test labs every two years, as well as potential revisions of the Commission's procedures for recognition and revocation of recognition. The Commission also seeks comment on any MRA-related issues/concerns that could arise from adoption of any of these possible rule revisions.

57. Finally, the Commission seeks comment on whether, in light of evolving national security concerns, the Commission should revisit its rules and procedures for recognizing test labs with regard to some or all of the countries in economies that do not have an MRA with the United States. For instance, should the Commission no longer recognize any test lab that is located within a ''foreign adversary'' country that does not have an MRA with the United States? To date, the Commission has recognized three accreditation bodies, all located in the United States, to designate test labs that are located in non-MRA countries. Under the Commission's current rules, these bodies accredit test labs based on ISO/IEC 17025, the same standard by which test labs located in the United States and other MRA-partnered countries are accredited. The Commission has recognized numerous test labs located in economies that do not have an MRA with the United States. The Commission also notes that a number of these test labs also are owned and controlled by TCBs, which must be located in economies that have entered into MRAs with the United States.

58. *FCC recognition.* The Commission seeks comment on revisions to its rules concerning eligibility restrictions on entities that will be recognized by the Commission as a test lab in its equipment authorization program. The Commission invites comment on whether any other clarifications or revisions to these Commission rules, policies, or guidance would be appropriate. For example, the Commission seeks comment on any necessary clarifications or revisions to the Commission's process for its initial recognition of test labs and to continued Commission recognition following any re-accreditation that occurs on a periodic basis at least every 2 years. The Commission also invites comment on whether it should adopt a more formal FCC review process before initially recognizing a test lab or continued recognition of test labs, and, if so, ask that commenters provide any suggestions they may have as to what such new procedures should look like. The Commission also seeks comment on any MRA-related issues or concerns that may arise from any changes to the current TCB recognition process.

59. *Withdrawal of recognition.* The Commission proposes and seeks comment on clarifying or modifying the steps that the Commission should take when it determines whether to withdraw recognition of a test lab if the Commission were to adopt changes regarding the type of entities that it will recognize as test labs, or continue to recognize, under the equipment authorization program.

60. To the extent that the Commission ultimately adopts any of the proposals discussed above (*e.g.,* making test labs associated with entities identified on the Covered List ineligible) or takes other actions to restrict eligibility on entities (*e.g.,* based on other ownership interests or controlling issues that the Commission may prohibit), the Commission proposes that it withdraw recognition of any test lab that cannot meet the revised requirements for an FCC-recognized test lab. The Commission seeks comment on this proposal, and on the procedures that the Commission should employ with regard to withdrawing continued recognition of such test labs.

61. As with the Commission's discussion of TCBs above, the Commission also believes that repeated failure of a test lab to provide accurate test results, or a test lab's lack candor with regard to interactions with the Commission, would constitute sufficient basis for withdrawal of recognition, and propose that were such circumstances to be presented, the Commission would move forward with withdrawing any existing FCC recognition of such a test lab. The Commission seeks comment on this proposal. The Commission also invites comment on other bases that would merit the Commission proceeding with withdrawing recognition of any existing test lab.

62. *Use of accredited, FCC-recognized test labs in SDoC process.* As discussed above, the Commission's current rules on authorization of equipment through the SDoC process do not require that any requisite testing of equipment be conducted by an accredited, FCC-recognized test lab. As the Commission seeks to ensure the integrity of its equipment authorization program, including ensuring test labs in which entities identified on the Covered List have certain direct or indirect ownership interests or control do not participate in the Commission's equipment authorization program, the Commission seeks comment on whether it also should require that all equipment authorized pursuant to the SDoC process be tested by accredited and

FCC-recognized test labs. Such action could serve to further promote the integrity of the program in precluding untrustworthy test labs from participation and the Commission's national security goals addressed in the proceeding. The Commission seeks comment on this approach.

63. *Other issues.* Finally, to the extent not specifically asked above, the Commission asks that commenters address whether and, if so, how any of the Commission's proposals herein might affect existing MRAs and/or necessitate further action regarding existing or potential MRAs. Commenters should address any legal authority issues that may arise and the extent to which MRAs or other trade policies may be affected by these proposals.

IV. Ordering Clauses

64. Accordingly, *it is ordered,* pursuant to the authority found in sections 1, 4(i), 229, 301, 302, 303, 309, 312, 403, and 503 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 229, 301, 302a, 303, 309, 312, 403, and 503, section 105 of the Communications Assistance for Law Enforcement Act, 47 U.S.C. 1004; the Secure and Trusted Communications Networks Act of 2019, 47 U.S.C. 1601–1609; and the Secure Equipment Act of 2021, Public Law 117–55, 135 Stat. 423, 47 U.S.C. 1601 note, that this Notice of Proposed Rulemaking *is hereby adopted.*

65. *It is further ordered* that the Commission's Office of the Secretary, *shall send* a copy of this Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 2

Administrative practice and procedures, Communications, Communications equipment, Disaster assistance, Radio, Reporting and recordkeeping requirements, and Telecommunications.

Federal Communications Commission.

Marlene Dortch,

Secretary.

Proposed Rules

For the reasons discussed in the document, the Federal Communications Commission proposes to amend 47 CFR part 2 as follows:

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, and 336, unless otherwise noted.

■ 2. Section 2.903 is amended by revising paragraph (b), and the definition of ''Affiliate'' in paragraph (c) to read as follows:

§ 2.903 Prohibition on authorization of equipment on the Covered List.

* * * * *

(b) Each entity named on the Covered List, as established pursuant to § 1.50002 of this chapter, must provide to the Commission the following information: the full name, mailing address or physical address (if different from mailing address), email address, and telephone number of each of that named entity's associated entities (*e.g.,* subsidiaries or affiliates).

(1) Each entity named on the Covered List must provide the information described in paragraph (b) of this section no later than [30 DAYS AFTER PUBLICATION OF FINAL RULES IN THE **FEDERAL REGISTER**];

(2) Each entity named on the Covered List must provide the information described in *paragraph (b)* of this section no later than 30 days after the effective date of each updated Covered List; and

(3) Each entity named on the Covered List must notify the Commission of any changes to the information described in *paragraph (b)* of this section no later than 30 days after such change occurs.

(c) * * *

Affiliate. The term ''affiliate'' means an entity that (directly or indirectly) owns or controls, is owned or controlled by, or is under common ownership or control with, another entity; for purposes of this paragraph, the term 'own' means to have, possess, or otherwise control an equity or voting interest (or the equivalent thereof) of 10 percent or more.

* * * * *

■ 3. Section 2.938 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 2.938 Retention of Records.

* * * * *

(b) * * *

(1) * * *

(ii) State the name of the test laboratory, company, or individual performing the testing. The Commission may request additional information regarding the test site, the test equipment, or the qualifications of the company or individual performing the tests, including documentation identifying any entity that holds a 5% or greater direct or indirect equity or voting interest in the test laboratory, company, or individual performing the testing;

* * * * *

■ 4. Section 2.948 is amended by:

■ a. Adding paragraphs (b)(1)(viii) and (b)(1)(ix);

■ b. Redesignating paragraph (c)(9) as paragraph (c)(10), and adding new paragraph (c)(9);

■ c. Adding paragraphs (g), and (h).

The revisions and additions read as follows:

§ 2.948 Measurement facilities.

* * * * *

(b) * * *

(1) * * *

(viii) Certification from each measurement facility that no entity identified on the Covered List has, possesses, or otherwise controls an equity or voting interest of 10% or more in the measurement facility; and

(ix) Documentation identifying any entity that holds a 5% or greater direct or indirect equity or voting interest in the measurement facility.

* * * * *

(c) * * *

* * * * *

(9) Each recognized laboratory must certify to the Commission, no later than [30 DAYS AFTER THE EFFECTIVE DATE OF A FINAL RULE], and no later than 30 days after any relevant change in the required information takes effect, that no entity identified on the Covered List has, possesses, or otherwise controls an equity or voting interest of 10% or more in the laboratory;

* * * * *

(g) No equipment will be authorized under either the certification procedure or the Supplier's Declaration of Conformity if such authorization is reliant upon testing performed at a laboratory or measurement facility in which any entity identified on the Covered List, as established pursuant to *§ 1.50002 of this chapter,* has, possesses, or otherwise controls an equity or voting interest of 10% or more.

(h) Regardless of accreditation, the Commission will not recognize any test lab:

(1) In which any entity identified on the Covered List, as established pursuant to *§ 1.50002 of this chapter,* has, possesses, or otherwise controls an equity or voting interest of 10% or more;

(2) That fails to provide, or provides a false or inaccurate, certification as required in paragraph (c)(9) of this section; or

(3) That repeatedly fails to provide accurate test results or lacks candor with regard to interactions with the Commission.

■ 5. Section 2.949 is amended by adding paragraph (c) as follows:

§ 2.949 Recognition of laboratory accreditation bodies.

* * * * *

(c) The Commission will not recognize a laboratory accreditation body that has any affiliation with a foreign adversary as designated by the U.S. Department of Commerce at 15 CFR 7.4.

■ 6. Section 2.960 is amended by adding paragraph (d) as follows:

§ 2.960 Recognition of Telecommunication Certification Bodies (TCBs).

* * * * *

(d) The Commission will not recognize any TCB for which any entity identified on the Covered List, as established pursuant to *§ 1.50002 of this chapter,* has, possesses, or otherwise controls an equity or voting interest of 10% or more.

■ 7. Section 2.962 is amended by revising paragraph (e)(2) and adding paragraphs (e)(6) through (e)(9) as follows:

§ 2.962 Requirements for Telecommunication Certification Bodies.

* * * * *

(e) * * *

(2) The Commission will notify a TCB in writing of its intention to withdraw or limit the scope of the TCB's recognition and provide at least 60 days for the TCB to respond. In the case of a TCB designated and recognized pursuant to an bilateral or multilateral mutual recognition agreement or arrangement (MRA), the Commission shall consult with the Office of the United States Trade Representative (USTR), as necessary, concerning any disputes arising under an MRA for compliance with the Telecommunications Trade Act of 1988 (Section 1371–1382 of the Omnibus Trade and Competitiveness Act of 1988).

(i) The Commission will withdraw its recognition of a TCB if:

(A) The TCB's designation or accreditation is withdrawn, if the Commission determines there is just cause for withdrawing the recognition;

(B) The TCB requests that it no longer hold its designation or recognition;

(C) The TCB fails to provide the certification required in paragraph (8); or

(D) The TCB fails to fulfill its obligations to the Commission to ensure that no authorization is granted for any equipment that is produced by any entity identified on the Covered List, established pursuant to § 1.50002 of this chapter.

(ii) The Commission will limit the scope of equipment that can be certified by a TCB if its accreditor limits the scope of its accreditation or if the Commission determines there is good cause to do so.

(iii) The Commission will notify a TCB in writing of its intention to withdraw or limit the scope of the TCB's recognition and provide at least 60 days for the TCB to respond. In the case of a TCB designated and recognized pursuant to an bilateral or multilateral mutual recognition agreement or arrangement (MRA), the Commission shall consult with the Office of the United States Trade Representative (USTR), as necessary, concerning any disputes arising under an MRA for compliance with the Telecommunications Trade Act of 1988 (Section 1371–1382 of the Omnibus Trade and Competitiveness Act of 1988).

* * * * *

(6) The Commission will not recognize as a TCB any organization in which any entity identified on the Covered List, as established pursuant to *§ 1.50002 of this chapter,* has, possesses, or otherwise controls an equity or voting interest of 10% or more.

(7) A TCB must have an organizational and management structure in place, including personnel with specific training and expertise, to verify that no authorization is granted for any equipment that is produced by any entity identified on the Covered List, established pursuant to § 1.50002 of this chapter.

(8) Each recognized TCB must certify to the Commission, no later than [30 DAYS AFTER THE EFFECTIVE DATE OF A FINAL RULE], and no later than 30 days after any relevant change in the required information takes effect that no entity identified on the Covered List has, possesses, or otherwise controls an equity or voting interest of 10% or more of the TCB.

(9) Each recognized TCB must provide to the Commission, no later than [90 DAYS AFTER THE EFFECTIVE DATE OF A FINAL RULE], and no later than 30 days after any relevant change in the required information takes effect, documentation identifying any entity that holds a 5% or greater direct or indirect equity or voting interest in the TCB.

* * * * *

[FR Doc. 2024–14491 Filed 7–3–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 10–90, 18–143, 19–126, 24–144; AU Docket Nos. 17–182, 20–34; GN Docket No. 20–32; FCC 24–64; FR ID 226925]

Connect America Fund, Connect America Fund Phase II Auction, The Uniendo a Puerto Rico Fund and the Connect USVI Fund, Rural Digital Opportunity Fund, Rural Digital Opportunity Fund Auction, Establishing a 5G Fund for Rural America, Letters of Credit for Recipients of High-Cost Competitive Bidding Support

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) seeks comment on changes to its rules regarding letters of credit for recipients of high-cost support awarded through competitive bidding. Specifically, the Commission seeks comment on changing the rules governing which United States banks are eligible to issue such letters. It also seeks comment on modifying the letter of credit rules for Connect America Fund Phase II (CAF II) support recipients that have met all of their deployment and reporting obligations, along with allowing certain Rural Digital Opportunity Fund (RDOF) support recipients to lower the value of their letters of credit.

DATES: Comments are due on or before August 5, 2024 and reply comments are due on or before August 19, 2024. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this document, you should advise the contact listed below as soon as possible.

ADDRESSES: 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 on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). You may submit comments, identified by WC Docket Nos. 10–90, 18–143, 19–126, 24–144; AU Docket Nos. 17–182, 20–34; GN Docket No. 20–32, by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the 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 a.m. and 4 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.

FOR FURTHER INFORMATION CONTACT: Nathan Eagan at *nathan.eagan@fcc.gov,* Wireline Competition Bureau, 202–418–7400.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's notice of proposed rulemaking (NPRM) in WC Docket Nos. 10–90, 18–143, 19–126, 24–144; AU Docket Nos. 17–182, 20–34; GN Docket No. 20–32; FCC 24–64, adopted June 6, 2024 and released June 7, 2024. The full text of this document is available for public inspection during regular business hours at Commission's headquarters 45 L Street NE, Washington, DC 20554 or at the following internet address: *https://docs.fcc.gov/public/attachments/FCC-24-64A1.pdf.*

Synopsis

I. Introduction

1. In the NPRM, the Commission seeks comment on modifying Letter of Credit (LOC) rules for Universal Service Fund High-Cost support authorized through a competitive process. The Commission also seeks comment on modifying the required value of a letter of credit for recipients of the RDOF support. Finally, it seeks comments on making the waiver of certain aspects of the LOC rules permanent for recipients of CAF II support to align with the RDOF LOC requirements. The Commission is seeking comment in these areas to explore potential ways to facilitate providers' compliance with program requirements while facilitating broadband deployment in unserved and underserved areas, and helping providers to meet their deployment milestones.

2. Currently, the Commission's rules require that entities authorized to receive High-Cost support authorized through a competitive process have an LOC from a United States bank with a Weiss bank safety rating of B− or better. When the Commission first adopted this rule, approximately 3,600 banks qualified to issue letters of credit. In the last 2 years, however, nearly half of those banks have lost their eligibility to issue LOCs as they have seen their Weiss rating fall below a B−. Therefore, many carriers authorized to receive CAFF II Auction or RDOF support face the possibility of having their support withheld until they obtain a new LOC from a qualifying bank, and these carriers must incur increased costs and administrative burdens associated with obtaining a new LOC from a qualifying bank. Accordingly, the Commission seeks comment on whether the Commission should modify the current requirement of a B− or better Weiss safety rating.

3. In addition, RDOF support recipients are required to maintain LOCs that increase in value on an annual basis. Banks issuing LOCs generally require RDOF support recipients to maintain sufficient cash reserves to support the LOC, which impacts the financial resources available for the provider's operations, including deployment. As part of RDOF's rules, support recipients that meet their optional or required deployment milestone are allowed to reduce the value of their required LOCs to one year of their total support once Universal Service Administrative Company (USAC) has verified deployment. This flexibility was intended to balance our responsibility to protect program funds while simultaneously reducing the financial burdens on RDOF support recipients to participate in the program as they met their deployment milestones. In the NPRM, the Commission seeks comment on providing additional flexibility by allowing an RDOF support recipient to lower the value of its LOC to one year of support if it has deployed service to 10 percent of its locations by the end of its second year of support, instead of 20 percent, and the Commission seeks comment on whether such a waiver would apply to recipients whose two-year optional milestone has already occurred.

4. Finally, the Commission seeks comment on making our waiver of certain aspects of the CAF II LOC rules permanent, and thereby continuing to allow CAF II support recipients that have met their deployment and reporting obligations to follow the RDOF's LOC rules, and maintain LOCs at lower values.

II. Discussion

5. *Weiss Bank Safety Rating.* In the NPRM, the Commission seeks targeted comment on whether and how to change the sections of the letter of credit rules requiring a minimum safety rating for issuing financial institutions. Currently, Auction 903 and 904 support recipients are required to obtain a letter of credit from United States banks maintaining a Weiss bank safety rating of B− or better. In light of the developments in the banking industry, the Commission seeks comment on this requirement. The Commission also seeks comment on whether to change the rule requiring United States banks to maintain a Weiss bank safety rating of B− or better for future recipients of support from the 5G Fund. If the Commission decides to alter those rules, the Commission seeks comment on what requirements to adopt for banks issuing letters of credit to support recipients, to further the dual goals of securing the financial commitments made through Auctions 903 and 904, and any auction of 5G Fund support, while maintaining a sufficiently expansive pool of issuing banks to enable broad participation in the programs by providers, and especially small providers. The Commission seeks comment on whether there are alternative, reliable ratings to use for assessing a bank's suitability for issuing an LOC to support recipients; or whether the Commission should continue to utilize only Weiss ratings, but accept a lower grade for bank eligibility. In making any changes to the issuing bank eligibility rules, how can the Commission minimize any potential public interest harms and continue to responsibly steward the funds disbursed through CAF II Auction and RDOF programs as well as the 5G Fund? The Commission anticipates that any changes to the bank eligibility rules could also apply to other FCC programs that currently have the same Weiss bank safety rating requirement. The Commission seeks comment on this.

6. When the Commission adopted its requirement that banks maintain a Weiss bank safety rating of B− or better, it reasoned that Weiss offered ''an

independent and objective perspective of the safety of the banks it rates based on capitalization, asset quality, profitability, liquidity, and stability indexes.'' The Commission also determined that using the Weiss ratings would significantly increase the number of banks that could issue LOCs to support recipients, compared to a previous program that had more restrictive bank eligibility requirements, and that this change would encourage small entities to participate in Auction 903. However, while approximately 3,600 banks were eligible to issue LOCs at the time of the Commission's previous order in 2016, that number has decreased by nearly half in the past two years. The Commission seeks comments on any potential reasons for the significant number of decline in banks meeting this rating standard, and whether the conditions relating to that decline relate to the factors the Commission cared about when creating the initial LOC requirement. The Commission also seeks comments on whether these ratings changes have burdened entities, in particular small entities, that receive Auction 903 or 904 support. The Commission seeks specific examples demonstrating how the requirement burdens carriers and affects their ability to serve consumers. The record and the petitions certain carriers have filed seeking relief from the Weiss rating requirement indicate this is an issue worth exploring. If the Commission ultimately concludes it is in the public interest to change the eligibility requirement for U.S. banks permitted to issue LOCs to support recipients, the Commission seeks comment on how to best adopt changes that are still consistent with the Commission's rationale in adopting the original Weiss rating requirement.

7. First, the Commission seeks comment on any alternatives to using the Weiss bank safety rating. The Commission notes that the objective is to protect the Universal Service Fund and expenditures, by ensuring that carriers have an LOC that can be relied upon, while simultaneously permitting carriers to choose from a reasonably wide range of banks that can issue LOCs for purposes of complying with program rules. The Commission seeks comment on alternative approaches that would balance these objectives.

8. The Commission seeks specific comment on Bank of America's (BOA) proposed alternative method of determining a bank's eligibility. BOA proposed that a U.S. bank could be eligible to issue LOCs to auction support recipients if the bank had either: (1) a Weiss bank safety rating of B− or better; or (2) a long-term unsecured credit rating issued by a widely-recognized credit rating agency that is equivalent to a BBB− or better rating by Standard & Poor's, which is the requirement for non-U.S banks. How would the Commission apply this proposed standard? Is the term ''widely-recognized'' credit rating agency a bright-line rule that Commission staff could easily apply? What constitutes a widely-recognized agency? Would Commission staff or the Administrator be able to quickly and easily determine a bank's long-term unsecured credit rating? Are these ratings publicly available and free to access? If these ratings are not publicly available and free to access, how would Commission staff or the Administrator verify a bank's rating? As noted, Commission staff or the Administrator should not be required to make any discretionary judgments about a bank's eligibility. Would this proposal provide additional alternatives to small businesses that have won support in Auction 903 or 904 or that may win support in a 5G Fund auction? The Commission also seeks comment more generally on alternative rating systems and alternative approaches to rating systems that could be used to evaluate the fitness of a U.S. bank, including any alternatives adopted by other agencies. What are the advantages or disadvantages of those rating systems and other approaches?

9. As another alternative, the Bank Policy Institute proposes that the ''FCC reconsider its use of Weiss Ratings'' and accept ''letters of credit from any federally-supervised bank with an investment grade-rating for banks of $100 billion or more in total assets or with a certificate that the bank is ''well capitalized'' for banks with assets below $100 billion.'' The Commission seeks comment on this proposal. The Bank Policy Institute also argues that if the Commission wishes to use a credit-rating organization, it should use one of the ten nationally recognized credit rating statistical organizations which, unlike Weiss, are subject to SEC regulation. The Commission also seeks comment on the Bank Policy Institute's contention that using ratings from credit-rating organizations would be inconsistent with section 939A of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

10. Second, the Commission seeks comment on whether continuing to use only the Weiss ratings, but instead allowing issuing banks to have a lower bank safety rating, would provide a solution. Weiss currently rates 4,526 banks, and 3,923 of them have a bank safety rating of C− or better. According to Weiss, a C rating means ''This is a cautionary or yellow flag. In the event of a recession or major financial crisis, the Commission feels this company may encounter difficulties in maintaining its financial stability.'' Would using that threshold address the issues that have been raised and still protect the Fund? The Commission notes that the LOC plays a vital role in ensuring ability to recoup funds in the event that an auction support recipient fails to complete its deployment obligations, and the Commission needs to be certain that the banks issuing the LOCs will be able to honor them. Weiss's ratings are publicly available and free to use, which allows for bright-line determinations about a bank's eligibility. Are there other advantages or disadvantages with using Weiss ratings but changing the requirement from B− or higher to C− or higher? Would changing the requirement from a minimum of a B− to C+ or C strike a better balance? The Commission notes that an interested party has suggested that any Weiss-rated bank with ''certain of the five Weiss indices'' ''at a certain level'' should be eligible to issue LOCs to participants in the programs that award high-cost support through competitive bidding. The Commission seeks comment on that proposal, and on how such a proposal could work. Are there any issues the Commission should consider with regard to administering and implementing a change in the rules regarding bank eligibility? If so, the Commission seeks comment on those issues, along with any potential solutions.

11. *RDOF Letter of Credit Reduction.* The Commission seeks comment on potential changes to the rules requiring an increase in the value of an LOC for RDOF support recipients. An RDOF recipient has raised the concern of ''the economic pressures being brought to bear on current RDOF recipients in light of the astronomical increase in broadband deployment costs,'' and says those pressures can be addressed by relief from the rules regarding an LOC's value. This recipient pointed out that because ''banks generally require these LOCs to be cash collateralized, RDOF recipients must tie up significant portions of their free cash to serve as collateral for the LOC, which, in turn, means that these funds cannot be used for build out of RDOF networks.'' This recipient specifically asks that all RDOF support recipients be allowed to reduce their LOCs to one year of their total authorized support.

12. The Commission seeks comment on the burdens of maintaining the LOC values currently required by the rules,

and what could provide relief related to the value of the LOC to address this concern. Have the rules requiring LOCs to increase in value on an annual basis impacted RDOF support recipients' ability to meet their deployment obligations? One specific option the Commission seeks comment on is allowing RDOF support recipients who have deployed service to at least 10%, rather than 20%, of their locations by the end of their second year of support to lower the value of their LOCs to one year of their total support upon verification by USAC. Does 10% ''demonstrate concrete progress in building its network'' as the Commission reasoned when it adopted a 20% optional milestone? Generally, what are the public interest harms and public interest benefits of a 10% two-year optional milestone? How should the Commission account for the fact that the two-year optional milestone has already passed for those RDOF carriers authorized in 2021? What, if any, form of additional LOC relief would be in the public interest for those carriers since they must meet the required 40% milestone by December 31, 2024?

13. The Commission emphasizes that any such change would be limited to the optional milestone and would not impact the requirement that all RDOF support recipients must deploy service to 40% of eligible locations by the end of their third year of support. In the event that an RDOF support recipient then failed to timely meet its 40% deployment obligation, the value of its LOC would need to increase to reflect the amount required under the current rules.

14. *CAF II Auction Letter of Credit Waiver.* The Commission separately seeks comment on a proposal made in the record to amend the relevant CAF II Auction rules to mirror the RDOF LOC rules. With a rule change, CAF II support recipients that have met all of their deployment and reporting obligations would be able to continue to follow the RDOF LOC rules through the end of CAF–II. The Bureau previously granted waivers allowing CAF II providers to follow the RDOF LOC rules because of the continued hardship posed by the COVID–19 pandemic. Are those conditions that justified multiple waivers still present? If those conditions have improved, would the public interest otherwise be served by providing this relief permanently? The Commission seeks specific examples showing why such relief remains necessary. Alternatively, would it be in the public interest to extend the waiver another year rather than making permanent rule changes?

15. *Digital Equity and Inclusion.* Finally, 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 benefits (if any) that may be associated with the proposals and issues discussed herein. Specifically, the Commission seeks comments on how the proposals in the NPRM may promote or inhibit advances in diversity, equity, inclusion, and accessibility, as well the scope of the Commission's relevant legal authority.

III. Procedural Matters

16. *Paperwork Reduction Act Analysis.* This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4).

17. *Regulatory Flexibility Act.* The Regulatory Flexibility Act of 1980, as amended (RFA), requires that an agency prepare a regulatory flexibility analysis for notice and comment rulemakings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' Accordingly, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) concerning the possible impact of potential rule and/or policy changes contained in the NPRM on small entities. The Commission invites the general public, in particular small businesses, to comment on the IRFA. Comments must be filed by the deadlines for comments on the NPRM and must have a separate and distinct heading designating them as responses to the IRFA.

18. *Ex Parte Presentations.* 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) of the Commission's rules, In proceedings governed by the Commission's rule § 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

19. *Providing Accountability Through Transparency Act:* Consistent with the Providing Accountability Through Transparency Act, Public Law 118–9, a summary of this document will be available on *https://www.fcc.gov/proposed-rulemakings.*

IV. Initial Regulatory Flexibility Analysis

20. As required by the Regulatory Flexibility Analysis (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 and rules proposed in the NPRM. 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. In addition, the NPRM and IRFA (or summaries thereof) will be published in the **Federal Register**.

A. Need for, and Objectives of, the Proposed Rules

21. In the NPRM, the Commission seeks comment regarding the rules determining a bank's eligibility to issue LOCs for winners of Auction 903 and 904 support, along with winners of 5G Fund support and Phase II fixed support from the Puerto Rico/USVI Fund. The Commission's rules currently require recipients for support to maintain a letter of credit from a United States bank with a Weiss bank safety rating of B− or better. More than 1,600 U.S. banks that had previously been eligible to issue LOCs to support recipients have seen their Weiss bank safety ratings fall below a B− in the past two years and, correspondingly, lost their eligibility to supply support recipients with LOCs. The Commission recognizes that the current rules may burden those support recipients who wish to maintain their existing relationship with a bank that previously issued them an LOC. The Commission seeks comments on using a different Weiss letter grade as the threshold for bank eligibility. The Commission alternatively seeks comments on using a different rating system to evaluate a bank's health. The Commission also seeks comments on allowing Auction 904 support recipients who have deployed service to at least 10% of their required locations by the end of their second year of support to lower the value of their LOCs to one year of support. Finally, the Commission seeks comments on allowing Auction 903 support recipients that have met their deployment and reporting obligations to continue to maintain their LOCs under the Auction 904 rules.

B. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

22. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.'' A ''small business concern'' is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

23. *Small Businesses, Small Organizations, and Small Governmental Jurisdictions.* The Commission's actions, over time, may affect small entities that are not easily categorized at present. Therefore, at the outset, three broad groups of small entities that could be directly affected herein. First, while there are industry specific size standards for small businesses that are used in the regulatory flexibility analysis, according to data from the Small Business Administration's (SBA) Office of Advocacy, in general a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States, which translates to 33.2 million businesses.

24. Next, the type of small entity described as a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' The Internal Revenue Service (IRS) uses a revenue benchmark of $50,000 or less to delineate its annual electronic filing requirements for small exempt organizations. Nationwide, for tax year 2022, there were approximately 530,109 small exempt organizations in the U.S. reporting revenues of $50,000 or less according to the registration and tax data for exempt organizations available from the IRS.

25. Finally, the small entity described as a ''small governmental jurisdiction'' is defined generally as ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' U.S. Census Bureau data from the 2022 Census of Governments indicate there were 90,837 local governmental jurisdictions consisting of general purpose governments and special purpose governments in the United States. Of this number, there were 36,845 general purpose governments (county, municipal, and town or township) with populations of less than 50,000 and 11,879 special purpose governments (independent school districts) with enrollment populations of less than 50,000. Accordingly, based on the 2022 U.S. Census of Governments data, the Commission estimates that at least 48,724 entities fall into the category of ''small governmental jurisdictions.''

26. The small entities that may be affected are Wireline Providers, Wireless Carriers and Service Providers, and internet Service Providers.

27. *All Other Information Services.* This industry comprises establishments primarily engaged in providing other information services (except news syndicates, libraries, archives, internet publishing and broadcasting, and Web search portals). The SBA small business size standard for this industry classifies firms with annual receipts of $30 million or less as small. U.S. Census Bureau data for 2017 show that there were 704 firms in this industry that operated for the entire year. Of those firms, 556 had revenue of less than $25 million. Consequently, we estimate that the majority of firms in this industry are small entities.

C. Description of Projected Reporting, Recordkeeping and Other Compliance Requirements for Small Entities

28. In the NPRM, the Commission seeks comment on alternative methods of evaluating a bank's ability to provide a LOC to winners of Auction 903 and 904 support, along with winners of 5G Fund auctions. The NPRM specifically seeks comment on modifying the rules to allow more banks to become or remain eligible to issue LOCs to Auctions 903 and 904 support recipients and to 5G Fund support recipients, which may alter reporting, recordkeeping, and compliance obligations for small entities that receive support. The NPRM also seeks comments on allowing more Auction 904 support recipients to lower the value of their LOCs.

29. The potential changes in the NPRM are intended to reduce the administrative burden on recipients of Auctions 903 and 904 support and 5G Fund support. The potential changes the Commission seeks comment on would allow support recipients, including small entities, to minimize their expenses by maintaining their existing LOC with the bank that issued it. As a result, if there is an economic impact on small entities as a result of these proposals, however, the Commission expects the impact to be a positive one. Any potential changes the Commission seeks comment on would not add any additional compliance requirements for small entities, or additional costs for professional skills, because support recipients are already required to maintain a LOC under the current rules. The proposed changes would allow support recipients to maintain their existing LOCs instead of obtaining new ones. The Commission also seeks comments on allowing Auction 904 support recipients who have deployed service to at least 10% of their required locations by the end of their second year of support to lower the value of their LOCs. Finally, the Commission seeks comment on allowing Auction 903 support recipients that have met their deployment and reporting obligations to

maintain LOCs in accordance with Auction 904's rules.

D. Steps Taken To Minimize the Significant Economic Impact on Small Entities and Significant Alternatives Considered

30. 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.''

31. In the NPRM, the Commission takes steps to minimize the economic impact on small entities and considers significant alternatives by proposing and seeking input on alternative proposals designed to balance our goal of allowing providers to obtain an LOC from a number of different banks while also ensuring these banks are able to fulfill those LOCs in the event that the LOCs need to be drawn upon. With these goals in mind, in the NPRM, the Commission sought comment on whether a different standard for evaluating banks would allow providers to obtain LOCs from a wider range of banks while simultaneously protecting our investment and the Universal Service Fund.

32. The Commission also considered alternatives to the existing rules, by seeking comment on alternative standards that could be used to evaluate the health and suitability of a bank. For example, Bank of America proposed on alternative method of determining a bank's eligibility that includes the current Weiss rating of B − or better or a long-term unsecured credit rating issued by a widely-recognized credit rating agency that is equivalent to a BBB − or better rating by Standard & Poor's, which is the requirement for non-U.S banks. In light of the economic burdens that auction support recipients could face by being required to obtain new LOCs from different banks, the Commission sought comments on the most effective ways of allowing those support recipients to maintain their LOCs with the banks that originally issued them, as long as the Commission is confident that the bank's economic health is sufficient.

33. The matters discussed in the NPRM are designed to ensure the Commission has a better understanding of both the benefits and the potential burdens associated with the different actions and methods before adopting its final rules. To assist in the Commission's evaluation of the economic impact on small entities, as a result of actions the Commission has proposed in the NPRM, and to better explore options and alternatives, the Commission has sought comment from the parties. In particular, the Commission seeks comment on whether any of the economic burdens associated the filing, recordkeeping and reporting requirements described can be minimized for small businesses. Through comments received in response to the NPRM and the IRFA, including costs and benefits information and any alternative proposals, the Commission expects to more fully consider ways to minimize the economic impact on small entities. The Commission's evaluation of the comments filed in this proceeding will shape the final alternatives it considers, the final conclusions it reaches, and the actions it ultimately takes in this proceeding to minimize any significant economic impact that may occur on small entities as a result of any final rules that are adopted.

E. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

34. None.

V. Ordering Clauses

35. Accordingly, *it is ordered,* pursuant to the authority contained in sections 4(i), 214, 254, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 214, 254, 303(r), and 403, and §§ 1.1 and 1.421 of the Commission's rules, 47 CFR 1.1 and 1.421, that the notice of proposed rulemaking *is adopted.*

36. *It is further ordered* that, pursuant to the authority contained in sections 4(i), 214, 254, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 214, 254, 303(r), and 403, and §§ 1.1 and 1.421 of the Commission's rules, 47 CFR 1.1 and 1.421, *notice is hereby given* of the proposals described in the notice of proposed rulemaking.

37. *It is further ordered* that pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments on the notice of proposed rulemaking on or before August 5, 2024, and reply comments on or before August 19, 2024.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2024–14145 Filed 7–3–24; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 89, No. 129
Friday, July 5, 2024

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.

INTERNATIONAL BROADCASTING ADVISORY BOARD

Sunshine Act Meetings

TIME AND DATE: July 10, 2024 10:00 a.m.–11:00 a.m. ET.

PLACE: On July 10, 2024, the Board will meet virtually.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: The International Broadcasting Advisory Board (Board) will conduct a meeting closed to the public at the date and time listed above. Board Members (membership includes Chair Kenneth Jarin, Luis Botello, Jamie Fly, Jeffrey Gedmin, Michelle Giuda, Kathleen Matthews, Under Secretary Elizabeth Allen (Secretary of State's Representative)), Chief Executive Officer of the U.S. Agency for Global Media (USAGM), the USAGM General Counsel and Acting Board Secretary to the Board, the Secretariat to the Board, and recording secretaries will attend the closed meeting. Certain USAGM staff members who may be called on to brief or support the Board also may attend.

The USAGM General Counsel and Acting Board Secretary has certified that, in his opinion, exemptions set forth in the Government in the Sunshine Act, in particular 5 U.S.C. 552b(c)(2), (6), and (9)(B), permit closure of this meeting.

The entirety of the Board's membership approved the closing of this meeting.

The closed meeting will focus on discussing the development of internal rules and practices to govern Board processes and functions. This includes developing processes or rules relating to IBAB, USAGM, and the USAGM networks. Publicizing these deliberations would frustrate the implementation of the very items they will be proposing. [This related to (2) and (9).]

In the event that the time, date, or location of this meeting changes, USAGM will post an announcement of the change, along with the new time, date, and/or place of the meeting on its website at *https://www.usagm.gov.*

Although a separate federal entity, USAGM prepared this notice and will continue to support the Board in accordance with 22 U.S.C. 6205(g).

CONTACT PERSON FOR MORE INFORMATION: Persons interested in obtaining more information should contact USAGM's Executive Director Oanh Tran at (202) 920–2583.

Authority: 5 U.S.C. 552b, 22 U.S.C. 6205(e)(3)(C).

Dated: July 1, 2024.

Meredith L. Meads,

Executive Assistant, USAGM.

[FR Doc. 2024–14818 Filed 7–2–24; 11:15 am]

BILLING CODE 8610–01–P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meeting Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of Commission public business meeting.

DATES: Friday, July 12, 2024, 10:00 a.m. ET.

ADDRESSES: Meeting to take place virtually and is open to the public via livestream on the Commission's YouTube page: *https://www.youtube.com/user/USCCR/videos.*

FOR FURTHER INFORMATION CONTACT: Angelia Rorison: 202–376–8371; *publicaffairs@usccr.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Government in Sunshine Act (5 U.S.C. 552b), the Commission on Civil Rights is holding a meeting to discuss the Commission's business for the month. This business meeting is open to the public. Computer assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on Friday, July 12, 2024, is *https://www.streamtext.net/player?event=USCCR.* Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript.

Meeting Agenda

I. Approval of Agenda

II. Business Meeting

A. Presentation by Arkansas Advisory Committee Chair on Released Reports and Memorandum on IDEA Compliance and Implementation in Arkansas Schools

B. Presentation by Nevada Advisory Committee Chair on Released Reports and Memorandum on Teacher and Professional Staff Shortages and Equity in Education in Nevada

C. Discussion and Vote on 2025 USCCR Business Meeting Calendar

D. Discussion and Vote on 2024 Statutory Enforcement Report: The Civil Rights Implications of the Federal Use of Facial Recognition Technology

E. Management and Operations

- Staff Director's Report

III. Adjourn Meeting

Dated: July 3, 2024.

Angelia Rorison,

USCCR Media and Communications Director.

[FR Doc. 2024–14935 Filed 7–2–24; 4:15 pm]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Census Bureau

2030 Census Advisory Committee

AGENCY: Census Bureau, Department of Commerce.

ACTION: Notice of public virtual meeting.

SUMMARY: The Census Bureau is giving notice of a virtual meeting of the 2030 Census Advisory Committee (2030 CAC or Committee). The Committee will assist the Census Bureau in devising strategies to increase awareness of and participation in the next decennial census, reduce barriers to response, and enhance the public's trust and willingness to respond. Last minute changes to the schedule are possible, which could prevent giving advance public notice of schedule adjustments.

DATES: The virtual meeting will be held on:

- Friday, July 26, 2024, from 10:30 a.m. to 5:30 p.m. EDT.

ADDRESSES: Please visit the Census Advisory Committee website at *https://www.census.gov/about/cac/2030cac/meetings/2024-07-meeting.html,* for the 2030 CAC summer meeting information, including the agenda, and how to join the meeting.

FOR FURTHER INFORMATION CONTACT: Shana Banks, Advisory Committee Branch Chief, Office of Program, Performance and Stakeholder Integration (PPSI), *shana.j.banks@census.gov,* Department of Commerce, Census Bureau, telephone 301–763–3815. For TTY callers, please use the Federal Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The Committee will provide insight, perspectives, and expertise through recommendations on planning and implementation of the 2030 Census. The members of the 2030 CAC are appointed by the Director of the Census Bureau. The Committee has been established in accordance with the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*).

All meetings are open to the public. Public comments will be accepted in writing only to *shana.j.banks@census.gov* (subject line ''2030 CAC Summer Virtual Meeting Public Comment''). A brief period will be set aside during the meeting to read public comments received in advance of 12:00 p.m. EDT, July 25, 2024. Any public comments received after the deadline will be posted to the website listed in the **ADDRESSES** section.

Robert L. Santos, Director, Census Bureau, approved the publication of this Notice in the **Federal Register**.

Dated: June 28, 2024.

Shannon Wink,

Program Analyst, Policy Coordination Office, U.S. Census Bureau.

[FR Doc. 2024–14721 Filed 7–3–24; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Business Trends and Outlook Survey

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on November 9, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau.

Title: Business Trends and Outlook Survey.

OMB Control Number: 0607–1022.

Form Number(s): This online survey has no form number.

Type of Request: Regular submission, Request for a Revision of a Currently Approved Collection.

Number of Respondents: 717,600.

Average Hours per Response: 9 minutes.

Burden Hours: 131,600.

Needs and Uses: The mission of the U.S. Census Bureau (Census Bureau) is to serve as the leading source of quality data about the nation's people and economy; in order to fulfill this mission, it is necessary to innovate to produce more detailed, more frequent, and more timely data products. The Coronavirus pandemic was an impetus for the creation of new data products by the Census Bureau to measure the pandemic's impact on the economy: the Small Business Pulse Survey (SBPS) and the weekly Business Formation Statistics. Policymakers and other federal agency officials, media outlets, and academia commended the Census Bureau's rapid response to their data needs during the largest economic crisis in recent American history. The Census Bureau capitalized on the successes that underlaid the high frequency data collection and near real time data dissemination engineered for the SBPS by creating the Business Trends and Outlook Survey (BTOS).

BTOS uses ongoing data collection to produce high frequency, timely, and granular information about current economic conditions and trends. BTOS is the only biweekly business tendency survey produced by the federal statistical system, providing unique and detailed data during times of economic or other emergencies. The BTOS initial target population is all nonfarm, single-location employer businesses with receipts of $1,000 or more in the United States, the District of Columbia, and Puerto Rico. The current sample consists of approximately 1.2 million single-unit businesses split into six panels. Data collection occurs every two weeks, and businesses in each panel are asked to report once every 12 weeks for one year. Current data from BTOS are representative of all single location employer businesses (excluding farms) in the U.S. economy and are published every two weeks. The data are available at the national and state levels, in addition to the 25 most-populous Metropolitan Statistical Areas (MSAs). North American Industry Classification System (NAICS) sector, subsector, and state by sector are also published, as are employment size class, and sector by employment size class data, according to the same timeline.

Data from BTOS are currently used to provide timely data to understand the economic conditions being experienced by single unit businesses; BTOS provides near real time data on key items such as revenue, paid employees, hours worked as well as inventories which is being added in for the second sample collection year; a new sample collection is conducted each year.

BTOS also provides high level information on the changing share of businesses facing difficulties stemming from supply chain issues, interest rate changes, or weather events. Previously, there had been few data sources available to policymakers, media outlets, and academia that delivered near real-time insights into economic trends and outlooks. BTOS data has been used by the Small Business Administration to evaluate the impact of regulatory changes. Use of the BTOS data (or additional requirements) is being determined by the Economic Development Agency (EDA) to understand the impact of natural disasters on U.S. businesses for the EDA to then guide the Federal Emergency Management Agency (FEMA) and/or policymakers in assisting in economic recovery support missions.

The BTOS consists of a set of core questions and supplemental content, when needed. The U.S. Census Bureau requests approval to add one question on Work from Home (WFH) schedules to the BTOS core content. Data collection for the BTOS core content will start August 12, 2024.

For 2024, the supplemental questionnaire will ask respondents about the business perspective on WFH. Using the same strategy as the 2023 BTOS AI core questions, the Census Bureau hopes to field one core WFH question to run during all cycles in addition to the supplement. The core WFH question will be a yes/no question intended to capture potential seasonality in WFH at the business level. Having this baseline will be important in understanding potential seasonal patterns picked up in the supplemental questions; preliminary findings from cognitive testing suggested that seasonality could be important in certain industries.

The Census Bureau plans to resubmit this package once cognitive testing concludes to gain approval for the WFH supplement which we plan to field

beginning in November 2024. The WFH supplement is intended to capture nuances in WFH from business perspective including intensity of WFH and factors impacting its availability.

Frequency: Bi-weekly.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Sections 131 and 182.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *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 and entering either the title of the collection or the OMB Control Number 0607–1022.

Mary Reuling Lenaiyasa,

Paperwork Reduction Act Program Manager, Policy Coordination Office, U.S. Census Bureau.

[FR Doc. 2024–14733 Filed 7–3–24; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–884]

Glycine From India: Preliminary Results and Partial Rescission of the Countervailing Duty Administrative Review; 2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to Kumar Industries, India (Kumar), a producer and exporter of glycine from India during the period of review (POR) January 1, 2022, through December 31, 2022. Interested parties are invited to comment on these preliminary results.

DATES: Applicable July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Scarlet Jaldin or Amber Hodak AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4275 or (202) 482–8034, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 21, 2019, Commerce published the countervailing duty (CVD) order on glycine from India.[1] On August 3, 2023, based on these timely requests for review, in accordance with 19 CFR 351.221(c)(1)(i), Commerce published a notice of initiation of an administrative review the *Order.*[2] Commerce partially extended the time period for issuing these preliminary results, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), to June 28, 2024.[3]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I 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 Order

The merchandise covered by the *Order* is glycine from India. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party or parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation of the requested review. Between June 28 and 30, 2023, Commerce received timely requests for administrative reviews of 31 producers/exporters from various interested parties, in accordance with section 751(a)(1) of the Act and 19 CFR 351.213(b)(1).[5] On September 22, 2023, Paras withdrew its request for review of itself.[6] On October 31, 2023, the petitioner[7] timely withdrew its request for administrative review of 30 producers/exporters.[8] Because the withdrawal letters were timely filed, and no other party requested a review of the companies listed in the withdrawal letters, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this review of the *Order* with respect to the 30 companies listed in Appendix II. For additional information regarding this determination, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(A) of the Act. For each of the subsidy programs found to be countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[9] For a full description of the

[1] *See Glycine from India and the People's Republic of China: Countervailing Duty Orders,* 84 FR 29173 (June 21, 2019) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 51271, 51277 (August 3, 2023) (*Initiation Notice*). GEO requested a review of 31 companies, including Pan Chem Corporation. Pan Chem Corporation was inadvertently omitted from the *Initiation Notice.* As a result, there was an incorrect total of 30, rather than 31, companies included in the *Initiation Notice* for this administrative review. As explained below, in these preliminary results of review, Commerce is rescinding the review of many of those companies, including Pan Chem, based on the timely withdrawal of the review request.

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review,'' dated January 24, 2024; *see also* Memorandum, ''Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review,'' dated June 3, 2024.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Countervailing Duty Order on Glycine from India; 2022,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See* Paras Intermediates Private Limited's (Paras) Letter, ''Request for Countervailing Duty Administrative Review,'' dated June 28, 2023; *see also* Kumar's Letter, ''Request for Administrative Review of Countervailing duty Order,'' dated June 29, 2023; GEO Specialty Chemicals, Inc.'s (GEO) Letter, ''Request for Administrative Review,'' dated June 30, 2023 (GEO Request for Administrative Review); and Memorandum, ''Phone Conversation with an Interested Party,'' dated July 20, 2023.

[6] *See* Paras' Letter, ''Withdrawal of Review Request for Countervailing Duty Administrative Review,'' dated September 22, 2023 (Paras Withdrawal of Review Request).

[7] On January 1, 2024, GEO, the former petitioner in this proceeding, filed an amended administrative protective order (APO) application, disclosing that it transferred all its glycine business to Deer Park Glycine, LLC. As a result, Deer Park Glycine, LLC (the petitioner) became the new petitioning party in this administrative review. *See* Memorandum, ''Amended APO Application,'' dated January 17, 2024.

[8] *See* GEO's Letter, ''Partial Withdrawal of Request for Administrative Review,'' dated October 31, 2023 (GEO Withdrawal of Review Request).

[9] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

methodology underlying our conclusions, *see* the accompanying Preliminary Decision Memorandum.

Preliminary Results of Review

As a result of this review, Commerce preliminary determines the following countervailable subsidy rate for the period January 1, 2022, through December 31, 2022:

Company	Subsidy rate (*ad valorem* percent)
Kumar Industries, India	2.01

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results to interested parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Case briefs or other written documents may be submitted to the Assistant Secretary for Enforcement and Compliance.[10] Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice. 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) table of contents listing each issue; (2) a table of authorities.[12] All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the established deadline.

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 review, 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 limited their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public 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, filed electronically via ACCESS. Hearing requests should contain the party's name, address, and telephone number, the number of participants, and a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically-filed hearing request must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time, within 30 days after the date of publication of this notice. If a request for a hearing is made, parties will be notified of the time and date of the hearing.[15]

Assessment Rates

Consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. Commerce intends to issue assessment instructions to CBP regarding mandatory respondent, Kumar, no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

For the companies rescinded from this review, as identified in Appendix II, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption during period January 1, 2022, through December 31, 2022, in accordance with 19 CFR 351.212(c)(1)(i). For these companies, Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these preliminary results of review in the **Federal Register**.

Cash Deposit Requirements

Pursuant to section 751(a)(1) of the Act, upon publication of the final results, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties for each of the companies listed above on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, except where the rate calculated in the final results is zero or *de minimis.* For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit instructions, when imposed, shall remain in effect until further notice.

Final Results

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2), Commerce intends to issue the final results of this administrative review, including the results of its analysis of issues by the parties in any written briefs, no later than 120 days after the date of publication of these preliminary results.

Notification to Interested Parties

These preliminary results are being issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: June 28, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

[10] *See* 19 CFR 351.309(c)(1)(ii); *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 Procedures*).

[12] *See* 19 CFR 351.309(c)(2) and 351.309(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 Procedures.*

[15] *See* 19 CFR 351.310(d).

Appendix II

Companies for Which Commerce Is Rescinding the Administrative Review

1. Avid Organics Private Limited
2. Paras Intermediates Private Limited
3. Aditya Chemicals
4. JR Corporation
5. Medilane Healthcare Pvt. Ltd.
6. Adwith Nutrichem Private Limited
7. Tarkesh Trading Company
8. Eagle Chemical Works
9. Alkanb Chemicals
10. Shari Pharmachem Pvt., Ltd.
11. Lucas-TVS Limited
12. Medbion Healthcare Private Limited
13. Alka Chemical Industries
14. J.R. International
15. Papchem Lifesciences (OPC) Private Limited
16. Kaaha Overseas
17. Bajaj Healthcare Limited
18. Global Merchants
19. Ladleadd
20. Jain Specialty Fine Chemicals
21. Alchemos Private Limited
22. Kronox Lab Sciences Ltd.
23. Venus International
24. Natural and Essential Oils Private Limited
25. Indiana Chem-Port
26. Pan Chem Corporation
27. Meteoric Biopharmaceuticals
28. Rudraa International
29. Rexisize Rasayan Industries
30. Reliance Rasayan Pvt. Ltd.

[FR Doc. 2024–14766 Filed 7–3–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–873]

Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel From India: Preliminary Results of Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty order on certain cold-drawn mechanical tubing of carbon and alloy steel (cold-drawn mechanical tubing) from India for the period of review (POR) June 1, 2022, through May 31, 2023. Commerce preliminarily finds that Goodluck India Limited (Goodluck) and Tube Products of India, Ltd., a unit of Tube Investments of India Limited (TII) made sales of subject merchandise at prices below normal value (NV) during the POR. We invite interested parties to comment on these preliminary results.

DATES: Applicable July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Alice Maldonado or Colin Thrasher, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington DC 20230; telephone: (202) 482–4682 or (202) 482–3004, respectively.

SUPPLEMENTARY INFORMATION:

Background

On August 3, 2023, Commerce initiated an administrative review of the antidumping duty order on cold-drawn mechanical tubing from India,[1] in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).[2] This review covers two producers/exporters of subject merchandise, Goodluck and TII. On January 31, 2024, Commerce extended the deadline for these preliminary results until June 28, 2024.[3] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4]

Scope of the Order

The merchandise subject to the *Order* is certain cold-drawn mechanical tubing of carbon and alloy steel from India. For a full description of the scope, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Act. We calculated export price in accordance with section 772(a) of the Act. We calculated NV in accordance with section 773 of the Act.

For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum. A list of the topics discussed in the Preliminary Decision Memorandum is included as an appendix 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.*

Preliminary Results of the Review

We preliminarily determine that the following estimated weighted-average dumping margins exist for the period June 1, 2022, through May 31, 2023:

Exporter/producer	Weighted-average dumping margin (percent)
Goodluck India Limited	2.64
Tube Products of India, Ltd., a unit of Tube Investments of India Limited	2.44

Disclosure

We intend to disclose the calculations performed to parties within five days after public announcement of the preliminary results or, if there is no public announcement, within five days of the date of publication of this notice.[5]

Verification

As provided in section 782(i)(3)(B) of the Act and 19 CFR 351.307(b)(1)(iv), Commerce intends to verify the information provided by Goodluck prior to the final results of this administrative review.

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 verification report is issued in this

[1] *See Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel from the People's Republic of China, the Federal Republic of Germany, India, Italy, the Republic of Korea, and Switzerland: Antidumping Duty Orders; and Amended Final Determinations of Sales at Less Than Fair Value for the People's Republic of China and Switzerland,* 83 FR 26962 (June 11, 2018); and *Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel from India: Notice of Second Amended Final Determination; Notice of Amended Order; Notice of Resumption of First and Reinitiation of Second Antidumping Duty Administrative Reviews; Notice of Opportunity for Withdrawal; and Notice of Assessment in Third Antidumping Duty Administrative Review,* 86 FR 74069 (December 29, 2021) (collectively, *Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 51271 (August 3, 2023), as corrected by *Initiation of Antidumping and Countervailing Duty Administrative Review,* 88 FR 71829 (October 18, 2023) (*Initiation Notice*). In the August 3, 2023, notice (88 FR 51271), Commerce inadvertently listed Tube Product of India, Ltd., a unit of Tube Investments of India Limited. The correct spelling for this company is Tube Products of India, Ltd., a unit of Tube Investments of India Limited.

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated January 31, 2024.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Antidumping Duty Order on Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel from India; 2022–2023,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See* 19 CFR 351.224(b).

review.[6] 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.[7] Interested parties who submit case or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[8]

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 review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[9] 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 public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public 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).[10]

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS,[11] within 30 days after the date of publication of this notice in the **Federal Register**. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in case and rebuttal briefs.[12] 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.

Assessment Rates

Upon completion of the final results of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[13] Pursuant to 19 CFR 351.212(b)(1), if the weighted-average dumping margin for Goodluck or TII is not zero or *de minimis* (*i.e.,* less than 0.50 percent) in the final results of this review, we will calculate importer-specific assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales. If either respondent's weighted-average dumping margin is zero or *de minimis* in the final results of review, or if an importer-specific assessment rate is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review, and for future deposits of estimated duties, where applicable.[14]

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by Goodluck or TII for which the company did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate established in the original less-than-fair-value (LTFV) investigation (*i.e.,* 5.87 percent) [15] if there is no rate for the intermediate company(ies) involved in the transaction.[16]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies listed above will be equal to the weighted-average dumping margins established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for merchandise exported by a company not covered in this review, but covered in a prior segment of the proceeding, the cash deposit rate will be the company-specific rate published for the most recently-completed segment in which it was reviewed; (3) if the exporter is not a firm covered in this review or in the original LTFV investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 5.87 percent, the all-others rate established in the LTFV investigation as adjusted for the export-subsidy rate in the companion countervailing duty investigation.[17] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, no later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent

[6] *See* 19 CFR 351.309(c)(1)(ii); *see also* 19 CFR 351.303 (for general filing requirements).

[7] *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).

[8] *See* 19 351.309(c)(2) and (d)(2).

[9] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[10] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

[11] *See* 19 CFR 351.310(c).

[12] *See* 19 CFR 351.310.

[13] *See* 19 CFR 351.212(b).

[14] *See* section 751(a)(2)(C) of the Act.

[15] *See Order,* 83 FR at 26965.

[16] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[17] *See Order,* 83 FR at 26965.

assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Notification to Interested Parties

Commerce is issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(h)(2) and 19 CFR 351.221(b)(4).

Dated: June 28, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–14764 Filed 7–3–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–833]

Raw Honey From the Socialist Republic of Vietnam: Preliminary Results of Antidumping Duty Administrative Review; 2021–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that Ban Me Thout Honeybee Joint Stock Company (BMT), Daklak Honeybee Joint Stock Company (DakHoney), and 13 non-individually examined and separate-rate eligible exporters of raw honey from the Socialist Republic of Vietnam (Vietnam) sold subject merchandise to the United States at less than normal value (NV) during the period of review (POR) August 25, 2021, through May 31, 2023.

DATES: Applicable July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Krisha Hill or Stephanie Trejo, 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) 482–4037 or (202) 482–4390, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 10, 2022, Commerce published in the **Federal Register** the antidumping duty (AD) order on raw honey from Vietnam. On June 1, 2023, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order*.[1] In the *June Opportunity Notice* Commerce inadvertently listed an incorrect POR for this proceeding.[2] Commerce noted this error in its *August Initiation Notice* in which it initiated the review for this proceeding.[3] Commerce also noted the error in a subsequent opportunity notice, giving parties a further opportunity to request an administrative review using the correct POR.[4]

On August 3, 2023, Commerce published in the **Federal Register** the initiation notice of an administrative review of the AD *Order* on raw honey from Vietnam.[5] Commerce further published an addendum to the *August Initiation Notice* in which it initiated a review of raw honey from Vietnam for two companies, one that requested a review based on the *August Opportunity Notice* and one company for which Commerce failed to initiate a review based on its request for review made pursuant to the *June Opportunity Notice*.[6] Commerce selected BMT and DakHoney as mandatory respondents in this administrative review.[7]

On January 29, 2024, Commerce extended the deadline for these preliminary results to June 28, 2024.[8] For a complete description of the events that followed the initiation of this administrative review, *see* the Preliminary Decision Memorandum.[9]

Scope of the Order

The product covered by this *Order* is raw honey from Vietnam. Raw honey is honey as it exists in the beehive or as obtained by extraction, settling and skimming, or coarse straining. The merchandise subject to this investigation is currently classifiable under statistical subheading 0409.00.0005, 0409.00.0035, 0409.00.0045, 0409.00.0056, and 0409.00.0065 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

A full description of the scope of the *Order* is contained in the Preliminary Decision Memorandum.[10]

Separate Rates

The Act and Commerce's regulations do not address the establishment of a separate rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for separate-rate respondents which Commerce did not examine individually in an administrative review. Section 735(c)(5)(A) of the Act states that the all-others rate should be calculated by averaging the weighted-average dumping margins calculated for individually-examined respondents, excluding dumping margins that are zero, *de minimis,* or based entirely on facts available. For the preliminary results of this review, Commerce determined the estimated dumping margins for BMT and DakHoney to be 100.54 percent and 154.47 percent, respectively, and we have assigned to the separate-rate companies a rate of 120.92 percent, which is the weighted-

[1] *See Raw Honey From Argentina, Brazil, India, and the Socialist Republic of Vietnam: Antidumping Duty Orders,* 87 FR 35501 (June 10, 2022) (*Order*); and *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List,* 88 FR 35835 (June 1, 2023) (*June Opportunity Notice*).

[2] *See June Opportunity Notice,* 88 FR at 35837.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 51271, 51276 (August 3, 2023) (*August Initiation Notice*).

[4] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List,* 88 FR 50840 (August 2, 2023) (*August Opportunity Notice*).

[5] *See August Initiation Notice.*

[6] *See Raw Honey From the Socialist Republic of Vietnam: Addendum to Initiation of Antidumping Duty Administrative Review,* 88 FR 65155 (September 21, 2023) (*August Initiation Notice Addendum*). The *August Initiation Notice* and *August Initiation Notice Addendum* list 35 companies. However, in the *August Initiation Notice,* Commerce mistakenly listed Hung Thinh Trading Pvt twice. Additionally, we note that review requests were filed for two separate companies with minor variations in their names: Daklak Honey Bee JSC and Daklak Honeybee Joint Stock Company, and Dong Nai Honey Bee Corp and Dongnai HoneyBee Corporation. Accordingly, Commerce initiated this administrative review with respect to the 32 companies.

[7] *See* Memorandum, ''Respondent Selection,'' dated October 5, 2023.

[8] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated January 29, 2024.

[9] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review: Raw Honey from the Socialist Republic of Vietnam; 2021–2023,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[10] *Id.*

average dumping margins of BMT and DakHoney weighted by their publicly ranged U.S. sales values.[11] For a listing of the separate rate companies, *see* Appendix II.

Vietnam-Wide Entity

Under Commerce's policy regarding the conditional review of the Vietnam-wide entity,[12] the Vietnam-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the Vietnam-wide entity in this review, the entity is not under review, and the entity's rate (*i.e.,* 60.03 percent) is not subject to change.[13]

With the exception of BMT, DakHoney, and the companies listed in Appendix II, Commerce considers all other companies for which a review was requested and did not demonstrate separate rate eligibility to be part of the Vietnam-wide entity.[14] For these preliminary results, we consider the following companies to be part of the Vietnam-wide entity because they did not file separate rate applications or certifications: (1) Bee Honey Corporation of Ho Chi Minh City; (2) Golden Bee Company Limited; (3) Golden Honey Co., Ltd.; (4) Hai Phong Honeybee Company Limited; (5) Highlands Honeybee Travel Co., Ltd.; (6) Hoa Viet Honeybee Co., Ltd.; (7) Hung Binh Phat; (8) Hung Thinh Trading Pvt; (9) Huong Rung Co., Ltd.; (10) Huong Viet Honey Co., Ltd.; (11) Nguyen Hong Honey Co., LTDTA; (12) Phong Son Co., Ltd.; (13) Saigon Bees Co., Limited; (14) Thai Hoa Mat Bees Raising Co., Ltd.; (15) Thai Hoa Viet Mat Bees Raising Co.; (16) TNB Foods Co., Ltd.; and (17) Vinawax Producing Trading and Service Company Limited. For additional information, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act). We calculated export price and constructed export price in accordance with section 772 of the Act. Because Vietnam is a non-market economy country within the meaning of section 771(18) of the Act, we calculated NV in accordance with section 773(c) of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. 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.* A list of topics discussed in the Preliminary Decision Memorandum is included in Appendix I of this notice. In addition, a complete version of the Preliminary Decision Memorandum can be found at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of the Administrative Review

Commerce preliminarily determines that the following weighted-average dumping margins exist for the administrative review covering the period August 25, 2021, through May 31, 2023:

Exporter	Estimated weighted-average dumping margin (percent)
Ban Me Thuot Honeybee Joint Stock Company	100.54
Daklak Honeybee Joint Stock Company	154.47
Separate Rate Companies[15]	120.92
Vietnam-wide Entity	60.03

Disclosure and Public Comment

We intend to disclose the calculations performed to parties within five days after public announcement of the preliminary results or, if there is no public announcement, within five days of the date of publication of this notice.[16] Interested parties may submit case briefs no later than 30 days after the date of publication of this notice.[17] 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.[18] Interested parties who submit case or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[19]

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 review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[20] 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 public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public 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).[21]

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS.[22] Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in case and rebuttal briefs.[23] If a request for a hearing is made, Commerce intends to hold the

[11] With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the dumping margins calculated for the examined respondents; (B) a simple average of the dumping margins calculated for the examined respondents; and (C) a weighted-average of the dumping margins calculated for the examined respondents using each company's publicly ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010).

[12] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[13] *See Order,* 87 FR at 35503.

[14] *See August Initiation Notice,* 88 FR at 51272 (''All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a Separate Rate Application or Certification, as described below.'').

[15] *See* Appendix II.

[16] *See* 19 CFR 351.224(b).

[17] *See* 19 CFR 351.309(c)(1)(ii); *see also* 19 CFR 351.303 (for general filing requirements).

[18] *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).

[19] *See* 19 351.309(c)(2) and (d)(2).

[20] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[21] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

[22] *See* 19 CFR 351.310(c).

[23] *See* 19 CFR 351.310.

hearing at a time and date to be determined. A hearing request must be filed electronically using ACCESS and received in its entirety by 5:00 p.m. Eastern Time within 30 days after the publication of this notice.

Verification

As provided in section 782(i)(3) of the Act, Commerce intends to verify the information submitted by BMT and DakHoney in advance of the final results of this review.

Final Results of Review

Unless the deadline is extended, Commerce intends to issue the final results of this review, including the results of its analysis of the issues raised in any written briefs, no later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Assessment Rates

Upon issuing the final results, Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[24] Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

For each individually examined respondent in this review whose weighted-average dumping margin in the final results of review is not zero or *de minimis* (*i.e.,* less than 0.5 percent), Commerce intends to calculate importer/customer-specific assessment rates.[25] Where the respondent reported reliable entered values, Commerce intends to calculate importer/customer-specific *ad valorem* assessment rates by aggregating the amount of dumping calculated for all U.S. sales to the importer/customer and dividing this amount by the total entered value of the merchandise sold to the importer/customer.[26] Where the respondent did not report entered values, Commerce will calculate importer/customer-specific assessment rates by dividing the amount of dumping for reviewed sales to the importer/customer by the total quantity of those sales. Commerce will calculate an estimated *ad valorem* importer/customer-specific assessment rate to determine whether the per-unit assessment rate is *de minimis;* however, Commerce will use the per-unit assessment rate where entered values were not reported.[27] Where an importer/customer-specific *ad valorem* assessment rate is not zero or *de minimis,* Commerce will instruct CBP to collect the appropriate duties at the time of liquidation. Where either the respondent's weighted average dumping margin is zero or *de minimis,* or an importer/customer-specific *ad valorem* assessment rate is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[28]

Pursuant to Commerce's refinement to its practice, for sales that were not reported in the U.S. sales database submitted by a respondent individually examined during this review, Commerce will instruct CBP to liquidate the entry of such merchandise at the dumping margin assigned to the Vietnam-wide entity.[29] For respondents not individually examined in this administrative review that qualified for a separate rate, the assessment rate will be equal to the weighted-average dumping margin assigned to the respondent in the final results of this review.[30]

Additionally, where Commerce determines that an exporter under review had no shipments of subject merchandise to the United States during the POR, any suspended entries of subject merchandise that entered under that exporter's CBP case number during the POR will be liquidated at the dumping margin assigned to the Vietnam-wide entity.

In accordance with section 751(a)(2)(C) of the Act, the final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated antidumping duties, where applicable.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) for the exporters listed above, the cash deposit rate will be equal to the weighted-average dumping margins established in the final results of this review, except if the rate is *de minimis,* in which case the cash deposit rate will be zero; (2) for previously-examined Vietnamese and non-Vietnamese exporters not listed above that at the time of entry are eligible for a separate rate base on a prior completed segment of this proceeding, the cash deposit rate will continue to the be the existing exporter-specific cash deposit rate; (3) for all non-Vietnamese exporters of subject merchandise which at the time of entry do not have a separate rate, the cash deposit rate will be the rate applicable to the Vietnamese exporter that supplied the non-Vietnamese exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

Commerce is issuing and publishing the preliminary results of this review in accordance with sections 751(a)(1)(B) and 777(i) of the Act, and 19 CFR 351.221(b)(4).

Dated: June 28, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

[24] *See* 19 CFR 351.212(b)(1).

[25] *See Antidumping Proceedings: Calculation of the Weighted Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012) (*Final Modification*).

[26] *See* 19 CFR 351.212(b)(1).

[27] *Id.*

[28] *See Final Modification,* 77 FR at 8103.

[29] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

[30] *See Drawn Stainless Steel Sinks from the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review and Preliminary Determination of No Shipments: 2014–2015,* 81 FR 29528 (May 12, 2016), and accompanying PDM at 10–11, unchanged in *Drawn Stainless Steel Sinks from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; Final Determination of No Shipments; 2014–2015,* 81 FR 54042 (August 15, 2016).

Appendix II

List of Companies Eligible for Separate Rate

(1) Bao Nguyen Honeybee Co., Ltd.
(2) Daisy Honey Bee Joint Stock Company
(3) Dak Nguyen Hong Exploitation of Honey Company Limited TA
(4) Dongnai HoneyBee Corporation
(5) Hanoi Honey Bee Joint Stock Company
(6) Hoa Viet Honeybee One Member Company Limited
(7) Hoang Tri Honey Bee Co., Ltd.
(8) Huong Rung Trading-Investment and Export Company Limited
(9) Nhieu Loc Company Limited
(10) Southern Honey Bee Company Ltd.
(11) Spring Honeybee Co., Ltd.
(12) Thanh Hao Bees Co., Ltd.
(13) Viet Thanh Food Co., Ltd.

[FR Doc. 2024–14762 Filed 7–3–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–155]

Certain Pea Protein From the People's Republic of China: Final Affirmative Countervailing Duty Determination and Final Affirmative Critical Circumstances Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of certain pea protein (pea protein) from the People's Republic of China (China). The period of investigation is January 1, 2022, through December 31, 2022.

DATES: Applicable July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Kristen Johnson or Laura Griffith, 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) 482–4793 or (202) 482–6430, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 18, 2023, Commerce published its *Preliminary Determination* in the **Federal Register** and invited interested parties to comment.[1] Subsequently, on April 23, 2024, Commerce issued its Post-Preliminary Determination.[2] For a complete description of the events that followed the *Preliminary Determination, see* the Issues and Decision Memorandum.[3] The Issues and Decision Memorandum is a public document and is made available to the public 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.*

Scope of the Investigation

The product covered by this investigation is pea protein from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

On February 7, 2024, Commerce issued a Preliminary Scope Decision Memorandum in which it determined not to modify the language of the scope as it regards pea protein from China.[4] We received no scope case briefs from interested parties. Therefore, the scope of the investigation, as contained in the *Preliminary Determination,* remains unchanged as noted in Appendix I.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation, and the issues raised in the case and rebuttal briefs that were submitted by parties in this investigation, are discussed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, *see* Appendix II to this notice.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[5] For a full description of the methodology underlying our final determination, *see* the Issues and Decision Memorandum.

In making this final determination, Commerce relied, in part, on facts otherwise available, including with an adverse inference, pursuant to sections 776(a) and (b) of the Act. For a full discussion of our application of adverse facts available, *see* the *Preliminary Determination* PDM[6] and section ''Use of Facts Otherwise Available and Application of Adverse Inferences'' in the Issues and Decision Memorandum.

Verification

Commerce was unable to conduct on-site verifications of the information relied on in making its final determination in this investigation. However, in January 2024, we took additional steps in lieu of on-site verifications to verify the information relied upon in making this final determination, in accordance with section 782(i) of the Act, by conducting virtual verifications of Yantai Oriental Protein Tech Co., Ltd. (Yantai Oriental) and Zhaoyuan Junbang Trading Co., Ltd. (Junbang).

Changes Since the Preliminary Determination

Based on our analysis of the comments received from interested parties and our verification findings, we made certain changes to the subsidy rate calculations for Junbang and Yantai Oriental. For a discussion of these changes, *see* the Issues and Decision Memorandum.

Final Affirmative Determination of Critical Circumstances

Pursuant to sections 705(a)(2), 776(a), and 776(b) of the Act, and 19 CFR 351.206, Commerce continues to find that critical circumstances exist with respect to imports of pea protein from China for Junbang, Yantai Oriental, all other producers and/or exporters, and the non-responsive companies. For

[1] *See Certain Pea Protein from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination, Preliminary Affirmative Critical Circumstances Determination, and Alignment of Final Determination with Final Antidumping Duty Determination,* 88 FR 87403 (December 18, 2023) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Post-Preliminary Decision Memorandum for the Countervailing Duty Investigation on Certain Pea Protein from the People's Republic of China,'' dated April 23, 2024.

[3] *See* Memorandum, ''Decision Memorandum for the Final Affirmative Determination in the Countervailing Duty Investigation of Certain Pea Protein from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See* Memorandum, ''Less-Than-Fair-Value and Countervailing Duty Investigations of Certain Pea Protein from the People's Republic of China: Preliminary Scope Decision Memorandum,'' dated February 7, 2024.

[5] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; *see also* section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[6] *See Preliminary Determination* PDM at 8–36.

further information on Commerce's critical circumstances analysis, *see* the section ''Final Critical Circumstances Determination'' in the accompanying Issues and Decision Memorandum.

All-Others Rate

Pursuant to section 705(c)(5)(A)(i) of the Act, Commerce will determine an all-others rate equal to the weighted-average countervailable subsidy rates established for exporters and/or producers individually examined, excluding any rates that are zero, *de minimis,* or rates based entirely under section 776 of the Act. We continue to calculate individual estimated countervailable subsidy rates for Junbang and Yantai Oriental that are not zero, *de minimis,* or based entirely on facts otherwise available. Therefore, we determined the all-others rate using the estimated countervailable subsidy rates calculated for Junbang and Yantai Oriental. For further information, *see* the section ''Calculation of the All-Others Rate'' in the accompanying Issues and Decision Memorandum.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent *ad valorem*)
Yantai Oriental Protein Tech Co., Ltd[7]	16.52
Zhaoyuan Junbang Trading Co., Ltd[8]	15.15
Focusherb LLC	355.89
Golden Protein Limited	355.89
Shandong Jianyuan Bio-engineering Co	355.89
Yantai Wanpy International Trade	355.89
All Others	15.84

Disclosure

Commerce intends to disclose to interested parties the calculations and analysis performed in this final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of the publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

[7] Commerce finds the following companies to be cross-owned with Yantai Oriental: Jiujiang Tiantai Food Co., Ltd.; Shandong Sanjia Investment Holding Group Co., Ltd.; Yantai Yiyuan Bioengineering Co., Ltd.; and Yantai Zhongzhen Trading Co., Ltd.

[8] Commerce finds Yantai Shuangta Food Co. Ltd. to be cross-owned with Junbang.

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination,* pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, and because we preliminarily determined that critical circumstances existed with respect to Junbang, Yantai Oriental, all other producers and/or exporters, and the non-responsive companies, we instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise from China that were entered, or withdrawn from warehouse, for consumption, on or after September 19, 2023, which is 90 days prior to the date of the publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 703(d) of the Act, we instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered or withdrawn from warehouse on, or after, April 16, 2024, but to continue the suspension of liquidation of all entries of subject merchandise between September 19, 2023 and April 15, 2024.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a countervailing duty order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for entries of subject merchandise in the amounts indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our final affirmative determination that countervailable subsidies are being provided to producers and exporters of pea protein from China. Because the final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of pea protein from China no later than 45 days after our final determination. In addition, we are making available to the ITC all non-privileged and nonproprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance. If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue a countervailing duty order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Administrative Protective Order

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO, in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/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

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: June 27, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The product within the scope of this investigation is high protein content (HPC) pea protein, which is a protein derived from peas (including, but not limited to, yellow field peas and green field peas) and which contains at least 65 percent protein on a dry weight basis. HPC pea protein may also be identified as, for example, pea protein concentrate, pea protein isolate, hydrolyzed pea protein, pea peptides, and fermented pea protein. Pea protein, including HPC pea protein, has the Chemical Abstracts Service (CAS) registry number 222400–29–5.

The scope covers HPC pea protein in all physical forms, including all liquid (*e.g.,* solution) and solid (*e.g.,* powder) forms, regardless of packaging or the inclusion of

additives (*e.g.,* flavoring, suspension agents, preservatives).

The scope also includes HPC pea protein described above that is blended, combined, or mixed with non-subject pea protein or with other ingredients (*e.g.,* proteins derived from other sources, fibers, carbohydrates, sweeteners, and fats) to make products such as protein powders, dry beverage blends, and protein fortified beverages. For any such blended, combined, or mixed products, only the HPC pea protein component is covered by the scope of this investigation. HPC pea protein that has been blended, combined, or mixed with other products is included within the scope, regardless of whether the blending, combining, or mixing occurs in third countries.

HPC pea protein that is otherwise within the scope is covered when commingled (*i.e.,* blended, combined, or mixed) with HPC pea protein from sources not subject to this investigation. Only the subject component of the commingled product is covered by the scope.

A blend, combination, or mixture is excluded from the scope if the total HPC pea protein content of the blend, combination, or mixture (regardless of the source or sources) comprises less than five percent of the blend, combination, or mixture on a dry weight basis.

All products that meet the written physical description are within the scope of the investigation unless specifically excluded. The following products, by way of example, are outside and/or specifically excluded from the scope of the investigation:

- burgers, snack bars, bakery products, sugar and gum confectionary products, milk, cheese, baby food, sauces and seasonings, and pet food, even when such products are made with HPC pea protein.
- HPC pea protein that has gone through an extrusion process to alter the HPC pea protein at the structural and functional level, resulting in a product with a fibrous structure which resembles muscle meat upon hydration. These products are commonly described as textured pea protein or texturized pea protein.
- HPC pea protein that has been further processed to create a small crunchy nugget commonly described as a pea protein crisp.
- protein derived from chickpeas.

The merchandise covered by the scope is currently classified under Harmonized Tariff Schedule of the United States (HTSUS) categories 3504.00.1000, 3504.00.5000, and 2106.10.0000. Such merchandise may also enter the U.S. market under HTSUS category 2308.00.9890. Although HTSUS categories and the CAS registry number 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 Issues and Decision Memorandum

[FR Doc. 2024–14687 Filed 7–3–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–154]

Certain Pea Protein From the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Critical Circumstances Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that certain pea protein (pea protein) from the People's Republic of China (China) is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation is January 1, 2023, through June 30, 2023.

DATES: Applicable July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Sofia Pedrelli or Katherine Smith, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4310 or (202) 482–0557, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 13, 2024, Commerce published its *Preliminary Determination* in the **Federal Register**, in which we postponed the final determination until June 27, 2024, and invited parties to comment on the *Preliminary Determination.*[1]

For a summary of the events that occurred since the *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, *see* the Issues and Decision Memorandum.[2] The Issues and Decision Memorandum is a public document and is made available to the public 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.*

Scope of the Investigation

The product covered by this investigation is pea protein from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

On February 7, 2024, Commerce issued a Preliminary Scope Decision Memorandum in which it determined not to modify the language of the scope as it regards pea protein from China.[3] We received no scope case briefs from interested parties. Therefore, the scope of the investigation, as contained in the *Preliminary Determination,* remains unchanged as noted in appendix I.

Final Affirmative Determination of Critical Circumstances

We continue to find that critical circumstances exist for imports of pea protein from China for the separate rate companies and the China-wide entity,

[1] *See Certain Pea Protein from the People's Republic Of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Affirmative Determination of Critical Circumstances, Postponement of Final Determination, and Extension of Provisional Measures,* 89 FR 10038 (February 13, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision memorandum (PDM).

[2] *See* Memorandum, ''Decision Memorandum for the Final Determination in the Less-Than-Fair Value Investigation of Certain Pea Protein from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memorandum, ''Less-Than-Fair-Value and Countervailing Duty Investigations of Certain Pea Protein from the People's Republic of China: Preliminary Scope Decision Memorandum,'' dated February 7, 2024.

pursuant to section 735(a)(3)(B) of Tariff Act of 1930, as amended (the Act), and 19 CFR 351.206. For further discussion of this issue, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs submitted by interested parties are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached as appendix II to this notice.

Application of Total Adverse Facts Available With Respect to the China-Wide Entity

Consistent with the *Preliminary Determination,* Commerce continues to find, pursuant to sections 776(a)(1) and (a)(2)(A)–(C) of the Act, that the use of facts available is warranted in determining the rate of the China-wide entity, which includes Junbang Trading Co., Ltd. (Junbang) and Yantai Zhongzhen Trading Co.; Yantai Oriental Protein Tech Co.; and Jiugiang Tinti Food., Ltd. (collectively, the Zhongzhen Companies).[4] Furthermore, we continue to find that an adverse inference is warranted in selecting from the facts otherwise available, pursuant to section 776(b) of the Act and 19 CFR 351.308(a), because the China-wide entity failed to cooperate by not acting to the best of its ability to comply with Commerce's requests for information. As adverse facts available (AFA), we continue to apply the highest rate from the petition (*i.e.,* 280.31 percent) because it is a rate derived from information submitted on the record and achieves the right balance between the goal of inducing future cooperation by the uncooperative respondent and the rate not being punitive.[5]

Separate Rates

We preliminarily found certain companies to be eligible for a separate rate in the *Preliminary Determination*.[6] No interested party commented on our preliminary separate rate determination with respect to the companies that we found were eligible for a separate rate, and we have no basis to otherwise reconsider this determination. Accordingly, we continue to find that these companies are eligible for a separate rate in the final determination. As noted above, we continue to treat Junbang and the Zhongzhen Companies as a part of the China-wide entity.

In calculating the rate for non-individually examined separate rate respondents in a non-market economy 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 any margins that are zero, *de minimis,* or based entirely under section 776 of the Act. The statute further provides that, where all margins are zero, *de minimis,* or based entirely on facts available under section 776 of the Act, Commerce may use ''any reasonable method'' for assigning the rate to non-selected respondents.[7]

The estimated weighted-average dumping margins in this final determination are based entirely under section 776 of the Act. In investigations 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 entities, in accordance with section 735(c)(5)(B) of the Act, Commerce typically calculates a simple average of the margins alleged in the petition and applies the results to all other entities not individually examined.[8] The simple average of the petition rates in this LTFV investigation is 122.19 percent.[9] *See* the table below in the ''Final Determination'' section of this notice.

Combination Rates

Consistent with the *Initiation Notice, Preliminary Determination,* and Policy Bulletin 05.1, Commerce calculated combination rates for the respondents that are eligible for a separate rate in this investigation.[10]

Final Determination

The final estimated weighted-average dumping margins are as follows: [11]

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset) (percent)
Fenchem Biotek Ltd	Yantai Shuangta Food Co., Ltd	122.19	111.65
Jianyuan International Co., Ltd	Shandong Jianyuan Bioengineering Co., Ltd	122.19	111.65
Jianyuan International Co., Ltd	Hengyuan Biotechnology Co., Ltd	122.19	111.65
KTL Pharmaceutical Co., Limited	Jiujiang Tiantai Food Co., Ltd	122.19	111.65
Linyi Yuwang Vegetable Protein Co., Ltd	Linyi Yuwang Vegetable Protein Co., Ltd	122.19	111.65
Nutracean Co., Ltd	Yantai Shuangta Food Co., Ltd	122.19	111.65
Nutracean Co., Ltd	Zhaoyuan Junbang Trading Co., Ltd	122.19	111.65
Shandong Yuwang Ecological Food Industry Co., Ltd	Linyi Yuwang Vegetable Protein Co., Ltd	122.19	111.65
Yantai T.Full Biotech Co., Ltd	Yantai T.Full Biotech Co., Ltd	122.19	111.65
Yosin Biotechnology (Yantai) Co., Ltd	Yosin Biotechnology (Yantai) Co., Ltd	122.19	111.65

[4] *See Preliminary Determination* PDM at 11–15. We preliminarily found that the Zhongzhen Companies should be treated as a single entity. *Id.* at 4–5; *see also* Memorandum, ''Preliminary Determination of Affiliation and Single Entity Determination for Yantai Zhongzhen Trading Co., Ltd.,'' dated February 7, 2024. No interested party commented on this finding, and we continue to find that these companies should be treated as a single entity for our final determination.

[5] *See* Issues and Decision Memorandum at Comment 5.

[6] *See Preliminary Determination* PDM at 6–7.

[7] *See* section 735(c)(5)(B) of the Act.

[8] *See, e.g., Certain Preserved Mushrooms from Spain: Final Affirmative Determination of Sales Less Than Fair Value,* 88 FR 18120 (March 27, 2023).

[9] *See* Puris Proteins, LLC's Letter, ''Response of Petitioner to Volume II Supplemental Questionnaire,'' dated July 21, 2023, at Exhibit II–S14; *see also* Issues and Decision Memorandum at Comment 4.

[10] S*ee Certain Pea Protein from the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 88 FR 52124 (August 7, 2023); *see also Preliminary Determination*; and 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,'' dated April 5, 2004 (Policy Bulletin 05.1), available on Commerce's website at *https://enforcement.trade.gov/policy/bull05-1.pdf.*

[11] We continue to find that neither the Zhongzhen Companies nor Junbang, the respondents selected for individual examination in this investigation, are eligible for a separate rate; thus the China-wide entity includes the Zhongzhen Companies and Junbang. *See* Issues and Decision memorandum at Comments 1 and 2 for additional details.

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset) (percent)
Yosin Import and Export (Yantai) Co., Ltd	Yosin Biotechnology (Yantai) Co., Ltd	122.19	111.65
Hainan Zhongxin Chemical Co., Ltd	Shandong Hua-Thai Food Products Co., Ltd	122.19	111.65
Hainan Zhongxin Chemical Co., Ltd	Shandong Jundu Talin Foods Co., Ltd	122.19	111.65
Hainan Zhongxin Chemical Co., Ltd	Yosin Biotechnology (Yantai) Co., Ltd	122.19	111.65
Hainan Zhongxin Chemical Co., Ltd	Yosin Import and Export (Yantai) Co., Ltd	122.19	111.65
Hainan Zhongxin Chemical Co., Ltd	Yantai Shuangta Food Co., Ltd	122.19	111.65
China-wide Entity		280.31	269.77

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a final 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). However, because Commerce continues to find the mandatory respondents are part of the China-wide entity, applied total AFA to the China-wide entity 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.

Continuation of Suspension of Liquidation

In accordance with section 735(c)(4) of the Act, because Commerce continues to find that critical circumstances exist for the non-selected separate rate companies and the China-wide entity, we will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of subject merchandise, as described in Appendix I of this notice, entered, or withdrawn from warehouse, for consumption, on or after November 15, 2023, which is 90 days prior to the date of publication of the affirmative *Preliminary Determination* in the **Federal Register**.

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 makes an affirmative determination for domestic subsidy pass-through or export subsidies, Commerce offsets the calculated estimated weighted-average dumping margin by the appropriate rates. However, suspension of liquidation of provisional measures in the companion CVD investigation has been discontinued; therefore, we are not instructing CBP to collect cash deposits based upon the adjusted estimated weighted-average dumping margin for those export subsidies at this time.[12]

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), we will instruct CBP to require a cash deposit for such entries of merchandise equal to the amount by which the normal value exceeds the U.S. price 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 subject merchandise 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 country exporters of subject merchandise not listed in the table above, the cash deposit rate is the cash deposit rate applicable to the Chinese producer/exporter combination (or China-wide entity) that supplied that third-country exporter. These suspension of liquidation instructions will remain in effect until further notice.

U.S. International Trade Commission (ITC) Notification

In accordance with section 735(d) of the Act, we will notify the ITC of our final affirmative determination of sales at LTFV. Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of pea protein from China no later than 45 days after this final determination. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all cash deposits will be refunded or canceled, and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Administrative Protective Order (APO)

This notice will serve as the final reminder to the parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written 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

This determination and this notice are issued and published in accordance with sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

[12] *See Certain Pea Protein from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination, Preliminary Affirmative Critical Circumstances Determination, and Alignment of Final Determination with Final Antidumping Duty Determination,* 88 FR 87403, (December 18, 2023); *see also* section 703(d) of the Act, which states that the provisional measures may not be in effect for more than four months, which in the companion CVD case is 120 days after the publication of the preliminary determination, or April 14, 2023.

Dated: June 27, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistance Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The product within the scope of this investigation is high protein content (HPC) pea protein, which is a protein derived from peas (including, but not limited to, yellow field peas and green field peas) and which contains at least 65 percent protein on a dry weight basis. HPC pea protein may also be identified as, for example, pea protein concentrate, pea protein isolate, hydrolyzed pea protein, pea peptides, and fermented pea protein. Pea protein, including HPC pea protein, has the Chemical Abstracts Service (CAS) registry number 222400–29–5.

The scope covers HPC pea protein in all physical forms, including all liquid (*e.g.,* solution) and solid (*e.g.,* powder) forms, regardless of packaging or the inclusion of additives (*e.g.,* flavoring, suspension agents, preservatives).

The scope also includes HPC pea protein described above that is blended, combined, or mixed with non-subject pea protein or with other ingredients (*e.g.,* proteins derived from other sources, fibers, carbohydrates, sweeteners, and fats) to make products such as protein powders, dry beverage blends, and protein fortified beverages. For any such blended, combined, or mixed products, only the HPC pea protein component is covered by the scope of this investigation. HPC pea protein that has been blended, combined, or mixed with other products is included within the scope, regardless of whether the blending, combining, or mixing occurs in third countries.

HPC pea protein that is otherwise within the scope is covered when commingled (*i.e.,* blended, combined, or mixed) with HPC pea protein from sources not subject to this investigation. Only the subject component of the commingled product is covered by the scope.

A blend, combination, or mixture is excluded from the scope if the total HPC pea protein content of the blend, combination, or mixture (regardless of the source or sources) comprises less than five percent of the blend, combination, or mixture on a dry weight basis.

All products that meet the written physical description are within the scope of the investigation unless specifically excluded. The following products, by way of example, are outside and/or specifically excluded from the scope of the investigation:

- burgers, snack bars, bakery products, sugar and gum confectionary products, milk, cheese, baby food, sauces and seasonings, and pet food, even when such products are made with HPC pea protein;
- HPC pea protein that has gone through an extrusion process to alter the HPC pea protein at the structural and functional level, resulting in a product with a fibrous structure which resembles muscle meat upon hydration. These products are commonly described as textured pea protein or texturized pea protein;
- HPC pea protein that has been further processed to create a small crunchy nugget commonly described as a pea protein crisp;
- protein derived from chickpeas.

The merchandise covered by the scope is currently classified under Harmonized Tariff Schedule of the United States (HTSUS) categories 3504.00.1000, 3504.00.5000, and 2106.10.0000. Such merchandise may also enter the U.S. market under HTSUS category 2308.00.9890. Although HTSUS categories and the CAS registry number 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 Issues and Decision Memorandum

[FR Doc. 2024–14686 Filed 7–3–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review; and Final Determination of No Shipments; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) has determined that Shenzhen Sungold Solar Co., Ltd. (Sungold), and the companies to which Commerce granted separate rates, did not sell subject merchandise at prices below normal value (NV) during the period December 1, 2021, through November 30, 2022, the period of review (POR). Commerce also determined that certain companies do not qualify for a separate rate, and that it is appropriate to rescind this review with respect to certain companies that did not ship subject merchandise during the POR.

DATES: Applicable July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Dakota Potts or Paola Aleman Ordaz, 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) 482–0223 or (202) 482–4031, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 4, 2024, Commerce published the *Preliminary Results* of this review in the **Federal Register**.[1] For details regarding the events that occurred since publication of the *Preliminary Results* in the **Federal Register**, *see* the Issues and Decision Memorandum.[2] Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order[3]

The merchandise covered by the *Order* 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. For a complete description of the scope of the *Order, see* the Issues Decision Memorandum.

Analysis of Comments Received

We addressed all the issues raised in interested parties' case and rebuttal briefs in the Issues and Decision Memorandum. A list of the issues raised

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Antidumping Administrative Review, and Preliminary Determination of No Shipments; 2021–2022,* 89 FR 457 (January 4, 2024) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum ''Decision Memorandum for the Final Results of the Administrative Review of the Antidumping Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China; 2021–2022'' dated concurrently with, and adopted by, this notice (Issues and Decision Memorandum).

[3] *See 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) (*Order*).

in parties' briefs is included in Appendix I 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.* In addition, 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, and for the reasons explained in the Issues and Decision Memorandum, we revised the surrogate value of the EVA input used by Sungold.

Partial Rescission of Administrative Review

In the *Preliminary Results,* Commerce determined that certain companies did not have suspended entries of subject merchandise during the POR and thus, announced its intent to rescind the review with respect to these companies.[4] For these final results, we continue to determine that, the companies that are listed in Appendix II do not have any suspended entries of subject merchandise during the POR. Accordingly, for the companies that are listed in Appendix II to this notice, Commerce has rescinded its review of these companies.

China-Wide Entity

In the *Preliminary Results,* Commerce found that 35 companies for which a review was initiated did not establish their eligibility for a separate rate.[5] No parties contested this finding (*see* discussion regarding the Yingli single entity below). As such, we continue to determine these 35 companies identified in Appendix III are part of the China-wide entity. Because no party requested a review of the China-wide entity, and Commerce no longer considers the China-wide entity as an exporter conditionally subject to administrative reviews,[6] we did not conduct a review of the China-wide entity. Thus, the weighted-average dumping margin for the China-wide entity rate (*i.e.,* 238.95 percent) is not subject to change.[7]

Final Determination of No Shipments

No parties commented on Commerce's preliminary no shipments determination [8] with respect to Trina Solar (Changzhou) Science and Technology Co., Ltd. (Trina Solar Changzhou) and Jinko Solar.[9] For these final results of review, Commerce has continued to determine that these two companies/company groupings did not export or sell subject merchandise, nor did they have knowledge that their subject merchandise was entered into the United States, during the POR.

Separate Rates

With the exception of Commerce's decision to deny Yingli [10] a separate rate, no parties commented on Commerce's preliminary separate rate determinations. Commerce has continued to grant the companies that are listed in the table in the ''Final Results of Review'' section of this notice a separate rate, but has continued to deny a separate rate to the companies, including Yingli,[11] that are listed in Appendix III to this notice, which are part of the China-wide entity and subject to the China-wide entity rate.

Dumping Margin for Separate Rate Companies

The statute and Commerce's regulations do not address what dumping margin to apply to respondents that are not selected for individual examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the dumping margin for respondents that are not individually examined in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''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* dumping margins, and any dumping margins determined entirely {on the basis of facts available}.'' When the weighted-average dumping margins established for all individually examined respondents are zero, *de minimis,* or based entirely on facts available, section 735(c)(5)(B) of the Act permits Commerce to ''use any reasonable method to establish the estimated all-others rate for exporters and producers not individually investigated, including averaging the estimated weighted average dumping margins determined for the exporters and producers individually investigated.'' Consistent with Commerce's practice,[12] we have determined that a reasonable method would be to assign a dumping margin to the non-individually examined separate rate companies equal to the zero percent dumping margin calculated for Sungold.

Final Results of Review

Commerce determines that the following weighted-average dumping margins exist for the period December 1, 2021, through November 30, 2022:

Exporter	Weighted-average dumping margin (percent)
Shenzhen Sungold Solar Co., Ltd	0.00
Separate Rate Companies	
BYD (Shangluo) Industrial Co., Ltd	0.00
Hongkong Hello Tech Energy Co., Ltd	0.00
Trina Solar Co., Ltd	0.00
Trina Solar Science & Technology (Thailand) Ltd	0.00
Zhejiang Aiko Solar Energy Technology Co., Ltd	0.00

Disclosure

Commerce intends to disclose to parties to the proceeding the

[4] *See Preliminary Results,* 89 FR at 458. Other than Red Sun Energy Co., Ltd., whose comments we address in the accompanying Issues and Decision Memorandum, no parties commented on Commerce's preliminary rescission determination.

[5] *Id.*

[6] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963, 65969–70 (November 4, 2013).

[7] *See Order,* 83 FR at 60397.

[8] See *Preliminary Results* PDM at 8–10.

[9] Jinko Solar refers to the following companies which Commerce treated as a single entity: Jinko Solar Import and Export Co., Ltd.; Jinko Solar Co., Ltd.; Jinko Solar Technology (Haining) Co., Ltd.; Yuhuan Jinko Solar Co., Ltd.; Zhejiang Jinko Solar Co., Ltd.; Jiangsu Jinko Tiansheng Solar Co., Ltd. ; JinkoSolar (Chuzhou) Co., Ltd.; JinkoSolar (Yiwu) Co., Ltd.; and JinkoSolar (Shangrao) Co., Ltd.

[10] Yingli refers to the following companies which Commerce treated as a single entity: (1) Shenzhen Yingli New Energy Resources Co., Ltd.; (2) Baoding Jiasheng Photovoltaic Technology Co. Ltd.; (3) Baoding Tianwei Yingli New Energy Resources Co., Ltd.; (4) Beijing Tianneng Yingli New Energy Resources Co., Ltd.; (5) Hainan Yingli New Energy Resources Co., Ltd.; (6) Hengshui Yingli New Energy Resources Co., Ltd.; (7) Lixian Yingli New Energy Resources Co., Ltd.; (8) Tianjin Yingli New Energy Resources Co., Ltd.; and (9) Yingli Energy (China) Company Limited.

[11] *See* Issues and Decision Memorandum at Comment 3.

[12] *See Wooden Cabinet and Vanities and Components Thereof From the People's Republic of China: Final Results* and Partial Rescission of the Antidumping Duty Administrative Review; 2019–2021, 87 FR 67674 (November 9, 2022), and accompanying Issues and Decision Memorandum at Comment 5.

calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Assessment Rates

Because the weighted average dumping margins for the companies that are listed in the table in the ''Final Results of Review'' section of this notice are zero percent, Commerce will instruct CBP to liquidate entries of the companies' subject merchandise during the POR without regard to antidumping duties. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of this notice in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, in its assessment instructions Commerce will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Pursuant to a refinement of its practice, Commerce will instruct CBP to liquidate entries of Sungold's subject merchandise for which sales were not reported in the U.S. sales database at the China-wide entity rate.[13]

Additionally, Commerce will instruct CBP to liquidate entries of subject merchandise during the POR that were recorded under the company-specific case numbers for Trina Solar Changzhou or Jinko Solar at the China-wide entity rate.

Cash Deposit Requirements

The following cash deposit requirements will be in effect for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on, or after, the date of publication of this notice in the **Federal Register**, as provided for by section 751(a)(2)(C) of the Act: (1) for the exporters that are listed in the table in the ''Final Results of Review'' section of this notice above, the cash deposit rate will be zero percent; (2) for previously investigated or reviewed Chinese and non-Chinese exporters that are not listed in the rate table in the ''Final Results of Review'' section of this notice above that have separate rates, the cash deposit rate will continue to be the exporter's existing cash deposit rate; (3) for all China exporters of subject merchandise that do not have a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin assigned to the China-wide entity, which is 238.95 percent, and (4) for all non-China exporters of subject merchandise that do not have a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin applicable to the China exporter(s) that supplied that non-China exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers Regarding the Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant POR entries. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties has occurred and the subsequent assessment of doubled antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Administrative Protective Order (APO)

This notice also serves as a reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under an APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written 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

We are issuing these final results of administrative review and publishing this notice in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.213(h)(2) and 19 CFR 351.221(b)(5).

Dated: June 28, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

Appendix II

Companies for Which Commerce Is Rescinding the Review

1. Canadian Solar International Limited; Canadian Solar Manufacturing (Changshu) Inc.; Canadian Solar Manufacturing (Luoyang) Inc.; CSI Cells Co., Ltd.; CSI Solar Co., Ltd.; and CSI Solar Manufacturing (Fu Ning) Co., Ltd.
2. Chint Solar (Hong Kong) Company Limited; Chint Solar (Jiuquan) Co., Ltd.; Chint Solar (Zhejiang) Co., Ltd.; and Chint New Energy Technology (Haining) Co., Ltd.
3. JA Solar Technology Yangzhou Co., Ltd.
4. Jiawei Solarchina Co., Ltd.
5. JingAo Solar Co., Ltd.
6. Longi Solar Technology Co. Ltd.
7. Red Sun Energy Long An Company Limited a.k.a Red Sun Energy Co., Ltd.
8. Risen Energy Co. Ltd.; Risen Energy (Changzhou) Co., Ltd.; Risen (Wuhai) New Energy Co., Ltd.; Zhejiang Twinsel Electronic Technology Co., Ltd.; Risen (Luoyang) New Energy Co., Ltd.; Jiujiang Shengchao Xinye Technology Co., Ltd.; Jiujiang Shengzhao Xinye Trade Co., Ltd.; Ruichang Branch, Risen Energy (HongKong) Co., Ltd.; and Risen Energy (YIWU) Co., Ltd.
9. Shanghai BYD Co., Ltd.
10. Shanghai JA Solar Technology Co., Ltd.
11. Shenzhen Topray Solar Co., Ltd.
12. Wuxi Tianran Photovoltaic Co., Ltd.
13. Xiamen Yiyusheng Solar Co., Ltd.

Appendix III

Companies Determined To Be Part of the China-Wide Entity

1. Renesola Jiangsu Ltd.
2. BYD H.K. Co., Ltd.
3. CSI Modules (DaFeng) Co., Ltd.
4. De-Tech Trading Limited HK
5. Hengdian Group DMEGC Magnetics Co. Ltd.
6. JA Solar Co., Ltd.
7. Jiawei Solarchina (Shenzhen) Co., Ltd.
8. Lightway Green New Energy Co., Ltd.
9. Longi (HK) Trading Ltd.
10. Ningbo ETDZ Holdings, Ltd.
11. Ningbo Qixin Solar Electrical Appliance Co., Ltd.
12. ReneSola Zhejiang Ltd.
13. Shanghai Nimble Co., Ltd.
14. Sumec Hardware & Tools Co., Ltd.
15. Suntech Power Co., Ltd.
16. Taizhou BD Trade Co., Ltd.
17. tenKsolar (Shanghai) Co., Ltd.
18. Trina Solar Energy Development PTE Ltd.

[13] *See Solar Cells from China AR1 Final,* 80 FR at 41002.

19. Jinko Solar International Limited
20. Luoyang Suntech Power Co., Ltd.
21. Trina Solar (Singapore) Science and Technology Pte. Ltd.
22. Yingli Green Energy International Trading Company Limited
23. Trina Solar Energy Development Company Limited
24. Changzhou Trina Hezhong Photoelectric Co., Ltd.
25. Changzhou Trina Solar Energy Co., Ltd.
26. Changzhou Trina Solar Yabang Energy Co., Ltd.
27. Hubei Trina Solar Energy Co., Ltd.
28. Trina Solar (Hefei) Science and Technology Co., Ltd.
29. Turpan Trina Solar Energy Co., Ltd.
30. Yancheng Trina Guoneng Photovoltaic Technology Co., Ltd.
31. Yancheng Trina Solar Energy Technology Co., Ltd.
32. Anji DaSol Solar Energy Science & Technology Co., Ltd.
33. Maodi Solar Technology (Dongguan) Co., Ltd.
34. Shenzhen Yingli New Energy Resources Co., Ltd.; Baoding Jiasheng Photovoltaic Technology Co. Ltd.; Baoding Tianwei Yingli New Energy Resources Co., Ltd.; Beijing Tianneng Yingli New Energy Resources Co., Ltd.; Hainan Yingli New Energy Resources Co., Ltd.; Hengshui Yingli New Energy Resources Co., Ltd.; Lixian Yingli New Energy Resources Co., Ltd.; Tianjin Yingli New Energy Resources Co., Ltd.; and Yingli Energy (China) Company Limited (Yingli Energy China).
35. Wuxi Suntech Power Co., Ltd.

[FR Doc. 2024–14763 Filed 7–3–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–883]

Glycine From India: Preliminary Results and Rescission, In Part, of Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that certain producers and/or exporters subject to this administrative review did not make sales of subject merchandise at less than normal value during the period of review (POR) June 1, 2022, through May 31, 2023. Interested parties are invited to comment on these preliminary results.

DATES: Applicable July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Peter K. Farrell or Tyler R. Weinhold, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2104 or (202) 482–1121, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 21, 2019, Commerce published in the **Federal Register** an antidumping duty order on glycine from India.[1] On June 1, 2023, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order.*[2] On August 3, 2023, Commerce published the notice of initiation of the administrative review of the *Order,* covering 30 foreign producers and/or exporters.[3] On February 27, 2024, we extended the time limit for completion of these preliminary results to June 27, 2024, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act).[4]

Scope of the Order

The product covered by the scope of the *Order* is glycine from India. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.[5]

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. Commerce received requests for review from Avid Organics Private Limited (Avid), a producer and exporter of subject merchandise,[6] Bajaj Healthcare Limited (Bajaj), a producer and exporter of subject merchandise,[7] Paras Intermediaries Private Limited (Paras), an exporter of subject merchandise,[8] and GEO Specialty Chemicals, Inc. (GEO), a domestic interested party.[9] On September 22, 2023, Paras withdrew its review request.[10] On November 1, 2023, GEO withdrew its requests for review with respect to 28 companies.[11] Therefore all review requests were withdrawn for all companies listed in the *Initiation Notice,* except for Avid, Bajaj, and Kumar. Because the requests for review were timely withdrawn for the remaining 27 companies and no other parties requested a review of these companies, in accordance with 19 CFR 351.213(d)(1), Commerce is partially rescinding this review of the *Order* for these companies, identified in Appendix II of this notice.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum.[12] A list of the topics discussed in the Preliminary Decision Memorandum is included in Appendix I. 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

[1] *See Glycine from India and Japan: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Orders,* 84 FR 29170 (June 21, 2019) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List,* 88 FR 35835 (June 1, 2023).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 44262 (July 12, 2023) (*Initiation Notice*).

[4] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated February 27, 2024.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Antidumping Duty Order on Glycine from India; 2022–2023,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] Avid requested a review of itself. *See* Avid's Letter, ''Request for Anti-Dumping Duty Administrative Review,'' dated June 28, 2023.

[7] Bajaj requested a review of itself. *See* Bajaj's Letter, ''Request for An Administrative Review,'' dated June 30, 2023.

[8] Paras requested a review of itself. *See* Paras' Letter, ''Request for Anti-Dumping Duty Administrative Review,'' dated June 28, 2023.

[9] GEO requested a review of the following companies: (1) Aditya Chemicals; (2) Adwith Nutrichem Private Limited; (3) Alchemos Private Limited; (4) Alka Chemical Industries; (5) Alkanb Chemicals; (6) Avid; (7) Bajaj; (8) Eagle Chemical Works; (9) Global Merchants; (10) Indiana Chem-Port; (11) J.R. International; (12) Jain Specialties Fine Chemicals; (13) JR Corporation; (14) Kaaha Overseas; (15) Kronox Lab Sciences Ltd.; (16) Kumar Industries (Kumar); (17) Ladleadd; (18) Lucas-TVS Limited; (19) Medbion Healthcare Private Limited; (20) Medilane Healthcare Pvt. Ltd.; (21) Meteoric Biopharmaceuticals; (22) Natural and Essential Oils Private Limited; (23) Pan Chem Corporation; (24) Papchem Lifesciences (OPC) Private Limited; (25) Paras; (26) Reliance Rasayan Pvt. Ltd.; (27) Rexisize Rasayan Industries; (28) Shari Pharmachem Pvt., Ltd.; (29) Tarkesh Trading Company; (30) Venus International; *see* Geo's Letter, ''Request for Administrative Review,'' June 30, 2023.

[10] *See* Paras' Letter, ''Withdrawal of Review Request for Anti-Dumping Duty Administrative Review,'' dated September 22, 2023.

[11] *See* GEO's letter, ''Partial Withdrawal of Request for Administrative Review,'' dated October 31, 2024. GEO withdrew its request for 28 out of the 30 companies for which it requested a review, including Bajaj and Paras, but did not withdraw its request for review for Avid or Kumar. Bajaj did not withdraw its own request for review of itself.

[12] *See* Preliminary Decision Memorandum.

complete version of the Preliminary Decision Memorandum can be found at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of Review

We preliminarily determine that the following weighted-average dumping margin exists for the period June 1, 2022, through May 31, 2023:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Avid Organics Private Limited	0.00
Kumar Industries	0.00
Bajaj Healthcare Limited	0.00

Disclosure and Public Comment

Commerce intends to disclose to interested parties its calculations performed in these preliminary results, 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 the **Federal Register**, in accordance with 19 CFR 351.224(b).

Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs or other written comments to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the date of publication of this notice.[13] 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.[14] Interested parties who submit case or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[15]

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 administrative review, we instead request that interested parties provide, at the beginning of their briefs, a public executive summary for each issue raised in their briefs.[16] 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 public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. 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).[17]

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: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) 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.

All submissions, including case and rebuttal briefs, as well as hearing requests, should be filed via ACCESS.[18] An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline.

Final Results of Review

Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, no later than 120 days after the date of publication of this notice in the **Federal Register**, unless extended, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Assessment Rates

Upon completion of this administrative review, pursuant to section 751(a)(2)(A) of the Act, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review. If the weighted-average dumping margin for a mandatory respondent is not zero or *de minimis* in the final results of this review, we will calculate an importer-specific assessment rate on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales and the total entered value of such sales in accordance with 19 CFR 351.212(b)(1).[19] If the weighted-average dumping margin is zero or *de minimis* in the final results of review, or if an importer-specific assessment rate is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[20] For entries of subject merchandise during the POR produced by the respondent(s) for which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate such entries at the all-others rate [21] if there is no rate for the intermediate company(ies) involved in the transaction.[22] The final results of this administrative review shall be the basis for the assessment of antidumping duties on entries of merchandise under review and for future cash deposits of estimated antidumping duties, where applicable.

For the companies for which we are rescinding this administrative review, antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period of review, in accordance with 19 CFR 351.212(c)(1)(i). For these companies, Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these preliminary results in the **Federal Register**.

Consistent with its recent notice,[23] Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has

[13] *See* 19 CFR 351.303 (for general filing requirements).

[14] *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).

[15] *See* 19 351.309(c)(2) and (d)(2).

[16] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[17] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

[18] *See* 19 CFR 351.303(b).

[19] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[20] *Id.,* 77 FR at 8102–03; *see also* 19 CFR 351.106(c)(2).

[21] The all-others rate is 7.23 percent. *See Glycine from India: Final Determination of Sales at Less Than Fair Value,* 84 FR 18487 (May 1, 2019).

[22] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[23] *See Notice of Discontinuation of Policy to Issue Liquidation Instructions After 15 Days in Applicable Antidumping and Countervailing Duty Administrative Proceedings,* 86 FR 3995 (January 15, 2021).

expired (*i.e.,* within 90 days of publication). The final results of this administrative review shall be the basis for the assessment of antidumping duties on entries of merchandise under review and for future cash deposits of estimated antidumping duties, where applicable.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication in the **Federal Register** of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for companies subject to this review will be equal to the company-specific weighted-average dumping margin established in the final results of this administrative review; (2) for merchandise exported by a company not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published in the completed segment for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation but the producer is, then the cash deposit rate will be the rate established in the most recently completed segment of the proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 7.23 percent, the all-others rate established in the less-than-fair value investigation.[24] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

[24] *See Order,* 88 FR at 29171.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: June 27, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Affiliation and Collapsing
V. Discussion of the Methodology
VI. Currency Conversion
VII. Recommendation

Appendix II

Companies Rescinded From Administrative Review

(1) Aditya Chemicals;
(2) Adwith Nutrichem Private Limited;
(3) Alchemos Private Limited;
(4) Alka Chemical Industries;
(5) Alkanb Chemicals;
(6) Eagle Chemical Works;
(7) Global Merchants;
(8) Indiana Chem-Port;
(9) J.R. International;
(10) Jain Specialties Fine Chemicals;
(11) JR Corporation;
(12) Kaaha Overseas;
(13) Kronox Lab Sciences Ltd.;
(14) Ladleadd;
(15) Lucas-TVS Limited;
(16) Medbion Healthcare Private Limited;
(17) Medilane Healthcare Pvt. Ltd.;
(18) Meteoric Biopharmaceuticals;
(19) Natural and Essential Oils Private Limited;
(20) Pan Chem Corporation;
(21) Paras;
(22) Papchem Lifesciences (OPC) Private Limited;
(23) Reliance Rasayan Pvt. Ltd.;
(24) Rexisize Rasayan Industries;
(25) Shari Pharmachem Pvt., Ltd.;
(26) Tarkesh Trading Company;
(27) Venus International

[FR Doc. 2024–14713 Filed 7–3–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) has received requests to conduct administrative reviews of various antidumping duty (AD) and countervailing duty (CVD) orders with May anniversary dates. In accordance with Commerce's regulations, we are initiating those administrative reviews.

DATES: Applicable July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

SUPPLEMENTARY INFORMATION:

Background

Commerce has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various AD and CVD orders with May anniversary dates.

All deadlines for the submission of various types of information, certifications, or comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting time.

Respondent Selection

In the event that Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review (POR). We intend to place the CBP data on the record within five days of publication of the initiation notice and to make our decision regarding respondent selection within 35 days of publication of the initiation **Federal Register** notice. Comments regarding the CBP data and respondent selection should be submitted within seven days after the placement of the CBP data on the record of this review. Parties wishing to submit rebuttal comments should submit those comments within five days after the deadline for the initial comments.

In the event that Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Tariff Act of 1930, as amended (the Act), the following guidelines regarding collapsing of companies for purposes of respondent selection will apply. In general, Commerce has found that determinations concerning whether particular companies should be ''collapsed'' (*e.g.,* treated as a single

entity for purposes of calculating AD rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this AD proceeding (*e.g.,* investigation, administrative review, new shipper review, or changed circumstances review). For any company subject to this review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection.

Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value (Q&V) Questionnaire for purposes of respondent selection, in general, each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where Commerce considered collapsing that entity, complete Q&V data for that collapsed entity must be submitted.

Notice of No Sales

With respect to AD administrative reviews, we intend to rescind the review where there are no suspended entries for a company or entity under review and/or where there are no suspended entries under the company-specific case number for that company or entity. Where there may be suspended entries, if a producer or exporter named in this notice of initiation had no exports, sales, or entries during the POR, it may notify Commerce of this fact within 30 days of publication of this notice in the **Federal Register** for Commerce to consider how to treat suspended entries under that producer's or exporter's company-specific case number.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that has requested a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of a particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[1] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial responses to section D of the questionnaire.

Separate Rates

In proceedings involving non-market economy (NME) countries, Commerce begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single AD deposit rate. It is Commerce's policy to assign all exporters of merchandise subject to an administrative review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, Commerce analyzes each entity exporting the subject merchandise. In accordance with the separate rates criteria, Commerce assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a Separate Rate Application or Certification, as described below.

For these administrative reviews, in order to demonstrate separate rate eligibility, Commerce requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on Commerce's website at *https://access.trade.gov/Resources/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the certification, please follow the ''Instructions for Filing the Certification'' in the Separate Rate Certification. Separate Rate Certifications are due to Commerce no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding[2] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate

[1] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[2] Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any currently incomplete segment of the proceeding (*e.g.,* an ongoing administrative review, new shipper review, *etc.*) and entities that lost their separate rate in the most recently completed segment of the proceeding in which they participated.

in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name,[3] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Application will be available on Commerce's website at *https://access.trade.gov/Resources/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Application, refer to the instructions contained in the application. Separate Rate Applications are due to Commerce no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

Exporters and producers must file a timely Separate Rate Application or Certification if they want to be considered for individual examination. Furthermore, exporters and producers who submit a Separate Rate Application or Certification and subsequently are selected as mandatory respondents will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.

Initiation of Reviews

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following AD and CVD orders and findings. We intend to issue the final results of these reviews not later than May 31, 2025.

	Period to be reviewed
AD Proceedings	
CANADA: Large Diameter Welded Pipe, A–122–863	5/1/23–4/30/24
Aciers Lague Steels Inc.	
Acier Profile SBB Inc.	
Amdor Inc.	
BPC Services Group.	
Bri-Steel Manufacturing.	
Canada Culvert.	
Canadian National Steel Corp.	
Canam (St Gedeon).	
Cappco Tubular Products Canada Inc.	
CFI Metal Inc.	
Dominion Pipe & Piling C.	
Enduro Canada Pipeline Services.	
Evraz Inc. NA.	
Fi Oilfield Services Canada.	
Forterra.	
Gchem Ltd.	
Graham Construction.	
Groupe Fordia Inc.	
Grupo Fordia Inc.	
Hodgson Custom Rolling.	
Hyprescon Inc.	
Interpipe Inc.	
K K Recycling Services.	
Kobelt Manufacturing Co.	
Labrie Environment.	
Les Aciers Sofatec.	
Lorenz Conveying P.	
Lorenz Conveying Products.	
Matrix Manufacturing.	
MBI Produits De Forge.	
Nor Arc.	
Peak Drilling Ltd.	
Pipe & Piling Sply Ltd.	
Pipe & Piling Supplies.	
Prudental.	
Prudential.	
Shaw Pipe Protecction.	
Shaw Pipe Protection.	
Tenaris Algoma Tubes Facility.	
Tenaris Prudential.	
Welded Tube of Can Ltd.	
BELGIUM: Carbon and Alloy Steel Cut-to-Length Plate, A–423–812	5/1/23–4/30/24
Ancofer Stahlhandel GmbH.	
Eastman Chemical Technology BV.	
Industeel Belgium S.A.	
NLMK Clabecq S.A.; NLMK Plate Sales S.A.; NLMK Sales Europe S.A.; NLMK Manage Steel Center S.A.; NLMK La Louviere S.A.[4]	
NLMK Dansteel A.S.	
NV Hengelhoef Concrete Joints.	

[3] Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Certification.

	Period to be reviewed
Steelforce Europe NV.	
BELGIUM: Stainless Steel Plate in Coils, A–423–808	5/1/23–4/30/24
Aperam Stainless Belgium NV.	
ArcelorMittal Genk.	
Fenixs Steel NV.	
Helaxa BVBA.	
Industeel Belgium.	
FRANCE: Carbon and Alloy Steel Cut-To-Length Plate, A–427–828	5/1/23–4/30/24
Dillinger France S.A.	
GERMANY: Carbon and Alloy Steel Cut-To-Length Plate, A–428–844	5/1/23–4/30/24
AG der Dillinger Hüttenwerke.	
GREECE: Large Diameter Welded Pipe, A–484–803	5/1/23–4/30/24
Corinth Pipeworks Pipe Industry S.A.	
INDIA: Carbon and Alloy Steel Threaded Rod,[5] A–533–887	4/1/23–3/31/24
Mangal Steel Enterprises Limited.	
INDIA: Certain Welded Carbon Steel Standard Pipes and Tubes, A–533–502	5/1/23–4/30/24
Apl Apollo Tubes Ltd.	
Asian Contec Ltd.	
Bhandari Foils & Tubes Ltd.	
Bhushan Steel Ltd.	
Blue Moon Logistics Pvt. Ltd.	
CH Robinson Worldwide.	
Ess-Kay Engineers, Manushi Enterprise & Nishi Boring Corporation.	
Garg Tube Export LLP.	
GCL Private Limited.	
Goodluck India Ltd.	
GVN Fuels Ltd.	
Fiber Tech Composite Pvt. Ltd.	
Hydromatik.	
Jindal Quality Tubular Ltd.	
KLT Automatic & Tubular Products Ltd.	
Lloyds Line Pipes Ltd.	
MARINEtrans India Private Ltd.	
Patton International Ltd.	
Raajratna Ventures Ltd.	
Ratnamani Metals & Tubes Ltd.	
SAR Transport Systems Pvt. Ltd.	
Surya Global Steel Tubes Ltd.	
Surya Roshni Ltd.	
Vallourec Heat Exchanger Tubes Ltd.	
Welspun India Ltd.	
Zenith Birla (India) Ltd.	
Zenith Birla Steels Private Ltd.	
Zenith Dyeintermediates Ltd.	
INDIA: Organic Soybean Meal, A–533–901	5/1/23–4/30/24
Aashiyana Foodstuffs.	
Abhay Oil Industries.	
Agrawal Oil & Biocheam.	
Alfa Engineering & Enterprise.	
Al Quresh Exp.	
Al Sameer Exp. Pvt., Ltd.	
Apac Sourcing Solutions Ltd.	
Artevet India LLP.	
Asa Agrotech Pvt., Ltd.	
Avt Natural Products Ltd.	
Bawa Fishmeal and Oil Co.	
Bergwerff Organic (India) Pvt., Ltd.; Suminter India Organics Pvt., Ltd.	
Bio Treasure Overseas.	
BNS Agro Industries Sarl on A C.	
Chandrashekhar Exp. Pvt., Ltd.	
Cloves Inc.	
Delight Likelike Products Private Ltd.	
Delight Sustainable Products LLP.	
Eco Gold Nutri & Organics LLP.	
Ecopure Organics Private Ltd.	
Ecopure Specialties Ltd.	
Euroasias Organics Private Ltd.	
Fair Exp. (India) Pvt., Ltd.	
Faze Three Ltd. Wec India.	
Gharda Chemicals Ltd.	
Grasim Industries Ltd.	
Himatsingaka Seide Ltd.	
Hnco Organics Pvt., Ltd.	
Indauto Filters.	

	Period to be reviewed
Indo Gulf Co.	
Januz Universal.	
Jay Agro Product.	
Jay Shree Agro Products.	
J. Lal Foods International.	
J Lal Foods Private Ltd.	
JSM Foods.	
Kaj Traders.	
Kalash International.	
Kan Biosys Pvt., Ltd.	
Kanishka Organics LLP.	
Kemin Industries South Asia Pvt., Ltd.	
Keshav Proteins and Organic LLP.	
Khanal Foods Pvt., Ltd.	
Kiesrriya Agro Exim Pvt., Ltd.	
Krishna Corncob Industries.	
Krishna Overseas Inc.	
K Uttamlal Exp. Pvt., Ltd.	
LG Balakrishnan Bros.	
Lupin Limited.	
Mani Loni.	
Medikonda Nutrients.	
Mehtra Pressing.	
Mj Herbal Extracts Pvt., Ltd.	
Mohit International Pvt., Ltd.	
Motto Ceramic Pvt., Ltd.	
Mrl Tyres Ltd.	
Natural Remedies Pvt., Ltd.	
Nature Bio Foods Ltd.	
Navjyot International.	
Nutrivin Agro Pvt., Ltd.	
Ox Emp. Co.	
Pachranga Foods.	
Paprika Oleos (India) Ltd.	
Patel Retail Private Ltd.	
Prasad Cotton Industries Pvt., Ltd.	
Quality Spices and Food Exp. Pvt., Ltd.	
Radha Krishna Oil Product.	
Rainbow Exim Trade LLP.	
Raj Foods International.	
Raj Natural Food Pvt., Ltd.	
Rajat Agro Commodities Pvt., Ltd.	
Ramdev Food Products Pvt., Ltd.	
Rayban Organics Pvt., Ltd.	
Reach 2 Farm LLP.	
Reindeer Organics LLP.	
R.M Trading Co.	
R.S. Lal International.	
Rudra Enterprises.	
Rupen Marketing Pvt., Ltd.	
Sai Smaran Foods Ltd.	
Salvi Chemical Industries Ltd.	
Samruddhi Organic Farm (India) Pvt., Ltd.	
Sar Transport Systems Pvt., Ltd.	
Satguru Agro Resources Private Ltd.	
Satguru Organics Pvt., Ltd.	
Satyendra Fibc Pvt., Ltd.	
Seasons International Pvt., Ltd.	
Sethi International Overseas (India) Limited.	
Shanti Worldwide.	
Shemach Impex.	
Shivam Enterprises.	
Shree Imp. & Exp.	
Shree Swaminarayan Siddhant Uttejak.	
Shree Uday Oil and Foods Industries.	
Shreeram Fibres India Pvt., Ltd.	
Shri Narayani Mfg. Co.	
Shri Sumati Industries Pvt., Ltd.	
Soliflex Packaging Pvt., Ltd.	
Sona Sunehri Exp.	
S S India Foods Private Ltd.	
Suprajit Engineering Ltd.	
Tejawat Organic Foods.	
Terra Bio Naturals Private Ltd.	

	Period to be reviewed
Thakar Exp.	
Tulsi Foods.	
Unique Fragrances.	
Unique Organics Ltd.	
Vimala Food Products.	
Vinod Kumar Ranjeet Singh Bafna.	
Vippy Industries.	
VS Trans Lojistik LLP.	
Vvf (India) Ltd.	
We Organic Nature Pvt. Ltd.	
Welspun Global Brands Ltd.	
INDIA: Silicomanganese, A–533–823	5/1/23–4/30/24
Maithan Alloys Limited.	
ITALY: Carbon and Alloy Steel Cut-To-Length Plate, A–475–834	5/1/23–4/30/24
NLMK Verona S.p.A.	
Officine Technosider s.r.l.	
F.A.R. Fonderie Acciaierie S.p.A.	
Ferriera Valsider SpA.	
Metinvest Trametal SpA.	
JAPAN: Certain Carbon and Alloy Steel Cut-to-Length Plate, A–588–875	5/1/23–4/30/24
Tokyo Steel Manufacturing Co., Ltd.	
JAPAN: Diffusion-Annealed, Nickel-Plated Flat-Rolled Steel Products, A–588–869	5/1/23–4/30/24
KAGA, Inc.	
Marubeni-Itochu Steel, Inc.	
Okaya & Co., Ltd.	
Oneda Corporation.	
Oneda Electric Corporation.	
Nikken Lath Kogyo Co., Ltd.	
Panasonic Operational Excellence Co., Ltd.	
Toyo Kohan Co., Ltd.	
NETHERLANDS: Certain Preserved Mushrooms, A–421–815	11/3/22–4/30/24
Okechamp B.V.	
OMAN: Polyethylene Terephthalate Resin, A–523–810	5/1/23–4/30/24
OCTAL Inc.	
OCTAL SAOC FZC.	
POLAND: Certain Preserved Mushrooms, A–455–806	11/3/22–4/30/24
Okechamp S.A.	
REPUBLIC OF KOREA: Carbon and Alloy Steel Cut-To-Length Plate, A–580–887	5/1/23–4/30/24
POSCO; POSCO International Corporation.	
REPUBLIC OF KOREA: Carbon and Alloy Steel Wire Rod, A–580–891	5/1/23–4/30/24
POSCO.	
REPUBLIC OF KOREA: Large Diameter Welded Pipe, A–580–897	5/1/23–4/30/24
AJU Besteel Co., Ltd.	
Chang Won Bending Co., Ltd.	
Daiduck Piping Co., Ltd.	
Dong Yang Steel Pipe Co., Ltd.	
Dongbu Incheon Steel Co., Ltd.	
EEW KHPC Co., Ltd.	
EEW Korea Co., Ltd.	
Geumok Tech. Co., Ltd.	
Hansol Metal Co. Ltd.	
HiSteel Co., Ltd.	
Husteel Co., Ltd.	
Hyundai RB Co., Ltd.	
Hyundai Steel Company.	
Hyundai Steel Pipe Co., Ltd.	
Il Jin Nts Co. Ltd.	
Kiduck Industries Co., Ltd.	
Kum Kang Kind. Co., Ltd.	
Kumsoo Connecting Co., Ltd.	
Nexteel Co., Ltd.	
SeAH Steel Corporation.	
Seonghwa Industrial Co., Ltd.	
SIN-E B&P Co., Ltd.	
Steel Flower Co., Ltd.	
WELTECH Co., Ltd.	
REPUBLIC OF KOREA: Polyester Staple Fiber, A–580–839	5/1/23–4/30/24
Huvis Corporation.	
Toray Advanced Materials Korea, Inc.	
REPUBLIC OF TÜRKIYE: Circular Welded Carbon Steel Pipes and Tubes, A–489–501	5/1/23–4/30/24
Borusan Birleşik Boru Fabrikalari Sanayi ve Ticaret A.Ş.	
REPUBLIC OF TÜRKIYE: Large Diameter Welded Pipe, A–489–833	5/1/23–4/30/24
Cagil Makina San ve Tic A.S. AKA Cagil Makina A.S.	
HDM Celik Boru Sanayi ve Ticaret A.S.; HDM Spiral Kaynakli Boru A.S.[6]	

	Period to be reviewed
Spirally Welded Steel Pipe Inc.	
Çimtaş Boru Imalatiral Ticaret Ltd.	
Ẻmek Boru Makina Sanayi ve Ticaret A.S.	
Erciyas Celik Boru Sanayi A.S.	
Mazlum Mangtay Boru Son. Ins. Tar.Urn.San.ve Tic. A.S.	
Noksel Celik Boru Sanayi A.S.	
Ozbal Celik Boru San. Tic. Ve TAAH A.S.	
Toscelik Profil ve Sac End. A.S.[7]	
Toscelik Spiral Boru Uretim A.S.	
Umran Celik Boru Sanayii A.S.	
SERBIA: Mattresses, A–801–002	5/1/23–4/30/24
Healthcare Europe DOO Ruma.	
Healthcare Europe Inc.	
SOCIALIST REPUBLIC OF VIETNAM: Mattresses, A–552–827	5/1/23–4/30/24
Saigon-Kymdan Rubber Stock Company.	
TAIWAN: Certain Circular Welded Carbon Steel Pipes and Tubes, A–583–008	5/1/23–4/30/24
Shin Yang Steel Co., Ltd.	
Yieh Hsing Enterprise Co., Ltd.	
TAIWAN: Certain Stainless Steel Plate in Coils, A–583–830	5/1/23–4/30/24
Alpha Metal International Co., Ltd.	
Aurora Metal International Co., Ltd.	
Best Win International Co., Ltd.	
Build Up Hardware Co., Ltd.	
Chain Chon Industrial Co., Ltd.	
Chang Mien Industries Co., Ltd.	
Chia Far Industries Factory Co., Ltd.	
Chien Shing Stainless Co., Ltd.	
China Steel Corporation.	
China Steel Global Trading Corp.	
China Tah Lee Special Steel Co., Ltd.	
Chung Hung Steel co., Ltd.	
Da Song Enterprise Co., Ltd.	
Da Tsai Stainless Steel Co., Ltd.	
East Track Enterprise Co., Ltd.	
Froch Enterprise Co., Ltd.	
Fu Sheng Rubber & Plastic Industries Co.	
Gifull Enterprise Co., Ltd.	
Goang Jau Shing Enterprise Co., Ltd.	
Goldioceans International Co., Ltd.	
High Point Steel Mfg. Co., Ltd.	
Hoka Elements Co., Ltd.	
Huang-Yi Steel Coil Co., Ltd.	
Hwa Yang Stainless Steel Ind Corp.	
JJSE Co., Ltd.	
JK Industrial Development Corp.	
Jye Chi Corporation.	
Kunn Chuan Enterprise Co., Ltd.	
Lien Chy Laminated Metal Co., Ltd.	
Lien Kuo Metal Industries Co., Ltd.	
Lung An Stainless Ind. Co., Ltd.	
Meglobe Co., Ltd.	
Omen Bright Co., Ltd.	
PFP Taiwan Co., Ltd.	
Po Chwen Metal Industrial Co., Ltd.	
Pyramid Metal Technology Co., Ltd.	
Shang Chen Steel Co., Ltd.	
Shiner Steel International Ltd.	
Shing Shong Ta Metal Co., Ltd.	
Shye Yao Steel Co., Ltd.	
Sinkang Industries Co., Ltd.	
S-More Steel Materials Co., Ltd.	
Stanch Stainless Steel Co., Ltd.	
Sun Chun Stainless Co., Ltd.	
Sunmax Industrial Inc.	
Ta Chen International, Inc.	
Ta Chen Stainless Pipe Co., Ltd.	
Vasteel Enterprises Co., Ltd.	
Ta Fong Steel Co., Ltd.	
Taiwan Nippon Steel Stainless.	
Tang Eng Iron Works.	
Ton Yi Industrial Corp.	
Top Sunny Group Corp.	
Tsung Yui Enterprise Co., Ltd.	
Tung Mung Development Co., Ltd.	

	Period to be reviewed
Tzong Ji Metals Co., Ltd.	
Unity Special Steel Co., Ltd.	
Yieh Corp.	
Walsin Lihwa Corp.	
Wu Fu Jin.	
Wuu Jing Enterprise Co., Ltd.	
Yc Inox Co., Ltd.	
Yeou Ting Industries Co., Ltd.	
Yeou Yih Steel Co., Ltd.	
Yes Stainless International Co.	
Yi Shuenn Enterprise Co., Ltd.	
Yue Send Industrial Co., Ltd.	
Yieh Loong Enterprise Co., Ltd.	
Yieh Mau Corporation.	
Yuan Long Stainless Steel Corp.	
Yuen Chang Stainless Steel Co., Ltd.	
Yuh Sheng Stainless Steel Co., Ltd.	
TAIWAN: Stilbenic Optical Brightening Agents, A–583–848	5/1/23–4/30/24
Teh Fong Min International Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Aluminum Extrusions, A–570–967	5/1/23–4/30/24
Guangdong Xin Wei Aluminum Products Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Certain Vertical Shaft Engines between 99cc and up to 225cc, and parts thereof, A–570–124	5/1/23–4/30/24
Changzhou Kawasaki and Kwang Yang Engine Co., Ltd.	
ChongQing AM Pride Power & Machinery Co., Ltd.	
Chongqing Chen Hui Electric Machinery Co., Ltd.	
Chongqing Dajiang Power Equipment Co., Ltd.	
Chongqing Dinking Power Machinery Co., Ltd.	
Chongqing Ducar Power Equipment Co., Ltd.	
Chongqing Hwasdan Power Technology Co., Ltd.	
Chongqing Kohler Engines, Ltd.	
Chongqing Kohler Motors Co., Ltd.	
Chongqing Rato Technology Co., Ltd.	
Chongqing Senci Import & Export Trade Co., Ltd.	
Chongqing Shineray Agricultural Machinery Co., Ltd.	
Chongqing Zongshen General Power Machine Co., Ltd.	
Fujian Everstrong Lega Power Equipments Co., Ltd.	
Kawasaki Heavy Industries, Ltd.	
Lifan Technology (Group) Co., Ltd.	
Loncin Motor Co., Ltd.	
Qianjiang Group Wenling Jennfeng Industry Inc.	
Taizhou Sabo Electronics Co., Ltd.	
Wenling Qianjiang Imp. & Exp. Co., Ltd.	
Zhejiang Amerisun Technology Co., Ltd.	
Zhejiang Dobest Power Tools Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Citric and Citrate Salts, A–570–937	5/1/23–4/30/24
RZBC Group Co., Ltd.	
RZBC Co., Ltd.	
RZBC Import & Export Co., Ltd.	
RZBC (Juxian) Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Non-refillable Steel Cylinders, A–570–126	5/1/23–4/30/24
Ningbo Eagle Machinery & Technology Co., Ltd.	
Sanjiang Kai Yuan Co. Ltd.	
Wuyi Xilinde Machinery Manufacture Co., Ltd.	
Zhejiang KIN–SHINE Technology Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Oil Country Tubular Goods, A–570–943	5/1/23–4/30/24
Petroleum Equipment (Thailand) Co., Ltd.	
Thai Oil Pipe Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Pure Magnesium, A–570–832	5/1/23–4/30/24
Tianjin Magnesium International Co., Ltd.	
Tianjin Magnesium Metal Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Stilbenic Optical Brightening Agents, A–570–972	5/1/23–4/30/24
Beijing Odyssey Chemical Ind. Co. Ltd.	
Hebei Dianchang Chemicals Co. Ltd.	
Jinan Subang Fine Chemical Co., Ltd.	
Zhejiang Hongda Chemicals Co., Ltd.	
Zhejiang Transfar Whyyon Chemical Co., Ltd.	
UNITED ARAB EMIRATES: Certain Steel Nails, A–520–804	5/1/23–4/30/24
Al Falaq Building Materials.	
Al Khashab Building Materials Co., LLC.	
Al Rafaa Star Building Materials Est.	
Al Sabbah Trading and Importing, Est.	
Al-Khatib Est.	
All Ferro Building Materials, LLC.	

	Period to be reviewed
Asgarali Yousuf Trading Co., LLC. Azymuth Consulting, LLC. Burj Al Tasmeem, Tr. Gheewala Hardware Trading Company, LLC. Madar UAE. Master Nails and Pins Manufacturing, LLC/Middle East Manufacturing Steel, LLC. Mustafa Building Materials Co. (LLC). New World International, LLC. Okzeela Star Building Materials Trading, LLC. Rich Well Steel Industries, LLC. Rishi International, FZCO. Samrat Wire Industry, LLC. Sea Lan Contracting. SK Metal International DMCC. Trade Circle Enterprises, LLC.	
CVD Proceedings	
INDIA: Organic Soybean Meal, C–533–902 Abhay Oil Industries. Agrawal Oil & Biocheam. Alfa Engineering & Enterprise. Allcargo Logistics Ltd. All Cargo Logistics Ltd. Al Quresh Exp. Al Sameer Exp. Pvt., Ltd. Artevet India LLP. Asa Agrotech Pvt., Ltd. Avt Natural Products Ltd. Bawa Fishmeal and Oil Co. Bergwerff Organic (India) Pvt., Ltd.; Suminter India Organics Pvt., Ltd. Bio Treasure Overseas. BNS Agro Industries Sarl. Chandrashekhar Exp. Pvt., Ltd. Chola Imp. & Exp. Decent Shipping Pvt., Ltd. Delight Likelike Products Private Ltd. Delight Sustainable Products LLP. Eco Gold Nutri and Organics LLP. Ecopure Specialties Ltd. Euroasia S. Ingredients Private Ltd. Euroasias Organics Private Ltd. Fair Exp. (India) Pvt., Ltd. Faze Three Ltd. Wec India. Grasim Industries Ltd. Himatsingaka Seide Ltd. Hnco Organics Pvt., Ltd. Indication Instruments Ltd. Jay Agro Product. Jay Shree Agro Products. J. Lal Foods International. J Lal Foods Private Ltd. JSM Foods. Kaj Traders. Kalash International. Kan Biosys Pvt., Ltd. Kanishka Organics LLP. Kemin Industries South Asia Pvt., Ltd. Keshav Proteins and Organic LLP. Khanal Foods Pvt., Ltd. Kiesrriya Agro Exim Pvt., Ltd. Krishna Exp. Private Ltd. K Uttamlal Exp. Pvt., Ltd. LG Balakrishnan Bros. Lupin Limited. Mani Loni. Medikonda Nutrients. Mehtra Pressing. Mj Herbal Extracts Pvt., Ltd. Mohit International Pvt., Ltd. Natraj Home Furnishings Pvt., Ltd. Natural Remedies Pvt., Ltd. Nature Bio Foods Ltd. Navjyot International.	1/1/23–12/31/23

	Period to be reviewed
Ox Emp. Co.	
Pachranga Foods.	
Paprika Oleos (India) Ltd.	
Patel Retail Private Ltd.	
Prasad Cotton Industries Pvt., Ltd.	
Promois International Ltd.	
Pt C Industries Ltd. Mehsana Plant.	
Quality Spices and Food Exp. Pvt., Ltd.	
Radha Krishna Oil Product.	
Rainbow Exim Trade LLP.	
Raj Foods International.	
Raj Natural Food Pvt., Ltd.	
Rajat Agro Commodities Pvt., Ltd.	
Ramdev Food Products Pvt., Ltd.	
Rayban Organics Pvt., Ltd.	
Reach 2 Farm LLP.	
Reindeer Organics LLP.	
R.S. Lal International.	
Rudra Enterprises.	
Rupen Marketing Pvt., Ltd.	
Rustam Foods Private Ltd.	
Safewater Lines (India) Pvt., Ltd.	
Sai Smaran Foods Ltd.	
Salvi Chemical Industries Ltd.	
Samruddhi Organic Farm (India) Pvt., Ltd.	
Sar Transport Systems Pvt., Ltd.	
Satguru Agro Resources Private Ltd.	
Satguru Organics Pvt., Ltd.	
Seasons International Pvt., Ltd.	
Sethi International.	
Shah Imp. & Exp.	
Shanti Overseas (India) Limited.	
Shanti Worldwide.	
Shemach Impex.	
Shivam Enterprises.	
Shree Imp. & Exp.	
Shree Swaminarayan Siddhant Uttejak.	
Shree Uday Oil and Foods Industries.	
Shreeram Fibres India Pvt., Ltd.	
Shri Narayani Mfg. Co.	
Shri Sumati Industries Pvt., Ltd.	
S S India Foods Private Ltd.	
Tejawat Organic Foods.	
Terra Bio Naturals Private Ltd.	
Thakar Exp.	
Thirumalai Chemicals Ltd.	
Unique Fragrances.	
Unique Organics Ltd.	
Vimala Food Products.	
Vinod Kumar Ranjeet Singh Bafna.	
Vippy Industries.	
VS Trans Lojistik LLP.	
We Organic Nature Pvt. Ltd.	
Welspun Global Brands Ltd.	
Wwi Sourcing Pvt., Ltd.	
Yashvi Food Private, Ltd	
INDIA: Polyethylene Terephthalate Resin, C–533–862	1/1/23–12/31/23
Ester Industries Ltd.	
REPUBLIC OF KOREA: Carbon and Alloy Steel Cut-To-Length Plate, C–580–888	1/1/23–12/31/23
Ajin Industrial Co., Ltd.	
BDP International.	
Blue Track Equipment.	
Boxco.	
Boxco, Inc.	
Bukook Steel Co., Ltd.	
Buma CE Co., Ltd.	
China Chengdu International Techno-Economic Cooperation Co., Ltd.	
Daehan I.M. Co., Ltd.	
Daehan Tex Co., Ltd.	
Daeik Eng Co. Ltd.	
Daelim Industrial Co., Ltd.	
Daesam Industrial Co., Ltd.	
Daesin Lighting Co., Ltd.	
Daewoo International Corp.	

	Period to be reviewed
Dong Yang Steel Pipe.	
DKC.	
DK Corporation.	
DK Dongshin Co., Ltd.	
Dongbu Steel Co., Ltd.	
Dongkuk Industries Co., Ltd.	
Dongkuk Steel Mill Co., Ltd.	
EAE Automotive Equipment.	
EEW KHPC Co., Ltd.	
Eplus Expo Inc.	
GS Global Corp.	
Haem Co., Ltd.	
Han Young Industries.	
Hyeon Dae Jong Hap Gong Gu Co. Ltd.	
Hyosung Corp.	
Hyundai Steel Co.	
Jinmyung Frictech Co., Ltd.	
Khana Marine Ltd.	
Kindus Inc.	
Korean Iron and Steel Co., Ltd.	
Kyoungil Precision Co., Ltd.	
LG Electronics Inc.	
Menics.	
POSCO; Pohang Scrap Recycling Distribution Center Co. Ltd.; POSCO Nippon Steel RHF Joint Venture Co., Ltd.; POSCO Chemical Co., Ltd.; POSCO M-Tech Co., Ltd.; POSCO Terminal Co., Ltd.; POSCO SPS Co., Ltd.; POSCO Holdings Inc.[8]	
POSCO International Corporation.	
Qian'an Rentai Metal Products Co., Ltd.	
Samjin Lnd Co., Ltd.	
Samsun C&T Corp.	
Samsung.	
Samsung Electronics Co., Ltd.	
Shinko.	
Shipping Imperial Co., Ltd.	
Sinchang Eng Co., Ltd.	
SK Networks Co., Ltd.	
SNP Ltd.	
Seogio O/A.	
Steel N People Ltd.	
Summit Industry.	
Sungjin Co., Ltd.	
Wonbang Tech Co., Ltd.	
Young Sun Steel.	
REPUBLIC OF KOREA: Large Diameter Welded Pipe, C–580–898	1/1/23–12/31/23
AJU Besteel Co., Ltd.	
Chang Won Bending Co., Ltd.	
Daiduck Piping Co., Ltd.	
Dong Yang Steel Pipe Co., Ltd.	
Dongbu Incheon Steel Co., Ltd.	
EEW KHPC Co., Ltd.	
EEW Korea Co., Ltd.	
Hansol Metal Co. Ltd.	
Histeel Co., Ltd.	
Husteel Co., Ltd.[9]	
Hyundai RB Co., Ltd.; Shinchang Construction Co., Ltd.	
Hyundai Steel Company.[10]	
Il Jin Nts Co. Ltd.	
Iljin Nts Co. Ltd.	
Kem Solutions Co., Ltd.	
Kiduck Industries Co., Ltd.	
Kum Kang Kind. Co., Ltd.	
Kumsoo Connecting Co., Ltd.	
Nexteel Co., Ltd.	
POSCO International Corporation.	
Samkang M&T Co., Ltd.	
SeAH Steel Corporation; ESAB SeAH Corporation; SeAH Steel Holdings Corporation.	
Seonghwa Industrial Co., Ltd.	
SIN-E B&P Co., Ltd.	
Steel Flower Co., Ltd.	
WELTECH Co., Ltd.	
REPUBLIC OF TÜRKIYE: Large Diameter Welded Pipe, C–489–834	1/1/23–12/31/23
Cagil Makina San ve Tic A.S. AKA Cagil Makina A.S.	
HDM Celik Boru Sanayi ve Ticaret A.S.; HDM Spiral Kaynakli Boru A.S.[11]	
Spirally Welded Steel Pipe Inc.	

	Period to be reviewed
Çimtaş Boru Imalatiral Ticaret Ltd.	
Emek Boru Makina Sanayi ve Ticaret A.S.	
Erciyas Celik Boru Sanayi A.S.	
Mazlum Mangtay Boru Son. Ins. Tar.Urn.San.ve Tic. A.S.	
Noksel Celik Boru Sanayi A.S.	
Ozbal Celik Boru San. Tic. Ve TAAH A.S.	
Toscelik Profil ve Sac End. A.S.[12]	
Toscelik Spiral Boru Uretim A.S.	
Umran Celik Boru Sanayii A.S	
THE PEOPLE'S REPUBLIC OF CHINA: Aluminum Extrusions, C–570–968	1/1/23–12/31/23
Guangdong Xin Wei Aluminum Products Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Certain Chassis and Subassemblies Thereof, C–570–136	1/1/23–12/31/23
CIMC Vehicles (Group) Co., Ltd.	
SinoTrailers.	
Qingdao CIMC Special Vehicles Co., Ltd.; Dongguan CIMC Vehicle Co., Ltd.; CIMC Vehicles (Group) Co., Ltd.; Shenzhen CIMC Vehicle Co., Ltd.; Zhumadian CIMC Huajun Casting Co., Ltd.; China International Marine Containers (Group) Co., Ltd.; Liangshan CIMC Dongyue Vehicles Co., Ltd.; Shandong Wanshida Special Vehicle Manufacturing Co., Ltd.; Yangzhou CIMC Tonghua Special Vehicles Co., Ltd.; Zhumadian CIMC Huajun Vehicle Co., Ltd.; Gansu CIMC Huajun Vehicles Co., Ltd.; CIMC Vehicles (Liaoning) Co., Ltd.; Zhumadian CIMC Wanjia Axle Co., Ltd.[13]	
THE PEOPLE'S REPUBLIC OF CHINA: Certain Vertical Shaft Engines Between 99 Cubic Centimeters and up to 225cc, and Parts Thereof, C–570–125	1/1/23–12/31/23
Changzhou Kawasaki and Kwang Yang Engine Co., Ltd.	
ChongQing AM Pride Power & Machinery Co., Ltd.	
Chongqing Chen Hui Electric Machinery Co., Ltd.	
Chongqing Dinking Power Machinery Co., Ltd.	
Chongqing Ducar Power Equipment Co., Ltd.	
Chongqing Hwasdan Power Technology Co., Ltd.	
Chongqing Kohler Engines, Ltd.	
Chongqing Kohler Motors Co., Ltd.	
Chongqing Rato Technology Co., Ltd.	
Chongqing Senci Import & Export Trade Co., Ltd.	
Chongqing Shineray Agricultural Machinery Co., Ltd.	
Chongqing Zongshen General Power Machine Co., Ltd.; Chongqing Zongshen Power Machinery Co., Ltd.; Zong Shen Industrial Group; Chongqing Zongshen Automobile Air Intake System Manufacturing Co., Ltd.; Chongqing Zongshen High Speed Boat Development Co., Ltd.; Chongqing Zong Shen Electrical Appliance Co., Ltd.; Chongqing Dajiang Power Equipment Co., Ltd.	
Fujian Everstrong Lega Power Equipments Co., Ltd.	
Kawasaki Heavy Industries, Ltd.	
Lifan Technology (Group) Co., Ltd.	
Loncin Motor Co., Ltd.	
Qianjiang Group Wenling Jennfeng Industry Inc.	
Taizhou Sabo Electronics Co., Ltd.	
Wenling Qianjiang Imp. & Exp. Co., Ltd.	
Zhejiang Amerisun Technology Co., Ltd.	
Zhejiang Dobest Power Tools Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Non-refillable Steel Cylinders, C–570–127	1/1/23–12/31/23
Sanjiang Kai Yuan Co. Ltd.	
Suspension Agreements	
None.	
Deferral of Initiation of Administrative Review	
INDONESIA: Mattresses,[14] A–560–836	5/1/23–4/30/24
Bali Natural Latex.	
CV. Aumireta Anggun.	
Duta Abadi Primantara, Pt.	
Ecos Jaya JL Pasir Awi.	
Mimpi.	
CV. Lautan Rezeki.	
P.T. Barat Daya Gemilang.	
PT Celebes Putra Prima.	
PT Demak Putra Mandiri.	
PT Ecos Jaya Indonesia.	
PT Graha Anom Jaya.	
PT Graha Seribusatujaya.	
PT Kline Total Logistics Indonesia.	
PT Rubberfoam Indonesia.	
PT Solo Murni Epte.	
PT. Ateja Multi Industri.	
PT. Ateja Tritunggal.	
PT. Aurora World Cianjur.	

	Period to be reviewed
PT. Cahaya Buana Furindotama. PT. CJ Logistics Indonesia. PT. Dinamika Indonusa Prima. PT. Dunlopillo Indonesia. PT. Dynasti Indomegah. PT. Grantec Jaya Indonesia. PT. Massindo International. PT. Ocean Centra Furnindo. PT. Quantum Tosan Internasional. PT. Romance Bedding & Furniture. PT. Royal Abadi Sejahtera. PT. Transporindo Buana Kargotama. PT. Zinus Global Indonesia. Sonder Canada Inc. Super Poly Industry PT. Zinus, Inc.	

Duty Absorption Reviews

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an AD order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), Commerce, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine whether ADs have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

Gap Period Liquidation

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant ''gap'' period of the order (*i.e.,* the period following the expiry of provisional measures and before definitive measures were put into place), if such a gap period is applicable to the POR.

Administrative Protective Orders and Letters of Appearance

Interested parties must submit applications for disclosure under administrative protective orders in accordance with the procedures outlined in Commerce's regulations at 19 CFR 351.305. Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that they meet the requirements of these procedures (*e.g.,* the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

Factual Information Requirements

Commerce's regulations identify five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). These regulations require any party, when submitting

[4] Commerce collapsed the following companies in the less-than-fair-value investigation and treated them as a single entity: NLMK Clabecq S.A., NLMK Plate Sales S.A., NLMK Sales Europe S.A., NLMK Manage Steel Center S.A., and NLMK La Louviere S.A. *See Certain Carbon and Alloy Steel Cut-To-Length Plate from Belgium: Final Determination of Sales at Less Than Fair Value and Final Determination of Critical Circumstances, in Part,* 82 FR 16378 (April 4, 2017).

[5] In the initiation notice published on June 12, 2024, Commerce incorrectly initiated a review of this order on ATC Tires Private Limited, ATC Tires AP Private Limited, and Yokohama Off-Highway Tires America, Inc., which are companies for which we did not receive requests for review. We are correcting that initiation notice here. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 89 FR 49844, 49846 (June 12, 2024).

[6] In English, the name HDM Spiral Kaynakli Celik Boru A.S. is HDM Spirally Welded Steel Pipe Inc.

[7] In English, the name Toscelik Profil ve Sac End. A.S. is Toscelik Profile and Sheet Ind. Co.

[8] We have preliminarily found that POSCO and POSCO Holdings Inc. are cross-owned. *See Certain Carbon and Alloy Steel Cut-to-Length Plate From the Republic of Korea: Preliminary Results and Partial Rescission of Countervailing Duty Administrative Review; 2022,* 89 FR 47131 (May 31, 2024) (*CTL Plate from Korea*), and accompanying Preliminary Decision Memorandum at 9.

[9] Subject merchandise both produced and exported by Husteel Co., Ltd. (Husteel) is excluded from the countervailing duty order. *See Large Diameter Welded Pipe from the Republic of Korea: Countervailing Duty Order,* 84 FR 18773 (May 2, 2019). Thus, Husteel's inclusion in this administrative review is limited to entries for which Husteel was not both the producer and exporter of the subject merchandise.

[10] Subject merchandise both produced and exported by Hyundai Steel Company (Hyundai Steel) and subject merchandise produced by Hyundai Steel and exported by Hyundai Corporation are excluded from the countervailing duty order. *See Large Diameter Welded Pipe from the Republic of Korea: Countervailing Duty Order,* 84 FR 18773 (May 2, 2019). Thus, Hyundai Steel's inclusion in this administrative review is limited to entries for which Hyundai Steel was not the producer and exporter of the subject merchandise and for which Hyundai Steel was not the producer and Hyundai Corporation was not the exporter of subject merchandise.

[11] In English, the name HDM Spiral Kaynakli Celik Boru A.S. is HDM Spirally Welded Steel Pipe Inc.

[12] In English, the name Toscelik Profil ve Sac End. A.S. is Toscelik Profile and Sheet Ind. Co.

[13] In a prior segment of this proceeding, Commerce determined that Qingdao CIMC Special Vehicles Co., Ltd.; Dongguan CIMC Vehicle Co., Ltd.; CIMC Vehicles (Group) Co., Ltd.; Shenzhen CIMC Vehicle Co., Ltd.; Zhumadian CIMC Huajun Casting Co., Ltd.; China International Marine Containers (Group) Co., Ltd.; Liangshan CIMC Dongyue Vehicles Co., Ltd.; Shandong Wanshida Special Vehicle Manufacturing Co., Ltd.; Yangzhou CIMC Tonghua Special Vehicles Co., Ltd.; Zhumadian CIMC Huajun Vehicle Co., Ltd.; Gansu CIMC Huajun Vehicles Co., Ltd.; CIMC Vehicles (Liaoning) Co., Ltd.; Zhumadian CIMC Wanjia Axle Co., Ltd. were cross-owned affiliates. *See Certain Chassis and Subassemblies Thereof from the People's Republic of China: Countervailing Duty Order and Amended Final Affirmative Countervailing Duty Determination,* 86 FR 24844 (May 10, 2021).

[14] Pursuant to 19 CFR 351.213(c), Commerce received a request from PT. Zinus Global Indonesia (which includes Zinus, Inc.) to defer the administrative review with respect to itself for one year. Commerce did not receive any objections to the deferral within 15 days after the end of the anniversary month. Furthermore, based on the CBP data, Zinus Indonesia accounts for virtually all U.S. imports of the subject merchandise during the POR (*See* memo to the file ''Customs and Border Protection Data,'' dated concurrently with this notice). As such, with respect to all companies listed in this deferral, we will initiate the administrative review in the month immediately following the next anniversary month.

factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The regulations, at 19 CFR 351.301, also provide specific time limits for such factual submissions based on the type of factual information being submitted. Please review the *Final Rule,*[15] available at *https://www.govinfo.gov/content/pkg/FR-2013-07-17/pdf/2013-17045.pdf,* prior to submitting factual information in this segment. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[16]

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information using the formats provided at the end of the *Final Rule.*[17] Commerce intends to reject factual submissions in any proceeding segments if the submitting party does not comply with applicable certification requirements.

Extension of Time Limits Regulation

Parties may request an extension of time limits before a time limit established under Part 351 expires, or as otherwise specified by Commerce.[18] In general, an extension request will be considered untimely if it is filed after the time limit established under Part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Examples include, but are not limited to: (1) case and rebuttal briefs, filed pursuant to 19 CFR 351.309; (2) factual information to value factors under 19 CFR 351.408(c), or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2), filed pursuant to 19 CFR 351.301(c)(3) and rebuttal, clarification and correction filed pursuant to 19 CFR 351.301(c)(3)(iv); (3) comments concerning the selection of a surrogate country and surrogate values and rebuttal; (4) comments concerning CBP data; and (5) Q&V questionnaires. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, Commerce will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This policy also requires that an extension request must be made in a separate, standalone submission, and clarifies the circumstances under which Commerce will grant untimely-filed requests for the extension of time limits. Please review the *Final Rule,* available at *https://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these segments.

These initiations and this notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: July 1, 2024.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2024–14771 Filed 7–3–24; 8:45 am]

BILLING CODE 3510–DS–P

[15] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* the frequently asked questions regarding the *Final Rule,* available at *https://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

[16] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

[17] *See* section 782(b) of the Act; *see also Final Rule;* and the frequently asked questions regarding the *Final Rule,* available at *https://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

[18] *See* 19 CFR 351.302.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–469–821]

Prestressed Concrete Steel Wire Strand From Spain: Preliminary Results of Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that the producer/exporter subject to this administrative review made sales of subject merchandise at prices below normal value (NV) during the period of review (POR), June 1, 2022, through May 31, 2023. We invite interested parties to comment on these preliminary results.

DATES: Applicable July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Lilit Astvatsatrian, 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) 482–6412.

SUPPLEMENTARY INFORMATION:

Background

On June 4, 2021, Commerce published the antidumping duty order on prestressed concrete steel wire strand from Spain in the **Federal Register**.[1] On August 3, 2023, based on timely requests for review, we initiated an administrative review of the *Order* with respect to one company, Global Special Steel Products S.A.U. (d.b.a. Trenzas y Cables de Acero PSC, S.L.) (TYCSA).[2] On February 6, 2024, Commerce extended the deadline for these preliminary results to June 28, 2024.[3]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4] A list of topics discussed in the Preliminary Decision Memorandum is attached as an appendix 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 Order

The products subject to the *Order* are prestressed concrete steel wire strand from Spain. For a full description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). We calculated export price and constructed export price in accordance with section 772 of the Act. We calculated NV in accordance with

[1] *See Prestressed Concrete Steel Wire Strand from Indonesia, Italy, Malaysia, South Africa, Spain, Tunisia, and Ukraine: Antidumping Duty Orders,* 86 FR 29998 (June 4, 2021) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 51271 (August 3, 2023).

[3] *See* Memorandum, ''Extension of Time Limit for Preliminary Results,'' dated February 6, 2024.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Antidumping Duty Order on Prestressed Concrete Steel Wire Strand from Spain; 2022–2023,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

section 773 of the Act. For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum.

Preliminary Results of the Review

As a result of this review, we preliminarily determine the following estimated weighted-average dumping margin exists for the period June 1, 2022, through May 30, 2023:

Producer/exporter	Weighted-average dumping margin (percent)
Global Special Steel Products S.A.U. (d.b.a. Trenzas y Cables de Acero PSC, S.L.)	3.04

Verification

On November 13, 2023, Insteel Wire Products Company, Sumiden Wire Products Corporation, and Wire Mesh Corp., the petitioners in this proceeding, requested that Commerce conduct verification of the factual information submitted by TYCSA in this administrative review.[5] Accordingly, as provided in section 782(i)(3) of the Act, Commerce intends to verify the information relied upon in determining its final results.

Disclosure and Public Comment

We intend to disclose the calculations performed in connection with these preliminary results to interested parties 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 the **Federal Register**.[6]

Interested parties may submit case briefs to Commerce no later than seven days after the date on which the verification report is issued in this administrative review.[7] 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.[8] Interested parties who submit case briefs or rebuttal briefs in this administrative review must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[9]

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 review, we instead request that interested parties provide, at the beginning of their briefs, a public executive summary for each issue raised in their briefs.[10] 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 public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing.[11]

All submissions, including case and rebuttal briefs, as well as hearing requests, should be filed via ACCESS.[12] An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[13]

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, no later than 120 days after the date of publication of this notice in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Assessment Rates

Upon completion of this administrative review, pursuant to section 751(a)(2)(A) of the Act, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.

Pursuant to 19 CFR 351.212(b)(1), we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of those sales. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review and for future deposits of estimated duties, where applicable.[14]

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by TYCSA for which the company did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate established in the less-than-fair-value (LTFV) investigation (*i.e.,* 14.75 percent) [15] if there is no rate for the intermediate company(ies) involved in the transaction.[16]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided

[5] *See* Petitioners' Letter, ''Petitioners' Request to Conduct In-Person Verification of TYCSA,'' dated November 13, 2023.

[6] *See* 19 CFR 351.224(b).

[7] *See* 19 CFR 351.309(c)(1)(ii); *see also* 19 CFR 351.303 (for general filing requirements).

[8] *See* 19 CFR 351.309(d)(1); *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 Procedures*).

[9] *See* 19 CFR 351.309(c)(2) and (d)(2).

[10] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[11] *See* 19 CFR 351.310(d).

[12] *See* 19 CFR 351.303.

[13] *See APO and Service Procedures.*

[14] *See* section 751(a)(2)(C) of the Act.

[15] *See Order.*

[16] For a full description of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the company listed above will be equal to the weighted average dumping margin established in the final results of this administrative review, except if the rate is less than 0.50 percent and therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not covered in this review, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which the company was reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or the LTFV investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 14.75 percent, the all-others rate established in the LTFV investigation.[17] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: June 28, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Discussion of the Methodology
V. Recommendation

[FR Doc. 2024–14765 Filed 7–3–24; 8:45 am]

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[17] *See Order.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–857]

Raw Honey From Brazil: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review; 2021–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that raw honey from Brazil was sold in the United States at below normal value (NV) during the period of review (POR) November 23, 2021, through May 31, 2023. We are also rescinding the review with respect to certain companies that had no entries of the subject merchandise during the POR. We invite interested parties to comment on these preliminary results.

DATES: Applicable July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Rachel Jennings, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202)–482–1110.

SUPPLEMENTARY INFORMATION:

Background

On August 3, 2023, Commerce initiated an administrative review of the antidumping duty order on raw honey from Brazil, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).[1] This review covers 23 companies.[2] On August 29, 2023, Commerce selected Apis Nativa Agroindustrial Exportadora Ltda. (Apis Nativa) and Melbras Importadora E Exportadora Agroindustrial Ltda. (Melbras) for individual examination as mandatory respondents.[3]

On February 14, 2024, Commerce extended the time limit for completing the preliminary results of this review until June 28, 2024.[4] For details regarding the events that occurred subsequent to the initiation of the review, *see* the Preliminary Decision Memorandum.[5]

Scope of the Order

The product covered by the scope of this *Order* is raw honey from Brazil. A complete description of the scope of the *Order* is contained in the Preliminary Decision Memorandum.[6]

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(3), when there are no reviewable entries of subject merchandise during the POR subject to the antidumping duty order for which liquidation is suspended, Commerce may rescind an administrative review, in whole or only with respect to a particular exporter or producer.[7]

At the end of the administrative review, any suspended entries are liquidated at the assessment rate computed for the review period.[8] Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry to be liquidated at the newly calculated assessment rate. On May 20, 2024, Commerce notified all interested parties of its intent to rescind this review with respect to certain companies because those companies had no reviewable, suspended entries of subject merchandise and invited parties to comment.[9] We received no comments on our intent to rescind the review with respect to these companies. Accordingly, pursuant to 19 CFR 351.213(d)(3) and (d)(4), we are rescinding this administrative review with respect to the five companies listed in Appendix III to this notice that had no reviewable, suspended entries of subject merchandise during the POR.[10]

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. We calculated export price and

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 51271 (August 3, 2023) (*Initiation Notice*); *see also Raw Honey from Argentina, Brazil, India, and the Socialist Republic of Vietnam: Antidumping Duty Orders,* 87 FR 35501 (June 10, 2022) (*Order*).

[2] *See Initiation Notice.*

[3] *See* Memorandum, ''Respondent Selection,'' dated August 29, 2023.

[4] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated February 14, 2024.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review of Raw Honey from Brazil and Partial Rescission of Administrative Review; 2021–2023,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *Id.* at ''Scope of the *Order*.''

[7] *See, e.g., Forged Steel Fittings from Taiwan: Rescission of Antidumping Duty Administrative Review; 2018–2019,* 85 FR 71317, 71318 (November 9, 2020); *see also Certain Circular Welded Non-Alloy Steel Pipe from Mexico: Rescission of Antidumping Duty Administrative Review; 2016–2017,* 83 FR 54084 (October 26, 2018).

[8] *See* 19 CFR 351.212(b)(1).

[9] *See* Memorandum, ''Notice of Intent to Rescind Review, In Part,'' released on May 20, 2024.

[10] *See* Memorandum, ''CBP Data Release,'' dated August 14, 2023, at Attachment.

constructed export price in accordance with sections 772(a) and 772(b) of the Act, respectively. For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum. *See* Appendix I for a complete list of topics discussed in the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum is available at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Rate for Non-Examined Companies

The Act and Commerce's regulations do not address the establishment of a rate to be applied to companies not selected for examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''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 {on the basis of facts available}.''

In this review, we have preliminarily calculated weighted-average dumping margins of zero percent and 2.31 percent for Apis Nativa and Melbras, respectively. Therefore, in accordance with section 735(c)(5)(A) of the Act, we are preliminarily applying Melbras' weighted-average dumping margin of 2.31 percent to the non-examined companies, because this is the only rate that is not zero, *de minimis,* or based entirely on facts available.

Preliminary Results of the Review

We preliminarily determine that the following estimated weighted-average dumping margins exist during the period November 23, 2021, through May 31, 2023:

Exporter/producer	Weighted-average dumping margin (percent)
Apis Nativa Agroindustrial Exportadora Ltda	0.00
Melbras Importadora E Exportadora Agroindustrial Ltda	2.31
Non-Examined Companies[11]	2.31

Disclosure and Public Comment

Commerce intends to disclose the calculations performed in connection with these preliminary results to interested parties within five days after the date of publication of this notice, 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).[12]

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. 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.[13] 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.[14] 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 review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[15] 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 public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public 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).[16]

Interested parties who wish to request a hearing must do so within 30 days of publication of these preliminary results by submitting a written request to the Assistant Secretary, filed electronically via ACCESS.[17] 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. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.[18] 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 the date and time of the hearing two days before the scheduled date. Parties are reminded that all briefs and hearing requests must be filed electronically using ACCESS and received successfully in their entirety by 5:00 p.m. Eastern Time on the due date.

Assessment Rates

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review and for future deposits of estimated duties, where applicable.[19]

Upon completion of the final results of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review. If a respondent's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). We intend to instruct CBP to assess antidumping duties on all appropriate entries covered by this review. Where an importer-specific assessment rate is zero or *de minimis* in the final results of this review, we intend to instruct CBP to liquidate the appropriate entries without regard to antidumping duties in accordance with 19 CFR 351.106(c)(2).

For the companies in Appendix III, we will instruct CBP to assess antidumping duties on any suspended entries that entered under their CBP case numbers (*i.e.,* at that exporter's

[11] *See* Appendix II for a list of these companies.

[12] *See* 19 CFR 351.224(b).

[13] *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 Procedures*).

[14] *See* 19 351.309(c)(2) and (d)(2).

[15] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[16] *See APO and Service Procedures.*

[17] *See* 19 CFR 351.310(c).

[18] *See* 19 CFR 351.310.

[19] *See* section 751(a)(2)(C) of the Act.

rate) at a rate equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, during the POR.

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced Apis Nativa or Melbras for which these companies did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate established in the original less-than-fair-value (LTFV) investigation (*i.e.,* 7.89 percent),[20] if there is no rate for the intermediate company(ies) involved in the transaction.[21] For the companies which were not selected for individual review, we will assign an assessment rate based on the review-specific average rate, calculated as noted in the ''Preliminary Results of Review'' section above.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the publication date of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies listed in the final results of this review will be equal to the weighted-average dumping margin established in the final results of this administrative review except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for merchandise exported by producers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review, or the original LTFV investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 7.89 percent, the all-others rate established in the LTFV investigation as adjusted for the export-subsidy rate in the companion countervailing duty investigation.[22] The cash deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

Commerce is issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: June 28, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Partial Rescission of Administrative Review
V. Discussion of the Methodology
VI. Currency Conversion
VII. Recommendation

Appendix II

List of Companies Not Individually Examined

1. Apidouro Comercial Exportadora E Importadora Ltda.
2. Apiários Adams Agroindustrial Comercial Exportadora Ltda.
3. Breyer & Cia. Ltda.
4. Cooperativa Mista Dos Apicultores D
5. Flora Nectar
6. Lambertucci
7. Minamel
8. Nectar Floral
9. S & A Honey Ltda.
10. Apiário Diamante Comercial Exportadora Ltda/Apiário Diamante Produção e Comercial de Mel Ltda (Supermel)
11. Central de Cooperativas Apícolas do Semiárido Brasileiro—CASA APIS [23]
12. Floranectar Ind. Comp. Imp. E Exp. De Mel
13. Minamel Agroindústria Ltda.
14. Annamell Imp. E Exp. De Produtos Apicoloas Ltda.
15. Conexão Agro Ltda ME
16. Wenzel's Apicultura Comercio Industria Importacao E Exportacao Ltda.[24]

Appendix III

Companies Rescinded from Administrative Review

1. Carnauba Do Brasil Ltda.
2. Novomel
3. Safe Logistics
4. Samel Honey
5. STM Trading

[FR Doc. 2024–14712 Filed 7–3–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Civil Nuclear Trade Advisory Committee: Meeting of the Civil Nuclear Trade Advisory Committee

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda for a meeting of the Civil Nuclear Trade Advisory Committee (CINTAC).

DATES: The meeting is scheduled for Thursday, July 18, 2024, from 10:00 a.m. to 4:00 p.m. Eastern Daylight Time (EDT). The deadline for members of the public to register, including requests to make comments during the meeting and

[20] *See Order,* 87 FR at 35503.

[21] For a full description of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[22] *See Order,* 85 FR at 19926.

[23] We also initiated this review on ''Central De Cooperativas Apicolas Do (CASA APIS),'' which we are preliminarily considering to be the same company. *See Initiation Notice.*

[24] We also initiated this review on ''Wenzel's Apicultura,'' which we are preliminarily considering to be the same company. *See Initiation Notice.*

for auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. EDT on Monday, July 15, 2024.

ADDRESSES: The meeting will be in-person at the Department of Commerce Herbert C. Hoover Building (1401 Constitution Ave. NW, Washington, DC 20230, Room 1412). Registered participants will be emailed instructions on accessing the designated meeting space. Requests to register (including to speak or for auxiliary aids) and any written comments should be submitted to Mr. Jonathan Chesebro, Office of Energy & Environmental Industries, International Trade Administration, (email: *jonathan.chesebro@trade.gov*). Members of the public should submit registration requests and written comments via email to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT: Mr. Jonathan Chesebro, Office of Energy & Environmental Industries, International Trade Administration, Room 28018, 1401 Constitution Ave. NW, Washington, DC 20230. (Phone: 202–482–1297; email: *jonathan.chesebro@trade.gov*).

SUPPLEMENTARY INFORMATION:

Background: The CINTAC was established under the discretionary authority of the Secretary of Commerce and in accordance with the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*), in response to an identified need for consensus advice from U.S. industry to the U.S. government regarding the development and administration of programs to expand U.S. exports of civil nuclear goods and services in accordance with applicable U.S. laws and regulations, including advice on how U.S. civil nuclear goods and services export policies, programs, and activities affect the U.S. civil nuclear industry's competitiveness and ability to participate in the international market.

Topics to be considered: The agenda for the Thursday, July 18, 2024, CINTAC meeting will include discussions of potential CINTAC recommendations to the Secretary, a briefing by the TeamUSA Civil Nuclear Working Group, and activities related to the U.S. Department of Commerce's Civil Nuclear Trade Initiative.

Members of the public wishing to attend the meeting must notify Mr. Jonathan Chesebro at the contact information above by 5:00 p.m. EDT on Monday, July 15, 2024, in order to pre-register. Please specify any requests for reasonable accommodation at least five business days in advance of the meeting.

A limited amount of time will be available for brief oral comments from members of the public attending the meeting. To accommodate as many speakers as possible, the time for public comments will be limited to two (2) minutes per person, with a total public comment period of 20 minutes. Individuals wishing to reserve speaking time during the meeting must contact Mr. Jonathan Chesebro and submit a brief statement of the general nature of the comments and the name and address of the proposed participant by 5:00 p.m. EDT on Monday, July 15, 2024. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, ITA may conduct a lottery to determine the speakers.

Any member of the public may submit written comments concerning the CINTAC's affairs at any time before and after the meeting. Comments may be submitted to Mr. Jonathan Chesebro in the International Trade Administration's Office of Energy & Environmental Industries. For consideration during the meeting, and to ensure transmission to the Committee prior to the meeting, comments must be received no later than 5:00 p.m. EDT on Monday, July 15, 2024. Comments received after that date will be distributed to the members but may not be considered at the meeting.

Copies of CINTAC meeting minutes will be available within 90 days of the meeting.

Man K. Cho,

Deputy Director, Office of Energy and Environmental Industries.

[FR Doc. 2024–14689 Filed 7–3–24; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–169]

Certain Alkyl Phosphate Esters From the People's Republic of China: Postponement of Preliminary Determination in the Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Benjamin Nathan or Gregory Taushani, Office II, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–3834 or (202) 482–1012, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 13, 2024, the U.S. Department of Commerce (Commerce) initiated a countervailing duty (CVD) investigation of imports of certain alkyl phosphate esters from the People's Republic of China. Currently, the preliminary determination is due no later than July 17, 2024.

Postponement of Preliminary Determination

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a CVD investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation if: (A) the petitioner makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.

On June 21, 2024, the petitioner [1] submitted a timely request to postpone the preliminary determination in the investigation.[2] The petitioner stated that postponement of the preliminary determination is necessary because the current schedule does not provide Commerce with adequate time to fully analyze the forthcoming questionnaire responses of the mandatory respondents and issue supplemental questionnaires, as necessary.[3]

In accordance with 19 CFR 351.205(e), the petitioner submitted its request for postponement of the preliminary determination in this investigation 25 days or more before the scheduled date of the preliminary determination and stated the reasons for its request. Commerce finds no

[1] The petitioner is ICL–IP America, Inc.

[2] *See* Petitioner's Letter, ''Request for Postponement of the Preliminary Determination,'' dated June 21, 2024.

[3] *Id.*

compelling reason to deny the request. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determination in this investigation to no later than 130 days after the date on which it initiated this investigation. The postponed deadline for the preliminary determination is September 20, 2024. Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination in this investigation will continue to be 75 days after the date of the preliminary determination.

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: June 28, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–14760 Filed 7–3–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Ecosystem Questionnaire for States and Territories To Inform CHIPS R&D Facility Site Selection Process

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for emergency review and approval in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden.

Agency: National Institute of Standards and Technology (NIST).

Title: Ecosystem Questionnaire for States and Territories to Inform CHIPS R&D Facility Site Selection Process.

OMB Control Number 0693–XXXX.

Form Number(s): None.

Type of Request: Emergency submission, New Information Collection Request.

Number of Respondents: 56.

Average Hours per Response: 10 hours.

Burden Hours: 560 hours.

Needs and Uses: CHIPS R&D is seeking to collect information needed for implementation of the CHIPS Act of 2022 (Division A of Pub. L. 117–167) (the Act). The Act tasks the Secretary of Commerce with carrying out sections 9904 and 9906 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (15 U.S.C. 4652, 4654, and 4656). This statute aims to catalyze long-term growth in the domestic semiconductor industry in support of U.S. economic resilience and national security. This information collection is needed in conjunction with a multi-phase site selection process that will be used to identify a flagship research and development prototyping and packaging facility that is anticipated to become the lynchpin of both the National Semiconductor Technology Center (NSTC) and the National Advanced Packaging Manufacturing Program (NAPMP), the two largest research and development programs established by Congress through the CHIPS Act of 2022. The information is important for the Department of Commerce and Natcast—the purpose-built nonprofit entity which serves as the operator of the NSTC, and which is anticipated to serve as the operator of this flagship facility—in order to establish at the outset of the site selection process which states and/or territories have existing semiconductor ecosystems that could support this facility.

Both the NSTC and NAPMP have a need to expeditiously identify facilities in order to accomplish their statutory missions. The NSTC is required to ''to conduct advanced semiconductor manufacturing, design and packaging research, and prototyping that strengthens the entire domestic ecosystem.'' 15 U.S.C. 4656(c)(2)(A). The NSTC is expected to ''significantly reduce the time and cost of moving from design idea to commercialization through access to shared facilities, digital assets and technical expertise for advancing design, prototyping, manufacturing, packaging, and scaling of semiconductors and semiconductor-related products'' (*https://www.nist.gov/system/files/documents/2023/04/26/NSTC-Vision-Strategy-Fact-Sheet.pdf*). The NAPMP is expected to ''include an Advanced Packaging Piloting Facility (APPF) where successful development efforts will be transitioned and validated for scaled transition to U.S. manufacturing. This is a key facility for technology transfer to high-volume manufacturing'' (*https://www.nist.gov/system/files/documents/2023/11/19/NAPMP-Vision-Paper-20231120.pdf,* pg. 3).

The information collection will take the form of an Ecosystem Questionnaire for States and Territories to Inform CHIPS R&D Facility Site Selection Process. The Questionnaire will pose identical questions to Economic Development Organizations (EDOs) in all 56 states and territories. This collection is subject to the Paperwork Reduction Act as the RFI would pose identical questions to all 56 states and territories. See 5 CFR 1320.3(c)(4) and (k)). The Ecosystem Questionnaire will request information regarding the extent to which a state or territory can demonstrate: the presence of entities from the semiconductor value chain; a semiconductor workforce and current workforce development programs; semiconductor-related advanced education and research programs; significant state, local, and private investment in the semiconductor ecosystem; and state incentives for semiconductor research and development. The Ecosystem Questionnaire is also structured to be as minimally burdensome as possible, both because responses are predominantly requested in the form of multiple-choice answers, and because the information the Questionnaire solicits should be easily available to EDOs. This will be a one-time collection of information to all 56 states and territories. Only states or territories that submit responses to the Ecosystem Questionnaire will be considered for selection of this facility.

Affected Public: State and local governments.

Frequency: Once.

Respondent's Obligation: Voluntary.

Legal Authority

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should by 11:59 p.m. EST on July 12, 2024 on the following website *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 and entering the title of the collection.

Peter Robbins,

Attorney-Advisor, Office of the General Counsel for Legislation and Regulation, Commerce Department.

[FR Doc. 2024–14794 Filed 7–3–24; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE040]

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; affirmative finding annual renewals for Ecuador, El Salvador, Guatemala, Mexico, Peru, and Spain.

SUMMARY: The NMFS Assistant Administrator (Assistant Administrator) has completed an affirmative finding annual renewal for the Governments of Ecuador, El Salvador, Guatemala, Mexico, Peru, and Spain (referred to hereafter as ''The Nations'') under the portions of the Marine Mammal Protection Act (MMPA) related to the eastern tropical Pacific Ocean (ETP) tuna purse seine fishery and the importation of yellowfin tuna from nations participating in this fishery. These affirmative findings will continue to allow the importation into the United States of yellowfin tuna and yellowfin tuna products harvested in the ETP for 1 year, in compliance with the Agreement on the International Dolphin Conservation Program (AIDCP), by purse seine vessels operating under The Nations' jurisdiction or exported from The Nations. NMFS bases the affirmative finding annual renewals on reviews of documentary evidence submitted by the Governments of The Nations and of information obtained from the Inter-American Tropical Tuna Commission (IATTC).

DATES: These affirmative finding annual renewals are effective for the 1-year period of April 1, 2024, through March 31, 2025.

FOR FURTHER INFORMATION CONTACT: Justin Greenman, West Coast Region, NMFS, by mail: 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802, email: *justin.greenman@noaa.gov,* or phone: (562) 980–3264.

SUPPLEMENTARY INFORMATION: The MMPA, 16 U.S.C. 1361 *et seq.,* allows for importation into the United States of yellowfin tuna harvested by purse seine vessels in the ETP from a nation with jurisdiction over purse seine vessels with carrying capacity greater than 400 short tons that harvest tuna in the ETP, only if the nation has an ''affirmative finding'' issued by the NMFS Assistant Administrator. See section 101(a)(2)(B) of the MMPA, 16 U.S.C. 1371(a)(2)(B); see also 50 CFR 216.24(f)(6)(i). If requested by the government of such a nation, the Assistant Administrator will determine whether to make an affirmative finding based upon documentary evidence provided by the government, the IATTC, or the Department of State.

The affirmative finding process requires that the harvesting nation is meeting its obligations under the AIDCP and its obligations of membership in the IATTC. Every 5 years, the government of the harvesting nation must request a new affirmative finding and submit the required documentary evidence directly to the Assistant Administrator. On an annual basis, NMFS must determine whether the harvesting nation continues to meet the requirements of their 5-year affirmative finding. NMFS does this by reviewing the documentary evidence from the last year. A nation may provide information related to compliance with AIDCP and IATTC measures directly to NMFS on an annual basis or may authorize the IATTC to release the information to NMFS to annually renew an affirmative finding determination without an application from the harvesting nation.

An affirmative finding will be terminated, in consultation with the Secretary of State, if the Assistant Administrator determines that the requirements of 50 CFR 216.24(f) are no longer being met or that a nation is consistently failing to take enforcement actions on violations, thereby diminishing the effectiveness of the AIDCP.

As a part of the affirmative finding process set forth in 50 CFR 216.24(f)(8), for this annual renewal, the Assistant Administrator considered documentary evidence submitted by the Governments of The Nations and obtained from the IATTC and has determined that The Nations have met the MMPA's requirements to receive affirmative finding annual renewals.

After consultation with the Department of State, the Assistant Administrator issued affirmative finding annual renewals to The Nations, allowing the continued importation into the United States of yellowfin tuna and products derived from yellowfin tuna harvested in the ETP by purse seine vessels operating under The Nations' jurisdiction or exported from The Nations. Issuance of affirmative finding annual renewals for The Nations does not affect implementation of an intermediary nation embargo under 50 CFR 216.24(f)(9), which applies to exports from a nation that exports to the United States yellowfin tuna or yellowfin tuna products that was subject to a ban on importation into the United States under section 101(a)(2)(B) of the MMPA, 16 U.S.C. 1371(a)(2)(B).

These affirmative finding annual renewals for The Nations are for the 1-year period of April 1, 2024, through March 31, 2025. The Nations' individual 5-year affirmative findings, which have varying start and end dates, remain valid. El Salvador's 5-year affirmative finding will remain valid through March 31, 2028. Peru's 5-year affirmative findings will remain valid through March 31, 2027. Ecuador, Guatemala, Mexico, and Spain's 5-year affirmative findings will remain valid through March 31, 2025, subject to subsequent annual reviews by NMFS.

Dated: June 25, 2024.

Janet Coit,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–14739 Filed 7–3–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE039]

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; new 5-year affirmative finding for Colombia.

SUMMARY: The NMFS Assistant Administrator (Assistant Administrator) has issued a new 5-year affirmative finding for the Government of Colombia under the portions of the Marine Mammal Protection Act (MMPA) related to the eastern tropical Pacific Ocean (ETP) tuna purse seine fishery and the importation of yellowfin tuna from nations participating in this fishery. This affirmative finding will allow the importation into the United States of yellowfin tuna and yellowfin tuna products harvested in the ETP, in compliance with the Agreement on the International Dolphin Conservation Program (AIDCP), by purse seine vessels operating under Colombia's jurisdiction or exported from Colombia. NMFS bases the affirmative finding determination on reviews of documentary evidence submitted by the Government of Colombia and of information obtained from the Inter-American Tropical Tuna Commission (IATTC).

DATES: This new affirmative finding is effective for the 5-year period of April 1, 2024, through March 31, 2029.

FOR FURTHER INFORMATION CONTACT: Justin Greenman, West Coast Region, NMFS, by mail: 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802, email: *justin.greenman@noaa.gov,* or phone: (562) 980–3264.

SUPPLEMENTARY INFORMATION: The MMPA, 16 U.S.C. 1361 *et seq.,* allows for importation into the United States of yellowfin tuna harvested by purse seine vessels in the ETP from a nation with jurisdiction over purse seine vessels with carrying capacity greater than 400 short tons that harvest tuna in the ETP, only if the nation has an ''affirmative finding'' issued by the NMFS Assistant Administrator. See section 101(a)(2)(B) of the MMPA, 16 U.S.C. 1371(a)(2)(B); see also 50 CFR 216.24(f)(6)(i). If requested by the government of such a nation, the Assistant Administrator will determine whether to make an affirmative finding based upon documentary evidence provided by the government, the IATTC, or the Department of State.

The affirmative finding process requires that the harvesting nation is meeting its obligations under the AIDCP and its obligations of membership in the IATTC. Every 5 years, the government of the harvesting nation must request a new affirmative finding and submit the required documentary evidence directly to the Assistant Administrator. On an annual basis, NMFS must determine whether the harvesting nation continues to meet the requirements of their 5-year affirmative finding. NMFS does this by reviewing the documentary evidence from the last year. A nation may provide information related to compliance with AIDCP and IATTC measures directly to NMFS on an annual basis or may authorize the IATTC to release the information to NMFS to annually renew an affirmative finding determination without an application from the harvesting nation.

An affirmative finding will be terminated, in consultation with the Secretary of State, if the Assistant Administrator determines that the requirements of 50 CFR 216.24(f) are no longer being met or that a nation is consistently failing to take enforcement actions on violations, thereby diminishing the effectiveness of the AIDCP.

As a part of the affirmative finding process set forth in 50 CFR 216.24(f)(8), the Assistant Administrator considered documentary evidence submitted by the Government of Colombia and obtained from the IATTC, and has determined that Colombia has met the MMPA's requirements to receive a new 5-year affirmative finding.

After consultation with the Department of State, the Assistant Administrator issued a new 5-year affirmative finding to Colombia, allowing the importation into the United States of yellowfin tuna and products derived from yellowfin tuna harvested in the ETP by purse seine vessels operating under Colombia's jurisdiction or exported from Colombia. Issuance of a new 5-year affirmative finding for Colombia does not affect implementation of an intermediary nation embargo under 50 CFR 216.24(f)(9), which applies to exports from a nation that exports to the United States yellowfin tuna or yellowfin tuna products that was subject to a ban on importation into the United States under section 101(a)(2)(B) of the MMPA, 16 U.S.C. 1371(a)(2)(B).

This new affirmative finding for Colombia is for the 5-year period of April 1, 2024, through March 31, 2029, subject to subsequent annual reviews by NMFS.

Dated: June 25, 2024.

Janet Coit,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–14738 Filed 7–3–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO–P–2024–0032]

Impact of the Proliferation of AI on Prior Art and PHOSITA: Notice of Public Listening Session

AGENCY: United States Patent and Trademark Office, U.S. Department of Commerce.

ACTION: Notice of public listening session.

SUMMARY: The United States Patent and Trademark Office (USPTO) plays an important role in incentivizing and protecting innovation, including innovation enabled by artificial intelligence (AI), to ensure continued U.S. leadership in AI and other emerging technologies (ET). On April 30, 2024, the USPTO published a request for comments (RFC) in the **Federal Register** regarding the impact of the proliferation of AI on prior art, the knowledge of a person having ordinary skill in the art (PHOSITA), and determinations of patentability made in view of the foregoing. In furtherance of its AI/ET Partnership, the USPTO hereby announces a public listening session on July 25, 2024, titled ''Listening Session on the Impact of the Proliferation of AI on Prior Art and PHOSITA.'' The purpose of the listening session is to obtain public input from stakeholders on the impact of the proliferation of AI on prior art and PHOSITA, as set forth in the questions for public comment of the RFC. The USPTO expects that the feedback received in this listening session and the written responses received for the RFC will help the USPTO evaluate the need for further guidance on these matters, aid in the development of any such guidance, and help inform the USPTO's work in the courts and in providing technical advice to Congress.

DATES: The Listening Session on the Impact of Proliferation of AI on Prior Art and PHOSITA will be held on July 25, 2024, from 10:00 a.m. to 3:00 p.m. ET. Persons seeking to speak at the listening session, either virtually or in person, must register by 8:00 p.m. ET on July 19, 2024, at the website provided in the **ADDRESSES** section of this notice. Persons seeking to attend, either virtually or in person, but not speak at the event, must register by 8:00 a.m. ET on July 25, 2024, at the website provided in the **ADDRESSES** section of this notice.

ADDRESSES: Register to speak or attend the listening session at *www.uspto.gov/initiatives/artificial-intelligence/ai-and-emerging-technology-partnership-engagement-and-events.* The listening session will take place virtually and in person at the USPTO Headquarters, National Inventors Hall of Fame Museum, 600 Dulany Street, Alexandria, VA 22314. Registration is required to speak for both virtual and in-person attendance. Seating is limited for in-person attendance. Registrants must indicate whether they are registering as a listen-only attendee or as a speaker participant.

The public meeting will be physically accessible to people with disabilities. Individuals requiring accommodation, such as sign language interpretation or other ancillary aids, should communicate their needs to an individual listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven business days prior to the public meeting.

FOR FURTHER INFORMATION CONTACT: Srilakshmi Kumar, Senior Advisor, Office of the Under Secretary, 571–272–7769, or Aleksandr Kerzhner, Supervisory Patent Examiner, 571–270–1760. You can also send inquiries to *AIPartnership@uspto.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

To continue its support for the National AI Initiative Act of 2020, which became law on January 1, 2021, the USPTO announced in June 2022 the formation of the AI/ET Partnership, which provides an opportunity to bring stakeholders together through a series of engagements to share ideas, feedback, experiences, and insights on the intersection of intellectual property and AI/ET. To build on the AI/ET Partnership efforts and the USPTO's recent AI-related efforts associated with Executive Order 14110,[1] on April 30, 2024, the USPTO issued an RFC titled ''Request for Comments on the Impact of Proliferation of AI on Prior Art, the Knowledge of a Person Having Ordinary Skill in the Art, and Determinations of Patentability Made in View of the Foregoing'' (89 FR 34217, April 30, 2024) (available at *www.federalregister.gov/documents/2024/04/30/2024-08969/request-for-comments-regarding-the-impact-of-the-proliferation-of-artificial-intelligence-on-prior-*). The RFC provides an overview of prior art considerations and discusses some concerns relevant to AI-generated prior art, discusses the current PHOSITA assessment as it is applied by the USPTO and the courts, and poses 15 questions for public comment on the impact of AI on prior art and the PHOSITA assessment.

II. Public Listening Session

The USPTO will hold a public listening session virtually and in person at the USPTO Headquarters in Alexandria, Virginia, on July 25, 2024.

Requests to participate as a speaker must include:

1. The name of the person desiring to participate;
2. The organization(s) that person represents, if any;
3. Contact information (zip code, telephone number, and email address);
4. Information on the specific topic or question(s) from the RFC of interest to the speaker (or their organization); and
5. A summary of comments to be articulated during the listening session (discussed further below).

Speaking slots are limited; preference will be given to speakers based on the specific topic or question(s) provided in the request to participate. Selected speakers may be grouped by topic. Topics and speakers will be announced a few days prior to the event and listening session. Speakers may attend virtually or in person and are required to submit their remarks for the listening session in advance through the Federal eRulemaking Portal at *www.regulations.gov.*

Each speaker will be informed of their assigned time slot in advance. Time slots will be at least three minutes, but may be longer, depending on the number of speakers registered. USPTO personnel may reserve time to ask questions of particular speakers after the delivery of a speaker's remarks.

III. Questions From the RFC on the Impact of AI on Prior Art and PHOSITA for Discussion at the Listening Session

The purpose of the listening session is to obtain public input from a broad group of stakeholders regarding the impact of the proliferation of AI on prior art and PHOSITA, as set forth in the questions for public comment of the RFC.

We encourage interested speakers to address the questions posed in the RFC and to submit research and data, if any, that inform their comments on these questions. Official written comments to the questions raised in the RFC should be submitted as outlined in the RFC. For convenience, a copy of the questions from the RFC is provided below in their entirety.

A. The Impact of AI on Prior Art

1. In what manner, if any, does 35 U.S.C. 102 presume or require that a prior art disclosure be authored and/or published by humans? In what manner, if any, does non-human authorship of a disclosure affect its availability as prior art under 35 U.S.C. 102?
2. What types of AI-generated disclosures, if any, would be pertinent to patentability determinations made by the USPTO? How are such disclosures currently being made available to the public? In what other ways, if any, should such disclosures be made available to the public?
3. If a party submits to the Office a printed publication or other evidence that the party knows was AI-generated, should that party notify the USPTO of this fact, and if so, how? What duty, if any, should the party have to determine whether a disclosure was AI-generated?
4. Should an AI-generated disclosure be treated differently than a non-AI-generated disclosure for prior art purposes? For example:

a. Should the treatment of an AI-generated disclosure as prior art depend on the extent of human contribution to the AI-generated disclosure?

b. How should the fact that an AI-generated disclosure could include incorrect information (*e.g.,* hallucinations) affect its consideration as a prior art disclosure?

c. How does the fact that a disclosure is AI-generated impact other prior art considerations, such as operability, enablement, and public accessibility?

5. At what point, if ever, could the volume of AI-generated prior art be sufficient to create an undue barrier to the patentability of inventions? At what point, if ever, could the volume of AI-generated prior art be sufficient to detract from the public accessibility of prior art (*i.e.,* if a PHOSITA exercising reasonable diligence may not be able to locate relevant disclosures)?

B. The Impact of AI on a PHOSITA

6. Does the term ''person'' in the PHOSITA assessment presume or require that the ''person'' is a natural person, *i.e.,* a human? How, if at all, does the availability of AI as a tool affect the level of skill of a PHOSITA as AI becomes more prevalent? For example, how does the availability of AI affect the analysis of the PHOSITA factors, such as the rapidity with which innovations are made and the sophistication of the technology?
7. How, if at all, should the USPTO determine which AI tools are in common use and whether these tools are presumed to be known and used by a PHOSITA in a particular art?
8. How, if at all, does the availability to a PHOSITA of AI as a tool impact:

a. Whether something is well-known or common knowledge in the art?

b. How a PHOSITA would understand the meaning of claim terms?

9. In view of the availability to a PHOSITA of AI as a tool, how, if at all, is an obviousness determination affected, including when:

a. Determining whether art is analogous to the claimed invention, given AI's ability to search across art fields? Does the ''analogous'' art standard still make sense in view of AI's capabilities?

b. Determining whether there is a rationale to modify the prior art, including the example rationales suggested by *KSR* (MPEP 2143, subsection I) (*e.g.,* ''obvious to try'') or the scientific principle or legal precedent rationales (MPEP 2144)?

c. Determining whether the modification yields predictable results with a reasonable expectation of success (*e.g.,* how to evaluate the predictability of results in view of the stochasticity (or lack of predictability) of an AI system)?

d. Evaluating objective indicia of obviousness or nonobviousness (*e.g.,* commercial success, long felt but unsolved needs, failure of others,

[1] Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence, Executive Order 14110, 88 FR 75191 (November 1, 2023).

simultaneous invention, unexpected results, copying, etc.)?

10. How, if at all, does the recency of the information used to train an AI model or that ingested by an AI model impact the PHOSITA assessment when that assessment may focus on an earlier point in time (*e.g.,* the effective filing date of the claimed invention for an application examined under the First-Inventor-to-File provisions of the America Invents Act)?

11. How, if at all, does the availability to a PHOSITA of AI as a tool impact the enablement determination under 35 U.S.C. 112(a)? Specifically, how does it impact the consideration of the *In re Wands* factors (MPEP 2164.01(a)) in ascertaining whether the experimentation required to enable the full scope of the claimed invention is reasonable or undue?

C. The Implications of AI That Could Require Updated Examination Guidance and/or Legislative Change

12. What guidance from the USPTO on the impact of AI on prior art and on the knowledge of a PHOSITA, in connection with patentability determinations made by the Office, would be helpful?

13. In addition to the considerations discussed above, in what other ways, if any, does the proliferation of AI impact patentability determinations made by the Office (*e.g.,* under 35 U.S.C. 101, 102, 103, 112, etc.)?

14. Are there any laws or practices in other countries that effectively address any of the questions above? If so, please identify them and explain how they can be adapted to fit within the framework of U.S. patent law.

15. Should title 35 of the U.S. Code be amended to account for any of the considerations set forth in this notice, and if so, what specific amendments do you propose, and why?

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2024–14691 Filed 7–3–24; 8:45 am]

BILLING CODE 3510–16–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete service(s) to the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Comments must be received on or before:* August 4, 2024.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 489–1322 or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following service(s) are proposed for deletion from the Procurement List:

Service(s)

Service Type: Janitorial/Custodial
Mandatory for: BLM, Billings Dispatch Center, 1299 Rimtop Drive, Billings, MT
Authorized Source of Supply: Community Option Resource Enterprises, Inc. (COR Enterprises), Billings, MT
Contracting Activity: BUREAU OF LAND MANAGEMENT, MT—MONTANA STATE OFFICE

Service Type: Janitorial/Custodial
Mandatory for: BLM, Fire Cache Office Facilities, 551 Northview Drive, Billings, MT
Authorized Source of Supply: Community Option Resource Enterprises, Inc. (COR Enterprises), Billings, MT
Contracting Activity: BUREAU OF LAND MANAGEMENT, MT—MONTANA STATE OFFICE

Service Type: Document Destruction
Mandatory for: NARA, Denver Federal Record Center (Rocky Mtn Reg): Building 48, 6th and Kipling, Denver, CO
Authorized Source of Supply: Bayaud Enterprises, Inc., Denver, CO
Contracting Activity: NATIONAL ARCHIVES AND RECORDS ADMINISTRATION, NARA FACILITIES

Service Type: Courier Service
Mandatory for: Department of Veterans Affairs, Michael E. DeBakey VA Medical Center, 2002 Holcombe Boulevard, Houston, TX
Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, 256–NETWORK CONTRACT OFC 16(00256)

Service Type: Grounds Maintenance
Mandatory for: Federal Aviation Administration, Norfolk Air Traffic Control Tower, Virginia Beach, VA and Patrick Henry Field Air Traffic Control Tower, Newport News, VA
Authorized Source of Supply: Portco, Inc., Portsmouth, VA
Contracting Activity: FEDERAL AVIATION ADMINISTRATION, 697DCK REGIONAL ACQUISITIONS SVCS

Michael R. Jurkowski,

Director, Business Operations.

[FR Doc. 2024–14736 Filed 7–3–24; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date added to the Procurement List:* August 4, 2024

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 489–1322, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 4/12/2024 (89 FR 25867) and 5/24/2024 (89 FR 45859), the Committee for Purchase From People Who Are Blind or Severely Disabled (operating as the U.S. AbilityOne Commission) published an initial notice of proposed additions to the Procurement List. The Committee determined that the service(s) listed below are suitable for procurement by the Federal Government and has added these service(s) to the Procurement List as a mandatory purchase for contracting activities listed. In accordance with 41 CFR 51–5.3(b), the mandatory purchase requirement is limited to those contracting activities at the locations listed, and in accordance with 41 CFR 51–5.2, the Committee has authorized nonprofit agencies listed as the authorized source(s) of supply.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the service(s) and impact of the additions on the current or most recent contractors, the Committee has determined that the service(s) listed below are suitable for procurement by

the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the service(s) to the Government.

2. The action will result in authorizing small entities to furnish the service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the service(s) proposed for addition to the Procurement List.

End of Certification

Accordingly, the following service(s) are added to the Procurement List:

Service Type: Custodial Service
Mandatory for: US Army, Air National Guard Readiness Center, Joint Base Andrews, Maryland
Authorized Source of Supply: Chimes District of Columbia, Baltimore, MD
Contracting Activity: DEPT OF THE ARMY, W39L USA NG READINESS CENTER

The Committee finds good cause to dispense with the 30-day delay in the effective date normally required by the Administrative Procedure Act. See 5 U.S.C. 553(d). This addition to the Committee's Procurement List is effectuated because of the expiration of the DEPT OF THE ARMY, W39L USA NG READINESS CENTER contract. The Federal customer contacted and has worked diligently with the AbilityOne Program to fulfill this service need under the AbilityOne Program. To avoid performance disruption, and the possibility that the DEPT OF THE ARMY, W39L USA NG READINESS CENTER will refer its business elsewhere, this addition must be effective on 7/14/2024, ensuring timely execution for a 7/16/2024 start date while still allowing nine (9) days for comment. The Committee also published a notice of proposed Procurement List addition in the **Federal Register** on 4/12/2024 (89 FR 25867) and did not receive any comments from any interested persons. This addition will not create a public hardship and has limited effect on the public at large, but, rather, will create new jobs for other affected parties—people with significant disabilities in the AbilityOne program who otherwise face challenges locating employment. Moreover, this addition will enable Federal customer operations to continue without interruption.

Service(s)

Service Type: Supply and Warehousing Service
Mandatory for: U.S. Navy, Naval Supply Systems Command, Fleet Logistics Center, Hawaii Zone, Pearl Harbor, HI
Mandatory for: U.S. Navy, Naval Supply Systems Command, Fleet Logistics Center, Diego Garcia Zone, San Diego, CA
Mandatory for: U.S. Navy, Naval Supply Systems Command, Fleet Logistics Center, Mayport Zone, Mayport, FL
Mandatory for: U.S. Navy, Naval Supply Systems Command, Fleet Logistics Center, Norfolk Zone, NAS Virginia Beach, VA
Mandatory for: U.S. Navy, Naval Supply Systems Command, Fleet Logistics Center, Pacific Northwest Zone, Seattle, WA
Mandatory for: U.S. Navy, Naval Supply Systems Command, Fleet Logistics Center, Southwest Zone, San Diego, CA
Authorized Source of Supply: South Texas Lighthouse for the Blind, Corpus Christi, TX
Contracting Activity: DEPT OF THE NAVY, NAVSUP FLT LOG CTR PEARL HARBOR

Michael R. Jurkowski,

Director, Business Operations.

[FR Doc. 2024–14734 Filed 7–3–24; 8:45 am]

BILLING CODE 6353–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 9:00 a.m. EDT, Friday, July 12, 2024.

PLACE: Virtual meeting.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Enforcement matters. In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.cftc.gov/.*

CONTACT PERSON FOR MORE INFORMATION: Christopher Kirkpatrick, 202–418–5964.

Authority: 5 U.S.C. 552b.

Dated: July 2, 2024.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2024–14948 Filed 7–2–24; 4:15 pm]

BILLING CODE 6351–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–133]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)
Filed June 24, 2024 10 a.m. EST
Through June 28, 2024 10 a.m. EST
Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search.*

EIS No. 20240115, Final, MARAD, USCG, TX, Texas Gulflink Deepwater Port License Application, Review Period Ends: 08/19/2024, Contact: Linden Houston 202–366–4839.
EIS No. 20240116, Final, BLM, CO, Gunnison Sage-Grouse Proposed Resource Management Plan Amendment—Final Environmental Impact Statement, Review Period Ends: 08/05/2024, Contact: Gina Phillips 970–589–9852.
EIS No. 20240117, Final, BLM, AK, ANCSA 17(d)(1) Withdrawals Final Environmental Impact Statement, Review Period Ends: 08/05/2024, Contact: Racheal Jones 907–290–0307.
EIS No. 20240118, Draft, Caltrans, CA, Albion River Bridge Project, Comment Period Ends: 09/09/2024, Contact: Liza Walker 707–502–9657.
EIS No. 20240119, Final, USFWS, OR, Final Environmental Impact Statement for the Barred Owl Management Strategy, Review Period Ends: 08/05/2024, Contact: Robin Bown 503–231–6179.

Amended Notice

EIS No. 20240098, Draft, USACE, MS, Pearl River Basin, Mississippi Federal Flood Risk Management Project, Comment Period Ends: 08/06/2024, Contact: Eric Williams 504–862–2862. Revision to FR Notice Published 06/07/2024; Extending the Comment Period from 07/22/2024 to 08/06/2024.

Dated: June 28, 2024.

Nancy Abrams,

Associate Director, Office of Federal Activities.

[FR Doc. 2024–14711 Filed 7–3–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OA–2024–0043; FRL–12069–01–OA]

National Environmental Youth Advisory Council; Notification of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), the U.S. Environmental Protection Agency (EPA) hereby provides notice that the National Environmental Youth Advisory Council (NEYAC) will meet on the date and time described below. The meeting is open to the public. For additional information about registering to attend the meeting or to provide a public comment, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document. *Due to unforeseen administrative circumstances, EPA is announcing this meeting with less than 15 calendar days public notice.*

DATES: The NEYAC will convene a virtual public meeting on Wednesday, July 17, 2024. A public comment period relevant to the NEYAC will be considered by the NEYAC at the meeting (see **SUPPLEMENTARY INFORMATION**). Members of the public who wish to participate during the public comment period must register by 11:59 p.m., eastern time, Wednesday, July 10, 2024.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OA–2024–0043, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Email: neyac@epa.gov.* Include Docket ID No. EPA–HQ–OA–2024–0043 in the subject line of the message.

Instructions: All submissions received must include the Docket ID No. for this public meeting. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. Comments must be submitted by 11:59 p.m. eastern time on Wednesday, July 31, 2024. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

The virtual meeting will be through an online audio and video platform. The meeting will convene on Wednesday, July 17, from 12 p.m. to 4:30 p.m. eastern time. Refer to the **SUPPLEMENTARY INFORMATION** section below for additional information.

FOR FURTHER INFORMATION CONTACT: Carissa Cyran, NEYAC Designated Federal Officer (1702A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566–1353; email address: *cyran.carissa@epa.gov.* Additional information about the NEYAC is available at *https://www.epa.gov/faca/national-environmental-youth-advisory-council-neyac.*

SUPPLEMENTARY INFORMATION: The NEYAC has been deliberating on the following issues and will discuss and vote on recommendations at this meeting.

Topic 1: Environmental Justice and Youth.

Topic 2: Office of Air and Radiation: Climate, Clean Air, and Environmental Justice.

Topic 3: Addressing Food Waste at Home and Abroad: A Case for Circular and Sustainable Materials Management Systems.

Read the charge memos and presentations here: *https://www.epa.gov/faca/national-environmental-youth-advisory-council-neyac-meetings.*

I. Public Participation

Individual registration is required for the public meeting. No two individuals can share the same registration link. Information on how to register is located at *https://www.epa.gov/faca/national-environmental-youth-advisory-council-neyac.* Registration for the meeting is available until the scheduled end time of the meeting. Registration to speak during the public comment period will close at 11:59 p.m., eastern time, on Wednesday, July 10, 2024. When registering, please provide your name, organization, city and state, and email address for follow up. Please also indicate whether you would like to provide public comment during the meeting, or if you are submitting written comments.

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OA–2024–0043, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Comments must be submitted by 11:59 p.m. eastern time on Wednesday, July 31, 2024. 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). Please visit *https://www.epa.gov/dockets/commenting-epa-dockets* for additional submission methods; the full EPA public comment policy; information about CBI, PBI, or multimedia submissions; and general guidance on making effective comments.

B. Participation Virtually Public Meeting

The NEYAC will hear comments from the public from approximately 2:35 p.m.–3:05 p.m. eastern time. EPA will begin pre-registering speakers for the public meeting upon publication of this document in the **Federal Register**. To register to speak, please use the online registration form available at *https://www.epa.gov/faca/national-environmental-youth-advisory-council-neyac.* The last day to pre-register to speak at the public meeting will be at 11:59 p.m., eastern time, on Wednesday, July 10, 2024.

Time will be allotted on a first-come first-served basis, and the total period for comments may be extended if the number of requests for appearances requires it. EPA will make every effort to follow the schedule as closely as possible on the day of the public meeting; however, please plan for the meeting to run either ahead of schedule or behind schedule.

Individuals or groups making remarks during the public comment period will be limited to two (2)—three (3) minutes. Please be prepared to briefly describe your issue and your recommendation relevant to the current charges, topics, and questions under consideration by the NEYAC. EPA also recommends submitting the text of your oral comments as written comments to the rulemaking docket.

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 public meeting.

Please note that any updates made to any aspect of the public meeting are posted online at *https://www.epa.gov/faca/national-environmental-youth-advisory-council-neyac.* While EPA expects the public meeting to go forward as set forth above, please monitor our website. EPA does not intend to publish a document in the **Federal Register** announcing updates.

C. Information About Services for Individuals With Disabilities or Requiring English Language Translation Assistance

To request special accommodations for a disability or other assistance, please submit your request at least five (5) working days prior to the meeting to give EPA sufficient time to process your request. All requests should be sent to the email listed in the **FOR FURTHER INFORMATION CONTACT** section.

Due to unforeseen administrative circumstances, EPA is announcing this meeting with less than 15 calendar days public notice.

Carissa Cyran,

National Environmental Youth Advisory Council Designated Federal Officer, Office of Public Engagement and Environmental Education, Office of the Administrator.

[FR Doc. 2024–14690 Filed 7–3–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2024–0159; FRL–11684–04–OCSPP]

Certain New Chemicals or Significant New Uses; Statements of Findings for April 2024

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Toxic Substances Control Act (TSCA) requires EPA to publish in the **Federal Register** a statement of its findings after its review of certain TSCA submissions when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to premanufacture notices (PMNs), microbial commercial activity notices (MCANs), and significant new use notices (SNUNs) submitted to EPA under TSCA. This document presents statements of findings made by EPA on such submissions during the period from April 1, 2024, to April 30, 2024.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2024–0159, is available online at *https://www.regulations.gov* or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Rebecca Edelstein, New Chemical Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–1667 email address: *edelstein.rebecca@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action provides information that is directed to the public in general.

B. What action is the Agency taking?

This document lists the statements of findings made by EPA after review of submissions under TSCA section 5(a) that certain new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment. This document presents statements of findings made by EPA during the reporting period.

C. What is the Agency's authority for taking this action?

TSCA section 5(a)(3) requires EPA to review a submission under TSCA section 5(a) and make one of several specific findings pertaining to whether the substance may present unreasonable risk of injury to health or the environment. Among those potential findings is that the chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment per TSCA Section 5(a)(3)(C).

TSCA section 5(g) requires EPA to publish in the **Federal Register** a statement of its findings after its review of a submission under TSCA section 5(a) when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to PMNs, MCANs, and SNUNs submitted to EPA under TSCA section 5.

Anyone who plans to manufacture (which includes import) a new chemical substance for a non-exempt commercial purpose and any manufacturer or processor wishing to engage in a use of a chemical substance designated by EPA as a significant new use must submit a notice to EPA at least 90 days before commencing manufacture of the new chemical substance or before engaging in the significant new use.

The submitter of a notice to EPA for which EPA has made a finding of ''not likely to present an unreasonable risk of injury to health or the environment'' may commence manufacture of the chemical substance or manufacture or processing for the significant new use notwithstanding any remaining portion of the applicable review period.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

II. Statements of Findings Under TSCA Section 5(a)(3)(C)

In this unit, EPA provides the following information (to the extent that such information is not claimed as Confidential Business Information (CBI)) on the PMNs, MCANs and SNUNs for which, during this period, EPA has made findings under TSCA section 5(a)(3)(C) that the new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment:

The following list provides the EPA case number assigned to the TSCA section 5(a) submission and the chemical identity (generic name if the specific name is claimed as CBI).

- P–23–0129, Benzyl fatty acid esters (Generic Name).
- P–23–0062, Cashew, nutshell., polymer-based polyether polyol (Generic Name).
- J–24–0009–0013, Chromosomally modified *Saccharomyces cerevisiae* (Generic Name).

To access EPA's decision document describing the basis of the ''not likely to present an unreasonable risk'' finding made by EPA under TSCA section

5(a)(3)(C), look up the specific case number at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely*.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: June 28, 2024.

Shari Z. Barash,

Director, New Chemicals Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2024–14688 Filed 7–3–24; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT ADMINISTRATION

Sunshine Act Meetings

TIME AND DATE: 10 a.m., Thursday, July 11, 2024.

PLACE: You may observe this meeting in person at 1501 Farm Credit Drive, McLean, Virginia 22102–5090, or virtually. If you would like to observe, at least 24 hours in advance, visit *FCA.gov,* select ''Newsroom,'' then select ''Events.'' From there, access the linked ''Instructions for board meeting visitors'' and complete the described registration process.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The following matters will be considered:

- Approval of Minutes for June 13, 2024
- Update on Farm Credit System Funding Conditions

CONTACT PERSON FOR MORE INFORMATION: If you need more information or assistance for accessibility reasons, or have questions, contact Ashley Waldron, Secretary to the Board. Telephone: 703–883–4009. TTY: 703–883–4056.

Ashley Waldron,

Secretary to the Board.

[FR Doc. 2024–14820 Filed 7–2–24; 11:15 am]

BILLING CODE 6705–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements 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. Copies of agreements are 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.: 201430.

Agreement Name: SM Line/Sealead Shipping Slot Exchange Agreement for Empty Containers.

Parties: Sealead Shipping DMCC; SM Line Corporation.

Filing Party: Rebecca Fenneman; Jeffrey/Fenneman Law and Strategy PLLC.

Synopsis: Agreement to swap slots to carry empty containers.

Proposed Effective Date: 06/25/2024.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/86567.

Agreement No.: 201431.

Agreement Name: CMA CGM/ONE Brazex Service Space Charter Agreement.

Parties: CMA CGM S.A.; Ocean Network Express Pte. Ltd.

Filing Party: Draughn Arbona; CMA CGM S.A.

Synopsis: This Agreement authorizes CMA CGM to charter space to ONE on vessels operated by CMA CGM or on which CMA CGM has space in the Trade between Mexico, Jamaica, Colombia, and Brazil, on one hand, and the U.S. Gulf Coast, on the other hand.

Proposed Effective Date: 06/27/2024.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/86568.

Dated: July 1, 2024.

Alanna Beck,

Federal Register Alternate Liaison Officer.

[FR Doc. 2024–14704 Filed 7–3–24; 8:45 am]

BILLING CODE 6730–02–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0007; Docket No. 2024–0001; Sequence No. 7]

Information Collection; General Services Administration Acquisition Regulation; Contractor Qualifications and Financial Information, GSA Form 527

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, and the Office of Management and Budget (OMB) regulations, GSA invites the public to comment on a request to review and approve an extension of a previously approved information collection requirement regarding contractor qualifications and financial information.

DATES: Submit comments on or before: September 3, 2024.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal searching Information Collection 3090–0007. Select the link ''Comment Now'' that corresponds with ''Information Collection 3090–0007, Contractor's Qualifications and Financial Information, GSA Form 527''. Follow the instructions provided on the screen. Please include your name, company name (if any), and ''Information Collection 3090–0007; Contractor's Qualifications and Financial Information, GSA Form 527'' on your attached document. If your comment cannot be submitted using *https://www.regulations.gov,* call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite ''Information Collection 3090–0007, Contractor's Qualifications and Financial Information, GSA Form 527'', in all correspondence related to this collection. Comments received generally will be posted without change to *regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *regulations.gov,* approximately two-to-three business days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Mr. Bryon Boyer, Procurement Analyst, at *gsarpolicy@gsa.gov* or 817–850–5580.

SUPPLEMENTARY INFORMATION:

A. Purpose

GSA requires prospective contractors to submit certain financial information for a contracting officer to make a determination that it is financially responsible for an award, in accordance with the Federal Acquisition Regulation (FAR) 9.103(a) and 9.104–1 and also the General Services Administration Acquisition Manual (GSAM) 509.105–1(a). GSA Form 527, Contractor's Qualifications and Financial Information is used to achieve

uniformity and consistency in the process.

B. Annual Reporting Burden

Respondents: 868.
Responses per Respondent: 1.2.
Total Responses: 1,042.
Hours per Response: 1.5.
Total Burden Hours: 1,563.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the functions of the General Services Administration Regulation, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the Regulatory Secretariat Division (MVCB), at *GSARegSec@gsa.gov.* Please cite OMB Control No. 3090–0007, Contractor Qualifications and Financial Information, in all correspondence.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2024–14754 Filed 7–3–24; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0076; Docket No. 2024–0053; Sequence No. 8]

Submission for OMB Review; Novation and Change-of-Name Agreements

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding novation and change-of-name agreements.

DATES: Submit comments on or before August 5, 2024.

ADDRESSES: Written comments and recommendations for this 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 Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or *zenaida.delgado@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0076, Novation and Change-of-Name Agreements.

B. Need and Uses

This clearance covers the information that contractors must submit to comply with the following requirements in Federal Acquisition Regulation (FAR) subpart 42.12:

- FAR *42.1203(a), Written Request.* If a contractor wishes the Government to recognize a successor in interest to its contracts or a name change, the contractor must submit a written request to the responsible contracting officer. The request is used by the contracting officer to determine what additional supporting documentation should be submitted by the contractor and to determine what other contract administration offices should be notified of the contractor's request.
- FAR *42.1204(e) and (f), Novation Agreement.* Pursuant to FAR 42.1203(b)(1), upon request from the contracting officer, the contractor shall submit three signed copies of the proposed novation agreement, plus copies of the supporting documentation listed at 42.1204(e) and (f), as applicable. The documentation is used by the contracting officer to evaluate and, if appropriate, execute a proposed agreement for recognizing a third party as a successor in interest.
- FAR *42.1205(a), Change-of-Name Agreement.* Pursuant to FAR 42.1203(b)(1), upon request from the contracting officer, the contractor shall submit three signed copies of the proposed change-of-name agreement, plus copies of the supporting documentation listed at 42.1205(a), as applicable. The documentation is used by the contracting officer to evaluate and, if appropriate, execute a proposed agreement for recognizing a contractor's name change.

C. Annual Burden

Respondents: 1,625.
Total Annual Responses: 1,625.
Total Burden Hours: 3,163.

D. Public Comment

A. A 60-day notice was published in the **Federal Register** at 89 FR 24001, on April 5, 2024. A 60-day notice was published in the **Federal Register** at 89 FR 24001, on April 5, 2024. Comments from 3 respondents were received; however, they did not change the estimate of the burden.

Comment: Three respondents submitted the following recommendations for changes to the FAR:

- For novation agreements:

✓ Define time frames in which the government will review the novation request and request any further information.

✓ Explicitly permitting the electronic submission of novation packages.

✓ Reserve the novation process for only actual transfer of assets which are embodied in a sale between two entirely separate unaffiliated legal entities.

✓ Include recognition of a successor in interest to Government contracts among entities registered in the System for Award Management (SAM) that have a common parent company when there is no transfer of assets.

✓ Allow for a streamlined process for a transfer of assets between two affiliated entities within the same corporate parent structure.

✓ Remove the requirement to provide the ''approximate remaining unpaid balance'' of contracts to be novated at FAR 42.1204(e)(2)(iv).

✓ Clarify that a novation process can begin before all the documents are submitted although it won't be complete until all necessary requirements are fully satisfied.

✓ Remove the requirement for a corporate seal or require it only if the novated contracts are above a very high dollar threshold.

✓ Replace the listed documents at FAR 42.1204(f)(1) to (3) with a simple Secretary's Certificate, certifying that all the activities (registration, approval by the board, etc.) have been completed.

✓ Require the government to appropriately deem an acquirer as a successor in interest to the proposals. This could be a confirmation or certification in SAM that the resources proposed remain available to perform and that the acquisition or novation does not change the ability to perform.

✓ Require that the contracting officer managing the contract with the largest total contract value be the responsible contracting officer to execute the novation agreement including a review by the government's legal counsel.

✓ Limit the list requested at FAR 42.1204(e)(2) to multiple year contracts identified at the time of submission of the request.

✓ Review the list of documentation being requested in light of the advancement of electronic records.

• For change-of-name agreements:

✓ Run the change-of-name process through SAM exclusively. Deem the name change automatically effective on all existing contracts and work orders and all pending submitted proposals via SAM.

✓ Limit the list requested at FAR 42.1205(a)(3) to multiple year contracts identified at the time of submission of the request.

✓ Explicitly permitting the electronic submission of change-of-name packages.

Response: The respondents' input is appreciated. The recommendations made by the commenters may be considered for future action. Any necessary revisions to FAR subpart 42.12, Novation and Change-of-Name Agreements, will be accomplished through rulemaking.

Comment: In the process of updating a legal entity name in SAM, Defense Logistics Agency (DLA) Commercial and Government Entity (CAGE) Review requires a signed statement from a contracting officer before an update to a contractor's CAGE will be made. At the same time, the responsible contracting officer requests that SAM be updated before issuing a novation or name change. This apparently irreconcilable administrative conflict causes delay in updating SAM resulting in more awards being issued against the original contractor that would need a modification. This creates additional burden for both the contractor and the government.

Response: If a contractor is changing its name in SAM—

1. After completing the steps required by FAR 42.1205, the contractor would have to update/renew its entire Entity Registration in SAM and should be able to upload either the signed Change-of-Name Agreement or the signed SF30, Modification of Contract, satisfying what's required by the DLA CAGE team for screening and validation. See SAM's Knowledge Base articles #KB 0016829 and KB 0016831.

2. Before completing the steps required by FAR 42.1205, the contractor—

a. Must provide the notification required by paragraph (d) of the FAR clause at 52.204–13, System for Award Management Maintenance.

b. Would have to update/renew its entire Entity Registration in SAM.

c. When SAM sends the CAGE for screening and validation to the CAGE team, the team may request legal documentation to support the name change. This could result in the contractor getting a request from the DLA CAGE team for the same documentation needed to complete the steps required by FAR 42.1205. See SAM's Knowledge Base article #KB 0016831.

3. But the contractor does not have any open federal government contracts, then, the contractor would have to update/renew its entire Entity Registration in SAM. The contractor must provide the legal documentation needed to support the name change to the CAGE team to complete the CAGE/SAM validation process.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 9000–0076, Novation and Change-of-Name Agreements.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2024–14725 Filed 7–3–24; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Extension of the Application Deadline: The REACH Lark Galloway-Gilliam Award for Advancing Health Equity Challenge (REACH Lark Award Challenge)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On April 25, 2024, the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), published in the **Federal Register** a notice announcing the 2024 Racial and Ethnic Approaches to Community Health (REACH) Lark Galloway-Gilliam for Advancing Health Equity Award Challenge (REACH Lark Award Challenge). The CDC established a deadline date of June 21, 2024, for the transmittal of applications. This notice extends the deadline date for applications through July 12, 2024.

DATES: The Challenge will accept applications through July 12, 2024.

FOR FURTHER INFORMATION CONTACT: Stormie Israel, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Hwy. NE, Mailstop S107–5, Atlanta, GA 30341, Telephone: 770–488–2964, Email: *dnpaopolicy@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Award Approving Official: Mandy K. Cohen, MD, MPH, Director, Centers for Disease Control and Prevention, and Administrator, Agency for Toxic Substances and Disease Registry.

On April 25, 2024, CDC published a **Federal Register** Notice (89 FR 31751) announcing the 2024 REACH Lark Award Challenge. The CDC established a deadline date of June 21, 2024, for the transmittal of applications. This notice extends the deadline date for transmittal of applications until July 12, 2024. CDC is extending the deadline to allow additional time for interested applicants to participate.

This biennial challenge was established in 2019 to recognize extraordinary individuals, organizations, or community coalitions associated with the REACH program whose work has contributed to the implementation of culturally tailored interventions that advance health equity, reduce health disparities, and increase community engagement to address preventable risk behaviors (*e.g.,* tobacco use, poor nutrition, and physical inactivity).

To participate and submit an application, interested parties should go to *https://www.challenge.gov.* All information for this competition remains the same, except for the deadline for the transmittal of applications.

General Conditions

CDC reserves the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at CDC's sole discretion.

Participation in this Challenge constitutes an applicants' full and unconditional agreement to abide by the Challenge's Official Rules found at *https://www.Challenge.gov.*

Authority: 15 U.S.C. 3719.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–14727 Filed 7–3–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–3105, FDA–2023–E–3106, FDA–2023–E–3109]

Determination of Regulatory Review Period for Purposes of Patent Extension; DAXXIFY

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for DAXXIFY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 3, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 2, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 3, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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 Nos. FDA–2023–E–3105, FDA–2023–E–3106, and FDA–2023–E–3109, for ''Determination of Regulatory Review Period for Purposes of Patent Extension; DAXXIFY.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the

biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product DAXXIFY (daxibotulinumtoxinA-lanm). DAXXIFY is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients. Subsequent to this approval, the USPTO received patent term restoration applications for DAXXIFY (U.S. Patent Nos. 9,340,587; 9,956,435; and 10,111,939) from Revance Therapeutics, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated January 30, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of DAXXIFY represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for DAXXIFY is 2,339 days. Of this time, 1,321 days occurred during the testing phase of the regulatory review period, while 1,018 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* April 14, 2016. The applicant claims October 15, 2016, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 14, 2016, which was the first date after receipt of an earlier IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* November 25, 2019. FDA has verified the applicant's claim that the biologics license application (BLA) for DAXXIFY (BLA 761127) was initially submitted on November 25, 2019.

3. *The date the application was approved:* September 7, 2022. FDA has verified the applicant's claim that BLA 761127 was approved on September 7, 2022.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,214 days, 1,305 days, or 1,587 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14732 Filed 7–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–E–0442]

Determination of Regulatory Review Period for Purposes of Patent Extension; RYSTIGGO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for RYSTIGGO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 3, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 2, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 3, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–E–0442 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; RYSTIGGO.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product RYSTIGGO (rozanolixizumab-noli). RYSTIGGO is indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibody positive. Subsequent to this approval, the USPTO received a patent term restoration application for RYSTIGGO (U.S. Patent No. 10,233,243) from UCB Biopharma SRL, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 3, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of RYSTIGGO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for RYSTIGGO is 2,283 days. Of this time, 2,036 days occurred during the testing phase of the regulatory review period, while 247 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* March 29, 2017. The applicant claims April 26, 2017, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 29, 2017, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* October 24, 2022. FDA has verified the applicant's claim that the biologics license application (BLA) for RYSTIGGO (BLA 761286) was initially submitted on October 24, 2022.

3. *The date the application was approved:* June 26, 2023. FDA has verified the applicant's claim that BLA 761286 was approved on June 26, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 902 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14723 Filed 7–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–2011; FDA–2023–E–2248]

Determination of Regulatory Review Period for Purposes of Patent Extension; VABYSMO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for VABYSMO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 3, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 2, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 3, 2024. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 3, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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

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- *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 Nos. FDA–2023–E–2011 and FDA–2023–E–2248 For Determination of Regulatory Review Period for Purposes of Patent Extension; VABYSMO. Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product VABYSMO (faricimab-svoa). VABYSMO is indicated for treatment of patients with neovascular (Wet) age-related macular degeneration and diabetic macular edema. Subsequent to this approval, the USPTO received patent term restoration applications for VABYSMO (U.S. Patent Nos. 8,268,314 and 9,695,233) from Genentech, Inc.(Agent of Hoffmann-La Roche Inc.), and the USPTO requested FDA's assistance in determining this patents' eligibility for patent term restoration. In a letter dated September 28, 2023, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of VABYSMO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for VABYSMO is 3,046 days. Of this time, 2,800 days occurred during the testing phase of the regulatory review period, while 246 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* September 28, 2013. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 28, 2013.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* May 28, 2021. FDA has verified the applicant's claim that the biologics license application (BLA) for VABYSMO (BLA 761235) was initially submitted on May 28, 2021.

3. *The date the application was approved:* January 28, 2022. FDA has verified the applicant's claim that BLA 761235 was approved on January 28, 2022.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 931 and 1,646 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket Nos. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14720 Filed 7–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2823]

Authorization of Emergency Use of Monkeypox Polymerase Chain Reaction Test Home Collection Kit in Response to an Outbreak of Mpox; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in response to an outbreak of Mpox. FDA has issued the Authorization for Labcorp Monkeypox PCR (Polymerase Chain Reaction) Test Home Collection Kit as requested by Laboratory Corporation of America. The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the August 9, 2022, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for

a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to the FD&C Act, subject to terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, and can be accessed on FDA's website from the link indicated.

DATES: The Authorization is effective as of March 22, 2024.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on FDA's website. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, or 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc).

FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii) of the FD&C Act, that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

III. The Authorization

The Authorization follows the August 9, 2022, determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves monkeypox virus. Notice of the Secretary's determination was provided in the **Federal Register** on August 15, 2022 (87 FR 50090). On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. Notice of the Secretary's declaration was provided in the **Federal Register** on September 13, 2022 (87 FR 56074). On March 22, 2024, having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA issued an EUA to Laboratory Corporation of America, for the Labcorp Monkeypox PCR Test Home Collection Kit, subject to the terms of the Authorization. The Authorization, which is included below in its entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provides an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent revision to the Authorization can be found from FDA's web page at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

IV. Electronic Access

An electronic version of this document and the full text of the Authorization is available at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

March 22, 2024

C. Donald Kafader II
Senior Director, Regulatory Affairs
Laboratory Corporation of America
8790 Devon Ridge Court
Sunbury, Ohio 43074

Device:	Labcorp Monkeypox PCR Test Home Collection Kit
EUA Number:	EUA230044
Company:	Laboratory Corporation of America ("Labcorp")
Indication:	For the collection of lesion swab specimens at home by individuals 18 years of age or older (self-collected), presenting with acute, generalized pustular or vesicular rash suspected of mpox[1] when determined to be appropriate by a healthcare provider.
Authorized Laboratories:	Testing is limited to the Center for Esoteric Testing, Burlington, North Carolina, and laboratories designated by Labcorp and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests and that test the lesion swab specimens collected using the Labcorp Monkeypox PCR Test Home Collection Kit with CDC's Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA when used consistent with its authorization.

Dear Donald Kafader:

This letter is in response to your[2] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[3] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On August 9, 2022, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health

[1] On November 28, 2022, following a series of consultations with global experts, the World Health Organization (WHO) began using a new preferred term "mpox" as a synonym for monkeypox, the disease cause by the monkeypox virus. Refer to: https://www.who.int/news/item/28-11-2022-who-recommends-new-name-for-monkeypox-disease.

[2] For ease of reference, this letter will use the term "you" and related terms to refer to Laboratory Corporation of America ("Labcorp").

[3] For ease of reference, this letter will use the term "your product" to refer to the Labcorp Monkeypox PCR Test Home Collection Kit used for the indication identified above.

emergency, or a significant potential for a public health emergency, that affects or has a significant potential to affect national security or the health and security of United States citizens living abroad that involves monkeypox virus.[4] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on September 7, 2022 that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, subject to the terms of any authorization issued under Section 564(a) of the Act.[5]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the EUA Summary (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The virus that causes mpox can cause a serious or life-threatening disease or condition, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing infection with the virus that causes mpox by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect this virus DNA from the collected human specimen, and that the known and potential benefits of your product when used for such use, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[6]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

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[4] 87 FR 50090 (August 15, 2022)
[5] 87 FR 56074 (September 13, 2022)
[6] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

Authorized Product Details

Your product is a collection kit intended for the collection of lesion swab specimens by any individual age 18 years or older (self-collected) presenting with acute, generalized pustular or vesicular rash suspected of mpox when determined to be appropriate by a healthcare provider.

Collection kit supplies for your product are sent to the designated entity by the authorized distributor, The Dot Corporation, where they are assembled and distributed to patients, when determined to be appropriate by a healthcare provider. Individuals using your product, then collect the specimen according to the provided authorized sample collection instructions (summarized in the authorized labeling below) and ship the specimen to Labcorp via FedEx according to the specimen return instructions.

Lesion swab specimens collected using your product are transported at ambient temperature for testing at an authorized laboratory. The non-variola *Orthopoxvirus* nucleic acid from the lesion swabs is maintained in the specimen packaging. Testing is limited to the Center for Esoteric Testing, Burlington, North Carolina, and laboratories designated by Labcorp and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests and that test the lesion swab specimens collected using the Labcorp Monkeypox PCR Test Home Collection Kit with CDC's Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA when used consistent with its authorization.

The Labcorp Monkeypox PCR Test Home Collection Kit includes specimen collection and storage materials (or other authorized materials as may be requested under Condition Q. below) as well as instructions for shipping the specimen to Labcorp via FedEx described in the "Labcorp Monkeypox PCR Test Home Collection Kit Instructions for Use."

The labeling entitled "Labcorp Monkeypox PCR Test Home Collection Kit Instructions for Use," the EUA Summary (available at https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices), the following standard operating procedures (SOPs): "SQNM-MPX-101 Accessioning Acceptance Questionnaire", and "Handling and Processing of Samples Submitted for SQNM-MPX-101 SOP", and the documents provided to authorized entities as part of the contract provisions is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling".

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific

evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing infection with the monkeypox virus by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect monkeypox virus DNA from the collected human specimen, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), Subpart O (Statistical Techniques, 21 CFR 820.250) and Subpart M (Complaint Files, 21 CFR 820.198).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Labcorp (You) and Authorized Distributor(s)[7]

A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

[7] "Authorized Distributor(s)" are identified by you, Laboratory Corporation of America ("Labcorp"), in your EUA submission as an entity allowed to distribute your product.

B. Your product must comply with the following quality system requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), Subpart O (Statistical Techniques, 21 CFR 820.250), and Subpart M (Complaint Files, 21 CFR 820.198).

C. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

D. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

E. You and authorized distributor(s) must make available all instructions related to the self-collection of lesion swab specimens using the Labcorp Monkeypox PCR Test Home Collection Kit both in the shipped kit and on your website.

F. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

G. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which your product is distributed.

H. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

I. You and authorized distributor(s) must maintain customer complaint files on record. You will report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.

J. You and authorized distributors must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the performance claimed in the authorized labeling.

K. If requested by FDA, you and authorized distributors must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of the Labcorp Monkeypox PCR Test Home Collection Kit for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

Labcorp (You)

L. You must register and list consistent with 21 CFR Part 807 within one month of this letter.

M. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

N. You must have a signed agreement with each authorized distributor that distribution of the authorized product must be consistent with this Letter of Authorization.

O. If requested by FDA, you must submit associated documents and records related to your quality system for FDA review within 48 hours of the request.

P. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials.

Q. You may request modifications to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for modification to this EUA should be submitted to DMD/OHT7/OPEQ/CDRH and require appropriate authorization from FDA.

R. You must have a process in place to track adverse events associated with the Labcorp Monkeypox PCR Test Home Collection Kit, including any occurrences of false results with your product, and report any such events to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov.

S. You must further evaluate the clinical performance of your product in an FDA agreed upon post authorization clinical evaluation study. After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

T. You must submit to FDA a summary report summarizing the results of any testing performed inclusive of the first ten positive lesion swab specimens collected with the Labcorp Monkeypox PCR Test Home Collection Kit, including the positivity rate for lesion swab specimens.

Authorized Laboratories

U. Authorized laboratories testing lesion swab specimens collected using your product must follow the "SQNM-MPX-101 Accessioning Acceptance Questionnaire", and "Handling and Processing of Samples Submitted for SQNM-MPX-101 SOP" Standard Operating Procedure (SOP) when accepting specimens for testing.

V. Authorized laboratories using your product must use it only in conjunction with CDC's Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA test consistent with its EUA.

W. Authorized laboratories must have a process in place to track adverse events associated with your product and report to you (1-800-833-3935 or OnDemandSupport@Labcorp.com)) and to FDA pursuant to 21 CFR Part 803.

Labcorp (You), Authorized Distributor(s) and Authorized Laboratories

X. You, authorized distributor(s), and authorized laboratories must collect information on the performance of your product and must report any significant deviations from the established performance characteristics of your product of which they become aware to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) In addition, authorized distributor(s) and authorized laboratories report to you (1-800-833-3935 or OnDemandSupport@Labcorp.com).

Y. You, authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA, are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

Z. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

AA. No descriptive printed matter, advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of monkeypox virus or other non-variola orthopoxviruses.

BB. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA;
- This product has been authorized only for the collection and maintenance of lesion swab specimens as an aid in detection of nucleic acid from non-variola *Orthopoxvirus*, including monkeypox virus, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use

of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Ellen J. Flannery -S Digitally signed by Ellen J. Flannery -S Date: 2024.03.22 10:12:42 -04'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure

Dated: July 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14714 Filed 7–3–24; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–2035 and FDA–2023–E–2247]

Determination of Regulatory Review Period for Purposes of Patent Extension; ENJAYMO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ENJAYMO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 3, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 2, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 3, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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 Nos. FDA–2023–E–2035 and FDA–2023–E–2247 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ENJAYMO.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product ENJAYMO (sutimlimab-jome). ENJAYMO is indicated to decrease the need for red blood cell transfusion due to hemolysis in adults with cold agglutinin disease. Subsequent to this approval, the USPTO received patent term restoration applications for ENJAYMO (U.S. Patent Nos. 8,877,197 and 10,450,382) from Bioverativ USA Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 28, 2023, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ENJAYMO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ENJAYMO is 1,845 days. Of this time, 1,151 days occurred during the testing phase of the regulatory review period, while 694 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* January 18, 2017. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 18, 2017.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* March 13, 2020. FDA has verified the applicant's claim that the biologics license application (BLA) for ENJAYMO (BLA 761164) was initially submitted on March 13, 2020.

3. *The date the application was approved:* February 4, 2022. FDA has verified the applicant's claim that BLA 761164 was approved on February 4, 2022.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension.

In its application for patent extension, this applicant seeks 766 or 825 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket Nos. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14729 Filed 7–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2754]

M14 General Principles on Plan, Design, and Analysis of Pharmacoepidemiological Studies That Utilize Real-World Data for Safety Assessment of Medicines; International Council for Harmonisation; 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 guidance for industry entitled ''M14 General Principles on Plan, Design, and Analysis of Pharmacoepidemiological Studies That Utilize Real-World Data for Safety Assessment of Medicines.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance outlines general principles on planning, designing, and analyzing observational (noninterventional) pharmacoepidemiological studies that utilize fit-for-purpose data for safety assessment of medicines (drugs, vaccines, and other biological products). The draft guidance includes recommendations and high-level best practices for the conduct of these studies. The draft guidance is intended to streamline the development and regulatory assessment of postmarketing pharmacoepidemiological safety studies that include Real-World Data. This guidance also seeks to improve the ability of the study protocol and/or results to be accepted across health authorities and support decision making in response to study results.

DATES: Submit either electronic or written comments on the draft guidance by September 3, 2024 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–2024–D–2754 for ''M14 General Principles on Plan, Design, and Analysis of Pharmacoepidemiological Studies That Utilize Real-World Data for Safety Assessment of Medicines.'' 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 draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Wei Hua, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 22, Rm. 2414, Silver Spring, MD 20993–0002, 240–402–8658, *OSE.PMKTREGS@fda.hhs.gov;* or 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.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''M14 General Principles on Plan, Design, and Analysis of Pharmacoepidemiological Studies That Utilize Real-World Data for Safety Assessment of Medicines.'' The draft guidance was prepared under the auspices of ICH. ICH seeks to achieve greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In May 2024, the ICH Assembly endorsed the draft guideline entitled ''M14 General Principles on Plan, Design, and Analysis of Pharmacoepidemiological Studies That Utilize Real-World Data for Safety Assessment of Medicines'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

This draft guidance provides general considerations and recommendations for use of real-world data for drug, vaccine, and other biologic product safety assessments. The draft guidance seeks to harmonize regional recommendations for the design, analysis, and reporting of postmarketing pharmacoepidemiologic studies that use real-world data as the number of pharmacoepidemiological studies utilizing real-world data in a regulatory context have increased globally.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''M14 General Principles on Plan, Design, and Analysis of Pharmacoepidemiologic Studies That Utilize Real-World Data for Safety Assessment of Medicines.'' 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 (44 U.S.C. 3501–3521). The collections of information supporting investigational new drug regulations in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information supporting FDA approval of new drugs in part 314 (21 CFR part 314) have been approved under OMB control number 0910–0001. The collections of information supporting general licensing provisions of biological products in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information supporting adverse experience reporting in 21 CFR 310.305 and 329.100, and §§ 314.80, 314.81, and 314.98, have been approved under OMB control number 0910–0230. The collections of information supporting MedWatch safety and adverse event reporting have been approved under OMB control number 0910–0291. The collections of information supporting biological products postmarket adverse experience reporting in 21 CFR part 600 have been approved under OMB control number 0910–0308 and the collections of information supporting medical device reporting have been approved under OMB control number 0910–0437.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*, or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: July 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14717 Filed 7–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0249]

Authorization of Emergency Use of an In Vitro Diagnostic Device in Response to an Outbreak of Mpox; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in response to an outbreak of Mpox. FDA has issued an Authorization for an in vitro diagnostic device, Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set as requested by the Centers for Disease Control and Prevention (CDC). The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the August 9, 2022, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to the FD&C Act, subject to terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, and can be accessed on FDA's website from the link indicated in Section III. Authorization.

DATES: The Authorization is effective as of March 22, 2024.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b,

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

or 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc).

FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii) of the FD&C Act, that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

III. The Authorization

The Authorization follows the August 9, 2022, determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves monkeypox virus. Notice of the Secretary's determination was provided in the **Federal Register** on August 15, 2022 (87 FR 50090). On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. Notice of the Secretary's declaration was provided in the **Federal Register** on September 13, 2022 (87 FR 56074). On March 22, 2024, having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA issued an EUA to CDC, for the Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set, subject to the terms of the Authorization. The Authorization, which is included below in its entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provides an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent revision to the Authorization can be found from FDA's web page at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

IV. Electronic Access

An electronic version of this document and the full text of the Authorization is available on the internet from: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

BILLING CODE 4164–01–P

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

U.S. FOOD & DRUG ADMINISTRATION

March 22, 2024

Mandy K. Cohen, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Device:	Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set - EUA
EUA Number:	EUA230054
Company:	Centers for Disease Control and Prevention (CDC)
Indication:	This test is authorized for the presumptive qualitative detection of DNA from non-variola *Orthopoxvirus* in human pustular or vesicular rash specimens and viral cell culture lysates submitted to a Centers for Disease Control and Prevention designated laboratory from individuals suspected of mpox[1] by their healthcare provider. This test is also authorized for use with acceptable human pustular or vesicular rash specimens collected using authorized home specimen collection kits that are indicated for use with the Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set – EUA when used consistent with their authorization. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to Centers for Disease Control and Prevention designated laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity tests.

[1] On November 28, 2022, following a series of consultations with global experts, the World Health Organization (WHO) began using a new preferred term "mpox" as a synonym for monkeypox, the disease cause by the monkeypox virus. Refer to: https://www.who.int/news/item/28-11-2022-who-recommends-new-name-for-monkeypox-disease.

Dear Dr. Cohen:

This letter is in response to your[2] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[3, 4] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On August 9, 2022, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency, or a significant potential for a public health emergency, that affects or has a significant potential to affect national security or the health and security of United States citizens living abroad that involves monkeypox virus.[5] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on September 7, 2022 that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, subject to the terms of any authorization issued under Section 564(a) of the Act.[6]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the EUA Summary (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

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[2] For ease of reference, this letter will use the term "you" and related terms to refer to Centers for Disease Control and Prevention (CDC).

[3] For ease of reference, this letter will use the term "your product" to refer to the Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set -EUA used for the indication identified above.

[4] The Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set has a granted De Novo and also received marketing clearances from FDA under section 510(k) of the Act (Product Code: PBK; DEN070001, K181205, K221658, K221834, K222558). This emergency use authorization authorizes certain modifications to the procedure and uses that are not under the cleared indications for use of the product and are an "unapproved use of an approved product" under section 564(a)(2)(B) of the FD&C Act. This letter only applies to the emergency use of the Non-variola Orthopoxvirus Real-time PCR Primer and Probe Set -EUA. To date, the FDA-cleared CDC Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set is the only test available in the United States with FDA clearance for the detection of non-variola *Orthopoxvirus* DNA, including vaccinia, cowpox, monkeypox and ectromelia viruses at varying concentrations. Available information indicates that timely detection of mpox cases in the United States requires wide availability of diagnostic testing to control the spread of this contagious infection and there is currently a need for additional diagnostic testing for the virus that causes mpox in the United States.

[5] 87 FR 50090 (August 15, 2022)

[6] 87 FR 56074 (September 13, 2022)

1. The virus that causes mpox can cause a serious or life-threatening disease or condition, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing infection with the virus that causes mpox, and that the known and potential benefits of your product when used for diagnosing infection with this virus, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[7]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a a real-time PCR test intended for the presumptive qualitative detection of DNA from non-variola *Orthopoxvirus* in human pustular or vesicular rash specimens and viral cell culture lysates submitted to a Centers for Disease Control and Prevention designated laboratory from individuals suspected of monkeypox virus infection by their healthcare provider. Testing is limited to Centers for Disease Control and Prevention designated laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity testing.

This test is also authorized for use with acceptable human pustular or vesicular rash specimens collected using authorized home specimen collection kits that are indicated for use with the Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set – EUA when used consistent with their authorization.

Results are for the identification of non-variola *Orthopoxvirus* DNA. This assay does not differentiate vaccinia virus or monkeypox virus from other orthopoxviruses detected by this assay and does not detect variola virus. The non-variola *Orthopoxvirus* DNA is generally detectable in human pustular or vesicular rash specimens and viral cell culture lysates during the acute phase of infection. Refer to the CDC algorithms, *Acute, Generalized Vesicular or Pustular Rash Illness Testing Protocol and Evaluating Patients for Smallpox: Acute, Generalized Vesicular or Pustular Rash Illness Protocol in the United States* for recommended testing and evaluation algorithms for patients presenting with acute, generalized pustular or vesicular rash illness. These results must be used in conjunction with other diagnostic assays and clinical observations to diagnose Orthopoxvirus infection.

[7] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

To use your product, non-variola *Orthopoxvirus* nucleic acid is first extracted, isolated and purified from human pustular or vesicular rash specimens and viral cell culture lysates followed by PCR amplification and detection using an authorized RT-PCR instrument described in the authorized labeling (described below). The Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set -EUA includes the materials (or other authorized materials as may be requested under Condition N. below) described in the authorized labeling (described below).

Your product requires control materials (or other authorized control materials as may be requested under Condition N. below) that are described in both of the authorized labeling (described below). Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the authorized labeling described below.

The above described product is authorized to be accompanied by the EUA summary, (available at https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices), the "Detection of Non-variola *Orthopoxvirus* DNA using the Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set – EUA with the ThermoFisher QuantStudio 7 Flex (QS7) PCR Instrument" and the "Extraction of *Orthopoxvirus* DNA using the KingFisher Flex Instrument for Use With the Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set – EUA" laboratory Standard Operating Procedures (SOPs), and the following fact sheets pertaining to the emergency use, are required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: Centers for Disease Control and Prevention (CDC) – Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set -EUA
- Fact Sheet for Patients: Centers for Disease Control and Prevention (CDC) – Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set -EUA

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing infection with the monkeypox virus, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), Subpart O (Statistical Techniques, 21 CFR 820.250) and Subpart M (Complaint Files, 21 CFR 820.198).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Centers for Disease Control and Prevention (CDC) (You) and Authorized Distributor(s)[8]

A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. Your product must comply with the following quality system requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), Subpart O (Statistical Techniques, 21 CFR 820.250), and Subpart M (Complaint Files, 21 CFR 820.198).

C. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

[8] "Authorized Distributor(s)" are identified by you, Centers for Disease Control and Prevention (CDC), in your EUA submission as an entity allowed to distribute your product.

D. You and authorized distributor(s) must make available on your website(s) the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

E. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which your product is distributed and the number of your product distributed.

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

Centers for Disease Control and Prevention (CDC) (You)

H. You must register and list consistent with 21 CFR Part 807 within one month of this letter.

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must have a signed agreement with each authorized distributor that distribution of the authorized product must be consistent with this Letter of Authorization.

K. You must maintain records of the laboratories you designate as authorized laboratories and you must also maintain records of test usage by all such authorized laboratories.

L. If requested by FDA, you must submit associated documents and records related to your quality system for FDA review within 48 hours of the request.

M. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

N. You may request modifications to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for modification to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA.

O. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

P. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

Q. You must evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s) if requested by FDA.[9] After submission to and concurrence with the data by FDA, you must update your labeling to reflect the additional testing if requested by FDA. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

R. You must have a process in place to track adverse events, including with any authorized home specimen collection kits, and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

S. You must evaluate the impact of monkeypox viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

T. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

Authorized Laboratories

U. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

V. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

[9] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

W. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

X. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

Y. Authorized laboratories using your product must maintain records of the use of any authorized Research Use Only (RUO) reagent kits, including lot numbers, when testing patient specimens.

Z. Authorized laboratories using your product must include positive and negative controls in every specimen run using authorized RUO reagent kits and/or instruments.

AA. Authorized laboratories using your product must evaluate the use of each authorized RUO extraction platform, authorized RUO instrument and/or each lot of authorized RUO reagent kit(s) using standard laboratory protocols in each laboratory for reagent lot and instrument qualification in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. § 263a) and implementing regulations to confirm that instruments and reagents are suitable for use with your product and to verify the performance of your product with each lot.

BB. Authorized laboratories testing authorized specimens collected using an authorized home specimen collection kit that are indicated for use with your product must follow any specimens accessioning protocols provided with the authorized home specimen collection kit when accepting specimens for testing.

CC. Authorized laboratories must have a process in place to track adverse events, including with any authorized home specimen collection kits, and report to you (via email: poxviruslab@cdc.gov) and to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

DD. All laboratory personnel using your product must be appropriately trained in real-time PCR techniques and use appropriate laboratory and personal protective equipment when handling your product and use your product in accordance with the authorized labeling.

Centers for Disease Control and Prevention (CDC) (You), Authorized Distributor(s) and Authorized Laboratories

EE. You, authorized distributor(s), and authorized laboratories must collect information on the performance of your product and must report any significant deviations from the established performance characteristics of your product of which they become aware to

DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) In addition, authorized distributor(s) and authorized laboratories report to you (via email: poxviruslab@cdc.gov).

FF. You, authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA, are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

GG. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

HH. No descriptive printed matter, advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of monkeypox virus or other non-variola orthopoxviruses.

II. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratories;
- This product has been authorized only for the detection of nucleic acid from non-variola orthopoxviruses, including monkeypox virus, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

Page 10 – Mandy K. Cohen, MD, MPH, Centers for Disease Control and Prevention (CDC)

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2024.03.22 10:16:17 -04'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure

Dated: July 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14719 Filed 7–3–24; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–3196; FDA–2023–E–3198; and FDA–2023–E–3199]

Determination of Regulatory Review Period for Purposes of Patent Extension; Imjudo

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for IMJUDO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 3, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 2, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 3, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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 Nos. FDA–2023–E–3196; FDA–2023–E–3198; and FDA–2023–E–3199 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; IMJUDO.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product IMJUDO (tremelimumab-actl). IMJUDO is indicated (1) in combination with durvalumab, for the treatment of adult patients with unresectable hepatocellular carcinoma and (2) in combination with durvalumab and platinum-based chemotherapy for the treatment of adult patients with metastatic non-small cell lung cancer with no sensitizing epidermal growth factor receptor mutation or anaplastic lymphoma kinase genomic tumor aberrations. Subsequent to this approval, the USPTO received patent term restoration applications for IMJUDO (U.S. Patent Nos. 9,487,581; 10,232,040; and 11,446,377) from AstraZeneca AB, and the USPTO requested FDA's assistance in determining this patents' eligibility for patent term restoration. In a letter dated January 30, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of IMJUDO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for IMJUDO is 7,634 days. Of this time, 7,393 days occurred during the testing phase of the regulatory review period, while 241 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* November 28, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 28, 2001.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* February 23, 2022. FDA has verified the applicant's claim that the biologics license application (BLA) for IMJUDO (BLA 761289) was initially submitted on February 23, 2022.

3. *The date the application was approved:* October 21, 2022. FDA has verified the applicant's claim that BLA 761289 was approved on October 21, 2022.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 32, 529, or 1,208 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14716 Filed 7–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–3238 and FDA–2023–E–3239]

Determination of Regulatory Review Period for Purposes of Patent Extension; LUNSUMIO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for LUNSUMIO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 3, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 2, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 3, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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 Nos. FDA–2023–E–3238 and FDA–2023–E–3239 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; LUNSUMIO.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase

begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product LUNSUMIO (mosunetuzumab-axgb). LUNSUMIO is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Subsequent to this approval, the USPTO received a patent term restoration application for LUNSUMIO (U.S. Patent Nos. 10,174,124 and 11,186,650) from Genentech, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 30, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of LUNSUMIO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for LUNSUMIO is 2,809 days. Of this time, 2,571 days occurred during the testing phase of the regulatory review period, while 238 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* April 16, 2015. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 16, 2015.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* April 29, 2022. FDA has verified the applicant's claim that the biologics license application (BLA) for LUNSUMIO (BLA 761263) was initially submitted on April 29, 2022.

3. *The date the application was approved:* December 22, 2022. FDA has verified the applicant's claim that BLA 761263 was approved on December 22, 2022.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 313 or 842 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14728 Filed 7–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting. Information about ACHDNC and the agenda for this meeting can be found on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html*.

DATES: Thursday, August 8, 2024, from 10:00 a.m. to 4:00 p.m. Eastern Time (ET) and Friday, August 9, 2024, from 10:00 a.m. to 2:00 p.m. ET.

ADDRESSES: This meeting will be held in person with webcast options. While this meeting is open to the public, advance registration is required. Please visit the ACHDNC website for information on registration: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html*. Please register by the deadline of 12:00 p.m. ET on Wednesday, August 6, 2024. Instructions on how to access the meeting via webcast will be provided upon registration.

If you are a non-U.S. citizen who would like to attend the August meeting in-person, please contact *ACHDNC@hrsa.gov* by July 22, 2024.

FOR FURTHER INFORMATION CONTACT: Kim Morrison, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room, Rockville, Maryland 20857; 301–443–6672; or *ACHDNC@hrsa.gov*.

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. The ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills

requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening on the Recommended Uniform Screening Panel, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

During the August 8–9, 2024, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Possible agenda items may include the following topics:

(1) A presentation on types of screening that are a part of the standard of care in a clinical setting;

(2) An update on the ACHDNC nomination process;

(3) A presentation on the revisions to the decision matrix and a potential vote on whether to adopt the proposed revisions to the ACHDNC decision matrix and process; and

(4) An update on the Metachromatic Leukodystrophy condition nomination and a potential vote on whether to move it forward to full evidence-based review, which, depending on the strength of the evidence, could lead to a future recommendation to add this condition to the Recommended Uniform Screening Panel.

Agenda items are subject to change as priorities dictate. Information about ACHDNC, including a roster of members and past meeting summaries, is also available on the ACHDNC website.

Members of the public will have the opportunity to provide comments on any of the above agenda items. Public participants may request to provide general oral comments and may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to provide a written statement or make oral comments to ACHDNC must be submitted via the registration website by 12:00 p.m. ET on Thursday, July 25, 2024. Written comments will be shared with the Committee prior to the meeting so that they have an opportunity to consider them in advance of the meeting.

Individuals who need special assistance or another reasonable accommodation should notify Kim Morrison at the address and phone number listed above at least 10 business days prior to the meeting.

Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 15 business days prior to the meeting to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–14743 Filed 7–3–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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 Small Business: Health Services and Systems B.

Date: July 24, 2024.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Michael J McQuestion, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, Bethesda, MD 20892, 301–480–1276, *mike.mcquestion@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Epidemiology and Population Health.

Date: July 25, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Steven Michael Frenk, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3141, Bethesda, MD 20892, (301) 480–8665, *frenksm@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR Panel: Implementation Research on Noncommunicable Disease Risk Factors among Low- and Middle-Income Country and Tribal Populations Living in City Environments.

Date: July 30, 2024.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Paul Hewett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room, Bethesda, MD 20892, (240) 672–8946, *hewettmarxpn@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: June 28, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–14699 Filed 7–3–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; 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: National Center for Advancing Translational Sciences Special Emphasis Panel; CTSA Collaborative and Innovative Acceleration Award (CCIA) Review.

Date: September 11, 2024.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Jing Chen, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, Rockville, MD 20892, (301) 827–3268, *chenjing@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: June 28, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–14700 Filed 7–3–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; 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: Office of Research Infrastructure Programs Special Emphasis Panel (ZOD1), STOD: Biomedical Research Facilities.

Date: July 25, 2024.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jonathan Ivins, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Rockledge II, 6701 Rockledge Drive, MSC 7806, Bethesda, MD 20892, (301) 594–1245, *ivinsj@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS).

Dated: June 28, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–14698 Filed 7–3–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning the opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276–0361.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (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.

Proposed Project: Minority AIDS Initiative: Substance Use Disorder Prevention and Treatment Pilot Program (MAI PT Pilot) Data Collection Instruments.

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) and Center for Substance Abuse Treatment (CSAT) are requesting approval from the Office of Management and Budget (OMB) to monitor the Minority AIDS Initiative: Substance Use Disorder Prevention and Treatment Pilot Program (MAI PT Pilot) through administration of a suite of data collection instruments for grant compliance and programmatic performance monitoring. This package describes the data collection activities and proposed instruments. Two instruments will facilitate grant compliance monitoring, and the third instrument is designed for program performance monitoring.

- The *MAI PT Pilot—Organizational Readiness Assessment (MAI–ORA)* is a one-time self-assessment tool intended to guide MAI PT Pilot grant recipients to objectively assess their capacity to provide substance use prevention, substance use disorder or co-occurring mental health disorder treatment, and HIV, viral hepatitis, and sexually transmitted infection prevention, screening, testing, and referral services for racial and ethnic individuals vulnerable to these conditions. Results from the MAI–ORA will allow SAMHSA to determine grantee readiness and capacity to implement their grant program, so that SAMHSA can provide additional support, as needed, to ensure grant compliance.
- The *MAI PT Pilot—Programmatic Progress Report (MAI–PPR)* is a template that grantees will use to report annual progress and will be used to monitor grant compliance.
- The *MAI PT Pilot—Online Reporting Tool (MAI–PORT)* will be used to conduct programmatic performance monitoring. The MAI–PORT is comprised of two main sections: (1) Annual Targets Report section for MAI PT Pilot grant recipients to report annual federal fiscal year programmatic goals, and (2) Quarterly Performance Report for grantees to report grant activities implemented during each federal fiscal quarter. In developing the MAI–PORT Annual Targets Report and the Quarterly Performance Report, CSAP/CSAT sought the ability to elicit programmatic information that demonstrates impact at the program aggregate level.

Data collected through the MAI–PORT are necessary to ensure SAMHSA and grantees comply with requirements under the Government Performance and Results Act Modernization Act of 2010

(GPRA) that requires regular reporting of performance measures. Additionally, data collected through these tools will provide critical information to SAMHSA's Government Project Officers (GPOs) related to grant oversight, including barriers and facilitators that the grantees have experienced, and an understanding of the technical assistance needed to help grantees implement their programs. The information also provides a mechanism to ensure grantees are meeting the requirements of the grant funding announcement as outlined in their notice of grant award. In addition, the tools reflect CSAP's and CSAT's desire to elicit pertinent program level data that can be used not only to guide future programs and practices, but also to respond to stakeholder, congressional and agency inquiries.

Background and Purpose

According to the Centers for Disease Control and Prevention (CDC), the spread of HIV in the United States is mainly through anal or vaginal sex or by sharing drug-use equipment. Although these risk factors are the same for everyone, due to a range of social, economic, and demographic factors, such as stigma, discrimination, income, education, and geographic region, some racial and ethnic groups are more affected than others. In 2021, CDC reported that although Black/African Americans represented 13 percent of the U.S. population, they accounted for 42 percent (15,305) of the 36,801 new HIV diagnoses; Latino/Hispanic people represent 18.7 percent of the U.S. population but accounted for 29 percent (10,494) of HIV diagnoses (CDC, 2024; United States Census Bureau, 2024). Between 2017 and 2021, American Indian/Alaska Native (AI/AN), Native Hawaiian and other Pacific Islander populations were the only demographic groups identified by the CDC with an increase in HIV diagnoses in the United States (CDC, 2024).

Viral hepatitis also impacts some racial and ethnic groups disproportionally. In 2020, non-Hispanic blacks were 1.4 times as likely to die from viral hepatitis, as compared to non-Hispanic whites (Office of Minority Health, 2022). Non-Hispanic blacks were almost twice as likely to die from hepatitis C as compared to the white population, and while having comparable case rates for hepatitis B in 2020, non-Hispanic blacks were 2.5 times more likely to die from hepatitis B than non-Hispanic whites (Office of Minority Health, 2022). Additionally, the percentage of people aged 12 or older with past year substance use disorder (SUD) differed by race and ethnicity with the highest rates among American Indian/Alaska Native populations (24.0 percent), followed by Black, non-Hispanic populations (18.4 percent) (SAMHSA, 2023).

The data clearly show the disproportionate burden faced by minority racial and ethnic groups and that these three issues should not be regarded as separate diseases acting independently, rather as a syndemic. To address this, SAMHSA is taking a syndemic approach to HIV, viral hepatitis, and substance use disorder through the MAI PT Pilot program. The purpose of this program is to provide substance use prevention, SUD treatment, HIV, and viral hepatitis prevention and treatment services for racial and ethnic medically underserved individuals vulnerable to a SUD and/or mental health condition, HIV, viral hepatitis, and other infectious disease (*e.g.,* sexually transmitted infection (STI)). The populations of focus for this program are individuals who are particularly vulnerable to or living with HIV/AIDS, including an emphasis on gay, bisexual, and other men who have sex with men, men who have sex with men and women (MSMW), Black, Latino, and AI/AN men who have sex with men (MSM), Asian and Pacific Islander, Black women, transgender men and women, youth aged 13–24 years, and People who Inject Drugs (PWID).

SAMHSA's MAI PT Pilot is informed by the key strategies and priority jurisdictions outlined in the Ending the HIV Epidemic in the U.S. (EHE) initiative, Viral Hepatitis National Strategic Plan and STI National Strategic Plan. The program also supports the National HIV/AIDS Strategy (NHAS) and 2023–2026 SAMHSA Strategic Plan. Recipients will be expected to take a syndemic approach to SUD, HIV, viral hepatitis, and STI by providing SUD prevention and treatment to racial and ethnic individuals at risk for or living with HIV. MAI PT Pilot is authorized under Sections 509 and 516 of the Public Health Service Act, as amended.

Annualized Data Collection Burden

Table 1 and Table 2 provides an overview of the data collection method, frequency of data collection, and number of data collections for each data collection instruments.

TABLE 1—GRANT COMPLIANCE: MAI–ORA AND MAI–PPR

Instrument	Data collection method	Frequency of data collection	Maximum number of data collections	Attachment No.
MAI–ORA	Grantees submit into SPARS	Once	Once in Year 1	1
MAI–PPR	Grantees submit into eRA	Annually	*Annually:* 5 times (1 time per year in Years 1–5).	2

TABLE 2—PROGRAM PERFORMANCE MONITORING: MAI–PORT

Instrument	Data collection method	Frequency of data collection	Maximum number of data collections	Attachment No.
MAI–PORT	Grantees submit into SPARS	*Yearly:* Annual Targets Report (ATR). *Quarterly:* Quarterly Performance Report (QPR).	*Yearly:* 5 times (1 time per year in Years 1–5). *Quarterly:* 20 times (4 times per year in Years 1–5).	3

The estimated time to complete each instrument by year is shown in Tables 3 through 8.

TABLE 3—ESTIMATES OF ANNUAL BURDEN FOR MAI PT DATA COLLECTION: YEAR 1

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Average hourly wage [1]	Total respondent cost
MAI–ORA	8	1	8	24	192	$48.35	$9,283.20
MAI–PPR	8	1	8	3	24	48.35	1,160.40
MAI–PORT/ATR	8	1	8	1	8	48.35	386.80
MAI–PORT/QPR	8	4	32	2	64	48.35	3,094.40
Total	8	7	56	30	288	48.35	13,924.80

[1] Average hourly wage is based on the mean hourly wage for state government managers, as reported in the 2022 Occupational Employment (OES) by the Bureau of Labor Statistics (BLS) found at *https://www.bls.gov/oes/current/naics4_999200.htm#11-0000* Accessed on January 15, 2024.

TABLE 4—ESTIMATES OF ANNUAL BURDEN FOR MAI PT DATA COLLECTION: YEAR 2

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Average hourly wage [1]	Total respondent cost
MAI–ORA	8	0	0	24	0	$48.35	$0.00
MAI–PPR	8	1	8	3	24	48.35	1,160.40
MAI–PORT/ATR	8	1	8	1	8	48.35	386.80
MAI–PORT/QPR	8	4	32	2	64	48.35	3,094.40
Total	8	6	48	30	96	48.35	4,641.60

[1] Average hourly wage is based on the mean hourly wage for state government managers, as reported in the 2022 Occupational Employment (OES) by the Bureau of Labor Statistics (BLS) found at *https://www.bls.gov/oes/current/naics4_999200.htm#11-0000* Accessed on January 15, 2024.

TABLE 5—ESTIMATES OF ANNUAL BURDEN FOR MAI PT DATA COLLECTION: YEAR 3

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Average hourly wage [1]	Total respondent cost
MAI–ORA	8	0	0	24	0	$48.35	$0.00
MAI–PPR	8	1	8	3	24	48.35	1,160.40
MAI–PORT/ATR	8	1	8	1	8	48.35	386.80
MAI–PORT/QPR	8	4	32	2	64	48.35	3,094.40
Total	8	6	48	30	96	48.35	4,641.60

[1] Average hourly wage is based on the mean hourly wage for state government managers, as reported in the 2022 Occupational Employment (OES) by the Bureau of Labor Statistics (BLS) found at *https://www.bls.gov/oes/current/naics4_999200.htm#11-0000* Accessed on January 15, 2024.

TABLE 6—ESTIMATES OF ANNUAL BURDEN FOR MAI PT DATA COLLECTION: YEAR 4

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Average hourly wage [1]	Total respondent cost
MAI–ORA	8	0	0	24	0	$48.35	$0.00
MAI–PPR	8	1	8	3	24	48.35	1,160.40
MAI–PORT/ATR	8	1	8	1	8	48.35	386.80
MAI–PORT/QPR	8	4	32	2	64	48.35	3,094.40
Total	8	6	48	30	96	48.35	4,641.60

[1] Average hourly wage is based on the mean hourly wage for state government managers, as reported in the 2022 Occupational Employment (OES) by the Bureau of Labor Statistics (BLS) found at *https://www.bls.gov/oes/current/naics4_999200.htm#11-0000* Accessed on January 15, 2024.

TABLE 7—ESTIMATES OF ANNUAL BURDEN FOR MAI PT DATA COLLECTION: YEAR 5

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Average hourly wage [1]	Total respondent cost
MAI–ORA	8	0	0	24	0	$48.35	$0.00
MAI–PPR	8	1	8	3	24	48.35	1,160.40
MAI–PORT/ATR	8	1	8	1	8	48.35	386.80
MAI–PORT/QPR	8	4	32	2	64	48.35	3,094.40
Total	8	6	48	30	96	48.35	4,641.60

[1] Average hourly wage is based on the mean hourly wage for state government managers, as reported in the 2022 Occupational Employment (OES) by the Bureau of Labor Statistics (BLS) found at *https://www.bls.gov/oes/current/naics4_999200.htm#11-0000* Accessed on January 15, 2024.

TABLE 8—ESTIMATES OF ANNUAL BURDEN FOR MAI PT DATA COLLECTION: ALL YEARS

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Average hourly wage [1]	Total respondent cost
MAI–ORA	8	1	8	24	192	$48.35	$9,283.20
MAI–PPR	8	5	40	3	120	48.35	5,802.00
MAI–PORT/ATR	8	5	40	1	40	48.35	1,934.00
MAI–PORT/QPR	8	20	160	2	320	48.35	15,472.00
Total	8	31	248	30	672	48.35	$32,491.20

[1] Average hourly wage is based on the mean hourly wage for state government managers, as reported in the 2022 Occupational Employment (OES) by the Bureau of Labor Statistics (BLS) found at *https://www.bls.gov/oes/current/naics4_999200.htm#11-0000* Accessed on January 15, 2024.

Send comments to SAMHSA Reports Clearance Officer, 5600 Fisher Lane, Room 15E45, Rockville, MD 20852 OR email him a copy at *samhsapra@samhsa.hhs.gov.* Written comments should be received by September 3, 2024.

Alicia Broadus,

Public Health Advisor.

[FR Doc. 2024–14730 Filed 7–3–24; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276–0361 or *carlos.graham@samhsa.hhs.gov*.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (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 the use of automated collection techniques or other forms of information technology.

Proposed Project: Programs To Reduce Underage Drinking—(OMB No. 0930–0316)—Revision

The Sober Truth on Preventing Underage Drinking Act (the ''STOP Act'') was passed by Congress in 2006, reauthorized in December 2016 as part of the 21st Century Cures Act (Pub. L. 114–255) and the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), and codified into law in 42 U.S.C. 290bb–25b: Programs to reduce underage drinking. The STOP Act contains four primary elements:

1. The award of community-based coalition enhancement grants for underage drinking prevention activities to eligible entities currently receiving funds under the Drug-Free Communities Act of 1997.
2. A national adult-oriented media public service campaign to prevent underage drinking (''Talk. They Hear You.'' (TTHY), and an annual report to Congress evaluating the campaign.
3. An annual report to Congress summarizing federal prevention activities and the extent of progress in reducing underage drinking nationally, including data from national surveys conducted by federal agencies.
4. An annual report to Congress ''on each State's performance in enacting, enforcing, and creating laws, regulations, and programs to prevent or reduce underage drinking.'' The State Survey that is the subject of this request gathers data used to develop the state-by-state report on prevention and enforcement activities related to underage drinking

Driven by the legislation and coordinated by the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD), each of these activities work together to prevent and reduce underage drinking. The Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD) provides national leadership in federal policy and programming to support state and community activities that prevent and reduce underage drinking. The data collection activities described in this package serve to assess the outputs and outcomes of public health messaging and interventions. The three data collection activities outlined in this package are:

1. The STOP Act State Survey: An annual survey mandated by the STOP Act legislation sent to an individual designated by the governor of all 50 states and the mayor of the District of Columbia;
2. The ICCPUD Alcohol Policy Academy Evaluation: An assessment of coalition capacity and workforce development throughout a 12 month Alcohol Policy Academy; and
3. The Parents Night Out Evaluation; An assessment of changes in knowledge, skills, and confidence of parents and caregivers after receiving the training and materials for Parents Night Out and TTHY products.

The STOP Act State Survey

The STOP Act states that the ''Secretary [of Health and Human Services] shall . . . annually issue a report on each state's performance in enacting, enforcing, and creating laws, regulations, and programs to prevent or reduce underage drinking.'' The Secretary has delegated responsibility for this report to SAMHSA. Therefore, SAMHSA has developed a ''Survey of State Underage Drinking Prevention Policies, Programs, and Practices'' (the ''State Survey'') to provide input for the state-by-state report on prevention and enforcement activities related to the underage drinking component of the ''Annual Report to Congress on the Prevention and Reduction of Underage Drinking'' (''Report to Congress'').

Congress' purpose in mandating the collection of data on state policies, programs, and practices through the *State Survey* is to provide policymakers and the public with otherwise unavailable but much needed information regarding state underage drinking prevention policies and programs. SAMHSA and other federal agencies that have underage drinking prevention as part of their mandate use the results of the *State Survey* to inform

federal programmatic priorities, as do other stakeholders, including community organizations. The information gathered by the *State Survey* has established a resource for state agencies and the public for assessing policies and programs in their own state and for becoming familiar with the policies, programs, practices, and funding priorities of other states.

SAMHSA has determined that data on Categories #2 and #3 mandated in the STOP Act (as listed on page 2) (enforcement and educational programs; programs targeting youth, parents, and caregivers) as well as states' collaborations with tribal governments, use of social marketing or counter-advertising campaigns, state-level interagency collaborations, and prevention workforce development activities *are not available from secondary sources* and therefore must be collected from the states themselves. The *State Survey* is therefore necessary to fulfill the Congressional mandate found in the STOP Act. Furthermore, the uniform collection of these data from the states over the last fifteen years has created a valuable longitudinal dataset, and the *State Survey's* renewal is vital to maintaining this resource.

The *State Survey* is a single document that is divided into three sections: (1) Enforcement of underage drinking laws; (2A) Underage drinking prevention programs targeted to youth, parents, and caregivers, including data on the approximate number of persons served by these programs; (2B) State collaborations and best practices; (2C) Interagency collaborations and state participation in social marketing media campaigns intended to reduce underage drinking; and (3) Workforce development activities, including strategies and funds expended on recruiting and retaining a behavioral health workforce.

SAMHSA collects the required data using an online survey data collection platform. Links to the survey are distributed to states via email. The *State Survey* is sent to each state governor's office and the Office of the Mayor of the District of Columbia. SAMHSA provides both telephone and electronic technical support to state agency staff and emphasizes that the states are expected to provide data from existing state databases and other data sources available to them. The burden estimate below considers these assumptions.

The estimated annual response burden to collect this information is as follows:

Instrument	Number of respondents	Responses/ respondent	Total responses	Hours per response	Total hour burden	Wage rate	Total hour cost
State Survey	51	1	51	18.5	943.50	$28.07	$26,484.05

The ICCPUD Alcohol Policy Academy Evaluation

The *Policy Academy* strives to reduce and prevent underage and excessive drinking by increasing the capacity of community coalitions to modify the community context through the policy process. The Policy Academy includes 14 coalitions from across the U.S., with two individuals from each coalition serving as the Academy participants. The *Policy Academy* evaluation is designed to measure the effectiveness of increasing coalition capacity through the training and coaching of the policy process. Additionally, the evaluation will measure the increase in the policy training workforce through a coaches and mentee development pipeline. The scope of the evaluation is limited to measuring the impact of the *Policy Academy* curriculum on participants and coaches.

The evaluation is comprised of seven surveys and one focus group. Surveys are conducted after each monthly training and coaching call. The participant surveys seek feedback on changes in knowledge, skills, and confidence after each training or coaches call, as well as feedback on the training content and training/coaching provider. The coach surveys track the progress of the coalitions. These surveys take the participants and coaches approximately 5–10 minutes each. The participants will also complete a baseline survey, a 12-month survey, and an 18-month survey. These surveys assess whether participants reach their own goals during the Policy Academy, how they share their knowledge and skills gained, and how they continue to progress in the policy process. All surveys will be fielded using a web-based survey tool. The focus group with the cohort will collect qualitative data from the participants on their experience and efforts to incorporate health equity into their policy campaign.

Table 2 indicates the estimated total annual burden on the participants and coaches of the *Policy Academy.* The survey estimates include reading the instructions and questions and responding to each question. The focus group is scheduled for one hour, and includes introductions, instructions, posing of questions, and open discussion.

The estimated annual response burden to collect this information is as follows:

Instrument	Number of respondents	Responses/ respondent	Total responses	Hours per response	Total hour burden	Wage rate	Total hour cost
Focus Group	28	1	28	1	28	$27.10	$758.80
Participant Post-Coaching Call Survey	28	11	308	0.125	38.5	27.10	1,043.35
Participant Post-Training Call Survey	28	10	280	0.125	35	27.10	948.50
Coach Post-Coaching Call Survey	3	77	231	0.17	39.27	50.00	1,963.50
Baseline	28	1	28	0.67	18.76	27.10	508.40
Follow-Up	28	1	28	1	28	27.10	758.80
Six-Month Follow-Up	28	1	28	0.67	18.76	27.10	508.40

''Talk. They Hear You.'' Parents Night Out Evaluation

The ''Talk. They Hear You'' campaign is comprised of a variety of tools and resources designed to decrease underage drinking by encouraging parents and caregivers, educators, and community members/organizations to proactively engage youth in conversations about alcohol another other drugs. Research has demonstrated that active and engaged adults can reduce underage drinking.[1] One TTHY mechanism to

[1] Glenn, S.D., Turrisi, R., Mallett, K.A., Waldron, M.S., Lenker, L.K. (2024). Examination of Brief Parent-Based Interventions to Reduce Drinking Outcomes on a Nationally Representative Sample of Teenagers. *Journal of Adolescent Health, 74*(3) 449–

Continued

engage parents and caregivers is through Parents' Night Out (PNO).

The *PNO Evaluation* will assess changes in knowledge, skills, and confidence of parents and caregivers after receiving the training and materials for PNO and TTHY products. This evaluation will be delivered in partnership with community partners, who will be exposed to varying combinations of PNO and materials to determine change before and after exposure. The information gleaned in a survey of parents and caregivers will allow the evaluation team to assess whether PNO is being implemented as intended, and which products are most useful in increasing parents' and caregivers' capacity and intentions. The results will be shared with the implementation team for PNO curriculum modifications and for updating TTHY materials.

PNO data will be collected from participants through a survey delivered via email using Qualtrics. Completing the survey is not a requirement of the event, but an option to provide feedback to the campaign team. Collecting data through Qualtrics will improve the participant experience and allow them to quickly provide feedback. The distribution of the *PNO Evaluation* survey will be facilitated by local organizations who host a PNO event. They will be provided with the link to the survey and will be asked to spend a few moments of the presentation to share the link The TTHY campaign team will develop, distribute, and support the survey.

Table 4 indicates the estimated total annual burden on the participants of PNO. The survey estimates include reading the instructions and questions and responding to each question, and totals 7 minutes. The wage rate was determined based on the highest state minimum wage, as site locations have not yet been identified.

The estimated annual response burden to collect this information is as follows:

Instrument	Number of respondents	Responses/ respondent	Total responses	Hours per response	Total hour burden	Wage rate	Total hour cost
PNO Evaluation Survey	150	1	150	0.12	18	$16.28*	$293.04

** https://www.dol.gov/agencies/whd/minimum-wage/state.*

Send comments to Alicia Broadus, SAMHSA Public Health Advisor at *alicia.broadus@samhsa.hhs.gov*. Written comments should be received by August 5, 2024.

Alicia Broadus,

Public Health Advisor.

[FR Doc. 2024–14681 Filed 7–3–24; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2024–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *https://msc.fema.gov*.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov*; or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html*.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov*.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Nicholas A. Shufro,

Assistant Administrator (Acting) for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

457. *https://doi.org/10.1016/j.jadohealth.2023.09.010.*

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Colorado: Douglas ..... (FEMA Docket No.: B–2424)	Town of Castle Rock (23-08-0509P).	The Honorable Jason Gray, Mayor, Town of Castle Rock, 100 North Wilcox Street, Castle Rock, CO 80104.	Water Department, 175 Kellogg Court, Castle Rock, CO 80109.	Jun. 21, 2024 ..	080050
Florida:					
Lee(FEMA Docket No.: B–2431).	Unincorporated areas of Lee County (24–04–0733P).	David Harner, Lee County Manager, 2115 2nd Street, Fort Myers, FL 33901.	Lee County Building Department, 1500 Monroe Street, Fort Myers, FL 33901.	Jun. 24, 2024 ..	125124
Orange ..... (FEMA Docket No.: B–2424).	City of Orlando (23-04-5329P).	The Honorable Buddy Dyer, Mayor, City of Orlando, 400 South Orange Avenue, Orlando, FL 32801.	City Hall, 400 South Orange Avenue, Orlando, FL 32801.	Jun. 24, 2024 ..	120186
Orange (FEMA Docket No.: B–2424).	Unincorporated areas of Orange County (23-04-5329P).	The Honorable Jerry L. Demings, Mayor, Orange County, 201 South Rosalind Avenue, 5th Floor, Orlando, FL 32801.	Orange County Public Works Department, Stormwater Management Division, 4200 South John Young Parkway, Orlando, FL 32839.	Jun. 24, 2024 ..	120179
Osceola (FEMA Docket No.: B–2424).	Unincorporated areas of Osceola County (23-04-0522P).	Donald Fisher, Osceola County Manager, 1 Courthouse Square, Suite 4700, Kissimmee, FL 34741.	Osceola County Public Works Department, 1 Courthouse Square, Suite 3100, Kissimmee, FL 34741.	Jun. 7, 2024	120189
Osceola ..... (FEMA Docket No.: B–2418).	Unincorporated areas of Osceola County (23–04–5105P).	Donald Fisher, Osceola County Manager, 1 Courthouse Square, Suite 4700, Kissimmee, FL 34741.	Osceola County Public Works Department, 1 Courthouse Square, Suite 3100, Kissimmee, FL 34741.	Jun. 14, 2024 ..	120189
Palm Beach (FEMA Docket No.: B–2418).	Town of Palm Beach (23–04–4383P).	Kirk Blouin, Manager, Town of Palm Beach, 360 South County Road, Palm Beach, FL 33480.	Building Department, 360 South County Road, Palm Beach, FL 33480.	Jun. 17, 2024 ..	120220
Palm Beach (FEMA Docket No.: B–2418).	Unincorporated areas of Palm Beach County (23–04–3795P).	Verdenia C. Baker, Palm Beach County Administrator, 301 North Olive Avenue, Suite 1101, West Palm Beach, FL 33401.	Palm Beach County Building Division, 2300 North Jog Road, West Palm Beach, FL 33411.	Jun. 10, 2024 ..	120192
Palm Beach (FEMA Docket No.: B–2418).	Unincorporated areas of Palm Beach County (23–04–4383P).	Verdenia C. Baker, Palm Beach County Administrator, 301 North Olive Avenue, Suite 1101, West Palm Beach, FL 33401.	Palm Beach County Building Division, 2300 North Jog Road, West Palm Beach, FL 33411.	Jun. 17, 2024 ..	120192
Polk (FEMA Docket No.: B–2418).	Unincorporated areas of Polk County (23–04–5421P).	Bill Beasley, Polk County Manager, 330 West Church Street, Bartow, FL 33831.	Polk County Land Development Division, 330 West Church Street, Bartow, FL 33831.	Jun. 13, 2024 ..	120261
Maine:					
Cumberland (FEMA Docket No.: B–2424).	City of Portland (24-01-0140P).	The Honorable Mark Dion, Mayor, City of Portland, 389 Congress Street, Portland, ME 04101.	Permitting and Inspections Department, 389 Congress Street, Portland, ME 04101.	Jun. 21, 2024 ..	230051
Cumberland (FEMA Docket No.: B–2424).	Town of Harpswell (24-01-0141P).	Kevin E. Johnson, Chair, Town of Harpswell Board of Selectmen, P.O. Box 39, Harpswell, ME 04079.	Code Department, 263 Mountain Road, Harpswell, ME 04079.	Jun. 21, 2024 ..	230169
Cumberland	Town of Harpswell (24–01–0301X)	Kevin E. Johnson, Chair, Town of Harpswell Board of Selectmen, P.O. Box 39, Harpswell, ME 04079.	Code Office, 263 Mountain Road, Harpswell, ME 04079.	Jun. 24, 2024 ..	230169
Maryland:					
Anne Arundel (FEMA Docket No.: B–2424).	City of Laurel (23–03–0580P).	The Honorable Keith R. Sydnor, Mayor, City of Laurel, 8103 Sandy Spring Road, Laurel, MD 20707.	Anne Arundel County Heritage Office Complex, 2664 Riva Road, Annapolis, MD 21401.	Jun. 24, 2024 ..	240053
Anne Arundel (FEMA Docket No.: B–2424).	Unincorporated areas of Anne Arundel County (23–03–0580P).	Steuart Pittman, Anne Arundel County Executive, 44 Calvert Street, Annapolis, MD 21401.	Anne Arundel County Heritage Office Complex, 2664 Riva Road, Annapolis, MD 21401.	Jun. 24, 2024 ..	240008
Montana: Granite (FEMA Docket No.: B–2424).	Unincorporated areas of Granite County (23-08-0605P).	Blanche McLure, Chair, Granite County Board of Commissioners, P.O. Box 925, Philipsburg, MT 59858.	Granite County Planning Department, 220 North Sansome Street, Philipsburg, MT 59858.	Jun.7, 2024	300141
North Carolina:					
Durham (FEMA Docket No.: B–2424).	Unincorporated areas of Durham County (23–04–1744P).	Nida Allam, Chair, Durham County Board of Commissioners, 200 East Main Street Durham, NC 27701.	Durham County Government Office, 101 City Hall Plaza, Durham, NC 27701.	Jun. 4, 2024	370085
Forsyth (FEMA Docket No.: B–2424).	City of Winston-Salem (22–04–5169P).	The Honorable Allen Joines, Mayor, City of Winston-Salem, 100 East 1st Street, Winston-Salem, NC 27101.	Planning and Development Department, 100 East 1st Street, Winston-Salem, NC 27101.	Apr. 22, 2024 ..	375360
Robeson (FEMA Docket No.: B–2431).	Unincorporated areas of Robeson County (23–04–4166P).	John Cummings, Chair, Robeson County Board of Commissioners, 550 North Chestnut Street, Lumberton, NC 28358.	Robeson County Planning and Zoning Department, 701 North Elm Street, Lumberton, NC 28358.	Jun. 10, 2024 ..	370202
Stanly (FEMA Docket No.: B–2424).	City of Albemarle (23–04–5871P).	The Honorable G. R. Michael, Mayor, City of Albemarle, 144 North 2nd Street Albemarle, NC 28001.	Engineering Department, 144 North 2nd Street 2nd Floor, Albemarle, NC 28001.	May 29, 2024.	370223

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Wake (FEMA Docket No.: B–2424).	Town of Wake Forest (23–04–3741P).	The Honorable Vivian A. Jones, Mayor, Town of Wake Forest, 301 South Brooks Street, Wake Forest, NC 27587.	Planning Department, 301 South Brooks Street, Wake Forest, NC 27587.	Jun. 5, 2024	370244
Wake (FEMA Docket No.: B–2424).	Unincorporated areas of Wake County (23–04–3741P).	Shinica Thomas, Chair, Wake County Board of Commissioners, P.O. Box 550, Raleigh, NC 27602.	Wake County Planning Department, 337 South Salisbury Street, Raleigh, NC 27601.	Jun. 5, 2024	370368
Watauga (FEMA Docket No.: B–2424).	Unincorporated areas of Watauga County (22–04–4623P).	Larry Turnbow, Chair, Watauga County Board of Commissioners, 814 West King Street, Suite 205, Boone, NC 28607.	Watauga County Planning and Inspections Department, 126 Poplar Grove Connector, Suite 201 Boone, NC 28607.	May 23, 2024 ..	370251
Watauga (FEMA Docket No.: B–2437).	Unincorporated areas of Watauga County (23–04–3107P).	Larry Turnbow, Chair, Watauga County Board of Commissioners, 814 West King Street, Suite 205, Boone, NC 28607.	Watauga County Planning and Inspections Department, 126 Poplar Grove Connector, Suite 201, Boone, NC 28607.	May 16, 2024 ..	370251
Pennsylvania: Monroe (FEMA Docket No.: B–2418).	Township of Pocono (24–03–0116P).	Richard Wielebinski, President, Township of Pocono Board of Commissioners, 112 Township Drive, Tannersville, PA 18372.	Township Hall, 112 Township Drive, Tannersville, PA 18372.	Jun. 10, 2024 ..	421892
Texas:					
Denton (FEMA Docket No.: B–2418).	City of Fort Worth (23–06–1671P).	The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Department of Transportation and Public Works, Engineering Vault and Map Repository, 200 Texas Street, Fort Worth, TX 76102.	Jun. 10, 2024 ..	480596
Denton (FEMA Docket No.: B–2418).	Unincorporated areas of Denton County (23–06–1671P).	The Honorable Andy Eads, Denton County Judge, 1 Courthouse Drive, Suite 3100, Denton, TX 76208.	Denton County Development Services Department, 3900 Morse Street, Denton, TX 76208.	Jun. 10, 2024 ..	480774
Tarrant (FEMA Docket No.: B–2418).	City of Arlington (23–06–1085P).	The Honorable Jim Ross, Mayor, City of Arlington, P.O. Box 90231, Arlington, TX 76004.	Public Works Department, 101 West Abram Street, Arlington, TX 76010.	Jun. 17, 2024 ..	485454
Tarrant (FEMA Docket No.: B–2418).	City of Fort Worth (23–06–1412P).	The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Department of Transportation and Public Works, Engineering Vault and Map Repository, 200 Texas Street, Fort Worth, TX 76102.	Jun. 17, 2024 ..	480596
Webb (FEMA Docket No.: B–2424).	City of Laredo (23–06–2007P).	The Honorable Victor D. Treviño, Mayor, City of Laredo, 1110 Houston Street, Laredo, TX 78040.	Building Development Services Department, 1413 Houston Street, Laredo, TX 78040.	Jun. 20, 2024 ..	480651
Williamson (FEMA Docket No.: B–2424).	City of Cedar Park (23–06–1459P).	The Honorable Jim Penniman-Morin, Mayor, City of Cedar Park, 450 Cypress Creek Road, Building 4, Cedar Park, TX 78613.	City Hall, 450 Cypress Creek Road, Building 1, Cedar Park, TX 78613.	Jun. 6, 2024	481282
Williamson, (FEMA Docket No.: B–2424).	Unincorporated areas of Williamson County (23–06–1459P).	The Honorable Bill Gravell, Jr., Williamson County Judge, 710 South Main Street, Suite 101, Georgetown, TX 78626.	Williamson County Engineering Department, 3151 Southeast Inner Loop, Georgetown, TX 78626.	Jun. 6, 2024	481079
Virginia:					
Buchanan (FEMA Docket No.: B–2424).	Unincorporated areas of Buchanan County (23–03–1041P).	Robert Craig Horn, Buchanan County Administrator, P.O. Box 950, Grundy, VA 24614.	Buchanan County Government Center, 4447 Slate Creek Road, Grundy, VA 24614.	Jun. 21, 2024 ..	510024
Loudoun (FEMA Docket No.: B–2418).	Unincorporated areas of Loudoun County (23–03–0567P).	Tim Hemstreet, Loudoun County Administrator, 1 Harrison Street Southeast, 5th Floor, Leesburg, VA 20175.	Loudoun County Government Center, 1 Harrison Street Southeast, 3rd Floor, MSC #60, Leesburg, VA 20175.	Jun. 17, 2024 ..	510090
Wyoming:					
Teton (FEMA Docket No.: B–2418).	Town of Jackson (23–08–0655P).	The Honorable Hailey Morton Levinson, Mayor, Town of Jackson, P.O. Box 1687, Jackson, WY 83001.	Public Works Department, 450 West Snow King Avenue, Jackson, WY 83001.	Jun. 6, 2024	560052
Teton (FEMA Docket No.: B–2418).	Unincorporated areas of Teton County (23–08–0655P).	The Honorable Luther Propst, Chair, Teton County Board of Commissioners, P.O. Box 3594, Jackson, WY 83001.	Teton County Public Works Department, 320 South King Street, Jackson, WY 83001.	Jun. 6, 2024	560094

[FR Doc. 2024–14749 Filed 7–3–24; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. ICEB–2023–0011]

Privacy Act of 1974; System of Records

AGENCY: Department of Homeland Security, U.S. Immigration and Customs Enforcement.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS) proposes to modify and reissue a current DHS system of records titled, ''DHS/U.S. Immigration and Customs Enforcement (ICE)-011 Criminal Arrest Records and Immigration Enforcement Records

(CARIER) System of Records.'' DHS/ICE collects, uses, and maintains CARIER records to support the identification, apprehension, and removal of aliens (a term defined in law but used hereinafter as ''non-citizens'') unlawfully entering or present in the United States in violation of the Immigration and Nationality Act (INA), including fugitive non-citizens. DHS/ICE also uses CARIER to support the identification and arrest of individuals (both citizens and non-citizens) who commit violations of federal laws enforced by DHS. DHS/ICE is reissuing this system of records notice to update the purpose of the system, add new categories of individuals, add new categories of records, and modify, remove, and propose new routine uses. Additionally, this notice includes non-substantive changes to simplify the formatting and text of the previously published notice. This modified system will be included in the Department's inventory of record systems.

DATES: Submit comments on or before August 5, 2024. This modified system will be effective August 5, 2024.

ADDRESSES: You may submit comments, identified by docket number ICEB–2023–0011 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Mason C. Clutter, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

Instructions: All submissions received must include the agency name and docket number ICEB–2023–0011. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, please visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Ieshah Geary, Privacy Officer, Office of Information Governance and Privacy, *iceprivacy-generalmailbox@ice.dhs.gov,* U.S. Immigration and Customs Enforcement, 500 12th Street SW, Mail Stop 5004, Washington, DC 20536. For privacy questions, please contact: Mason C. Clutter, (202) 343–1717, *Privacy@hq.dhs.gov,* Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, DHS/ICE proposes to modify and reissue a current DHS system of records titled, ''DHS/ICE–011 Criminal Arrest Records and Immigration Enforcement Records (CARIER) System of Records.'' DHS/ICE maintains the CARIER system of records to support the identification, apprehension, and removal of individuals unlawfully entering or present in the United States; and to support the identification and arrest of individuals who commit violations of federal laws enforced by DHS.

DHS/ICE is modifying and reissuing this system of records notice to update the purpose of the system to include the following purposes: (1) to monitor individuals unlawfully entering or present in the United States in violation of the Immigration and Nationality Act, including non-detained non-citizens; (2) to support geolocation tracking, biometric verification, and rapid enrollment of non-citizens into the ICE Enforcement and Removal Operations (ERO) Alternatives to Detention (ATD) program; and (3) to improve coordination necessary to efficiently transfer/transport individuals from the U.S. Customs and Border Protection (CBP) to ICE and subsequently from ICE to various family residential centers and detention facilities. DHS/ICE is also updating the categories of individuals covered by this system of records to include those individuals on the ''non-detained'' docket and Alternatives to Detention program. Additionally, DHS/ICE is updating the categories of records to include geolocation records derived from technologies such as the Global Positioning System (GPS) and records pertaining to family unit identification number (FAMU ID).

ICE is also removing several routine uses from the previous system of records notice. After careful review and consideration, ICE is removing previous redundancies to ensure the System of Records Notice is focused solely on the system's purpose, categories of individuals, records, and routine uses for the identification, apprehension, and removal of non-citizens unlawfully present in the United States. The previous routine uses have been removed: Routine Use O, Routine Use S, Routine Use V, Routine Use Z, Routine Use AA, Routine Use BB, Routine Use JJ, and Routine Use YY.

Finally, DHS/ICE is proposing to modify and add the following routine uses:

- Modify routine use (E) and add routine use (F) to allow DHS/ICE to share records with appropriate federal agencies or entities when reasonably necessary to respond to a breach of personally identifiable information and to prevent, minimize, or remedy the risk of harm to individuals or the Federal Government, or assist an agency in locating individuals affected by a breach in accordance with Office of Management and Budget (OMB) Memorandum M–17–12 ''Preparing for and Responding to a Breach of Personally Identifiable Information,'' (Jan. 3, 2017).
- Add routine use (XX) to allow ICE to share records through the Law Enforcement Information Sharing Service (LEISS) with federal, state, local, tribal, regional, foreign, or international law enforcement agencies that are party to a LEISS Memorandum of Agreement. LEISS is a non-public facing web service that functions as a bi-directional data sharing system between DHS and member agencies for the purpose of criminal law enforcement, homeland/national security, or applicant background investigations.
- Add routine use (YY) to allow ICE to share information with an appropriate federal, state, local, tribal, territorial, foreign, or international agency and third-party organizations assisting in the repatriation of non-citizens who are returning voluntarily to their home countries.

The Routine Use Section is also being renumbered to account for the added and removed routine uses listed above. Non-substantive language changes have been made to the added routine uses to clarify disclosure policies that are standard across DHS and to align with previously published DHS system of records notices.

Consistent with DHS's information sharing mission, information stored in the DHS/ICE–011 CARIER System of Records may be shared with other DHS Components that have a need to know the information to carry out their national security, law enforcement, immigration, intelligence, or other homeland security functions. In addition, DHS/ICE may share information with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this system of records notice. This modified system will be included in DHS's inventory of records systems.

II. Privacy Act

The fair information practice principles found in the Privacy Act underpin the statutory framework governing the means by which Federal Government agencies collect, maintain,

use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. Additionally, and similarly, the Judicial Redress Act (JRA) provides a statutory right to covered persons to make requests for access to and amendment of covered records, as defined by the Judicial Redress Act, along with judicial review for denials of such requests. In addition, the Judicial Redress Act prohibits disclosures of covered records, except as otherwise permitted by the Privacy Act.

Below is the description of the DHS/ICE–011 CARIER System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM NAME AND NUMBER:

Department of Homeland Security (DHS)/U.S. Immigration and Customs Enforcement (ICE)-011 Criminal Arrest Records and Immigration Enforcement Records (CARIER).

SECURITY CLASSIFICATION:

Unclassified. The data may be retained on classified networks, but this does not change the nature and character of the data until it is combined with classified information.

SYSTEM LOCATION:

Records are maintained in DHS/ICE information technology (IT) systems (*e.g.,* the Enforcement Integrated Database (EID) and their associated ICE applications. and contractor-owned IT systems, including those supporting the ICE Alternatives to Detention program). Records are also maintained in associated electronic and paper files located at ICE Headquarters in Washington, DC, ICE field and attaché offices, contractor offices, and detention facilities operated by or on behalf of ICE, or that otherwise house individuals arrested or detained by ICE. Finally, records are replicated from the operational DHS/ICE IT systems and maintained on DHS unclassified and classified networks used for analysis and vetting.

SYSTEM MANAGER(S):

Executive Associate Director, Office of Enforcement and Removal Operations, U.S. Immigration & Customs Enforcement, 500 12th Street SW, Washington, DC 20536.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for maintaining this system is in sections 103, 235, 236, 274, 287, and 290 of the Immigration and Nationality Act (INA), 8 United States Code, sections 1103, 1225, 1226, 1324, 1357, 1360, and 1365(a)(b); Title 18, United States Code, Chapters 27, 77, 85, 95, 109A, 110, 113, and 117; Title 31, United States Code, Chapter 53, Subchapter II; Title 50 Appendix, United States Code; The Tariff Act of 1930; Justice for All Act of 2004 (Pub. L. 108–405); DNA Fingerprint Act of 2005 (Pub. L. 109–162); Adam Walsh Child Protection and Safety Act of 2006 (Pub. L. 109–248); and 28 CFR part 28, ''DNA-Sample Collection and Biological Evidence Preservation in the Federal Jurisdiction.''

PURPOSE(S) OF THE SYSTEM:

The purposes of this system are:

1. To support the identification, arrest, charging, monitoring, detention, and/or removal of individuals unlawfully entering or present in the United States in violation of the INA, including fugitive non-citizens, non-detained non-citizens, and non-lawful re-entrants.

2. To support the identification and arrest of individuals (both citizens and non-citizens) who commit violations of criminal laws enforced by DHS/ICE.

3. To track the process and results of administrative and criminal proceedings, including compliance with court orders and hearing dates, against individuals who are alleged to have violated the INA or other laws enforced by DHS.

4. To support the grant or denial of parole and tracking of individuals who seek or receive parole into the United States.

5. To provide criminal and immigration history information during DHS enforcement encounters, and to support background checks on applicants for DHS immigration benefits (*e.g.,* employment authorization and petitions).

6. To identify potential criminal activity, immigration violations, and threats to homeland security, to ensure public safety, and to uphold laws enforced by DHS.

7. To support the geolocation tracking, biometric verification, and rapid enrollment of non-citizens into the ICE Alternatives to Detention program.

8. To improve the coordination necessary to efficiently transfer/transport individuals from CBP to ICE and from ICE to various detention facilities.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include: (1) individuals arrested, detained, or removed from the United States for criminal or administrative violations of the INA, or individuals issued a Notice to Appear in immigration court; (2) individuals who are the subject of an immigration detainer issued to another law enforcement or custodial agency; (3) individuals arrested by ICE for violations of criminal laws enforced by ICE or DHS; (4) individuals who fail to leave the United States after receiving a final order of removal, deportation, or exclusion, or who fail to report to ICE for removal after receiving notice to do so (fugitive non-citizens); (5) individuals who non-lawfully re-enter the United States after departing pursuant to an order of voluntary departure or being removed from the United States (non-lawful re-entrants); (6) individuals who request to be removed at their own expense or are eligible for voluntary removal from the United States pursuant to section 250 of the INA; (7) individuals who are granted parole into the United States under section 212(d)(5) of the INA (parolees); (8) individuals awaiting immigration proceedings under a ''non-detained'' or Alternatives to Detention program; (9) other individuals whose information may be collected or obtained during the course of an immigration enforcement or criminal matter, such as witnesses, associates, and relatives; (10) persons who post or arrange bond for the release of an individual from ICE detention, or receive custodial property of a detained non-citizen; (11) prisoners of the U.S. Marshals Service held in ICE detention facilities; and (12) attorneys or representatives who represent individuals listed in the categories above.

CATEGORIES OF RECORDS IN THE SYSTEM:

Biographic, biometric, descriptive, historical, and other identifying data, including:

- Full name;
- Alias(es);
- A-Number;
- Social Security number (SSN);
- Date of birth;
- Place of birth;
- Nationality;
- Fingerprint Identification Number (FIN);
- Federal Bureau of Investigation (FBI) number;

- Other unique identifying numbers (*e.g.,* federal, state, local, and tribal identification numbers);
- Government-issued identification (*e.g.,* passport, driver's license):
  - Document type;
  - Issuing organization;
  - Document number;
  - Expiration date;
- Visa information;
- Contact or location information (*e.g.,* known or possible addresses, phone numbers);
- Employment history;
- Education history;
- Immigration history (*e.g.,* citizenship/naturalization certificate number, removals, explanations);
- Domestic and foreign criminal history (*e.g.,* arrest, charges, dispositions, and sentencing, corresponding dates, jurisdictions);
- Physical description (*e.g.,* height, weight, eye color, hair color, race, ethnicity, identifying marks like scars, tattoos, or birthmarks); and
- Biometric data (*i.e.,* fingerprints, voiceprints, iris images, photographs, facial verification images/templates, and DNA samples).
  - DNA samples required by DOJ regulation (see 28 CFR part 28) are collected and sent to the FBI. DNA samples are not retained or analyzed by DHS, nor does ICE receive or maintain the results of the FBI's DNA analysis (*i.e.,* DNA sequences).
  - Information pertaining to ICE's collection of DNA samples, limited to the date and time of successful collection and confirmation from the FBI that the sample was able to be sequenced, is maintained by ICE and DHS.

Case-related data:

- Case number;
- Family unit identification number ID numbers;
- Record number;
- Case category;
- Description of charges and disposition of arrest;
- Case agent;
- Data initiated and completed;
- Location-related data, including geotags from metadata associated with other record categories collected; geographical indicators; and geolocation information (*e.g.,* GPS) derived from the ICE Alternatives to Detention program;
- National Sex Offender Registry (NSOR) status; and
- Other data describing an event involving alleged violations of criminal or immigration law (*i.e.,* location; date; time; type of criminal or immigration law violations alleged; type of property involved; use of violence, weapons, or assault against DHS personnel or third parties; attempted escape; and other related information).

Information presented to or collected by ICE during immigration and law enforcement proceedings or activities:

- Date of birth;
- Place of birth;
- Marital status;
- Education history;
- Employment history;
- Travel history; and
- Other information derived from affidavits, certificates, manifests, and other documents. This data typically pertains to subjects, relatives, associates, and witnesses.

Detention data on non-citizens:

- Immigration detainers issued;
- Transportation information;
- Detention-related identification numbers;
- Detention facility;
- Security, risk, and custody classification;
- Custody recommendation and status;
- Flight risk indication;
- Book-in/book-out date and time;
- Mandatory detention and criminal flags;
- Aggravated felon status;
- Other alerts (*e.g.,* gang affiliation, community ties, health accommodation, humanitarian or medical considerations);
- Information about a non-citizen's release from custody on bond, recognizance, or supervision;
- Information related to prosecutorial discretion determinations;
- Property inventory and receipt;
- Information related to disciplinary issues or grievances;
- Documents and video recordings related to alleged misconduct and other incidents involving detainees; and
- Other detention-related information (*e.g.,* documentation of an allegation of sexual abuse or assault, documentation of strip and body cavity searches, documentation of reasons for segregation or other housing placement, documentation of participation in the orientation process).

Detention data for U.S. Marshals Service prisoners:

- Full name;
- Date of birth;
- Country of birth;
- Identification numbers (*e.g.,* detainee, FBI, state);
- Book-in/book-out date and time; and
- Security classification.

Limited health information relevant to an individual's placement in an ICE detention facility or transportation requirements:

- Medical alerts, mental competency, or general information on physical disabilities or other special needs or vulnerabilities to facilitate placement in a facility or bed that best accommodates these needs. Medical records about individuals in ICE custody (*i.e.,* records relating to the diagnosis or treatment of individuals) are maintained in DHS/ICE–013 Alien Medical Records System of Records.

Progress, status, and final result of removal, prosecution, and other DHS processes and related appeals:

- Information relating to criminal convictions;
- Incarceration;
- Travel documents; and
- Other information pertaining to the actual removal of non-citizens from the United States.

Contact, biographical, and identifying data about Relatives, Attorneys, Representatives, Associates, or Witnesses of a noncitizen in proceedings initiated or conducted by DHS may include:

- Full name;
- Date of birth;
- Place of birth; and
- Contact or location information (*e.g.,* addresses, phone numbers, and business or agency name).

Data concerning personnel of other agencies that arrested, or assisted or participated in the arrest or investigation of, or are maintaining custody of an individual whose arrest record is contained in this system of records may include:

- Full name;
- Title; and
- Contact or location information (*e.g.,* addresses, phone numbers, and business or agency name).

Data about persons who post or arrange an immigration bond for the release of an individual from ICE custody, or receive custodial property of an individual in ICE custody may include:

- Full name;
- Address;
- Phone numbers; and
- Social Security number.

Recordings of detainee telephone calls when responding as part of an alternative to detention program or of detainee calls made in detention facilities. Information about these calls may include:

- Date;
- Time;
- Duration; and
- Phone number called. (Note: protected telephone calls, such as calls with an attorney, are not recorded and information about protected telephone calls is not retained.)

Information related to detainees' accounts for telephone or commissary services in a detention facility.

RECORD SOURCE CATEGORIES:

Records are obtained from several sources. In general, information is obtained from individuals covered by this system, and other federal, state, local, tribal, or foreign governments. More specifically, DHS/ICE–011 records derive from the following sources:

(a) Individuals covered by the system and other individuals (*e.g.,* witnesses, family members);

(b) Other federal, state, local, tribal, or foreign governments and government information systems;

(c) Business records;

(d) Evidence, contraband, and other seized material; and

(e) Public and commercial sources, including social media.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including Offices of the United States Attorneys, or other federal agencies conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is relevant and necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;

2. Any employee or former employee of DHS in their official capacity;

3. Any employee or former employee of DHS in their individual capacity when DOJ or DHS has agreed to represent the employee; or

4. The United States or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. secs. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when (1) DHS suspects or has confirmed that there has been a breach of the system of records; (2) DHS has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DHS (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 DHS's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

F. To another federal agency or federal entity when DHS 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.

G. To an appropriate federal, state, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

I. To prospective claimants and their attorneys for the purpose of negotiating the settlement of an actual or prospective claim against DHS or its current or former employees, in advance of the initiation of formal litigation or proceedings.

J. To appropriate federal, state, local, tribal, territorial, or foreign government agencies, as well as to other individuals and organizations during the course of an investigation by DHS or the processing of a matter under DHS's jurisdiction, or during a proceeding within the purview of immigration and nationality laws, when DHS deems that such disclosure is necessary to carry out its functions and statutory mandates or to elicit information required by DHS to carry out its functions and statutory mandates.

K. To federal, state, local, tribal, or territorial government agencies, or other entities or individuals, or through established liaison channels to selected foreign governments, to provide intelligence, counterintelligence, or other information for the purposes of national security, intelligence, counterintelligence, or antiterrorism activities authorized by U.S. law, Executive Order, or other applicable national security directive.

L. To federal and foreign government intelligence or counterterrorism agencies or components when DHS becomes aware of an indication of a threat or potential threat to national or international security, or when such disclosure is to support the conduct of national intelligence and security investigations or to assist in anti-terrorism efforts.

M. To any federal agency to enable such agency to make determinations regarding the payment of federal benefits to the record subject in accordance with that agency's statutory responsibilities.

N. To foreign governments for the purpose of coordinating and conducting the removal of non-citizens from the United States to other nations under the Immigration and Nationality Act; and to international, foreign, intergovernmental, and multinational agencies, authorities, and organizations in accordance with law and formal or informal international arrangements.

O. To the DOJ Executive Office of Immigration Review (EOIR) or its contractors, consultants, or others performing or working on a contract for EOIR, for the purpose of providing information about non-citizens who are or may be placed in removal proceedings so that EOIR may arrange for the provision of educational services to those non-citizens under EOIR's Legal Orientation Program, or for other purposes or activities within the scope of the EOIR contract.

P. To disclose information to the DOJ EOIR and to the Board of Immigration Appeals, to the extent necessary to carry out their authorized duties pertaining to the adjudication of matters arising under the Immigration and Nationality Act.

Q. To attorneys or legal representatives for the purpose of facilitating group presentations to non-

citizens in detention that will provide the non-citizens with information about their rights under U.S. immigration law and procedures.

R. To the Department of State in the processing of petitions or applications for benefits under the Immigration and Nationality Act, and all other immigration and nationality laws including treaties and reciprocal agreements; or when the Department of State requires information to consider or provide an informed response to a request for information from a foreign, international, or intergovernmental agency, authority, or organization about a non-citizen or an enforcement operation with transnational implications.

S. To OMB in connection with the review of private relief legislation as set forth in OMB Circular No. A–19 at any stage of the legislative coordination and clearance process as set forth in the Circular.

T. To federal, state, local, territorial, tribal, international, or foreign criminal, civil, or regulatory law enforcement authorities when the information is necessary for collaboration, coordination, and de-confliction of investigative matters, prosecutions, and/or other law enforcement actions to avoid duplicative or disruptive efforts and to ensure the safety of law enforcement officers who may be working on related law enforcement matters.

U. To the U.S. Marshals Service (USMS) concerning USMS prisoners that are or will be held in detention facilities operated by or on behalf of ICE, and to federal, state, local, tribal, or territorial law enforcement or correctional agencies concerning individuals in DHS custody that are to be transferred to such agency's custody, to coordinate the transportation, custody, and care of these individuals.

V. To third parties to facilitate placement or release of an individual (*e.g.,* at a group home, homeless shelter) who has been or is about to be released from DHS custody but only such information that is relevant and necessary to arrange housing, continuing medical care, or other social services for the individual.

W. To victims and witnesses regarding custodial information, such as transfer to another custodial agency or location, release on bond, order of supervision, removal from the United States, or death in custody, about an individual who is the subject of a criminal or immigration investigation, proceeding, or prosecution. This would also authorize disclosure of custodial information to individuals with a legal responsibility to act on behalf of a victim or witness (*e.g.,* attorney, parent, legal guardian) and individuals acting at the request of a victim or witness; as well as external victim notification systems that make such information available to victims and witnesses in electronic form.

X. To the Federal Bureau of Prisons (BOP) and other federal, state, local, territorial, tribal, and foreign law enforcement or custodial agencies for the purpose of facilitating the transfer of custody of an individual to or from that agency. This will include the transfer of information about unaccompanied minor children to the U.S. Department of Health and Human Services (HHS) to facilitate the custodial transfer of such children from DHS to HHS.

Y. To DOJ and other law enforcement or custodial agencies to facilitate payments and reporting under the State Criminal Alien Assistance Program or similar programs.

Z. To any law enforcement agency or custodial agency (such as a jail or prison) to serve that agency with notice of an immigration detainer, or to update or remove a previously issued immigration detainer, for an individual who is believed to be in that agency's custody.

AA. To DOJ, disclosure of DNA samples and related information as required by 28 CFR part 28.

BB. To DOJ, disclosure of arrest and removal information for inclusion in relevant DOJ law enforcement databases and for use in the enforcement of federal firearms laws (*e.g.,* Brady Handgun Violence Prevention Act, as amended by the NICS Improvement Amendments Act).

CC. To the attorney or guardian ad litem of an individual's child, or to federal, state, local, tribal, territorial, or foreign governmental or quasi-governmental agencies or courts, to confirm the location, custodial status, removal, or voluntary departure of an individual from the United States, to facilitate the recipients' exercise of responsibilities pertaining to the custody, care, or legal rights (including issuance of a U.S. passport) of the individual's children, or the adjudication or collection of child support payments or other similar debts owed by the individual.

DD. To an individual or entity seeking to post or arrange, or who has already posted or arranged, an immigration bond for a noncitizen to aid the individual or entity in (1) identifying the location of the noncitizen; (2) posting the bond; (3) obtaining payments related to the bond; or (4) conducting other administrative or financial management activities related to the bond.

EE. To federal, state, local, tribal, territorial, or foreign government agencies or entities or multinational governmental agencies when DHS needs to exchange relevant data for the purpose of developing, testing, or implementing new software or technology whose purpose is related to this system of records.

FF. Limited detainee biographical information will be publicly disclosed via the ICE Online Detainee Locator System or any successor system for the purpose of identifying whether a detainee is in ICE custody and the custodial location.

GG. To courts, magistrates, administrative tribunals, opposing counsel, parties, and witnesses, in immigration, civil, or criminal proceedings (including discovery, presentation of evidence, and settlement negotiations) and when DHS determines that use of such records is relevant and necessary to the litigation before a court or adjudicative body when any of the following is a party to or have an interest in the litigation:

1. DHS or any component thereof;

2. Any employee of DHS in their official capacity;

3. Any employee of DHS in their individual capacity when DOJ or DHS has agreed to represent the employee; or

4. The United States, when DHS determines that litigation is likely to affect DHS or any of its components.

HH. To federal, state, local, tribal, territorial, international, or foreign government agencies or entities for the purpose of consulting with that agency or entity:

1. To assist in making a determination regarding redress for an individual in connection with the operations of a DHS component or program;

2. To verify the identity of an individual seeking redress in connection with the operations of a DHS component or program; or

3. To verify the accuracy of information submitted by an individual who has requested such redress on behalf of another individual.

II. To federal, state, local, tribal, territorial, or foreign governmental agencies; multilateral governmental organizations; or other public health entities, for the purposes of protecting the vital interests of a record subject or other persons, including to assist such agencies or organizations during an epidemiological investigation, in facilitating continuity of care, in preventing exposure to or transmission of a communicable or quarantinable disease of public health significance, or

to combat other significant public health threats.

JJ. To foreign governments for the purpose of providing information about their citizens or permanent residents, or family members thereof, during local or national disasters or health emergencies.

KK. To a coroner for purposes of affirmatively identifying a deceased individual (whether or not such individual is deceased as a result of a crime) or cause of death.

LL. To a former employee of DHS for purposes of responding to an official inquiry by Federal, State, local, tribal, or territorial government agencies or professional licensing authorities; or facilitating communications with a former employee that may be relevant and necessary for personnel-related or other official purposes, when DHS requires information or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

MM. To federal, state, local, tribal, territorial, foreign, or international agencies, if the information is relevant and necessary to a requesting agency's decision concerning the hiring or retention of an individual, or the issuance, grant, renewal, suspension or revocation of a security clearance, license, contract, grant, or other benefit; or if the information is relevant and necessary to a DHS decision concerning the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit.

NN. To a public or professional licensing organization when such information indicates, either by itself or in combination with other information, a violation or potential violation of professional standards, or reflects on the moral, educational, or professional qualifications of licensed professionals or those seeking to become licensed professionals.

OO. To an attorney or representative (as defined in 8 CFR 1.2, 202.1, 1001.1(f), or 1202.12) who is acting on behalf of an individual covered by this system of records in connection with any proceeding before U.S. Citizenship and Immigration Services (USCIS), ICE, CBP, or EOIR, as required by law or as deemed necessary in the discretion of the Department.

PP. To members of the public, with regard to disclosure of limited detainee biographical information for the purpose of facilitating the deposit of monies into detainees' accounts for telephone or commissary services in a detention facility.

QQ. To federal, state, local, tribal, or territorial government agencies seeking to verify or ascertain the citizenship or immigration status of any individual within the jurisdiction of the agency for any purpose authorized by law.

RR. To federal, state, local, tribal, and territorial courts or government agencies involved in criminal investigation or prosecution, pre-trial, sentencing, parole, probation, bail bonds, or any other aspect of the criminal justice process, and to defense counsel representing an individual in a domestic criminal proceeding, to ensure the integrity and efficiency of the criminal justice system by informing these recipients of the existence of an immigration detainer or the individual's status in removal proceedings, including removal or custodial status/location. Disclosure of the individual's A-Number and country of birth is also authorized to facilitate these recipients' use of the ICE Online Detainee Locator System for the purposes listed above.

SS. To a foreign government to notify it concerning its citizens or residents who are incapacitated, an unaccompanied minor, or deceased.

TT. To family members, guardians, committees, friends, or other agents identified by law or regulation to receive notification, decisions, and other papers as provided in 8 CFR 103.8 from DHS or EOIR following verification of a familial or agency relationship with a non-citizen when DHS is aware of indicia of incompetency or when a non-citizen has been determined to be mentally incompetent by an immigration judge.

UU. To an organization or person in either the public or private sector, either foreign or domestic, when there is a reason to believe that the recipient is or could become the target of a particular terrorist activity or conspiracy, or when the information is relevant to the protection of life, property, or other vital interests of a person.

VV. To clerks and judges of courts exercising naturalization jurisdiction for the purpose of granting or revoking naturalization.

WW. To federal, state, local, tribal, territorial, foreign, or international agencies, after discovery of such information, if DHS determines: (1) The information is relevant and necessary to that agency's decision concerning the hiring or retention of an individual, or issuance of a security clearance, license, contract, grant, or other benefit; and (2) Failure to disclose the information is likely to create a substantial risk to government facilities, equipment, or personnel; sensitive information; critical infrastructure; or public safety.

XX. To an appropriate federal, state, local, tribal, regional, foreign, or international law enforcement agency, where use is consistent with the official duties of the recipient agencyand the requirements set forth in a related memorandum of agreement between DHS and the recipient agency authorizing information sharing through LEISS for the purpose of criminal law enforcement, homeland security, or to support applicant background investigations for ICE law enforcement partners.

YY. To an appropriate federal, state, local, tribal, territorial, foreign, or international agency and third-party organizations assisting in the repatriation of non-citizens who are returning voluntarily to their home countries.

ZZ. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information, when disclosure is necessary to preserve confidence in the integrity of DHS, or when disclosure is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent the Chief Privacy Officer determines that release of the specific information in the context of a particular case would constitute a clearly unwarranted invasion of personal privacy.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

DHS/ICE stores records in this system electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, and digital media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by name, biometric identifiers, identification numbers including, but not limited to, A-Number, fingerprint identification number, Social Security number, case or record number if applicable, case related data, or a combination of other personal identifiers including, but not limited to, date of birth and nationality.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

ICE retains records in accordance with an applicable National Archives and Records Administration (NARA) General Records Schedule (GRS) or a NARA-approved agency-specific records control schedule. ICE retains records of arrests, detentions, and removals in the Enforcement Integrated Database and its

modules, such as the ENFORCE Alien Removal Module and the ICE Integrated Decision Support (IIDS), for seventy-five (75) years pursuant to the Biometric with Limited Biographical Data Schedule, DAA–563–2013–0001–0006.

The Online Detainee Locator System (ODLS) uses an extract of Enforcement Integrated Database data about current detainees and detainees that were released during the last sixty (60) days. Records are retained in the Online Detainee Locator System for as long as they meet the extract criteria in accordance with the schedule, N1–567–11–7. The electronic Travel Document System (eTD) stores travel documents for twenty (20) years after the issuance of a travel document or denial letter in accordance with the schedule, DAA–0567–2017–0004. Alternatives to Detention program records are retained for seven (7) years after the individual has been removed from the Alternatives to Detention program and is no longer being monitored in accordance with the schedule, DAA–567–2018–0001–0001.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

DHS/ICE safeguards records in this system according to applicable rules and policies, including all applicable DHS automated systems security and access policies. DHS/ICE has imposed strict controls to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RECORD ACCESS PROCEDURES:

The Secretary of Homeland Security has exempted this system from the notification, access, and amendment procedures of the Privacy Act, and the Judicial Redress Act if applicable, because it is a law enforcement system. However, DHS/ICE will consider individual requests to determine whether or not information may be released. Thus, individuals seeking access to and notification of any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Chief Privacy Officer and ICE FOIA Officer whose contact information can be found at *http://www.dhs.gov/foia.* If an individual believes more than one component maintains Privacy Act records concerning them, the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, Department of Homeland Security, Washington, DC 20528–0655 or electronically at *https://www.dhs.gov/dhs-foia-privacy-act-request-submission-form.* Even if neither the Privacy Act nor the Judicial Redress Act provide a right of access, certain records about an individual may be available under the Freedom of Information Act.

When seeking records about oneself from this system of records or any other Departmental system of records, an individual's request must conform with the Privacy Act regulations set forth in 6 CFR part 5. The individual must first verify their identity, meaning that they must provide their full name, current address, and date and place of birth. The individual must sign the request, and their signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, one may obtain forms for this purpose from the Chief Privacy Officer and Chief Freedom of Information Act Officer, *http://www.dhs.gov/foia* or 1–866–431–0486. In addition, individuals should:

- Explain why they believe the Department would have information on them;
- Identify which component(s) of the Department they believe may have the information about them;
- Specify when they believe the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records.

If the request is seeking records pertaining to another living individual, the request must include an authorization from the individual whose record is being requested, authorizing the release to the requester.

Without the above information, the component(s) may not be able to conduct an effective search, and the individual's request may be denied due to lack of specificity or lack of compliance with applicable regulations.

CONTESTING RECORD PROCEDURES:

For records covered by the Privacy Act or covered Judicial Redress Act records, individuals may make a request for amendment or correction of a Department record about the individual by writing directly to the Department component that maintains the record, unless the record is not subject to amendment or correction. The request should identify each record in question, state the amendment or correction desired, and state why the individual believes that the record is not accurate, relevant, timely, or complete. The individual may submit any documentation that would be helpful to support the request. If the individual believes that the same record is in more than one system of records, the request should state this belief and be addressed to each component that maintains a system of records containing the record.

NOTIFICATION PROCEDURES:

See ''Record Access procedure.''

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

The Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(j)(2), has exempted this system from the following provisions of the Privacy Act: 5 U.S.C. secs. 552a(c)(3), (c)(4); (d); (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(5), (e)(8); (f); and (g). Additionally, the Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(k)(2), has exempted this system of records from the following provisions of the Privacy Act: 5 U.S.C. secs. 552a(c)(3); (d); (e)(1), (e)(4)(G), (e)(4)(H); and (f). When a record received from another system has been exempted in that source system under 5 U.S.C. secs. 552a(j)(2) or (k)(2), DHS will claim the same exemptions for those records that are claimed for the original primary systems of records from which they originated and claim any additional exemptions set forth here.

HISTORY:

81 FR 72080 (November 18, 2016); 80 FR 24269 (April 30, 2015); 80 FR 11214 (March 2, 2015); 75 FR 23274 (May 3, 2010); 75 FR 9238 (March 1, 2010); 74 FR 20719 (May 5, 2009); 74 FR 5665 (January 30, 2009); 74 FR 4965 (January 28, 2009).

Mason C. Clutter,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2024–14768 Filed 7–3–24; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6086–N–09]

RIN 2577–AD05

Economic Growth Regulatory Relief and Consumer Protection Act: Implementation of National Standards for the Physical Inspection of Real Estate (NSPIRE); Extension of NSPIRE Compliance Date for HCV, PBV and Section 8 Moderate Rehab and CPD Programs

AGENCY: Office of the Assistant Secretary for Public and Indian

Housing, U.S. Department of Housing and Urban Development (HUD); Office of the Assistant Secretary for Community Planning and Development, U.S. Department of Housing and Urban Development (HUD).

ACTION: Notice.

SUMMARY: This notice further extends the compliance date for HUD's National Standards for the Physical Inspection of Real Estate (NSPIRE) final rule for the Housing Choice Voucher (HCV), Project Based Voucher (PBV) and Section 8 Moderate Rehabilitation programs, and for the HOME Investment Partnerships Program (HOME) and Housing Trust Fund (HTF), Housing Opportunities for Persons With AIDS (HOPWA), Emergency Solution Grants (ESG) and Continuum of Care (COC) programs (''CPD programs''), until October 1, 2025. HUD is taking this action to allow Public Housing Authorities (PHAs), jurisdictions, participants, recipients, and grantees additional time to implement HUD's NSPIRE standards. This is the second extension of this compliance date.

DATES:

Compliance Date: Jurisdictions, participants, and grantees subject to 24 CFR parts 92, 93, 574, 576, 578, 882, 982, and 983 are not required to comply with the changes to these parts in the NSPIRE final rule until October 1, 2025.

FOR FURTHER INFORMATION CONTACT:

Regarding the HCV and PBV programs: Dana M. Kitchen, Real Estate Assessment Center, Office of Public and Indian Housing, Department of Housing and Urban Development, 550 12th Street SW, Suite 100, Washington, DC 20410–4000; telephone 202–708–1112 (this is not a toll-free number), *NSPIRE@hud.gov.*

Regarding CPD programs: Caitlin Renner, Supervisory Affordable Housing Specialist, Room 7160, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410–7000; telephone (202) 708–2684. (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

PHAs administering the HCV and PBV programs currently use the Housing Quality Standards (HQS) for inspections, which are defined at 24 CFR 982.401. The Economic Growth Regulatory Relief and Consumer Protection Act: Implementation of National Standards for Physical Inspection of Real Estate (NSPIRE) final rule (''NSPIRE final rule'') was published on May 11, 2023 (88 FR 30442). The NSPIRE final rule included amendments to 24 CFR parts 982 and 983 effective October 1, 2023. For CPD programs, the NSPIRE final rule included amendments to 24 CFR parts 92, 93, 570, 574, 576, and 578 to conform their various inspection requirements to NSPIRE and established an effective date for these amendments of October 1, 2023. In September 2023, HUD delayed the compliance date for CPD programs (88 FR 63971) and for the HCV and PBV programs (88 FR 66882) until October 1, 2024, to allow PHAs, jurisdictions, participants, recipients, and HUD grantees additional time for implementation.

II. Basis for Delay of Compliance Date

Through this notice, HUD further delays the compliance date for CPD programs and for the HCV and PBV programs until October 1, 2025. HUD encourages any PHA, participating jurisdiction, or grantee that is ready to implement NSPIRE to do so at their earliest convenience. However, HUD has determined that additional time is necessary for some PHAs to implement NSPIRE for the HCV, PBV, and Moderate Rehabilitation (Mod Rehab) programs. This will provide PHAs with additional time to train staff and communicate with landlords and give HUD more time to provide additional technical resources needed for PHAs to transition to the NSPIRE standards. PHAs have reported to HUD that they are still recovering from the effects of the COVID–19 pandemic on their operations and are struggling to recruit and retain private landlords to participate in the HCV program. PHAs have also reported that staff time is being dedicated to administrative changes relating to the Housing Opportunity through Modernization Act (HOTMA), Public Law 114–201, 130 Stat. 782, which has impacted their ability to implement a new inspection protocol. Additionally, private software vendors have not finished their inspection products for PHAs, and HUD has not released its updated inspection software for HCV inspections.

HUD is also delaying the compliance date for CPD programs to allow jurisdictions, participants, recipients, and grantees that also administer housing or rental assistance, and that may rely on inspections performed under the HCV or PBV programs, to align their implementation timelines. As stated in the last compliance date extension for CPD programs, HUD intends to publish standards specific to each of the several CPD programs before the compliance date. These notices have not yet been published, and it will be a challenge for participating jurisdictions, recipients and grantees to revise their inspection procedures in time.

III. Instructions for PHAs Under the HCV, PBV and Section 8 Mod Rehab Programs

Only PHAs who will implement NSPIRE prior to the new compliance date of October 1, 2025, must notify HUD of the date on which they plan to transition to NSPIRE. This notification must be sent via email to *NSPIREV_AlternateInspection@hud.gov* with a courtesy copy to their Field Office representative. The email's subject line must read ''*Notification of Extension of HQS, [PHA code]*'' and the body of the email should include the PHA name, PHA code, and what date the PHA *tentatively* plans to implement NSPIRE (which may be no later than October 1, 2025).

PHAs are reminded that the NSPIRE Standards [1] for installing carbon monoxide devices and smoke alarms will still apply, as they implement statutory mandates under the Consolidated Appropriations Act, 2021 [2] and 2023,[3] respectively. The NSPIRE Standard for smoke alarms will be updated for the new smoke alarm requirements before the statutory compliance date of December 29, 2024.

IV. Instructions for HOME Participating Jurisdictions and HTF Grantees

As stated in the previous compliance date extension for CPD, HOME participating jurisdictions and HTF grantees should prepare for the compliance date by updating property standard regulatory citations and requirements in written agreement templates with State recipients, subrecipients, and project owners, as

[1] REAC NSPIRE Standards are posted at *https://www.hud.gov/program_offices/public_indian_housing/reac/nspire/standards.*

[2] Section 101, ''Carbon Monoxide Alarms or Detectors in Federally Insured Housing'' of Title I of Division Q, Financial Services Provisions and Intellectual Property, of the Consolidated Appropriations Act, 2021, Public Law 116–260, 134 (2020).

[3] Section 601, ''Smoke Alarms in Federally Assisted Housing'' of Title VI of Division AA, Financial Services Matters, of the Consolidated Appropriations, 2023, Public Law No 117–328 (2022).

required by 24 CFR 92.504(c) and 24 CFR 93.404(c).

In addition, participating jurisdictions and HTF grantees that intend to comply with the changes in the NSPIRE final rule as of the effective date should review the deficiencies established in the NSPIRE Standards notice at 88 FR 40832 and compare these requirements to their existing rehabilitation and property standards and their inspection procedures and checklists. While HUD intends to publish a subset of the deficiencies in the NSPIRE Standards that are applicable to HOME and HTF projects, participating jurisdictions and HTF grantees that implement the changes in the NSPIRE final rule before publication of the subset of deficiencies for HOME and HTF must implement the full set of deficiencies in the NSPIRE Standards in their rehabilitation and ongoing property standards and policies and procedures. Further, participating jurisdictions and HTF grantees may not implement the changes in the NSPIRE final rule until such rehabilitation and ongoing property standards and policies and procedures are updated consistent with NSPIRE.

V. Instructions for CoC, ESG, and HOPWA Programs

CoC and ESG program recipients and HOPWA grantees may apply the NSPIRE standards at 88 FR 40832 before October 1, 2025, provided that their program documents reflect the standards they are using and the date of transition to those standards. Otherwise, CoC and ESG recipients and HOPWA grantees that are not ready to make the transition to the new standards will be expected to adhere to the former program requirements until the new compliance date. However, when HUD issues the standards specific to the HOPWA, ESG and CoC programs, all grantees and recipients will be encouraged to prepare for the compliance date by updating their policies and procedures to reflect the program-specific standards.

HOPWA grantees are reminded of the requirements for installing carbon monoxide devices and smoke alarms as required by the Consolidated Appropriations Act, 2021 and 2023, respectively. HUD will update the NSPIRE Standard for the new smoke alarm requirements before the statutory compliance date of December 23, 2024.

VI. Conclusion

Accordingly, HUD revises the October 1, 2024, compliance date for the changes made to 24 CFR parts 92, 93, 574, 576, 578, 882, 982, and 983 to October 1, 2025, at which time PHAs, jurisdictions, grantees, recipients, and participants subject to these parts must comply with the NSPIRE final rule. Until October 1, 2025, PHAs, jurisdictions, grantees, recipients and participants subject to these parts may instead choose to comply with the provisions of these parts that were amended by the NSPIRE final rule as they existed prior to October 1, 2023.

Maria Claudette Fernandez,

General Deputy Assistant Secretary for Community Planning and Development.

Dominique Blom,

General Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 2024–14718 Filed 7–3–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R1–ES–2022–0074; ES11140100000–245–FF01E0000]

Final Environmental Impact Statement for the Barred Owl Management Strategy; Washington, Oregon, and California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; final environmental impact statement.

SUMMARY: The U.S. Fish and Wildlife Service (Service) developed a proposed barred owl management strategy (strategy) to address the threat that the nonnative and invasive barred owl (*Strix varia*) poses to two native western owl subspecies—the northern spotted owl (*Strix occidentalis caurina*) and the California spotted owl (*Strix occidentalis occidentalis*). In accordance with the National Environmental Policy Act, this notice announces the availability of a final environmental impact statement (FEIS) evaluating the impacts on the human environment related to the proposed management strategy and associated take of barred owls, which is prohibited under the Migratory Bird Treaty Act unless authorized by the Service by permit or regulation. With this notice, we also make available the revised proposed management strategy.

DATES: The Service's decision on the proposed management strategy will occur no sooner than 30 days after publication of the U.S. Environmental Protection Agency's notice of availability of the FEIS in the **Federal Register**, and will be documented in a record of decision.

ADDRESSES: You may obtain copies of the strategy and FEIS documents by any of the following methods:

- *Internet: https://www.regulations.gov* (search for Docket No. FWS–R1–ES–2022–0074) or at *https://www.fws.gov/project/barred-owl-management.*
- *Phone:* You may call Robin Bown at 503–231–6923, to request alternative formats of the documents.

FOR FURTHER INFORMATION CONTACT: Robin Bown, U.S. Fish and Wildlife Office, Oregon Fish and Wildlife Office (see **ADDRESSES**), by telephone at 503–231–6923, or by email at *robin_bown@fws.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: The U.S. Fish and Wildlife Service (Service) announces the availability of a final environmental impact statement (FEIS) addressing the proposed barred owl management strategy (strategy) developed to address the threat that the nonnative and invasive barred owl poses to two native western owl subspecies, the northern spotted owl (*Strix occidentalis caurina*) and the California spotted owl (*Strix occidentalis occidentalis*). Implementation of the proposed management strategy would involve the reduction of barred owl populations in designated management areas in Washington, Oregon, and northern California. Where barred owls are in the early stages of invasion in the California spotted owl's range, the proposed strategy would allow for removal of all barred owls in order to prevent establishment of barred owl populations.

This FEIS provides updates and clarifications to information presented in the draft environmental impact statement (DEIS), including revisions in response to issues raised in comments received during the public review period for that document, and identifies a preferred alternative. The Service, with input from 11 Federal and State cooperating agencies, has prepared this FEIS pursuant to the Council on Environmental Quality's (CEQ's) implementing NEPA regulations at 40 CFR parts 1500–1508, which became effective on May 20, 2022 (87 FR 23453; April 20, 2022).

Background

Spotted owls are native to western North America. Competition from nonnative and invasive barred owls has been identified as a primary threat to the northern spotted owl, which is listed as threatened under the Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*), as well as a threat to the persistence of California spotted owl, which the Service has proposed for listing (88 FR 11600; February 23, 2023). Additional primary threats include the loss of habitat to timber harvest on non-Federal lands and to wildfires on Federal and non-Federal lands.

Barred owls, native to eastern North America, began to expand their range around 1900. Barred owls are larger and more aggressive than the northern spotted owl and the California spotted owl. Upon reaching the Pacific Northwest, barred owls quickly displaced spotted owls from their historic territories. Without management of barred owls, extirpation of northern spotted owls from major portions of their historic range is likely in the near future. While barred owls have not substantially impacted California spotted owl populations to date, the establishment of a small barred owl population in the northern Sierra Nevada mountains, and the history of the invasion and impacts on northern spotted owls following such expansion, demonstrates that barred owls are also a significant threat to the persistence of California spotted owls.

The barred owl is protected under the Migratory Bird Treaty Act (MBTA; 16 U.S.C. 703–712), which prohibits take of protected migratory bird species unless authorized by the Service through permit or regulation (50 CFR 21.10).

Purpose and Need for the Proposed Action

The purpose of this proposed action is to reduce barred owl populations to improve the survival and recovery of northern spotted owls and to prevent declines in California spotted owls from barred owl competition. Relative to northern spotted owls, the purpose is to reduce barred owl populations within selected treatment areas in the short term and to increase northern spotted owl populations in those treatment areas. Relative to the California spotted owl, the purpose is to limit the invasion of barred owls into the range of the subspecies and to provide for a rapid response to reduce barred owl populations that may become established.

As described in the FEIS, these actions are needed because barred owls compete with northern and California spotted owls. Competition from the barred owl is a primary cause of the rapid and ongoing decline of northern spotted owl populations. Due to the rapidity of the decline, it is critical that we manage barred owl populations to reduce their negative effects before northern spotted owls are extirpated from large portions of their native range. There is also a need to focus on limiting the invasion of barred owls into the California spotted owl range, as we expect that additional impacts to California spotted owl populations would be inevitable without barred owl management, and invasive species are very difficult to remove once established.

Proposed Action and Alternatives

The proposed action, identified as the preferred alternative in the FEIS, is the issuance of a Migratory Bird Special Purpose permit under the MBTA (50 CFR 21.95) and implementation of the management strategy. The FEIS analyzed the proposed action, a no action alternative, and four alternatives to the proposed action, including the environmental consequences of each alternative. All action alternatives include issuance of an MBTA permit for management to reduce barred owl populations in areas within the northern spotted owl's range, and prevent establishment of barred owl populations within the California spotted owl's range. The locations and relative priorities for removal would vary by action alternative. None of the alternatives would require any entity to implement barred owl management; rather, they outline various combinations of management approaches, geographic areas, and other components that would allow for and guide management actions and the ability to prioritize areas of greatest need.

Six alternatives are analyzed in detail in the FEIS:

Alternative 1—No Action: Under the no action alternative, a comprehensive management strategy would not be finalized or implemented, and the Service would not issue an MBTA permit for systematic management of barred owls. Ongoing barred owl removal as part of research efforts in California would still occur, and future efforts that may be proposed anywhere in the range of the spotted owl could still occur.

Alternative 2—Management Strategy Implementation (Preferred Alternative): Under the preferred alternative, the proposed strategy would include three approaches to barred owl management within the northern spotted owl's range: spotted owl site management, General Management Areas with associated Focal Management Areas, and Special Designated Areas. In the California spotted owl's range, where we are focused on early detection and rapid response at the invasion front, the proposed action focuses on surveys, inventory, and monitoring to detect invading barred owls, and rapid removal of any barred owls detected.

Alternative 3—Management Across the Range: Under this alternative, barred owl management could be implemented anywhere within the range of the northern or California spotted owls or within 15 miles of the range of the subspecies on up to 50 percent of the area.

Alternative 4—Limited Management by Province/Population: Within the northern spotted owl's range, this alternative would focus barred owl management on a single large General Management Area within each physiographic province. In the California spotted owl's range, barred owl management would be delayed until detections reached 10 percent of surveys in areas within the Sierra Nevada portion of the population, or 5 percent within the Coastal-Southern California portion of the province.

Alternative 5—Management Focused on Highest Risk Areas: In the northern spotted owl's range, this alternative would focus barred owl management in the northern provinces, where the subspecies is at greatest risk of extirpation from barred owl competition. In the California spotted owl's range, barred owl management would be limited to the northern Sierra Nevada portion of the subspecies' range.

Alternative 6—Management Focused on Best Conditions: This alternative would focus barred owl management in the southern portion of the northern spotted owl's range. In the California spotted owl's range, barred owl management would be focused on areas with the best remaining habitat and areas with higher fire resiliency.

Lead and Cooperating Agencies

The Service is the lead agency for the NEPA process, including development of the FEIS. The following agencies were cooperating agencies in the NEPA process and provided input and assistance with the development of the FEIS: U.S. Forest Service (Regions 5 and 6), Bureau of Land Management (Oregon), Bureau of Land Management (California), National Park Service (Interior Regions 8, 9, 10, 12), Animal and Plant Health Inspection Service–Wildlife Services (U.S. Department of

Agriculture), Washington State Department of Fish and Wildlife, Washington State Department of Natural Resources, Oregon Department of Forestry, Oregon Department of Fish and Wildlife, California Department of Fish and Wildlife, and California Department of Forestry and Fire Protection.

Anticipated Permits and Authorizations

As described above, if an action alternative is selected, the Service expects to obtain a Migratory Bird Special Purpose permit under the MBTA to implement the selected management strategy. Depending on the location and landowners involved in implementation of the management strategy, barred owl management could require additional Federal and State permits. We anticipate the potential need for implementors to acquire permits from the States of Washington, Oregon, and California to carry out the proposed barred owl removal actions under the proposed management strategy.

Public Involvement

The Service published a notice of intent to prepare an EIS, opening a public scoping period on July 22, 2022 (87 FR 43886), which closed on August 22, 2022. A virtual public scoping meeting was held July 28, 2022. The Service prepared a DEIS and opened a 60-day public comment period on the DEIS and draft management strategy on November 17, 2023 (88 FR 80329). Two virtual public meetings were held, on December 4, 2023, and December 14, 2023, during the comment period, which ended on January 16, 2024. A total of 8,613 public comments were received during the DEIS comment period, including duplicates.

In preparing the FEIS, the Service considered all of the public comments on the DEIS and draft strategy in accordance with the requirements of NEPA (42 U.S.C. 4321 *et seq.*) and pursuant to the CEQ's implementing NEPA regulations at 40 CFR parts 1500–1508.

Environmental Protection Agency's Role in the EIS Process

The Environmental Protection Agency (EPA) is charged under section 309 of the Clean Air Act with reviewing all Federal agencies' EISs and commenting on the adequacy and acceptability of the environmental impacts of proposed actions. Under the CEQ NEPA regulations, EPA is also responsible for administering the EIS filing process. EPA is publishing a notice in the **Federal Register** announcing this FEIS. EPA serves as the repository (EIS database) for EISs prepared by Federal agencies. You may search for EPA comments on EISs, along with EISs themselves, at *https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search.*

Next Steps and Decision To Be Made

The Service will evaluate the associated documents and public comments received during the public comment periods in reaching a final decision on the proposed management strategy and issuance of an MBTA permit. At least 30 days after the FEIS is published, the Service expects to complete a record of decision pursuant to 40 CFR 1505.2, in accordance with applicable timeframes established in 40 CFR 1506.11. The Service expects to issue a record of decision in August 2024.

Authority

We provide this notice in accordance with the requirements of NEPA and its implementing regulations (40 CFR 1503.1 and 1506.6).

Hugh Morrison,

Regional Director, Pacific Region.

[FR Doc. 2024–14724 Filed 7–3–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–MB–2024–0092; FXMB1231092MFR0–245–FF09M28100; OMB Control Number 1018–0185]

Agency Information Collection Activities; Online Eastern Population Sandhill Crane Survey Data Entry Portal

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to renew information collection without change.

DATES: Interested persons are invited to submit comments on or before September 3, 2024.

ADDRESSES: Send your comments on the information collection request (ICR) by one of the following methods (please reference ''1018–0185'' in the subject line of your comments):

- *Internet (preferred): https://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–MB–2024–0092.
- *U.S. mail:* Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W), Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. 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. You may also view the information collection request (ICR) at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this 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) How might the agency 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 response.

Comments that you submit in response to this notice are a matter of

public record. 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 us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Migratory Bird Treaty Act (16 U.S.C. 703–712) designates the Department of the Interior as the primary agency responsible for managing migratory bird populations frequenting the United States and setting hunting regulations that allow for the well-being of migratory bird populations. These responsibilities dictate that we gather accurate data on various characteristics of migratory bird populations.

The Service's fall survey for the eastern population of the sandhill crane was established in 1979. It is implemented by State and Federal agencies and public volunteers from eight States in the Atlantic and Mississippi Flyways, as well as Ontario, Canada. Sandhill cranes are widely dispersed during the breeding and wintering seasons and are difficult to count. The optimal time to survey cranes is during the last week of October, when the majority of eastern population cranes breeding in Canada migrate to traditional staging grounds in the Great Lakes States (*e.g.,* the Jasper-Pulaski Fish and Wildlife Area, in Medaryville, Indiana). Since the initial survey in 1979, crane numbers have increased to over 90,000 birds.

The information collected through this survey is vital in assessing the relative changes in the geographic distribution of the species. We use the information primarily to inform managers of changes in sandhill crane distribution and population trends. Without information on the population's status, we might promulgate hunting regulations that:

- Are not sufficiently restrictive, which could cause harm to the sandhill crane population, or
- Are too restrictive, which would unduly restrict recreational opportunities afforded by sandhill crane hunting.

Notifications for the survey are sent to volunteers, and data results are entered into the data portal (*https://www.fws.gov/epsandhill/*) in order to calculate numbers of sandhill cranes. This survey is conducted via an online survey platform to reduce cost, improve data quality, and decrease respondent burden. This survey has no statistical design. We collect the following information in conjunction with the account setup process and survey data submission:

- Account setup process:

—Email address,
—Username,
—Photo (optional),
—Option for other users to contact the registrant,
—Time zone,
—First and last name,
—Phone number, and
—Start date.

- Survey data submission:

—Data submission location via online map,
—Date and time of observation,
—Number of cranes,
—Method (ground count or point count),
—Habitat (agricultural field, sandbar, wetland, or mixed-wetland agricultural field), and
—Any additional notes the user would like to submit.

Upon request, copies of the screenshots for the web survey are available by sending a request to the Service Information Collection Clearance Officer at *Info_Coll@fws.gov.*

Title of Collection: Online Eastern Population Sandhill Crane Survey Data Entry Portal.

OMB Control Number: 1018–0185.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Individuals and State agencies.

Total Estimated Number of Annual Respondents: 112.

Total Estimated Number of Annual Responses: 157.

Estimated Completion Time per Response: Varies from 3 minutes to 5 minutes, depending on activity.

Total Estimated Number of Annual Burden Hours: 11.

Respondent's Obligation: Voluntary.

Frequency of Collection: One time for the initial registration, and on occasion for survey submission.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2024–14710 Filed 7–3–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2024–0116; FXIA16710900000–245–FF09A30000]

Foreign Endangered Species; Receipt of Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications to conduct certain activities with foreign species that are listed as endangered under the Endangered Species Act (ESA). With some exceptions, the ESA prohibits activities with listed species unless Federal authorization is issued that allows such activities. The ESA also requires that we invite public comment before issuing permits for any activity otherwise prohibited by the ESA with respect to any endangered species.

DATES: We must receive comments by August 5, 2024.

ADDRESSES: *Obtaining Documents:* The applications, application supporting materials, and any comments and other materials that we receive will be available for public inspection at *https://www.regulations.gov* in Docket No. FWS–HQ–IA–2024–0116.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet: https://www.regulations.gov.* Search for and submit comments on Docket No. FWS–HQ–IA–2024–0116.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2024–0116; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, by phone at 703–358–

2185 or via email at *DMAFR@fws.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:

I. Public Comment Procedures

A. How do I comment on submitted applications?

We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

B. May I review comments submitted by others?

You may view and comment on others' public comments at *https://www.regulations.gov* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who will see my comments?

If you submit a comment at *https://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(c) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, the ESA prohibits certain activities with listed species unless Federal authorization is issued that allows such activities. Permits issued under section 10(a)(1)(A) of the ESA allow otherwise prohibited activities for scientific purposes or to enhance the propagation or survival of the affected species. Service regulations regarding prohibited activities with endangered species, captive-bred wildlife registrations, and permits for any activity otherwise prohibited by the ESA with respect to any endangered species are available in title 50 of the Code of Federal Regulations in part 17.

III. Permit Applications

We invite comments on the following applications.

Applicant: Zoological Subdistrict of the Metropolitan Zoological Park and Museum District dba Saint Louis Zoo, St. Louis, MO; Permit No. PER10867343

The applicant requests a permit to export two live, captive-born ring-tailed lemurs (*Lemur catta*) to Zoologico de Cali, Colombia, for the purpose of enhancing the propagation or survival of the species. This notification is for a single export.

Applicant: Cornell University Animal Health Diagnostic Center and NYS Veterinary Diagnostic Laboratory, Ithaca, NY; Permit No. PER10970319

On November 21, 2022, we published a **Federal Register** notice inviting the public to comment on an application for a permit to conduct certain activities with endangered species (87 FR 70860). The permit was issued on February 15, 2023, for activities to be conducted over a 1-year period. The permittee did not utilize their permit within the 1-year period and has applied for a renewal. We are opening a new comment period to allow the public the opportunity to review the information submitted as part of the renewal request for the import of biological samples collected from captive-bred African wild dogs (*Lycaon pictus*) for the purpose of scientific research. This notification is for a single import.

Applicant: University of New Orleans, New Orleans, LA; Permit No. PER5817086

On February 9, 2024, we published a **Federal Register** notice inviting the public to comment on an application for a permit to conduct certain activities with endangered species (89 FR 9170). We are now reopening the comment period to allow the public the opportunity to review additional information submitted for the import of hair and blood samples collected from wild lowland tapir (*Tapirus terrestris*) for the purpose of scientific research. This notification is for a single import.

Applicant: Wild Wonders, Bonsall, CA; Permit No. PER10468252

The applicant requests a permit to purchase in interstate commerce for one captive-born cheetah (*Acinonyx jubatus*) from Metro Richmond Zoo, Moseley, Virginia, for the purpose of enhancing the propagation or survival of the species. This notification is for a single interstate commerce activity.

Applicant: University of Florida, Archie Carr Center for Sea Turtle Research, Gainesville, FL; Permit No. PER11113890

The applicant requests authorization to import biological samples of green sea turtle (*Chelonia mydas*), loggerhead sea turtle (*Caretta caretta*), hawksbill sea turtle (*Eretmochelys imbricata*), Kemp's ridley sea turtle (*Lepidochelys kempii*), olive ridley sea turtle (*Lepidochelys olivacea*), and leatherback sea turtle (*Dermochelys coriacea*) for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 1-year period.

IV. Next Steps

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *https://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to *regulations.gov* and search for ''12345A''.

V. Authority

We issue this notice under the authority of the Endangered Species Act

of 1973, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations.

Brenda Tapia,

Supervisory Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2024–14755 Filed 7–3–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R3–ES–2024–0088; FXES11140300000–245–FF03E00000]

Draft Environmental Assessment and Proposed Habitat Conservation Plan; Receipt of an Application for an Amended Incidental Take Permit, Cardinal Point Wind Project, McDonough and Warren Counties, Illinois

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment and information.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have received an application from Cardinal Point Wind Farm, LLC (applicant), to amend its existing incidental take permit (ITP) under the Endangered Species Act, for its Cardinal Point Wind Project (project). The applicant requests that the ITP be amended to include an increased take authorization for the tricolored bat. We request public comment on the application, which includes the applicant's revised HCP, and the Service's draft supplemental environmental assessment, prepared pursuant to the National Environmental Policy Act. The Service provides this notice to seek comments from the public and Federal, Tribal, State, and local governments.

DATES: We will accept comments received or postmarked on or before August 5, 2024.

ADDRESSES: *Obtaining Documents:* Electronic copies of the documents this notice announces, along with public comments received, will be available online in Docket No. FWS–R3–ES–2024–0088 at *https://www.regulations.gov.*

Submitting Comments: If you wish to submit comments on any of the documents, you may do so in writing by one of the following methods:

- *Online: https://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R3–ES–2024–0088.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R3–ES–2024–0088; U.S. Fish and Wildlife Service; 5275 Leesburg Pike, MS: PRB/3W; Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Kraig McPeek, Field Supervisor, Illinois-Iowa Ecological Services Field Office, by email at *kraig_mcpeek@fws.gov* or by telephone at 309–757–5800, extension 202; or Andrew Horton, Regional HCP Coordinator, by email at *andrew_horton@fws.gov* or by telephone at 612–713–5337. 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: We, the U.S. Fish and Wildlife Service (Service), have received an application from Cardinal Point Wind Farm, LLC (applicant), to amend its existing incidental take permit (ITP) for four bat species under the Endangered Species Act, for its Cardinal Point Wind Project (project). The applicant requests that the ITP be amended to include an increased take authorization for the tricolored bat. The taking will be incidental to the otherwise lawful activities associated with the project. The applicant will continue the original conservation program to minimize and mitigate for the unavoidable incidental take as described in their habitat conservation plan (HCP) and will now include additional mitigation for the tricolored bat as well as updated adaptive management measures. The Service requests public comment on the application, which includes the applicant's revised HCP, and the Service's draft supplemental environmental assessment, prepared pursuant to the National Environmental Policy Act. The Service provides this notice to seek comments from the public and Federal, Tribal, State, and local governments.

Background

Section 9 of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and its implementing regulations prohibit the ''take'' of animal species listed as endangered or threatened. Take is defined under the ESA as to ''harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect ''listed animal species,'' or to attempt to engage in such conduct'' (16 U.S.C. 1538). However, under section 10(a) of the ESA, we may issue permits to authorize incidental take of listed species. ''Incidental take'' is defined by the ESA as take that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing incidental take permits for endangered and threatened species, respectively, are found in the Code of Federal Regulations at 50 CFR 17.22 and 50 CFR 17.32.

On June 27, 2023, we published a **Federal Register** notice announcing receipt of an application for an ITP from the applicant, and opened a 30-day comment period, which ended on July 27, 2023 (88 FR 41655). After determining that the application met the requirements of section 10(a) of the ESA and evaluating the effects of the proposed take pursuant to section 7 of the ESA. we determined that the permit issuance criteria of section 10(a)(l)(B) of the ESA were met and issued the requested ITP.

Applicant's Proposed Project

The applicant requests an amendment to the existing ITP for take of the federally endangered Indiana bat (*Myotis sodalis*), federally endangered northern long-eared bat (*Myotis septentrionalis*), the tricolored bat (*Perimyotis subflavus;* proposed for listing) and the unlisted little brown bat (*Myotis lucifugus*). The applicant determined through post-permit monitoring that take of tricolored bats at the 60-turbine wind project is very likely to exceed their currently permitted level; therefore, they are requesting a revised take authorization for this species only. The currently authorized take rate for the tricolored bat is 3 per year for the 6-year permit duration, for a total authorized ITP take of 18. The new requested take rate for the tricolored bat is 25 per year for the permit duration, to reflect changes to the project, bringing the total authorized ITP take to 150.

The Service requests public comments on the permit application, which includes an amended HCP, and a supplemental EA prepared in accordance with the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*).

The applicant's HCP and amendments describe the activities that will be undertaken to implement the project, as well as the mitigation and minimization measures proposed to address the impacts to the covered species. Pursuant to NEPA, the supplemental EA analyzes the impacts the ITP amendment would

have on the tricolored bat and the environment.

National Environmental Policy Act

The issuance of an ITP is a Federal action that triggers the need for compliance with NEPA. We prepared a draft supplemental EA that analyzes the environmental impacts on the human environment resulting from two alternatives: A no-action alternative, and the applicant's proposed action of amending the ITP.

Request for Public Comments

The Service invites comments and suggestions from all interested parties during a 30-day public comment period (see **DATES**). In particular, information and comments regarding the following topics are requested:

1. The direct, indirect, or cumulative effects that implementation of any alternative could have on the human environment;
2. Whether or not the significance of the impact on various aspects of the human environment has been adequately analyzed; and
3. Any other information pertinent to evaluating the effects of the proposed action on the human environment.

Availability of Public Comments

You may submit comments by one of the methods shown under **ADDRESSES**. We will post on *https://regulations.gov* all public comments and information received electronically or via hardcopy. All comments received, including names and addresses, will become part of the administrative record associated with this action. 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 request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

The Service will evaluate the permit amendment application and the comments received to determine whether the application meets the requirements of section 10(a) of the ESA. We will also reinitiate our intra-Service consultation pursuant to section 7 of the ESA to evaluate the effects of the proposed changes. After considering the above findings, we will determine whether the permit issuance criteria of section 10(a)(l)(B) of the ESA have been met. If met, the Service will issue the requested amended ITP to the applicant.

Authority

We provide this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22) and the NEPA (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6; 43 CFR part 46).

Lori Nordstrom,

Assistant Regional Director, Ecological Services.

[FR Doc. 2024–14757 Filed 7–3–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLHQ430000.L12200000.PM0000; OMB Control No. 1004–0217]

Agency Information Collection Activities; Surveys and Focus Groups To Support Outcomes-Focused Management (Recreation Survey and Focus Groups)

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Land Management (BLM) proposes to renew an information collection.

DATES: Interested persons are invited to submit comments on or before September 3, 2024.

ADDRESSES: Send your written comments on this information collection request (ICR) by mail to Darrin King, Information Collection Clearance Officer, U.S. Department of the Interior, Bureau of Land Management, Attention PRA Office, 440 W 200 S #500, Salt Lake City, UT 84101; or by email to *BLM_HQ_PRA_Comments@blm.gov*. Please reference Office of Management and Budget (OMB) Control Number 1004–0217 in the subject line of your comments. Please note that the electronic submission of comments is recommended.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Matt Blocker, Outdoor Recreation Planner, by email at *mblocker@blm.gov,* or by telephone at (385) 341–3403. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. The BLM may not conduct or sponsor a collection of information, and a response to a request for information is not required, unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps the BLM assess impacts of its information collection requirements and minimize the public's reporting burden. It also helps the public understand BLM information collection requirements and provide the requested data in the desired format.

The BLM is especially interested in public comment addressing the following:

(1) Whether collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) determination of the accuracy of BLM's estimate of the burden for collection of information, including the validity of the methodology and assumptions used;

(3) methods to enhance the quality, utility, and clarity of the information to be collected; and

(4) how might the agency minimize the burden of information collection on those who respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments submitted in response to this notice are a matter of public record. The BLM will include or summarize each comment in its request to OMB to approve this ICR. 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 us in your comment to withhold your personal identifying

information from public review, we cannot guarantee that we will be able to do so.

Abstract: Information is collected from visitors of public lands and residents of communities near public lands. Information gathered from visitors and local community residents is used to inform planning decisions in support of BLM's Planning for Recreation and Visitor Services Handbook H–8320–1. OMB approval for this information collection is currently due to expire on April 30, 2025. The BLM plans to request that OMB renew these surveys and focus groups for additional three (3) years.

Title of Collection: Surveys and Focus Groups to Support Outcomes-Focused Management (Recreation Survey and Focus Groups).

OMB Control Number: 1004–0217.

Form Numbers: None.

Type of Review: Extension of currently approved collection.

Respondents/Affected Public: Individuals or households.

Total Estimated Number of Annual Respondents: 5,330.

Total Estimated Number of Annual Responses: 7,230.

Estimated Completion Time per Response: Varies from 3 minutes to complete an on-site survey to 90 minutes to complete a focus group.

Total Estimated Number of Annual Burden Hours: 2,046.

Respondent's Obligation: Voluntary.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and, notwithstanding any other provision of law, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Darrin A. King,

Information Collection Clearance Officer.

[FR Doc. 2024–14745 Filed 7–3–24; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_AK_FRN_MO4500180306]

Notice of Availability of the ANCSA 17(d)(1) Withdrawals Final Environmental Impact Statement, Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) announces the availability of the Alaska Native Claims Settlement Act (ANCSA) 17(d)(1) Withdrawals Final Environmental Impact Statement (EIS). The BLM held public meetings on the Draft EIS and subsistence-related hearings to receive comments on the Draft EIS and the project's potential to impact subsistence resources and activities. The Final EIS considers those comments.

DATES: The BLM will publish the Record of Decision for the project no earlier than 30 days following the date the Environmental Protection Agency publishes its Notice of Availability of the Final EIS in the **Federal Register**.

ADDRESSES: The Final EIS and documents pertinent to this proposal are available for review on the BLM ePlanning project website at *https://eplanning.blm.gov/eplanning-ui/project/2018002/510,* and in-person at the BLM Anchorage Field Office, and at the BLM Alaska State Office, BLM Alaska Public Information Center.

FOR FURTHER INFORMATION CONTACT: Racheal Jones, BLM Project Manager, telephone (907) 290–0307; address ANCSA 17(d)(1) EIS, BLM Anchorage District Office, Attn: Racheal Jones, 4700 BLM Road, Anchorage, Alaska 99507; email *rajones@blm.gov.* Individuals in the United States who are deaf, blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Ms. Jones. 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: The U.S. Department of the Interior (DOI), BLM Alaska State Office, prepared this EIS to evaluate the effects of any Secretarial decision to revoke withdrawals established following enactment of ANCSA Section 17(d)(1) affecting the lands described in Public Land Order (PLO) Nos. 7899 through 7903. The potential revocation of these 17(d)(1) withdrawals is hereafter referred to as the 2021 Action. PLO Nos. 7900, 7901, 7902, and 7903, which would revoke withdrawals on lands in the Ring of Fire, Bay, Bering Sea-Western Interior, and East Alaska planning areas, respectively, were signed on January 15 and 16, 2021; however, they were never published in the **Federal Register**. PLO No. 7899, which would revoke withdrawals on lands in the Kobuk-Seward Peninsula planning area, was signed on January 11, 2021, and published in the **Federal Register** on January 19, 2021 (86 FR 5236). Subsequently, the DOI identified certain procedural and legal defects in the decision-making process for these PLOs, as described in the April 16, 2021, **Federal Register** notice (86 FR 20193), including insufficient analysis under NEPA. The DOI extended the opening order for PLO No. 7899 until August 31, 2024, to provide an opportunity to review the decision and to ensure the orderly management of the public lands (88 FR 21207). The BLM used this time to address identified deficiencies and to update the NEPA analysis.

The 2021 Action under review is revocation of the ANCSA 17(d)(1) withdrawals as described in PLO No. 7899, 7900, 7901, 7902, and 7903, affecting approximately 28 million acres in total. This EIS evaluates the resource conditions on these lands and incorporates and describes additional coordination with other Federal agencies; State and local governments; Federally recognized Tribes; Alaska Native Corporations; and other stakeholders to ensure that the environmental analyses previously conducted are updated and expanded upon as appropriate. This additional analysis is necessary to ensure display of the impacts of revocation of the ANCSA 17(d)(1) withdrawals; to correct errors in the previous decision-making process regarding these withdrawals; and to ensure that opening these lands is consistent with the purposes of ANCSA 17(d)(1), which requires that ''the public interest in these lands is properly protected,'' including factors such as subsistence hunting and fishing, habitat connectivity, protection of cultural resources, and protection of threatened and endangered species. This evaluation is needed to make an informed public interest determination to support revocation in full, revocation in part, or retention in full of the ANCSA 17(d)(1) withdrawals.

The BLM considered alternatives that represent retention or revocation of the 17(d)(1) withdrawals and different configurations of the areas affected in each of the five planning areas (Bay, Bering Sea-Western Interior, East Alaska, Kobuk-Seward, and Ring of Fire). Each of the alternatives identifies 17(d)(1) withdrawals in the five planning areas as retained or revoked. The alternatives range from retaining

the withdrawals on all lands (Alternative A) to revoking the withdrawals on all lands (Alternative D). Alternatives B and C include partial revocations based on natural resource factors. Full or partial revocation of the ANCSA 17(d)(1) withdrawals would result in changes to land use that could affect local residents, wildlife, vegetation, cultural resources, subsistence, and recreation. No development plans have been submitted, and no stipulations are attached to selected lands that would prevent any specific development from taking place. Therefore, the EIS provides a reasonably foreseeable development scenario that identifies and quantifies potential development activity in the decision area, including the extraction of leasable, locatable, and salable minerals, as well as the establishment of associated rights-of-way, assuming the land is not withdrawn from availability for such activities.

Section 810 of the Alaska National Interest Lands Conservation Act (ANILCA) requires the BLM to evaluate the effects of the alternatives presented in the Final EIS on subsistence uses and needs and to hold public hearings if it finds that any alternative may significantly restrict subsistence uses.

The BLM found in the evaluation of subsistence impacts that Alternatives B, C, or D, in combination with the cumulative case as analyzed in the Draft EIS, may significantly restrict subsistence uses in many communities. Therefore, the BLM held public hearings on subsistence resources and activities in conjunction with the public meetings on the Draft EIS in the vicinity of potentially affected communities. In consideration of public comments received on the Draft EIS and at the public hearings, the BLM revised the ANILCA Section 810 evaluation, published as Appendix C of the Final EIS, but did not change its ''may significantly restrict subsistence uses'' findings for the identified communities.

The input of Alaska Native Tribes and Corporations is of critical importance to this EIS. Therefore, during the NEPA process, the BLM consulted with potentially affected Federally recognized Tribes on a government-to-government basis, and with affected Alaska Native Corporations in accordance with Executive Order 13175, as well as Public Law 108–199, Div. H, sec. 161, 118 Stat. 452, as amended by Public Law 108–447, Div. H, sec. 518, 118 Stat. 3267, and other Department and Bureau policies.

(Authority: 40 CFR 1506.6(b))

Steven M. Cohn,

State Director.

[FR Doc. 2024–14658 Filed 7–3–24; 8:45 am]

BILLING CODE 4331–10–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_CO_FRN_MO4500179560]

Notice of Availability of the Proposed Resource Management Plan Amendment and Final Environmental Impact Statement for the Gunnison Sage-Grouse (Centrocercus minimus), Colorado and Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLMPA), the Bureau of Land Management (BLM) has prepared a proposed resource management plan (RMP) amendment and final environmental impact statement (EIS) for the Gunnison Sage-Grouse (*Centrocercus minimus*) and by this notice is announcing the start of a 30-day protest period of the proposed RMP amendment.

DATES: This notice announces the beginning of a 30-day protest period to the BLM on the proposed RMP amendment. Protests must be postmarked or electronically submitted on the BLM's ePlanning site within 30 days of the date that the Environmental Protection Agency (EPA) publishes its Notice of Availability (NOA) in the **Federal Register**. The EPA usually publishes its NOAs on Fridays.

ADDRESSES: The proposed RMP amendment and final EIS is available on the BLM ePlanning project website at *https://eplanning.blm.gov/eplanning-ui/project/2019031/510.* Documents pertinent to this proposal may also be examined at the Grand Junction, Uncompahgre, Tres Rios, Gunnison, San Luis Valley, Moab, and Monticello Field Offices.

Instructions for filing a protest with the BLM for the Gunnison Sage-Grouse (*Centrocercus minimus*) RMP amendment can be found at: *https://www.blm.gov/programs/planning-and-nepa/public-participation/filing-a-plan-protest* and at 43 CFR 1610.5–2. All protests must be submitted in writing by one of the following methods:

Website: https://eplanning.blm.gov/eplanning-ui/project/2019031/510.

Regular mail and overnight mail: BLM Director, Attention: Protest Coordinator (HQ210), Denver Federal Center, Building 40 (Door W–4), Lakewood, CO 80215.

FOR FURTHER INFORMATION CONTACT: Gina Phillips, Project Manager, BLM Colorado, telephone 970–589–9852; BLM Southwest District Office, 2465 S. Townsend Ave., Montrose, CO 81401; email *BLM_CO_GUSG_RMPA@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 for contacting Ms. Phillips. 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: The RMP amendment would change the following existing plans.

Colorado

- Canyons of the Ancients National Monument RMP (2010)
- Dominguez-Escalante National Conservation Area RMP (2017)
- Grand Junction Field Office RMP (2015)
- Gunnison Gorge National Conservation Area RMP (2004)
- Gunnison Resource Area RMP (1993)
- McInnis Canyons National Conservation Area RMP (2004)
- San Luis Resource Area RMP (1991)
- Tres Rios Field Office RMP (2015)
- Uncompahgre Field Office RMP (2020)

Utah

- Moab Field Office RMP (2008)
- Monticello Field Office RMP (2008)

The Gunnison Sage-Grouse RMP amendment updates management decisions and actions to promote Gunnison sage-grouse recovery and maintain and enhance habitat, as identified in the 2020 U.S. Fish and Wildlife Service (USFWS) Recovery Plan, across the eight currently recognized populations in southwest Colorado and southeast Utah. Gunnison sage-grouse is federally listed as a threatened species under the Endangered Species Act (ESA) (16 U.S.C. 1531–1544).

Planning Area

The planning area spans portions of 19 Colorado Counties: Alamosa, Archuleta, Conejos, Costilla, Delta, Dolores, Garfield, Gunnison, Hinsdale,

La Plata, Mesa, Mineral, Montezuma, Montrose, Ouray, Rio Grande, Saguache, San Juan, and San Miguel; and two Utah Counties: Grand and San Juan; and encompasses approximately 25 million acres of public land.

Purpose and Need

The BLM's purpose consists of the following:

- Promote the recovery of the threatened Gunnison sage-grouse and maintain and enhance BLM-administered occupied and unoccupied habitat upon which the species depends, while continuing to manage the land wherever possible for multiple use and sustained yield;
- Ensure management actions on BLM-administered lands support conservation goals for Gunnison sage-grouse and their habitat;
- Ensure that BLM management aligns with current science and data; relevant Federal, State, and local decisions supporting recovery; the Department of the Interior Climate Action Plan; and the USFWS Final Recovery Plan for Gunnison Sage-Grouse and Recovery Implementation Strategy for Gunnison Sage-Grouse (*Centrocercus minimus*); and
- Provide consistent guidance for addressing threats to Gunnison sage-grouse populations and their habitat.

This BLM action is necessary to accomplish the following:

- Address the range-wide downward population trend of Gunnison sage-grouse since 2014 and address issues related to land management that may affect occupied and unoccupied habitat;
- Respond to the ESA section 7(a)(1) (16 U.S.C. 1536(a)(1)) requirement that the BLM use its authority to further the purposes of the ESA by implementing management actions for the conservation of federally listed species and the ecosystems upon which they depend; and
- Respond to changing ecological and climate conditions affecting BLM-administered lands, including drought, habitat loss and fragmentation, reduced riparian areas, and more frequent wildland fires.

Alternatives Considered, Including the Proposed Plan Alternative

The BLM analyzed six alternatives in detail, including the no action alternative. This land use plan amendment addresses management actions impacting, or with the potential to impact, Gunnison sage-grouse and occupied and unoccupied habitat in the decision area. The decision area consists of approximately 2,182,660 acres of BLM-managed surface lands (1,951,440 acres in Colorado and 231,220 acres in Utah) and 2,852,390 acres of Federal subsurface mineral estate (2,563,220 acres in Colorado and 289,170 acres in Utah). Alternative A (No Action Alternative—Current Management) would continue current BLM management direction in the 11 administrative units in the planning area.

Alternative B would prioritize removing identified threats within occupied and unoccupied habitat and reduce impacts within the decision area, which includes a 4-mile buffer around habitat and potential linkage-connectivity areas to the maximum extent allowable. Alternative B contains two sub-alternatives for livestock grazing management actions in response to recommendations made in public scoping comments. Alternative B would designate all nominated Areas of Critical Environmental Concern (ACECs) that meet relevance and importance criteria.

Alternative C would minimize, mitigate, or compensate for impacts from resource uses and activities in occupied and unoccupied habitat. No new ACECs would be designated under Alternative C.

Alternative D would allocate resource uses and conserve resource values while sustaining and enhancing ecological integrity across the decision area and designate a specific subset of nominated ACECs. Conservation measures focus on occupied and unoccupied habitat that includes a 1-mile buffer around habitat and could extend to linkage-connectivity areas.

Alternative E considers adopting applicable management direction from the interagency Candidate Conservation Agreement for the Gunnison sage-grouse, Gunnison Basin Population.

Alternative F (proposed plan amendment) was developed in response to public comments on the draft RMP amendment/EIS and, similar to Alternative D, focuses conservation measures on occupied and unoccupied habitat. For all populations, Alternative F would apply buffers to all lek statuses (active, inactive, historic, unknown, occupied, and unoccupied) and manage with the objective of no increase in net surface disturbance; and it proposes management to increase available habitat for all Gunnison sage-grouse populations.

The BLM considered three additional alternatives but dismissed them from detailed analysis as explained in section 2.1.2.2 of the proposed RMP amendment/EIS.

Public Involvement

The BLM published a notice of intent in the **Federal Register** to initiate the public scoping period for this planning effort on July 6, 2022 (87 FR 40262). The BLM hosted four public scoping meetings (in Dove Creek, CO and Gunnison, CO) and two virtual public meetings to solicit nominations for ACECs, identify the scope of issues to be addressed in the RMP amendment, and gather input to assist in formulating a reasonable range of alternatives. The resource concerns identified during the scoping process included Gunnison sage-grouse habitat, vegetation, livestock grazing management, mineral development, renewable energy development, wildland fire ecology and management, ACECs, recreation, lands and realty, air resources, soil resources, lands with wilderness characteristics, and social and economic conditions.

After preparing the draft RMP amendment/EIS in coordination with 30 cooperating agencies and working with Tribes, the BLM announced the 90-day comment period through publication of its NOA in the **Federal Register** on November 9, 2023 (88 FR 77353). During the comment period, the BLM held two in-person public meetings (in Dove Creek, CO and Gunnison, CO) and one virtual public meeting to inform the public and solicit comments on the draft documents. The BLM received 141 comment letters (including 115 unique letters and 26 form, form plus, or duplicate letters) during the comment period. The BLM reviewed all letters submitted, analyzed the comments, considered substantive comments, and revised the RMP amendment/EIS accordingly. Comments and responses are attached as Appendix W in the proposed RMP amendment/EIS.

Changes Between Draft RMP Amendment and Proposed RMP Amendment

Based on public comments received on the draft RMP amendment/draft EIS, the BLM updated the proposed RMP amendment/final EIS (Alternative F) by incorporating management actions and allowable uses from Alternatives A, B, C, D, and E, including corrections and rewording for clarification of purpose and intent. Language throughout the document was revisited for readability and to meet the required page limits for an EIS. In consideration of comments received, the following management was updated in Alternative F:

- Uses would be avoided in buffer distances for all Gunnison sage-grouse lek statuses (active, inactive, historic,

unknown in Colorado, occupied, and unoccupied in Utah);

- Objectives and management for net surface disturbance rather than disturbance caps were clarified;
- Management for Gunnison sage-grouse satellite populations was recognized as different in some aspects from the Gunnison Basin population under Lands and Realty and Recreation;
- Management in the current and proposed ACECs was refined, and a new Backcountry Conservation Area would be designated; and
- Appendices were also developed and expanded upon.

Protest of the Proposed RMP Amendment

The BLM planning regulations state that any person who participated in the preparation of the RMP and has an interest that will or might be adversely affected by approval of the proposed RMP amendment may protest its approval to the BLM. Protest on the proposed RMP amendment constitutes the final opportunity for administrative review of the proposed land use planning decisions prior to the BLM adopting an approved RMP amendment. Instructions for filing a protest with the BLM regarding the proposed RMP amendment may be found online (see **ADDRESSES**). All protests must be in writing and mailed to the appropriate address or submitted electronically through the BLM ePlanning project website (see **ADDRESSES**). Protests submitted electronically by any means other than the ePlanning project website will be invalid unless a hard copy of the protest is also submitted. The BLM will render a written decision on each protest. The protest decision of the BLM shall be the final decision of the Department of the Interior. Responses to valid protest issues will be compiled and documented in a Protest Resolution Report made available following the protest resolution online at: *https://www.blm.gov/programs/planning-and-nepa/public-participation/protest-resolution-reports.* Upon resolution of protests, the BLM will issue a Record of Decision and approved RMP amendment.

Before including your phone number, email address, or other personal identifying information in your protest you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2; 43 CFR 1610.5)

Douglas J. Vilsack,

State Director.

[FR Doc. 2024–14531 Filed 7–3–24; 8:45 am]

BILLING CODE 4331–16–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1629–1631, 1633, 1636–1638, and 1640 (Final)]

Mattresses From Bosnia and Herzegovina, Bulgaria, Burma, Italy, Philippines, Poland, Slovenia, and Taiwan; Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of mattresses from Bosnia and Herzegovina, Bulgaria, Burma, Italy, Philippines, Poland, Slovenia, and Taiwan, provided for in subheadings 9404.21.00, 9404.29.10, and 9404.29.90 of the Harmonized Tariff Schedule of the United States, that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV'').[2] [3]

Background

The Commission instituted these investigations effective July 28, 2023, following receipt of petitions filed with the Commission and Commerce by Brooklyn Bedding LLC, Phoenix, Arizona; Carpenter Company, Richmond, Virginia; Corsicana Mattress Company, Dallas, Texas; Future Foam, Inc., Council Bluffs, Iowa; FXI, Inc., Radnor, Pennsylvania; Kolcraft Enterprises, Inc., Chicago, Illinois; Leggett & Platt, Incorporated, Carthage, Missouri; Serta Simmons Bedding, Inc., Doraville, Georgia; Southerland Inc., Antioch, Tennessee; Tempur Sealy International, Inc., Lexington, Kentucky; the International Brotherhood of Teamsters, Washington, DC; and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, Washington, DC. The Commission scheduled the final phase of the investigations following notification of preliminary determinations by Commerce that imports of mattresses from Bosnia and Herzegovina, Bulgaria, Burma, Italy, Philippines, Poland, Slovenia, and Taiwan were being sold at LTFV within the meaning of § 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of March 6, 2024 (89 FR 16026). The Commission conducted its hearing on May 9, 2024. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to § 735(b) of the Act (19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on June 28, 2024. The views of the Commission are contained in USITC Publication 5520 (June 2024), entitled *Mattresses from Bosnia and Herzegovina, Bulgaria, Burma, Italy, Philippines, Poland, Slovenia, and Taiwan: Investigation Nos. 731–TA–1629–1631, 1633, 1636–1638, and 1640 (Final).*

By order of the Commission.

Issued: June 28, 2024.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2024–14697 Filed 7–3–24; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 89 FR 42448 (Bosnia and Herzegovina), 89 FR 42443 (Bulgaria), 89 FR 42427 (Burma), 89 FR 42429 (Italy), 89 FR 42432 (Philippines), 89 FR 42435 (Poland), 89 FR 42437 (Slovenia), 89 FR 42439 (Taiwan), May 15, 2024.

[3] The Commission finds that imports subject to Commerce's affirmative critical circumstances determinations on Burma are likely to undermine seriously the remedial effect of the antidumping duty order. Commissioner David S. Johanson dissents with respect to the Commission's affirmative critical circumstances finding on imports of mattresses from Burma. The Commission also finds that imports subject to Commerce's affirmative critical circumstances determinations on Bosnia and Herzegovina, Italy, Philippines, and Taiwan are not likely to undermine seriously the remedial effect of the antidumping duty orders. Commissioner Jason E. Kearns dissents with respect to the Commission's negative critical circumstances finding on imports of mattresses from Bosnia and Herzegovina.

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Arts Advisory Panel Meetings

AGENCY: National Endowment for the Arts, National Foundation on the Arts and the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that 9 meetings of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference or videoconference.

DATES: See the **SUPPLEMENTARY INFORMATION** section for individual meeting times and dates. All meetings are Eastern time and ending times are approximate:

ADDRESSES: National Endowment for the Arts, Constitution Center, 400 7th St. SW, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Further information with reference to these meetings can be obtained from David Travis, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; *travisd@arts.gov,* or call 202–682–5001.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chair of March 11, 2022, these sessions will be closed to the public pursuant to 5 U.S.C. 10.

The upcoming meetings are:

Folk and Traditional Arts (review of applications): This meeting will be closed.

Date and time: August 1, 2024; 2:00 p.m. to 4:00 p.m.

National Heritage Fellowships (review of applications): This meeting will be closed.

Date and time: August 6, 2024; 1:00 p.m. to 3:00 p.m.

Literary Arts (review of applications): This meeting will be closed.

Date and time: August 7, 2024; 1:00 p.m. to 3:00 p.m.

Literary Arts (review of applications): This meeting will be closed.

Date and time: August 8, 2024; 12:00 p.m. to 2:00 p.m.

National Heritage Fellowships (review of applications): This meeting will be closed.

Date and time: August 8, 2024; 1:00 p.m. to 3:00 p.m.

Literary Arts (review of applications): This meeting will be closed.

Date and time: August 8, 2024; 3:00 p.m. to 5:00 p.m.

Literature Fellowships: Translation (review of applications): This meeting will be closed.

Date and time: August 14, 2024; 1:00 p.m. to 3:00 p.m.

Literature Fellowships: Translation (review of applications): This meeting will be closed.

Date and time: August 15, 2024; 1:00 p.m. to 3:00 p.m.

Literature Fellowships: Creative Writing (review of applications): This meeting will be closed.

Date and time: September 13, 2024; 1:00 p.m. to 3:00 p.m.

Dated: July 1, 2024.

David Travis,

Specialist, National Endowment for the Arts.

[FR Doc. 2024–14726 Filed 7–3–24; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by August 5, 2024. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314 or *ACApermits@nsf.gov.*

FOR FURTHER INFORMATION CONTACT: Andrew Titmus, ACA Permit Officer, at the above address, 703–292–4479.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 671), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Application Details

Permit Application: 2025–004

1. *Applicant:* Heather Liwanag, California Polytechnic State University, Department of Biological Sciences, 1 Grand Avenue, San Luis Obispo, CA 93407–0401.

Activity for Which Permit is Requested: Import into USA. The applicant seeks an Antarctic Conservation Act permit to import samples comprising oral swabs, rectal swabs, and serum from 36 adult Weddell seals (*Leptonychotes weddellii*). The samples were collected in 2019 and 2020 by the New Zealand Antarctic program as part of a collaborative disease investigation study. The samples complement additional samples collected by the applicant in 2017 and 2019 under ACA permit 2018–013M#1. The previously collected samples have been stored at McMurdo Station, Antarctica since collection. The samples will assist in investigating the cause of lesions observed in seals during prior fieldwork.

Location: None.

Dates of Permitted Activities: September 01, 2024–August 31, 2025.

Permit Application: 2025–005

2. *Applicant:* Zheng Wang, Center for Biomolecular Science and Engineering, US Naval Research Laboratory, 4555 Overlook Ave. SW, Washington, DC 20375.

Activity for Which Permit is Requested: Introduce Non-Indigenous Species into Antarctica, Import into USA, Export from USA. The applicant seeks an Antarctic Conservation Act permit to introduce desiccated spores of four Aspergillus niger strains in Antarctica in order to study the biological effects of cosmic ionizing radiation. The desiccated spores are incapable of growing or dispersing and will be plated onto quartz coupons and glued into a box, which would be assembled in the USA and shipped to McMurdo Station, Antarctica. The samples will be loaded onto a payload of a NASA Long Duration Balloon to be flown over the Antarctic continent at an altitude of 115,000–160,000 ft for approximately 8–15 days. Anticipated flight window would be in December, 2024. Upon termination of the flight, the payload would be recovered from the field and transported back to McMurdo Station. The box containing the desiccated spores would then be shipped back to the USA for analysis.

Location: McMurdo Station, Antarctica.

Dates of Permitted Activities: October 15, 2024–April 1, 2025.

Permit Application: 2025–006

3. *Applicant:* Paul Ponganis, CMBB, Scripps Institution of Oceanography, UCSD, La Jolla, CA 92093–0204.

Activity for Which Permit is Requested: Take, Harmful Interference, Enter Antarctic Specially Protected Area, Import into USA. The applicant requests an Antarctic Conservation Act permit authorizing take and harmful interference associated with ongoing research examining the oxygen transport systems of emperor penguins (*Aptenodytes forsteri*) in Antarctica. The applicant proposes capturing up to 35 non-breeding or sub-adult penguins from the McMurdo Sound region or, if necessary, in Cape Washington (ASPA 173). The applicant will access ASPA 173 by fixed-wing aircraft in accordance with the ASPA management plan. Throughout the course of the physiology study, penguins will be kept captive on the sea ice, but will be allowed to dive and forage at will. Research activities involve the administration of general anesthesia and the attachment of instrumentation to measure oxygen levels, heart rate/stroke rate, and dive depth/activity. In some penguins, blood samples may be collected during dives. RNA will be isolated from up to 20 samples and imported into the USA. At the end of each dive study, equipment will be removed, and the penguins will be released at the McMurdo Sea ice edge, where they will be able to rejoin nearby colonies.

Location: McMurdo Sound, ASPA 173–Cape Washington and Silverfish Bay.

Dates of Permitted Activities: October 1, 2024–December 20, 2024.

Kimiko S. Bowens-Knox,

Program Analyst, Office of Polar Programs.

[FR Doc. 2024–14705 Filed 7–3–24; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 72–1041, 50–498, and 50–499; NRC–2024–0104]

South Texas Project Nuclear Operating Company; South Texas Project Electric Generating Station, Units 1 and 2; Independent Spent Fuel Storage Installation; Exemption

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) issued an exemption to South Texas Project Nuclear Operating Company permitting South Texas Project Electric Generating Station to shuffle (relocate) 10 already loaded model 37 multi-purpose canisters (MPC) with continuous basket shims (MPC–37–CBS) in January 2025 and to load two new MPC–37–CBS in the HI–STORM Flood/Wind MPC Storage System at its South Texas Project Electric Generating Station, Units 1 and 2 independent spent fuel storage installation in a storage condition where the terms, conditions, and specifications in the Certificate of Compliance No. 1032, Amendment No. 2, are not met.

DATES: The exemption was issued on June 26, 2024.

ADDRESSES: Please refer to Docket ID NRC–2024–0104 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2024–0104. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Yen-Ju Chen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone: 301–415–1018; email: *Yen-Ju.Chen@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated: July 1, 2024.

For the Nuclear Regulatory Commission.

Yoira Diaz-Sanabria,

Chief, Storage and Transportation Licensing Branch, Division of Fuel Management, Office of Nuclear Material Safety, and Safeguards.

Attachment—Exemption

Nuclear Regulatory Commission

Docket Nos. 72–1041, 50–498, and 50–499

South Texas Project Nuclear Operating Company

South Texas Project Electric Generating Station Units 1 and 2

Independent Spent Fuel Storage Installation

I. Background

South Texas Project Nuclear Operating Company (STPNOC) is the holder of Facility Operating License Nos. NPF–76 and NPF–80, which authorize operation of the South Texas Project Electric Generating Station (STP), Units 1 and 2 in Bay City, Texas, pursuant to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities.'' The licenses provide, among other things, that the facility is subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC) now or hereafter in effect.

Consistent with 10 CFR part 72, subpart K, ''General License for Storage of Spent Fuel at Power Reactor Sites,'' a general license is issued for the storage of spent fuel in an Independent Spent Fuel Storage Installation (ISFSI) at power reactor sites to persons authorized to possess or operate nuclear power reactors under 10 CFR part 50. STPNOC is authorized to operate nuclear power reactors under 10 CFR part 50 and holds a 10 CFR part 72 general license for storage of spent fuel at the STP ISFSI. Under the terms of the general license, STPNOC stores spent fuel at its STP ISFSI using the HI–STORM Flood/Wind (FW) Multi-Purpose Canister (MPC) Storage System in accordance with Certificate of Compliance (CoC) No. 1032, Amendment No. 2.

II. Request/Action

By a letter dated May 7, 2024 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML24128A157), and

supplemented on March 15, 2024 (ML24136A284), STPNOC requested an exemption from the requirements of 10 CFR 72.212(a)(2), 72.212(b)(3), 72.212(b)(5)(i), 72.212(b)(11), and 72.214 that require STP to comply with the terms, conditions, and specifications of the CoC No. 1032, Amendment No. 2 (ML16280A008). If approved, STPNOC's exemption request would accordingly allow STP to shuffle (relocate) 10 loaded and to load two Multi-Purpose Canisters (MPC) with continuous basket shims (CBS) (*i.e.,* MPC–37–CBS), an unapproved, variant basket design, in the HI–STORM FW MPC Storage System, and thus, to load the systems in a storage condition where the terms, conditions, and specifications in the CoC No. 1032, Amendment No. 2, are not met.

STPNOC currently uses the HI–STORM FW MPC Storage System under CoC No. 1032, Amendment No. 2, for dry storage of spent nuclear fuel in the MPC–37 at the STP ISFSI. Holtec International (Holtec), the designer and manufacturer of the HI–STORM FW MPC Storage System, developed a variant of the design with CBS for the MPC–37, known as MPC–37–CBS. Holtec performed a non-mechanistic tip-over analysis with favorable results and implemented the CBS variant design under the provisions of 10 CFR 72.48, ''Changes, tests, and experiments,'' which allows licensees to make changes to cask designs without a CoC amendment under certain conditions (listed in 10 CFR 72.48(c)). After evaluating the specific changes to the cask designs, the NRC determined that Holtec erred when it implemented the CBS variant design under 10 CFR 72.48, as this is not the type of change allowed without a CoC amendment. For this reason, the NRC issued three Severity Level IV violations to Holtec (ML24016A190).

STPNOC has near-term plans to shuffle (relocate) 10 already loaded MPC–37–CBS on the STP ISFSI pad in January 2025 and load two new MPC–37–CBS in the HI–STORM FW MPC Storage System in March 2025. While Holtec was required to submit a CoC amendment to the NRC to seek approval of the CBS variant design, such a process will not be completed in time to inform decisions for this near-term shuffling and loading campaign. Therefore, STPNOC submitted this exemption request in order to allow for the shuffling of 10 already loaded MPC–37–CBS in January 2025, and the future loading of two MPC–37–CBS in March 2025 at the STP ISFSI. This exemption is limited to the use of MPC–37–CBS in the HI–STORM FW MPC Storage System only for shuffling the 10 already loaded canisters and specific near-term planned loading of two new canisters using the MPC–37–CBS variant basket design.

III. Discussion

Pursuant to 10 CFR 72.7, ''Specific exemptions,'' the Commission may, upon application by any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations of 10 CFR part 72 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

A. The Exemption Is Authorized by Law

This exemption would allow STPNOC to shuffle (relocate) 10 already loaded and to load two MPC–37–CBS in the HI–STORM FW MPC Storage System, in January and March 2025, respectively, at its STP ISFSI in a storage condition where the terms, conditions, and specifications in the CoC No. 1032, Amendment No. 2, are not met. STPNOC is requesting an exemption from the provisions in 10 CFR part 72 that require the licensee to comply with the terms, conditions, and specifications of the CoC for the approved cask model it uses. Section 72.7 allows the NRC to grant exemptions from the requirements of 10 CFR part 72. This authority to grant exemptions is consistent with the Atomic Energy Act of 1954, as amended, and is not otherwise inconsistent with NRC's regulations or other applicable laws. Additionally, no other law prohibits the activities that would be authorized by the exemption. Therefore, the NRC concludes that there is no statutory prohibition on the issuance of the requested exemption, and the NRC is authorized to grant the exemption by law.

B. The Exemption Will Not Endanger Life or Property or the Common Defense and Security

This exemption would allow STPNOC to shuffle (relocate) 10 already loaded MPC–37–CBS in January 2025 and to load two MPC–37–CBS in the HI–STORM FW MPC Storage System in March 2025, at the STP ISFSI in a storage condition where the terms, conditions, and specifications in the CoC No. 1032, Amendment No. 2, are not met. In support of its exemption request, STPNOC asserts that issuance of the exemption would not endanger life or property because a tip-over or handling event is administratively controlled, and that the containment boundary would be maintained in such an event. STPNOC relies, in part, on the approach in the NRC's Safety Determination Memorandum (ML24018A085). The NRC issued this Safety Determination Memorandum to address whether, with respect to the enforcement action against Holtec regarding this violation, there was any need to take an immediate action for the cask systems that were already loaded with non-compliant basket designs. The Safety Determination Memorandum documents a risk-informed approach concluding that, during the design basis event of a non-mechanistic tip-over, the fuel in the basket in the MPC–37–CBS remains in a subcritical condition.

STPNOC also provided site-specific technical information, including information explaining why the use of the approach in the NRC's Safety Determination Memorandum is appropriate for determining the safe use of the CBS variant baskets at the STP ISFSI. Specifically, STPNOC described that the analysis of the tip-over design basis event that is relied upon in the NRC's Safety Determination Memorandum, which demonstrates that the MPC confinement barrier is maintained, is documented in the updated final safety analysis report (UFSAR) for the HI–STORM FW MPC Storage System CoC No. 1032, Amendment 2, that is used at the STP site. STPNOC stated the transporter for handling of the HI–STORM FW MPC Storage System at the STP ISFSI meets the design requirements described in the CoC No. 1032 technical specifications 5.2.c.

Additionally, STPNOC provided specific information from STP's 72.212 Evaluation Report, Revision 3, indicating the calculated dose rate is in compliance with 10 CFR 72.104(a), ''Criteria for radioactive materials in effluents and direct radiation from an ISFSI or MRS.'' The analysis of a design basis accident scenario also demonstrates compliance with 72.106, ''Controlled area of an ISFSI or MRS.'' Specifically, STPNOC stated that, as described in section 12.2 of HI–STORM FW MPC Storage System UFSAR, there are no accidents which could significantly affect shielding effectiveness of the HI–STORM FW MPC Storage System. Coupled with the distance of the STP ISFSI to the site area boundary, STPNOC concluded that compliance with 72.104 and 72.106 is not impacted by approving this exemption request.

The NRC staff reviewed the information provided by STPNOC and concludes that issuance of the exemption would not endanger life or property because the administrative controls STPNOC has in place at the

STP ISFSI sufficiently minimize the possibility of a tip-over or handling event, and that the containment boundary would be maintained in such an event. The staff confirmed that these administrative controls comply with the technical specifications and UFSAR for the HI–STORM FW MPC Storage System CoC No. 1032, Amendment 2, that is used at the STP site. In addition, the staff confirmed that the information provided by STPNOC regarding STP's 72.212 Evaluation Report, Revision 3, demonstrates that the consequences of normal and accident conditions would be within the regulatory limits of the 10 CFR 72.104 and 10 CFR 72.106. The staff also determined that the requested exemption is not related to any aspect of the physical security or defense of the STP ISFSI; therefore, granting the exemption would not result in any potential impacts to common defense and security.

For these reasons, the NRC staff has determined that under the requested exemption, the storage system will continue to meet the safety requirements of 10 CFR part 72 and the offsite dose limits of 10 CFR part 20 and, therefore, will not endanger life or property or the common defense and security.

C. The Exemption Is Otherwise in the Public Interest

The proposed exemption would allow STPNOC to shuffle (relocate) 10 already loaded MPC–37–CBS in the HI–STORM FW MPC Storage System on the ISFSI pad at the STP ISFSI in January 2025, and load two MPC–37–CBS in the HI–STORM FW MPC Storage System in March 2025 at the STP ISFSI, even though the CBS variant basket design is not part of the approved CoC No. 1032, Amendment No. 2. According to STPNOC, the exemption is in the public interest because being able to load the two MPC–37–CBS will ensure adequate full core offload margin that is necessary for completing refueling outages, implementing enterprise projects, and sustaining safe and efficient operation of the nuclear facilities. STPNOC stated that the full core offload margin was adversely impacted when STP could not load the two MPC–37–CBS canisters in its 2022 campaign. Further delay in the loading campaign would further impact the full core offload margin, and STPNOC would lose its ability to refuel the operating reactor. In addition, each fuel bundle contributes to the decay heat removal demand on the spent fuel pool cooling system, and removing the spent fuel bundles from the pool would allow for dispersion of the remaining heat load and reduce the consequence of a design basis accident associated with a loss of spent fuel pool cooling event. A crowded pool would also increase the likelihood of a fuel handling accident based on the additional fuel moves required to manage spent fuel pool loading with extra assemblies in the pool. STPNOC further stated that the shuffling (relocating) of the 10 already loaded MPC–37–CBS is necessary to optimize available space on the STP ISFSI pad for cask transporter maneuverability and minimize long-term damage to the STP ISFSI pad from cask transporter use, and thus ensures long-term safe storage of fuel-loaded spent fuel storage canisters. The shuffling also provides additional shielding to plant structures (such as warehouses and fabrication shops which are to the south of the STP ISFSI pad) by moving the spent fuel storage canisters with higher calculated dose rates (*i.e.,* those loaded in MPC–37–CBS) further north from the plant structures and also by placing the canisters with lower dose rate between the plant structures and MPC–37–CBS canisters.

STPNOC has considered procuring empty MPC–37 canisters from other utilities; however, STP's fuel assemblies are longer than fuel assemblies of other utilities that load the MPC–37 model. Therefore, procuring MPC–37 canisters from other utilities is not an option.

STPNOC has also considered procuring new MPC–37 canisters from the vendor and confirmed the approximate delivery would be in April 2025, which is after the planned March 2025 loading campaign. The loading campaigns are scheduled, budgeted, and planned several years in advance based on planned refueling outages, new fuel receipts, and other enterprise-level projects while considering the availability of specialty resources (equipment, vendors) to complete a campaign. Any delay to the March 2025 loading campaign would have cascading impacts to future new fuel receipts, refueling outages, and other enterprise projects. STPNOC asserted that delaying loading the two canisters beyond 2025 would result in loading these two canisters during the next scheduled loading campaign in 2028. Then, the number of canisters to be loaded would increase even more based on the new criticality analysis for the spent fuel pools to accommodate the planned storage of accident tolerant fuel.

For the reasons described by STPNOC in the exemption request, as supplemented, the NRC agrees that it is in the public interest to grant the exemption. If the exemption is not granted, in order to comply with the CoC, STPNOC would have to keep the loaded MPC–37–CBS at the current location on the STP ISFSI pad, and would have to keep spent fuel in the spent fuel pool since it is not permitted to be loaded into MPC–37–CBS. This would impact STPNOC's ability to manage the full core offload margin in STP's spent fuel pool, resulting in undesirable cascading impacts to new fuel receipts, refueling outages, other enterprise projects, and potentially safe reactor operation. Denying the exemption request could also challenge the cask transporter maneuverability on the STP ISFSI pad, and thus increase the use of a cask transporter on the STP ISFSI pad, which could increase the long-term damage to the STP ISFSI pad and result in likely longer personnel radiation exposure from increased cask transporter use.

Therefore, the staff concludes that approving the exemption is in the public interest.

Environmental Consideration

The NRC staff also considered whether there would be any significant environmental impacts associated with the exemption. For this proposed action, the NRC staff performed an environmental assessment pursuant to 10 CFR 51.30. The environmental assessment concluded that the proposed action would not significantly impact the quality of the human environment. The NRC staff concluded that the proposed action would not result in any changes in the types or amounts of any radiological or non-radiological effluents that may be released offsite, and there would be no significant increase in occupational or public radiation exposure because of the proposed action. The environmental assessment and the finding of no significant impact was published on June 26, 2024 (89 FR 53452).

IV. Conclusion

Based on these considerations, the NRC has determined that, pursuant to 10 CFR 72.7, the exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest. Therefore, the NRC grants STPNOC an exemption from the requirements of §§ 72.212(a)(2), 72.212(b)(3), 72.212(b)(5)(i), 72.212(b)(11), and 72.214 with respect to the shuffling of 10 MPC–37–CBS in the HI–STORM FW MPC Storage System in January 2025 and the future loading in the HI–STORM FW MPC Storage System of two MPC–37–CBS in March 2025.

This exemption is effective upon issuance.

Dated: June 26, 2024.

For the Nuclear Regulatory Commission.

/RA/

Christian Jacobs,

Acting Chief, Storage and Transportation Licensing Branch, Division of Fuel Management, Office of Nuclear Material Safety, and Safeguards.

[FR Doc. 2024–14715 Filed 7–3–24; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: USAJOBS Resume Builder and Application Profile, OMB Control No. 3206–0219

AGENCY: Office of Personnel Management (OPM).

ACTION: 30-Day notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, OPM is proposing revisions to a currently approved information collection, USAJOBS Resume Builder and Application Profile, OMB Control No. 3206–0219.

DATES: Comments are encouraged and will be accepted until August 5, 2024. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Office of Personnel Management'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to this information collection activities, please contact. Human Resources Solution, Office of Personnel Management, 1900 E Street NW, Washington, DC 20415, Attention: Cori Schauer, or via electronic mail to *USAJOBSEngagement@opm.gov* or 202–606–1800.

SUPPLEMENTARY INFORMATION: OPM, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the public with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Agency assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Agency's information collection requirements and provide the requested data in the desired format. OPM is soliciting comments on the proposed information collection request (ICR) that is described below. This information collection was previously published in the **Federal Register** on April 16, 2024, at 88 FR 74540 allowing for a 60-day public comment period. No comments were received for this information collection.

The purpose of this notice is to allow an additional 30 days for public comments.

The Agency is especially interested in public comment addressing the following issues: (1) whether this collection is necessary to the proper functions of the Agency; (2) whether this information will be processed and used in a timely manner; (3) the accuracy of the burden estimate; (4) ways in which the Agency may enhance the quality, utility, and clarity of the information to be collected; and (5) ways in which the Agency may minimize the burden of this collection on the respondents, including through the use of information technology. Written comments received in response to this notice will be considered public records.

Analysis

Agency: Office of Personnel Management.

Title: OPM Customer Experience.

OMB Number: 3206–0219.

Affected Public: Individuals.

Number of Resumes Built in One Year: 25,725,380.

Estimated Time per Respondent: 38 minutes.

Total Burden Hours for Resume Builder: 16,206,989 hours.

Number of Profiles Created in One Year: 3,013,003.

Estimated Time per Profile: 5 minutes.

Total Burden Hours for Application Profile: 241,040 hours.

Total Burden Hours for Resume Builder and Application Profile: 16,448,029 hours.

Office of Personnel Management.

Kayyonne Marston,

Federal Register Liaison.

[FR Doc. 2024–14680 Filed 7–3–24; 8:45 am]

BILLING CODE 6325–43–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2024–391 and CP2024–399; MC2024–392 and CP2024–400; MC2024–393 and CP2024–401; MC2024–394 and CP2024–402; MC2024–395 and CP2024–403; MC2024–396 and CP2024–404; MC2024–397 and CP2024–405]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 9, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://*

www.prc.gov). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2024–391 and CP2024–399; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 130 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* June 28, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* July 9, 2024.

2. *Docket No(s).:* MC2024–392 and CP2024–400; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 131 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* June 28, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* July 9, 2024.

3. *Docket No(s).:* MC2024–393 and CP2024–401; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 132 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* June 28, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* July 9, 2024.

4. *Docket No(s).:* MC2024–394 and CP2024–402; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 133 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* June 28, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* July 9, 2024.

5. *Docket No(s).:* MC2024–395 and CP2024–403; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 134 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* June 28, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* July 9, 2024.

6. *Docket No(s).:* MC2024–396 and CP2024–404; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 135 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* June 28, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Almaroof Agoro; *Comments Due:* July 9, 2024.

7. *Docket No(s).:* MC2024–397 and CP2024–405; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 136 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* June 28, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Almaroof Agoro; *Comments Due:* July 9, 2024.

This Notice will be published in the **Federal Register**.

Jennie Jbara,

Primary Certifying Official.

[FR Doc. 2024–14744 Filed 7–3–24; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20299 and #20300; KANSAS Disaster Number KS–20004]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Kansas

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Kansas (FEMA–4774–DR), dated 04/28/2024.

Incident: Severe Winter Storm.

Incident Period: 01/08/2024 through 01/16/2024.

DATES: Issued on 06/27/2024.

Physical Loan Application Deadline Date: 06/27/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 01/28/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Kansas, dated 04/28/2024, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Marion.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–14770 Filed 7–3–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20303 and #20304; OKLAHOMA Disaster Number OK–20001]

Presidential Declaration Amendment of a Major Disaster for the State of Oklahoma

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 8.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Oklahoma (FEMA–4776–DR), dated 04/30/2024.

Incident: Severe Storms, Straight-line Winds, Tornadoes, and Flooding.

Incident Period: 04/25/2024 through 05/09/2024.

DATES: Issued on 06/25/2024.

Physical Loan Application Deadline Date: 07/31/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 01/30/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster

Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Oklahoma, dated 04/30/2024, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to 07/31/2024.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–14751 Filed 7–3–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20415 and #20416; IOWA Disaster Number IA–20005]

Presidential Declaration of a Major Disaster for the State of Iowa

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Iowa (FEMA–4796–DR), dated 06/24/2024.

Incident: Severe Storms, Flooding, Straight-line Winds, and Tornadoes.

Incident Period: 06/16/2024 and continuing.

DATES: Issued on 06/24/2024.

Physical Loan Application Deadline Date: 08/23/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 03/24/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 06/24/2024, applications for disaster loans may be submitted online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Clay, Emmet, Lyon, Plymouth, Sioux.

Contiguous Counties (Economic Injury Loans Only):

Iowa: Buena Vista, Cherokee, Dickinson, Kossuth, O'Brien, Osceola, Palo Alto, Pocahontas, Woodbury.

Minnesota: Rock, Nobles, Jackson, Martin.

South Dakota: Lincoln, Union, Minnehaha.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	5.375
Homeowners without Credit Available Elsewhere	2.688
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 204156 and for economic injury is 204160.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–14752 Filed 7–3–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20320 and #20321; TEXAS Disaster Number TX–20010]

Presidential Declaration Amendment of a Major Disaster for the State of Texas

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 9.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Texas (FEMA–4781–DR), dated 05/17/2024.

Incident: Severe Storms, Straight-line Winds, Tornadoes, and Flooding.

Incident Period: 04/26/2024 through 06/05/2024.

DATES: Issued on 06/25/2024.

Physical Loan Application Deadline Date: 08/15/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 02/18/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Texas, dated 05/17/2024, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to 08/15/2024.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–14741 Filed 7–3–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20421 and #20422; IOWA Disaster Number IA–20007]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Iowa

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Iowa (FEMA–4784–DR), dated 06/27/2024.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 05/20/2024 through 05/31/2024.

DATES: Issued on 06/27/2024.

Physical Loan Application Deadline Date: 08/26/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 03/27/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Vanessa Morgan, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street

SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 06/27/2024, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Adair, Adams, Buena Vista, Butler, Calhoun, Cedar, Cherokee, Clay, Dallas, Franklin, Hamilton, Hancock, Harrison, Humboldt, Iowa, Jackson, Jasper, Kossuth, Marshall, Mitchell, Montgomery, Muscatine, Polk, Pottawattamie, Poweshiek, Shelby, Story, Tama, Wright.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 20421C and for economic injury is 204220.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–14742 Filed 7–3–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20434 and #20435; MINNESOTA Disaster Number MN–20003]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Minnesota

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Minnesota (FEMA–4797–DR), dated 06/28/2024.

Incident: Severe Storms and Flooding.

Incident Period: 06/16/2024 and continuing.

DATES: Issued on 06/28/2024.

Physical Loan Application Deadline Date: 08/27/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 03/28/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 06/28/2024, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Blue Earth, Carver, Cass, Cook, Cottonwood, Faribault, Fillmore, Freeborn, Goodhue, Jackson, Lake, Le Sueur, Murray, Nobles, Pipestone, Rice, Rock, St. Louis, Steele, Wabasha, Waseca, Watonwan.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 204346 and for economic injury is 204350.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–14747 Filed 7–3–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20403 and #20404; FLORIDA Disaster Number FL–20006]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Florida

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Florida (FEMA–4794–DR), dated 06/17/2024.

Incident: Severe Storms, Straight-line Winds, and Tornadoes.

Incident Period: 05/10/2024.

DATES: Issued on 06/27/2024.

Physical Loan Application Deadline Date: 08/16/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 03/17/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Florida, dated 06/17/2024, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Jefferson, Santa Rosa.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–14753 Filed 7–3–24; 8:45 am]

BILLING CODE 8026–09–P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2024–0025]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections, and one new collection for OMB-approval.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB) Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974

(SSA) Social Security Administration, OLCA, Attn: Reports Clearance Director, Mail Stop 3253 Altmeyer, 6401 Security Blvd., Baltimore, MD 21235, Fax: 833–410–1631, Email address: *OR.Reports.Clearance@ssa.gov*

Or you may submit your comments online through *https://www.reginfo.gov/public/do/PRAmain* by clicking on Currently under Review—Open for Public Comments and choosing to click on one of SSA's published items. Pleas reference Docket ID Number [SSA–2024–0025] in your submitted response.

I. The information collection below is pending at SSA. SSA will submit it to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than September 3, 2024. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. *Social Security Number Verification Services—20 CFR 401.45—0960–0660.* Internal Revenue Service regulations require employers to provide wage and tax data to SSA using Form W–2, or its electronic equivalent. As part of this process, the employer must furnish the employee's name and Social Security number (SSN). In addition, the employee's name and SSN must match SSA's records for SSA to post earnings to the employee's earnings record, which SSA maintains. SSA offers the Social Security Number Verification Service (SSNVS), which allows employers to verify the reported names and SSNs of their employees match those in SSA's records. SSNVS is a cost-free, voluntary method for employers to verify employee information via the internet. SSA annotates data an employer supplies to SSA for verification that does not match SSA's records with a no match indicator and returns it to the employer. The respondents are employers who need to verify SSN data using SSA's records.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSNVS	44,891	60	2,663,460	5	221,955	* $43.65	** $9,688,336

* We based this figure on the average hourly wage for Accountants and Auditors, as reported by the U.S. Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes132011.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. *Request for Deceased Individual's Social Security Record—20 CFR 402.130—0960–0665.* The Freedom of Information Act (FOIA), at 5 U.S.C. 552(a)(3) of the U.S. Code, provides instructions for members of the public to request records from Federal Agencies. When a member of the public requests an individual's Social Security record under FOIA, SSA needs the name and address of the requestor as well as a description of the requested record to process the request. While SSA respondents may submit these requests in writing, SSA also allows for the use of Form SSA–711, Deceased Individual's Social Security Records, for FOIA requests for a deceased individual's records for genealogical research, family estate matters, and other reasons. SSA then uses the information the respondent provides on Form SSA–711, or via an internet request through SSA's electronic Freedom of Information Act Xpress (FOIAXpress) website, to: (1) verify the wage earner is deceased; and (2) access the correct Social Security record. Respondents are members of the public requesting deceased individuals' Social Security records.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office or for teleservice centers (minutes) **	Total annual opportunity cost (dollars) ***
Internet Request through FOIAXpress	49,800	1	7	5,810	* $31.48		*** $182,899
SSA–711 (paper)	200	1	7	23	* 31.48	** 21	*** 2,928
Total	50,000			5,833			*** 185,827

* We based this figure on average U.S. worker's hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm*).

** We based this figure on averaging both the average FY 2024 wait times for field offices and teleservice centers, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

II. SSA submitted the information collections below to OMB for clearance. Your comments regarding these information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than August 5, 2024. Individuals can obtain copies of these OMB clearance packages by writing to the *OR.Reports.Clearance@ssa.gov.*

1. Supportive Housing & Individual Placement and Support (SHIPS) Study—0960–NEW

Background: Homelessness and unemployment are linked issues, with rising housing costs often leaving people unable to afford homes when combined with unemployment. The instability of housing makes finding employment even more challenging, creating a difficult cycle to break. While studies have shown that supportive housing programs improve housing stability, there is no significant evidence that such programs reliably increase employment among residents. (For the purposes of this study, we define supportive housing as housing services coupled with additional services that include case management support. These include place-based permanent supportive housing, scattered site permanent supportive housing, and rapid rehousing.) Conversely, Individual Placement and Support (IPS), a proven method for supporting employment, has not demonstrated effectiveness in stabilizing housing. SSA is requesting clearance to collect data for the Supportive Housing and Individual Placement and Support (SHIPS) study, under the Interventional Cooperative Agreement Program (ICAP), to determine whether participation in Individual Placement and Support (IPS) improves the employment, income, health, and self-sufficiency of people who are recently homeless and living in supportive housing. ICAP allows SSA to partner with various non-federal groups and organizations to advance interventional research connected to the Supplemental Security Income (SSI) and Social Security Disability Insurance (SSDI) programs. SSA awarded Westat a cooperative agreement to conduct SHIPS. In addition to SSA, Westat is partnering with three subrecipients for this project: (1) People Assisting the Homeless (PATH), (2) the University of Southern California (U.S.C.), and (3) the Research Foundation for Mental Hygiene (RFMH) to implement the SHIPS study.

ICAP SHIPS Study Project Description

The SHIPS study is a randomized controlled trial (RCT) designed to determine whether participation in Individual Placement and Support (IPS) improves the employment, income, health, and self-sufficiency of people who are recently homeless and living in supportive housing. The SHIPS study will mark the first study testing the effectiveness of implementing IPS in a supportive housing program. SSA hypothesizes that combining the two most successful evidence-based practices that separately address homelessness and supported employment will yield a single intervention that effectively addresses both. The intent of the SHIPS study is to measure the effectiveness of evidence-based IPS compared to the services provided by local WorkSource Centers broadly available to jobseekers in the Los Angeles area, The housing case managers will refer PATH clients interested in finding employment and will randomly assign participants to one of two groups:

a. *IPS:* The Individual Placement and Support (IPS) service team will offer a range of structured services customized to participants' personal needs, preferences, and challenges related to disabilities and/or mental health conditions. IPS was specifically designed as a supported employment model for individuals with serious mental illness and includes standardized training and fidelity requirements. Components of IPS that differ from those offered by WorkSource Services include integrated treatment that incorporates vocational and mental health services; benefits planning; and focus on rapid job search without extensive training.

b. *WorkSource Centers:* Under PATH's current housing model, housing case managers refer PATH clients who express interest in finding employment to local American Job Centers, known as WorkSource Centers in Los Angeles. The City of Los Angeles Economic and Workforce Development Department operates the WorkSource Centers, and follow an employment services model that varies by WorkSource Center; is not evidence-based or subject to fidelity monitoring, and is not necessarily responsive to the individual needs of jobseekers with disabilities.

The primary goals of the SHIPS study are:

- To measure the effects of IPS participation on employment, income, health, and long-term self-sufficiency measured as a combination of housing stability, income, and receipt of DI and SSI benefits.
- To describe the study population in order to understand both the generalizability of the study's findings and the potential reasons for the observed effects.
- To explore the IPS implementation process to understand barriers and facilitators to high-fidelity IPS implementation in the supportive housing context.

Grantee researchers and SSA will use the information collected during this study to (1) assess the short-term and long-term effectiveness of the proposed intervention to improve employment, income, and self-sufficiency; (2) understand the implementation process; (3) provide detailed subgroup-specific data related to the effect of IPS.

The respondents are residents in supportive housing units operated by PATH who are unemployed and looking for employment.

Modality of completion	Number of respondents	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in office or for teleservice centers (minutes) **	Total annual opportunity cost (dollars) ***
Study enrollees: baseline interview	200	1	200	60	200	* $13.30	** 24	*** $3,724
Study enrollees: quarterly interviews	200	7	1,400	10	233	* 13.30	** 21	*** 4,030
Study enrollees: final interview	200	1	200	60	200	* 13.30	** 21	*** 3,591
PATH Interviews: Staff	5	1	5	60	5	* 31.94	** 24	*** 224
SHIPS Interviews: enrollees	5	1	5	60	5	* 13.30	** 24	*** 93

Modality of completion	Number of respondents	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in office or for teleservice centers (minutes) **	Total annual opportunity cost (dollars) ***
Totals	610			250	643			*** 11,662

* We based this figure on the average DI payments based on SSA's current FY 2024 data (*https://mwww.ba.ssa.gov/legislation/2024FactSheet.pdf*), and survey researchers (*https://www.bls.gov/oes/current/oes193022.htm*).

** We based this figure on averaging both the average FY 2024 wait times for field offices and teleservice centers, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. Partnership Questionnaire—20 CFR 404.1080–404.1082—0960–0025. SSA considers partnership income in determining entitlement to Social Security benefits. SSA uses information from Form SSA–7104 to determine several aspects of eligibility for benefits, including the accuracy of reported partnership earnings; the veracity of a retirement; and lag earnings where SSA needs this information to determine the status of the insured. The respondents are applicants for, and recipients of, Title II Social Security benefits who are reporting partnership earnings.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
SSA–7104 (mailed)	2,154	1	30	1.077	* $31.48		*** $33,904
SSA–7104 (completed in or brought to a field office)	2,154	1	30	1,077	* 31.48	** 24	*** 61,040
Totals	4308			2154			*** 94,944

* We based this figure on average the U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm).*

** We based this figure on the average FY 2024 wait times for field offices, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

3. *Certification by Religious Group—20 CFR 404.1075—0960–0093.* SSA is responsible for determining whether religious groups meet the qualifications exempting certain members and sects from payment of Self-Employment Contribution Act taxes under the Internal Revenue Code, Section 1402(g). SSA sends Form SSA–1458, Certification by Religious Group, to a group's authorized spokesperson to complete and verify organizational members meet or continue to meet the criteria for exemption. The respondents are spokespersons for religious groups or sects.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) ***
SSA–1458	142	1	15	35	* $31.48	** $1,102

* We based this figure on average U.S. worker's hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

4. *Medical Source Statement of Ability To Do Work Related Activities (Physical and Mental)—20 CFR 404.1512–404.1513, 416.912–416.913, 404.1517, and 416.917—0960–0662.* When a claimant appeals a denied disability claim, SSA may ask the claimant to have a consultative examination at the agency's expense, if the claimant's medical sources cannot, or will not, give the agency sufficient evidence to determine whether the claimant is disabled. The medical providers who perform these consultative examinations provide a statement about the claimant's state of disability. Specifically, these medical source statements determine the work-related capabilities of these claimants. SSA collects the medical data on the HA–1151 and HA–1152 to assess the work-related physical and mental capabilities of claimants who appeal SSA's previous determination on their issue of disability. The respondents are medical sources who provide reports based either on existing medical evidence or on consultative examinations.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) ***
HA–1151	5,000	30	15	37,500	*$49.07	**$1,840,125
HA–1152	5,000	30	15	37,500	*49.07	**1,840,125
Totals	10,000			75,000		**3,680,250

*We based this figure on average medical professionals' salaries, as reported by the U.S. Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes290000.htm*).

**This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

5. Filing Claims Under the Federal Tort Claims Act—20 CFR 429.101–429.110—0960–0667. The Federal Tort Claims Act (FTCA) is the mechanism for compensating people who Federal employees injured through negligent or wrongful acts that occurred during the performance of those employees' official duties. SSA accepts claims filed under the FTCA for damages against the United States; loss of property; personal injury; or death resulting from an SSA employee's wrongful act or omission. The various types of claims included under this information collection request require claimants to provide information SSA can use to determine whether to make an award, compromise, or settlement under the FTCA. The respondents are individuals or entities making a claim under the FTCA.

Type of Request: Revision of an OMB-approved information collection.

Regulation citations	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) **	Total annual opportunity cost (dollars) ***
429.102; 429.103*	1	1	1	0	**$31.48	***$0
429.104(a)	8	1	60	8	**31.48	***252
429.104(b)	30	1	60	30	**31.48	***944
429.104(c)	1	1	60	1	**31.48	***32
429.106(b)	1	1	60	1	**31.48	***32
Totals	41			40		***1,260

*We are including a one-hour placeholder burden for 20 CFR 429.102 and 429.103, as respondents complete OMB-approved Form SF–95, OMB No. 1105–0008. Since the burden for these citations is covered under a separate OMB number, we are not double-counting the burden here.

**We based this figure on the average U.S. citizen's hourly salary, as reported by the U.S. Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes_nat.htm#00-0000*).

***This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

6. *Internet and Telephone Appointment Applications—20 CFR 404.620–404.630, 416.330–416.340—0960–0822.* SSA offers both internet and Telephone appointment options for applicants or recipients who wish to request an appointment when they are unable to complete one of SSA's online or automated telephone applications because they failed the initial verification checks, or when they state their reading language preference is other than English.

SSA offers two modalities for scheduling appointments: (1) an internet-based option (iAppointment), and (2) the Enhanced Leads and Appointment System (eLAS):

iAppointment: iAppointment is an online process that allows members of the public an easy-to-use method to schedule an appointment with the servicing office of their choice. Since the application date can affect when a claimant's benefit begins, iAppointment establishes a protective filing date and provides respondents information related to the date by which they must file their actual application. The iAppointment application propagates information the applicant already entered onto any of SSA's internet applications for SSN, name, date of birth, and gender. However, applicants must provide minimal additional information: mailing address; telephone number; language preference; type of appointment (Disability, Retirement, Medicare); and whether they prefer a telephone interview or in-office appointment. iAppointment is a customer-centric application. If the available appointment times do not meet the customer's needs, iAppointment allows them to enter a different zip code to identify another field office, which may offer different appointment times. At this time, SSA only allows domestic first party applicants to use iAppointment. If users indicate they are filing as third parties, iAppointment provides a message directing them to call the National 800 Number for assistance. If a foreign first party user is unable to complete iClaim, iAppointment directs them to contact a Social Security representative, and provides a link to SSA's Service Around the World website.

Enhanced Leads and Appointment System (eLAS)—eLAS is an Intranet-based version of the iAppointment screens for use by SSA technicians both in the field offices and call centers. eLAS interacts with iAppointment directly to ensure we always record the same information whether an individual requests an appointment through our internet screens, or via telephone. eLAS is a non-public facing system that allows SSA employees in the field offices, workload support units, and teleservice centers to use an telephone interview process to schedule appointments and document an individual's intent to file using a specific script and asking the same questions to each individual. We use eLAS with individuals who use our automated telephone system, or who prefer not to use iAppointment to set up their appointment.

The respondents are individuals who are unable to use our internet or automated telephone systems because they failed the initial verification

checks, or because they state their reading language preference is other than English.

Type of Request: Request for a new information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated annual burden (hours)	Average theoretical cost amount (dollars) *	Average combined wait time in field office or for teleservice center (minutes) **	Total annual opportunity cost (dollars) ***
iAppointment	20,965	1	10	3,494	*$31.48		***$103,981
eLAS	7,270,161	1	10	1,211,694	*31.48	**21	***111,786
Totals	7,291,126			1,215,188			***215,767

*We based these figures on average U.S. worker's hourly wages (based on *BLS.gov* data, (*https://www.bls.gov/oes/current/oes_nat.htm#00-0000*).
**We based this figure on the combined average FY 2024 wait times for field offices (approximately 24 minutes per respondent) and teleservice centers (approximately 17 minutes per respondent), based on SSA's current management information data.
***This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

Dated: June 28, 2024.

Tasha Harley,

Acting Reports Clearance Officer, Social Security Administration.

[FR Doc. 2024–14685 Filed 7–3–24; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket # FAA–FAA–2024–0868]

Airport Terminal Program; FY 2025 Funding Opportunity

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of funding opportunity.

SUMMARY OF KEY INFORMATION: FY 2025 AIRPORT TERMINAL PROGRAM (ATP)

Issuing Agency	Department of Transportation, Federal Aviation Administration.
Program Overview	ATP grants will be awarded on a competitive basis, per statute, to upgrade, modernize, and rebuild our nation's airport terminals and airport-owned Airport Traffic Control Towers (ATCTs).
Objectives	To address aging airport infrastructure; bring airport facilities into conformity with current standards; construct, modify, or expand facilities as necessary to meet demonstrated aeronautical demand; enhancing environmental sustainability; encouraging actual and potential competition; and providing a balanced system of airports to support civil aeronautical demand.
Eligible Projects	Eligible projects: • Airport passenger terminals, including access roads servicing exclusive airport traffic, and walkways that lead directly to or from an airport passenger terminal building; • On-airport rail access projects; and • Airport-owned Airport Traffic Control Towers (ATCT).
Deadlines	FY 2025 ATP deadline: No later than 5:00 pm Eastern time, July 31, 2024.
Funding	The Infrastructure Investment and Jobs Act (Pub. L. 117–58), November 15, 2021, ''Bipartisan Infrastructure Law,'' or BIL) provides $1 billion annually for FY 2022–2026.
Eligible Applicants	Eligible applicants are those airport sponsors normally eligible for Airport Improvement Program (AIP) discretionary grants as defined in 49 U.S.C. 47115. This includes a public agency, private entity, State agency, Indian Tribe or Pueblo owning a public-use NPIAS airport, the Secretary of the Interior for Midway Island airport, the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau.

The Department of Transportation (DOT), Federal Aviation Administration (FAA) announces the opportunity to apply for approximately $1 billion in FY 2025 discretionary funds for the Airport Terminal Program (ATP), made available under the Infrastructure Investment and Jobs Act of 2021 (IIJA), Pub. L. 117–58, herein referred to as the Bipartisan Infrastructure Law (BIL). The purpose of the ATP is to make annual grants available to eligible airports for airport terminal and airport-owned Airport Traffic Control Tower development projects that address the aging infrastructure of our nation's airports.

In addition, ATP grants will align with DOT's Strategic Framework FY2022–2026 at *https://www.transportation.gov/administrations/office-policy/fy2022-2026-strategic-framework*. The FY 2025 ATP will be implemented consistent with law and in alignment with the priorities in Executive Order 14052, *Implementation of the Infrastructure Investments and Jobs Act* (86 FR 64355), which are to invest efficiently and equitably; promote the competitiveness of the U.S. economy; improve job opportunities by focusing on high labor standards; strengthen infrastructure resilience to all hazards including climate change; and to effectively coordinate with State, local, Tribal, and territorial government partners.

DATES: Airport sponsors that wish to be considered for FY 2025 ATP discretionary funding should submit an application that meets the requirements of this Notice of Funding Opportunity (NOFO) as soon as possible, but no later than 5:00 p.m. Eastern time, July 31, 2024.

ADDRESSES: Submit applications electronically at *www.faa.gov/bil/airport-terminals* per instructions in this NOFO.

FOR FURTHER INFORMATION CONTACT: Jesse Carriger, Manager, BIL Branch APP–540, FAA Office of Airports, at (202) 267–3263 or our FAA BIL email address: *9-ARP-BILAirports@faa.gov.*

SUPPLEMENTARY INFORMATION:

A. Program Description

BIL established the ATP, a competitive discretionary grant program, which provides approximately $1 billion in grant funding annually for five years (Fiscal Years 2022–2026) to upgrade, modernize, and rebuild our nation's airport terminals and airport-owned Airport Traffic Control Towers (ATCTs). This includes bringing airport facilities into conformity with current standards; constructing, modifying, or expanding facilities as necessary to meet demonstrated aeronautical demand; enhancing environmental sustainability; encouraging actual and potential competition; and providing a balanced system of airports to meet the roles and functions necessary to support civil aeronautical demand. The FAA is committed to advancing safe, efficient transportation, including projects funded under the ATP. The ATP also supports the President's goals to mobilize American ingenuity to build modern infrastructure and an equitable, clean energy future. In support of the goals of Executive Order 13985, *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* (86 FR 7009) and Executive Order 14096, *Revitalizing Our Nation's Commitment to Environmental Justice for All,* the FAA encourages applicants to consider how the project will address the challenges faced by individuals in underserved communities and rural areas, communities with environmental justice concerns, as well as accessibility for persons with disabilities.

The ATP falls under the project grant authority for the Airport Improvement Program (AIP) in 49 United States Code (U.S.C.) 47104. Per 2 Code of Federal Regulations (CFR) part 200—*Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards,* the AIP Federal Assistance Listings Number is 20.106, with the objective to assist eligible airports in the development and improvement of a nationwide system that adequately meets the needs of civil aeronautics. The FY 2025 ATP will be implemented, as appropriate and consistent with BIL, in alignment with the priorities in Executive Order 14052, *Implementation of the Infrastructure Investments and Jobs Act* (86 FR 64355), which are to invest efficiently and equitably; promote the competitiveness of the U.S. economy; improve opportunities for good-paying jobs with the free and fair choice to join a union by focusing on high labor standards; strengthen infrastructure resilience to all hazards including climate change; and to effectively coordinate with State, local, Tribal, and territorial government partners.

Consistent with statutory criteria and Executive Order 14008, *Tackling the Climate Crisis at Home and Abroad* (86 FR 7619), the FAA also seeks to fund projects under the ATP that reduce greenhouse gas emissions and are designed with specific elements to address climate change impacts. Specifically, the FAA is looking to award projects that align with the President's greenhouse gas reduction goals, promote energy efficiency, support fiscally responsible land use and transportation efficient design, support terminal development compatible with the use of sustainable aviation fuels and technologies, increase climate resilience, incorporate sustainable and less emissions-intensive pavement and construction materials as allowable, and reduce pollution.

The FAA will also consider projects that advance the goals of the Executive Orders listed under section E.2.

B. Federal Award Information

This NOFO announces up to $1,000,000,000, subject to availability of funds, for the Fiscal Year 2025 ATP. The ATP is a $5 billion grant program, distributed as approximately $1 billion annually for five years (Fiscal Years 2022, 2023, 2024, 2025, and 2026), subject to annual allocations limitations based on airport roles found in the published National Plan of Integrated Airport Systems (NPIAS), as updated with current year data. In general, the $5 billion in ATP grant funding is subject to the following annual award allocation limitations: not more than 55 percent shall be for large hub airports, not more than 15 percent shall be for medium hub airports, not more than 20 percent shall be for small hub airports, and not less than 10 percent shall be for nonhub and nonprimary airports.

The FAA will consider projects that increase capacity and passenger access; projects that replace aging infrastructure; projects that achieve compliance with the Americans with Disabilities Act (42 U.S.C. 12101, *et seq.*) and expand accessibility for persons with disabilities; projects that improve airport access for historically disadvantaged populations; projects that improve energy efficiency, including upgrading environmental systems, upgrading plant facilities, and achieving Leadership in Energy and Environmental Design (LEED) accreditation standards; projects that improve airfield safety through terminal relocation; and projects that encourage actual and potential competition. This includes applicable Executive Orders as listed in section E.2. Additionally, the FAA will provide preference to projects that achieve a complete development objective even if awards for the project must be phased, and priority to projects that have received partial awards.

Projects for relocating, reconstructing, repairing, or improving an airport-owned ATCT will also be considered. In addition to the considerations above, these projects will also be assessed based on overall impact on the National Airspace System, including age of facility, operational constraints, and nonstandard facilities.

The FAA will publish a NOFO that will announce its final round of funding made available, approximately $1 billion, in Fiscal Year 2026.

C. Eligibility Information

1. Eligible Applicants

Eligible applicants are those airport sponsors normally eligible for Airport Improvement Program (AIP) discretionary grants as defined in 49 U.S.C. 47115. This includes a public agency, private entity, State agency, Indian Tribe or Pueblo owning a public-use NPIAS airport, the Secretary of the Interior for Midway Island airport, the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau.

2. Cost Sharing or Matching

The Federal cost share of ATP grants is 80 percent for large and medium hub airports, and 95 percent for the remainder of airports eligible to receive ATP grants, which includes small hub, nonhub, and nonprimary airports.

3. Project Eligibility

All projects funded from the ATP must be:

i. Airport terminal development, defined in 49 U.S.C. 47102(28) as development of an airport passenger terminal building, including terminal gates; access roads servicing exclusively airport traffic that leads directly to or from an airport passenger terminal building; and walkways that lead directly to or from an airport passenger terminal building. Under the ATP, the

FAA may consider projects that qualify as ''terminal development'' (including multimodal terminal development), as that term is defined in 49 U.S.C. 47102(28); or

ii. On-airport rail access projects as set forth in Passenger Facility Charge (PFC) Update 75–21 (86 FR 48793, August 31, 2021); or

iii. Airport-owned ATCT that includes relocating, reconstructing, repairing, or improving the ATCT; and

iv. Justified based on civil aeronautical demand.

D. Application and Submission Information

1. Address To Request Application Package

An application for ATP terminal or ATCT projects, FAA Form 5100–144, *Bipartisan Infrastructure Law, Airport Terminal and Tower Project Information,* can be found at: *www.faa.gov/bil/airport-terminals.*

Direct all inquiries regarding applications to the appropriate Regional Office (RO), Airports District Office (ADO) at *https://www.faa.gov/about/office_org/headquarters_offices/arp/offices/regional_offices* or State Agency for Airports covered under the FAA State Block Grant Program (SBGP), or contact the FAA BIL Team at *9-ARP-BILAirports@faa.gov.*

2. Content and Form of Application Submission

Applicants are required to submit FAA Form 5100–144, *Bipartisan Infrastructure Law, Airport Terminal and Tower Project Information.* The applicant should submit Form 5100–144 as a fillable digitally signed PDF document via email. If the applicant cannot provide a digital signature, the application may be submitted as two documents: (1) the completed fillable PDF without a signature and (2) a scanned version of the completed application with a written signature. Applicants should follow the instructions and provide a response to applicable items on the form.

The ''Submit by Email'' button at the bottom of the form will generate an email for the applicant to send to the FAA BIL Team at: *9-ARP-BILAirports@faa.gov.* If the ''Submit by Email'' button does not generate an email the applicant can save the fillable PDF by selecting ''File>Save As'' to save as a fillable PDF. Once saved, the applicant can email the application to the FAA BIL Team at *9-ARP-BILAirports@faa.gov.* The fillable PDF application must contain either a digital signature or the applicant's written signature in accordance with the procedures described above.

Applicants selected to receive an ATP grant will then be required to follow AIP grant application procedures prior to award, which include meeting all prerequisites for funding, and submission of Standard Form SF–424, *Application for Federal Assistance,* and FAA Form 5100–100, *Application for Development Projects.*

Airports covered under the FAA's State Block Grant Program or airports in a channeling act state should coordinate with their associated State agency on the process for who should submit an application, via the procedures listed above.

Applicants must address Administration and Departmental priorities in safety, climate change and sustainability, equity, and workforce development which are further defined in section E.1 Criteria.

Grant Funds, Sources and Uses of Project Funds: The FAA requests that each project application have a financial plan (or project budget) available for review upon request. Project budgets should show how different funding sources will share in each activity and present those data in dollars and percentages. The budget should identify other Federal funds the applicant is applying for or has been awarded, if any, that the applicant intends to use. Funding sources should be grouped into three categories: non-Federal, ATP, and other Federal with specific amounts from each funding source.

Sharing of Application Information: The FAA may share application information within the Department or with other Federal agencies if the FAA determines that sharing is relevant to the respective program's objectives.

3. Unique Entity Identifier and System for Award Management (SAM)

Applicants must comply with 2 CFR part 25—*Universal Identifier and System for Award Management.* All applicants must have a unique entity identifier provided by SAM. Additional information about obtaining a Unique Entity Identifier (UEI) and registration procedures may be found at *http://www.sam.gov.* Each applicant is required to: (1) be registered in SAM; (2) provide a valid UEI prior to grant award; and (3) continue to maintain an active SAM registration with current information at all times during which the applicant has an active Federal award or an application or plan under consideration by the FAA. Under the ATP, the UEI and SAM account must belong to the entity that has the legal authority to apply for, receive, and execute ATP grants.

Once awarded, the FAA grant recipient must maintain the currency of its information in SAM until the grantee submits the final financial report required under the grant or receives the final payment, whichever is later. A grant recipient must review and update the information at least annually after the initial registration and more frequently if required by changes in information or another award term.

The FAA may not make an award until the applicant has complied with all applicable UEI and SAM requirements. If an applicant has not fully complied with the requirements by the time the FAA is ready to make an award, the FAA may determine that the applicant is not qualified to receive an award and use that determination as a basis for making a federal award to another applicant.

Non-Federal entities that have received a federal award are required to report certain civil, criminal, or administrative proceedings to SAM to ensure registration information is current and complies with federal requirements. Applicants should refer to 2 CFR 200.113 for more information about this requirement.

4. Submission Dates and Times

Airports that wish to be considered for FY 2025 ATP discretionary funding must submit an application that meets the requirements of this NOFO as soon as possible, but no later than 5:00 p.m. Eastern time on July 31, 2024. Submit applications electronically to *9-ARP-BILAirports@faa.gov* per instructions on *www.faa.gov/bil/airport-terminals* and in this NOFO.

5. Intergovernmental Review

Not applicable.

6. Funding Restrictions

All projects funded from the ATP must be airport terminal development or for relocation, reconstruction, repair, or improvement of an airport-owned Airport Traffic Control Tower, defined under section C–3 Project Eligibility. ATP funds may not be used to support or oppose union organizing.

Pre-Award Authority: All project costs must be incurred after the grant execution date unless specifically permitted under 49 U.S.C. 47110(c) and 49 U.S.C. 47142. Certain airport development costs incurred before execution of the grant agreement, but after November 15, 2021, are allowable, only if certain conditions under 49 U.S.C. 47110(c) or 49 U.S.C. 47142 are met [see Table 3–60 of the AIP Handbook, FAA Order 5100.38 D Change 1, for a specific list of the

guidance regarding when project costs can be incurred in relation to section 47110(c)].

7. Other Submission Requirements

Applications will only be accepted on FAA Form 5100–144 fillable PDF via email and must be received on or before July 31, 2024, 5:00 p.m. Eastern time. No other forms of applications will be accepted.

E. Application Review Information

1. Criteria

Applications for FY 2025 ATP will be rated using the following criteria:

i. Projects must meet eligibility requirements under the ATP, which includes terminal development (including multimodal terminal development) as defined in 49 U.S.C. 47102(28): on-airport rail access projects: or airport-owned ATCT relocation, reconstruction, repair, or improvements.

ii. The FAA will consider timeliness of implementation, with priority given to those projects, including ''design only'' projects, that can satisfy all statutory and administrative requirements for grant award by July 2025.

iii. Favorable consideration will be given to eligible and justified (based on civil aeronautical demand) terminal development projects (including multimodal terminal development), on-airport rail access projects, and ATCT projects that:

a. *Increase capacity and passenger access:* The applicant should describe the extent to which the project contributes to the functioning and growth of the economy, including the extent to which the project addresses congestion or service gaps in rural areas. The applicant should demonstrate how the proposed project increases capacity and provides ongoing market access to the airport by competing carriers as economic and competitive conditions change (such as by constructing common use gates or updating gates and other areas with common use equipment). The applicant should also demonstrate how the proposed project increases capacity and market access or relieves congestion based on current and/or forecast needs.

b. *Replace aging infrastructure:* Applicants should describe how the project addresses replacing or upgrading facilities that have reached the end of their useful life. This includes information on the current age and condition of the asset that will be affected by the project and how the proposed project will improve asset condition. The applicant should describe how the facility no longer meets the current or forecasted operational needs of the airport. This includes the renovation, expansion, or replacement of a facility that is too small or cannot efficiently meet current or future demand. This also includes projects aimed at terminal modernization or upgrades to meet the changing user or community expectations. This can be met by including multimodal terminal development, climate resiliency, sustainability initiatives and practices incorporated therein, and the incorporation of common-use equipment and practices, all with the goal of providing a terminal that focuses on the most efficient movement of passengers and baggage possible. This also includes projects that address changing environmental conditions and improve resilience to climate change, and that will be constructed consistent with the Federal Flood Risk Management Standard, per the President's January 30, 2015, Executive Order 13690, ''Establishing a Federal Flood Risk Management Standard and a Process for Further Soliciting and Considering Stakeholder Input'' to the extent consistent with current law.

c. *Achieve compliance with the Americans with Disabilities Act (ADA), including expand accessibility for persons with disabilities:* Applicants should describe how the project increases mobility, expands access, and improves connectivity for people with disabilities both inside and outside the terminal or ATCT. The information should demonstrate how the proposed project will meet the requirements under the Americans with Disabilities Act and improve equitable access for people with disabilities.

d. *Improve airport access for historically disadvantaged populations:* Applicants should describe how the project increases mobility, expands access, and improves connectivity for disadvantaged communities and underserved populations. The information should demonstrate how the proposed project provides a significant local and regional impact and benefits disadvantaged communities. The applicant should include a description of public engagement on a local and regional level that has occurred, demonstrates proactive inclusivity of disadvantaged communities and access for underserved populations, and the degree to which public comments and commitments have been integrated into the project. DOT is providing a list of communities that meet the definition of Disadvantaged Communities, available at *https://screeningtool.geoplatform.gov/en/#3/33.47/-97.5.*

Improve energy efficiency, including upgrading environmental systems, upgrading plant facilities, and achieving Leadership in Energy and Environmental Design (LEED) accreditation standards: Applicants should estimate and commit to tracking the carbon dioxide reduction anticipated from potential projects by providing information that demonstrates how the project will reduce air pollution and greenhouse gas emissions from a reduction in energy consumption through energy-efficient design. This includes how the project may facilitate the airport in achieving LEED or similar accreditation standards through reliance on alternative energy, water use reduction, sustainable site selection and development, responsible materials selection and waste management, incorporating lower-carbon pavement and construction materials, enhanced indoor environmental quality, use of terminal facility for renewable energy production, or other sustainability efforts (*e.g.,* vehicle charging stations attached to the terminal) that further reduce long-term impact on the climate. A proposed project, including utility support facilities, should be part of an overall plan that sets targets to lower carbon emissions, working toward a carbon-neutral airport by 2050.

e. *Improve airfield safety through terminal relocation:* Applicants should describe how the proposed terminal project is improving airfield safety through the relocation of the terminal building or its components. This could also include a project to relocate a terminal that assists in addressing nonstandard airfield configurations.

f. *Encourage actual and potential competition:* The applicant should describe the extent to which the project promotes competition in air service by providing greater ability to accommodate new entrants; increasing the ability of competing air carriers to access constrained facilities on an ongoing basis; and facilitating the efficient and reliable movement of passengers and cargo. The applicant should describe the extent to which the project leads to common use gates and software (*e.g.,* common use software updates, construction of common use gates versus preferential use by a specific carriers). The applicant may also wish to describe how the project will offer regional and national impacts by improving the economic strength of regions and cities; increase opportunities for tourism; result in long-

term job creation by supporting good-paying jobs with the free and fair choice to join a union directly related to the project; and help the United States compete in a global economy by encouraging the location of important industries and future innovations and technology in the United States.

iv. ATCT projects that relocate, reconstruct, repair, or improve an airport owned ATCT will also be assessed based on overall impact on the National Airspace System, including age of facility, operational constraints, and nonstandard facility conditions.

v. The FAA will provide a preference to projects that achieve a complete development objective, even if awards for the project must be phased; and prioritize projects that have received partial awards.

vi. The applicant should describe whether and how project delivery and implementation create good-paying jobs with the free and fair choice to join a union to the greatest extent possible; the use of demonstrated strong labor standards, practices and policies (including for direct employees, contractors, sub-contractors, and service workers on airport property); use of project labor agreements; distribution of workplace rights notices; union neutrality agreements; wage and/or benefit standards; safety and health standards; the use of Local Hire Provisions; [1] registered apprenticeships; joint-labor management partnerships; or other similar standards or practices. The applicant should describe how planned methods of project delivery and implementation (for example, use of Project Labor Agreements and/or Local Hire Provisions,[2] training, placement, and the provision of supportive services for underrepresented workers) provide opportunities for all workers, including workers underrepresented in construction jobs to be trained and placed in good-paying jobs directly related to the project. The FAA will consider this information in considering the application.

Applicants are encouraged to submit projects that meet as many of the above criteria as possible, but do not need to meet all criteria to be considered.

2. Review and Selection Process

Federal awarding agency personnel will assess applications based on how well the projects meet the criteria in E.1, including project eligibility, justification, readiness, impact on the National Airspace System, and the availability of matching funds. The FAA will also consider how well projects advance the goals of the following Executive Orders, which are incorporated into the criteria under E.1.: the President's January 20, 2021, Executive Order 13990, ''*Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis*''; the President's January 20, 2021, Executive Order 13985, ''*Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*''; the President's January 27, 2021, Executive Order 14008, ''*Tackling the Climate Crisis at Home and Abroad*''*;* the President's May 20, 2021, Executive Order 14030, ''*Climate Related Financial Risk*''; the President's July 9, 2021, Executive Order 14036, ''*Promoting Competition in the American Economy*''*; the President's December 8, 2021, Executive Order 14057,* ''*Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability*''; and the President's April 21, 2023, Executive Order 14096, ''*Revitalizing Our Nation's Commitment to Environmental Justice for All.*''

Applications are first reviewed for eligibility, justification, and timeliness of implementation consistent with the requirements of this NOFO and the intent of the ATP. Applications are then reviewed for how well the proposed project(s) meets the criteria in E.1. and ranked by field and regional office staff. The top projects for each airport category (as outlined in BIL) are then assessed by a National Control Board (NCB). The NCB has representatives from each Region and Headquarters management. The NCB recommends project and funding levels to senior leadership.

3. Integrity and Performance Check

Prior to making a Federal award with a total amount of Federal share greater than the simplified acquisition threshold, the FAA is required to review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently FAPIIS) (see 41 U.S.C. 2313). An applicant, at its option, may review information in the designated integrity and performance systems accessible through SAM and comment on any information about itself that a Federal awarding agency previously entered. The FAA will consider any comments by the applicant, in addition to the other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 2 CFR 200.206.

F. Federal Award Administration Information

1. Federal Award Notices

BIL awards are announced through a Congressional notification process and a DOT Secretary's Notice of Intent to Fund. The FAA RO/ADO representative will contact the airport with further information and instructions. Once all pre-grant actions are complete, the FAA RO/ADO will offer the airport sponsor a grant for the announced project. This offer may be provided through postal mail or by electronic means. Once this offer is signed by the airport sponsor, it becomes a grant agreement. Awards made under this program are subject to conditions and assurances in the grant agreement.

2. Administrative and National Policy Requirements

i. Grant Requirements

All grant recipients are subject to the grant requirements of the AIP, found in 49 U.S.C. Chapter 471. Grant recipients are subject to requirements in the FAA's *AIP Grant Agreement* for financial assistance awards; the annual Certifications and Assurances required of applicants; and any additional applicable statutory or regulatory requirements, including nondiscrimination requirements and 2 CFR part 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.* Grant requirements include, but are not limited to, approved projects on an airport layout plan; compliance with Federal civil rights laws; Buy American requirements under 49 U.S.C. 50101; Build America, Buy America requirements in sections 70912(6) and 70914 in Public Law No: 117–58; the *Department of Transportation's Disadvantaged Business Enterprise (DBE) Program* regulations for airports (49 CFR part 23 and 49 CFR part 26); the Infrastructure Investment and Jobs Act; and prevailing wage rate requirements under the Davis-Bacon Act, as amended (40 U.S.C. 276a–276a–5, and reenacted at 40 U.S.C. 3141–3144, 3146, and 3147).

Domestic Preference Requirements: As expressed in Executive Order 14005, Ensuring the Future Is Made in All of America by All of America's Workers (86 FR 7475), executive branch should

[1] IIJA div. B section 25019 provides authority to use geographical and economic hiring preferences, including local hire, for construction jobs, subject to any applicable State and local laws, policies, and procedures.

[2] Project labor agreement should be consistent with the definition and standards outlined in Executive Order 14063.

maximize, consistent with law, the use of goods, products, and materials produced in, and services offered in, the United States. Funds made available under this notice are subject to the domestic preference requirements in the Buy American requirements under 49 U.S.C. 50101 and the Build America, Buy America requirements in section 70914 in the Infrastructure Investment and Jobs Act (Pub. L. 117–58). The FAA expects all applicants to comply with that requirement without needing a waiver. However, to obtain a waiver, a recipient must be prepared to demonstrate how they will maximize the use of domestic goods, products, and materials in constructing their project.

Civil Rights and Title VI: As a condition of a grant award, grant recipients should demonstrate that the recipient has a plan for compliance with civil rights obligations and nondiscrimination laws, including Title VI of the Civil Rights Act of 1964 and implementing regulations (49 CFR part 21), the Americans with Disabilities Act of 1990 (ADA), and section 504 of the Rehabilitation Act, all other civil rights requirements, and accompanying regulations. This should include a current Title VI plan, completed Community Participation Plan, and a plan to address any legacy infrastructure or facilities that are not compliant with ADA standards. DOT's and the applicable Operating Administrations' Office of Civil Rights may work with awarded grant recipients to ensure full compliance with Federal civil rights requirements.

Critical Infrastructure Security, Cybersecurity, and Resilience: It is the policy of the United States to strengthen the security and resilience of its critical infrastructure against all hazards; including both physical and cyber risks, consistent with the President's National Security Memorandum on Critical Infrastructure Security and Resilience (NSM–22) and the National Security Memorandum on Improving Cybersecurity for Critical Infrastructure Control Systems (NSM–5). Each applicant selected for Federal funding under this notice must demonstrate, prior to the signing of the grant agreement, effort to consider and address physical and cyber security risks relevant to the transportation mode and type and scale of the project. Projects that have not appropriately considered and addressed physical and cyber security and resilience in their planning, design, and project oversight, as determined by the Department and the Department of Homeland Security, will be required to do so before receiving funds for construction. Information on cybersecurity performance goals can be found at *https://www.cisa.gov/cpg.* These performance goals provide a baseline set of cybersecurity practices broadly applicable across critical infrastructure with known risk-reduction value, a benchmark for critical infrastructure owners and operators to measure and improve their cybersecurity maturity, and recommended practices for information technology (IT) and operational technology (OT) systems, including a prioritized set of security practices. Additionally, funding recipients must be in compliance with 2 CFR 200.216 and the prohibition on certain telecommunications and video surveillance services or equipment.

Federal Contract Compliance: As a condition of grant award and consistent with E.O. 11246, Equal Employment Opportunity (30 FR 12319, and as amended), all federally assisted contractors are required to make good faith efforts to meet the goals of 6.9 percent of construction project hours being performed by women, in addition to goals that vary based on geography for construction work hours and for work being performed by people of color.

The U.S. Department of Labor's Office of Federal Contract Compliance Programs (OFCCP) is charged with enforcing Executive Order 11246, section 503 of the Rehabilitation Act of 1973, and the Vietnam Era Veterans' Readjustment Assistance Act of 1974. OFCCP has a Mega Construction Project Program through which it engages with project sponsors as early as the design phase to help promote compliance with non-discrimination and affirmative action obligations. OFCCP will identify projects that receive an award under this notice and are required to participate in OFCCP's Mega Construction Project Program from a wide range of federally-assisted projects over which OFCCP has jurisdiction and that have a project cost above $35 million. DOT will require project sponsors with costs above $35 million that receive awards under this funding opportunity to partner with OFCCP, if selected by OFCCP, as a condition of their DOT award.

Performance and Program Evaluation: As a condition of grant award, grant recipients may be required to participate in an evaluation undertaken by the DOT, FAA, or another agency or partner. The evaluation may take different forms, such as an implementation assessment across grant recipients, an impact and/or outcomes analysis of all or selected sites within or across grant recipients, or a benefit/cost analysis or assessment of return on investment. DOT may require applicants to collect data elements to aid the evaluation. As a part of the evaluation, as a condition of award, grant recipients must agree to: (1) make records available to the evaluation contractor or DOT staff; (2) provide access to program records and any other relevant documents to calculate costs and benefits; (3) in the case of an impact analysis, facilitate the access to relevant information as requested; and (4) follow evaluation procedures as specified by the evaluation contractor or DOT staff. Requested program records or information will be consistent with record requirements outlined in 2 CFR 200.334–338 and the grant agreement.

ii. Standard Assurances

Each grant recipient must assure that it will comply with all applicable Federal statutes, regulations, executive orders, directives, FAA circulars, and other Federal administrative requirements in carrying out any project supported by the ATP grant. The grant recipient must acknowledge that it is under a continuing obligation to comply with the terms and conditions of the grant agreement issued for its project with the FAA. The grant recipient understands that Federal laws, regulations, policies, and administrative practices might be modified from time to time and may affect the implementation of the project. The grant recipient must agree that the most recent Federal requirements will apply to the project unless the FAA issues a written determination otherwise.

The grant recipient must submit the Certifications at the time of grant application and Assurances must be accepted as part of the grant agreement at the time of accepting a grant offer. Grant recipients must also comply with the requirements of 2 CFR part 200, which ''are applicable to all costs related to Federal awards,'' and which are cited in the grant assurances of the grant agreements. The Airport Sponsor Assurances are available on the FAA website at: *https://www.faa.gov/airports/aip/grant_assurances.*

3. Reporting

Grant recipients are subject to financial reporting per 2 CFR 200.328 and performance reporting per 2 CFR 200.329. Under the ATP, the grant recipient is required to comply with all Federal financial reporting requirements and payment requirements, including the submittal of timely and accurate reports. Financial and performance reporting requirements are available in

the FAA October 2020 Financial Reporting Policy, which is available at *https://www.faa.gov/airports/aip/grant_payments.*

The grant recipient must comply with annual audit reporting requirements. The grant recipient and sub-recipients, if applicable, must comply with 2 CFR part 200, subpart F, *Audit Reporting Requirements.* The grant recipient must also comply with any requirements outlined in 2 CFR part 180, *Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension.*

G. Federal Awarding Agency Contact(s)

For further information concerning this notice, please contact the FAA BIL Branch via email at *9-ARP-BILAirports@faa.gov.* In addition, the FAA will post answers to frequently asked questions and requests for clarifications on the FAA's website at *www.faa.gov/bil/airport-terminals.* To ensure applicants receive accurate information about eligibility of the program, the applicant is encouraged to contact the FAA directly, rather than through intermediaries or third parties, with questions.

All applicants, including those requesting full Federal share of eligible projects costs, should have a plan to address potential cost overruns as part of an overall funding plan.

Issued in Washington, DC, on July 1, 2024.

Jesse Carriger,

Manager, FAA Office of Airports BIL Infrastructure Branch, APP–540.

[FR Doc. 2024–14707 Filed 7–3–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA–2024–1318; Summary Notice No.–2024–29]

Petition for Exemption; Summary of Petition Received; Airbus SAS

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before July 25, 2024.

ADDRESSES: Send comments identified by docket number FAA–2024–1318 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: William Andrews, (202) 267–8181, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Dan Ngo

Manager, Part 11 Petitions Branch, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2024–1318.
Petitioner: Airbus SAS.
Section(s) of 14 CFR Affected: §§ 25.981(a)(3) and 25.1309(b).

Description of Relief Sought: Airbus SAS seeks a 5-year time limited exemption for the incorporation of a modified Hydraulic Monitoring and Control Application Software (HMCA) standard S6 on the A350–941 and A350–1041 aircraft models fitted with Engine Driven Pumps (EDP–06) prior to a planned upgrade to Engine Driven Pump (EDP–07) for full compliance.

[FR Doc. 2024–14748 Filed 7–3–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2024–1458]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Verification of Authenticity of Foreign License, Rating, and Medical Certification

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The information is used to identify foreign airmen in order to allow the agency to verify their foreign license when used to qualify for a U.S. certificate. Respondents are holders of foreign licenses wishing to obtain U.S. Certificates.

DATES: Written comments should be submitted by September 3, 2024.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: [Jay Tevis, Federal Aviation Administration, AFB–720, P.O. Box 25082, Oklahoma City, OK 73107.

FOR FURTHER INFORMATION CONTACT: Margaret Hawkins by email at: *Margaret.A.Hawkins@faa.gov*, phone: 405–954–3261.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be

minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0724.

Title: Verification of Foreign License, Rating and Medical Certification.

Form Numbers: Form 8060–71.

Type of Review: Renewal of an information collection.

Background: The information collected is used to properly identify airmen to allow the agency to verify their foreign license being used to qualify for a U.S. certificate. The respondents are holders of foreign license wishing to obtain a U.S. certificate. A person who is applying for a U.S. pilot certificate or rating on the basis of a foreign pilot license must apply for verification of that license at least 90 days before arriving at the designated FAA FSDO where the applicant intends to receive the U.S. pilot certificate.

Respondents: Approximately 12,000 foreign applicants for U.S. certificates annually.

Frequency: On occasion.

Estimated Average Burden per Response: 10 Minutes.

Estimated Total Annual Burden: 2,000 Hours.

Margaret A. Hawkins,

Airmen Certification Specialist, Airmen Certification Branch, AFB–720.

[FR Doc. 2024–14008 Filed 7–3–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Transportation Project in Delaware

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for judicial review of actions by FHWA and other Federal agencies.

SUMMARY: This notice announces action taken by FHWA and other Federal agencies that are final. The actions relate to the Wilmington Riverfront Transportation Infrastructure Project (Project) proposed by the City of Wilmington, consisting of 0.5 mile of City grid network in City of Wilmington, New Castle County, Delaware. The actions grant licenses, permits, or approvals for the Project. The Revised Environmental Assessment (EA), Finding of No Significant Impact (FONSI) under the National Environmental Policy Act (NEPA), and other documents in the Project file provide details on the Project and FHWA's actions.

DATES: By this notice, FHWA 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 December 2, 2024. 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: Douglas Atkin, Division Administrator, Federal Highway Administration, 1201 College Park Drive, Suite 102, Dover, DE 19904, Telephone (302) 734–3819.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA and other Federal agencies have taken final agency actions by issuing approvals for the following highway project in Delaware: Wilmington Riverfront Transportation Infrastructure Project (Project).

The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Revised EA and FONSI and the associated agency records. That information is available by contacting FHWA at the address provided above and can also be viewed and downloaded from the project website at: *https://www.riverfronteastconnect.com/.*

This notice applies to FHWA 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 [42 U.S.C. 4321–4351].
2. Federal-Aid Highway Act [23 U.S.C. 109].
3. Clean Air Act [42 U.S.C. 7401–7671(q)].
4. Endangered Species Act [16 U.S.C. 1531–1544 and 1536].
5. Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)].
6. Migratory Bird Treaty Act [16 U.S.C. 703–712].
7. Bald and Golden Eagle Protection Act [16 U.S.C. 668–668c].
8. Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 306101 *et seq.*]
9. Civil Rights Act of 1964 [42 U.S.C. 2000d *et seq.*]
10. Farmland Protection Policy Act [7 U.S.C. 4201–4209].
11. Clean Water Act (section 319, section 401, section 402, section 404) [33 U.S.C. 1251–1377].
12. Safe Drinking Water Act [42 U.S.C. 300(f) *et seq.*].
13. Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 [42 U.S.C. 4601 *et seq.*].
14. Noise Control Act of 1972 [42 U.S.C. 4901 *et seq.*].
15. Resource Conservation and Recovery Act [42 U.S.C. 6901–6992(k)].
16. Comprehensive Environmental Response, Compensation, and Liability Act [42 U.S.C. 9601–9675].
17. Americans with Disabilities Act of 1990 [42 U.S.C. 12101].
18. Executive Order 11990 Protection of Wetlands.
19. Executive Order 11988 Floodplain Management.
20. Executive Order 12898 Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.
21. Executive Order 11593 Protection and Enhancement of Cultural Resources.
22. Executive Order 11514 Protection and Enhancement of Environmental Quality.
23. Executive Order 13112 Invasive Species.
24. Executive Order 13166 Improving Access to Services for Persons with Limited English Proficiency.
25. Executive Order 13045 Protection of Children From Environmental Health Risks and Safety Risks.
26. Executive Order 14096 Revitalizing Our Nation's Commitment to Environmental Justice for All.

(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), as amended by Moving Ahead for Progress in the 21st Century Act, (Pub. L. 112–141, 126 Stat. 405).

Douglas S. Atkin,

Division Administrator, Dover, Delaware.

[FR Doc. 2024–14709 Filed 7–3–24; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2024–0010]

Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 10 individuals from

the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. The exemptions enable these hard of hearing and deaf individuals to operate CMVs in interstate commerce.

DATES: The exemptions were applicable on June 22, 2024. The exemptions expire on June 22, 2026.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 366–4001, *fmcsamedical@dot.gov.* Office hours are from 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number (FMCSA–2024–0010) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Older-Newer),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in 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. 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.

B. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption requests. DOT posts these comments, without edit, 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), which can be reviewed at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices,* the comments are searchable by the name of the submitter.

II. Background

On May 16, 2024, FMCSA published a notice announcing receipt of applications from 10 individuals requesting an exemption from the hearing requirement in 49 CFR 391.41(b)(11) to operate a CMV in interstate commerce and requested comments from the public (89 FR 42920). The public comment period ended on June 17, 2024, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that granting exemptions to these individuals would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(11).

The physical qualification standard for drivers regarding hearing found in § 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5—1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid (35 FR 6458, 6463 (Apr. 22, 1970) and 36 FR 12857 (July 8, 1971), respectively).

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period 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 such exemption. The statutes also allow the Agency to renew exemptions at the end of the 5-year period. However, FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The Agency's decision regarding these exemption applications is based on relevant scientific information and literature, and the 2008 Evidence Report, ''Executive Summary on Hearing, Vestibular Function and Commercial Motor Driving Safety.'' The evidence report reached two conclusions regarding the matter of hearing loss and CMV driver safety: (1) no studies that examined the relationship between hearing loss and crash risk exclusively among CMV drivers were identified; and (2) evidence from studies of the private driver's license holder population does not support the contention that individuals with hearing impairment are at an increased risk for a crash. In addition, the Agency reviewed each applicant's driving record found in the Commercial Driver's License Information System, for commercial driver's license (CDL) holders, and inspections recorded in the Motor Carrier Management Information System. For non-CDL holders, the Agency reviewed the driving records from the State Driver's Licensing Agency. Each applicant's record demonstrated a safe driving history. Based on an individual assessment of each applicant that focused on whether an equal or greater level of safety would likely be achieved by permitting each of these drivers to drive in interstate commerce, the Agency finds the drivers granted this exemption have demonstrated that they do not pose a risk to public safety.

Consequently, FMCSA finds further that in each case exempting these applicants from the hearing standard in § 391.41(b)(11) would likely achieve a level of safety equal to that existing without the exemption, consistent with the applicable standard in 49 U.S.C. 31315(b)(1).

V. Conditions and Requirements

The terms and conditions of the exemption are provided to the applicants in the exemption document and include the following: (1) each driver must report any crashes or accidents as defined in § 390.5T; (2) each driver must report all citations and convictions for disqualifying offenses under 49 CFR parts 383 and 391 to FMCSA; and (3) each driver is prohibited from operating a motorcoach or bus with passengers in interstate commerce. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. In addition, the exemption does not exempt the individual from meeting the applicable CDL testing requirements.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the 10 exemption applications, FMCSA exempts the following drivers from the hearing standard; in § 391.41(b)(11), subject to the requirements cited above:

Monica Garris (NC)
Jason Goldsmith (KY)
Richard Greene (NC)
Michael Hidalgo (CA)
Bret Hoefer (AZ)
Victor Howard (FL)
Gabriel Lerma (CA)
LaJuan Roper (TX)
William Soloman (OH)
George Vlahos (NJ)

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136, 49 U.S.C. chapter 313, or the FMCSRs.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2024–14735 Filed 7–3–24; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0093]

Deepwater Port License Application: Texas GulfLink LLC—Final Environmental Impact Statement

AGENCY: Maritime Administration, U.S. Department of Transportation.

ACTION: Notice of availability; request for comments.

SUMMARY: The Maritime Administration (MARAD) and the U.S. Coast Guard (USCG) announce the availability of the Final Environmental Impact Statement (FEIS) for the Texas GulfLink LLC (GulfLink) deepwater port license application for the export of oil from the United States to nations abroad. The GulfLink deepwater port license application describes a project that would be located approximately 26.2 nautical miles off the coast of Brazoria County, Texas. Publication of this notice announces a 45-day comment period ending on Monday, August 19, 2024, requests public participation in the final environmental impact review process and provides information on how to participate in the final environmental impact review process.

DATES: MARAD and USCG will hold one Final Hearing in connection with the GulfLink Application. The time and location for the Final Hearing will be published in a future notice. Public comments on the FEIS must be submitted to *www.regulations.gov* or the Federal Docket Management Facility as detailed in the **ADDRESSES** section below by the close of business on Monday, August 19, 2024.

ADDRESSES: Comments on the FEIS must be submitted to the U.S. Department of Transportation's Docket Management Facility or online to *www.regulations.gov* under docket number MARAD–2019–0093. The address of the Docket Management Facility is as follows: U.S. Department of Transportation, MARAD–2019–0093, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590. Instructions are listed in the Public Participation section of this Notice.

FOR FURTHER INFORMATION CONTACT: Mr. Patrick W. Clark, Project Manager, USCG, telephone: 202–372–1358, email: *DeepwaterPorts@USCG.mil;* or Dr. Linden Houston, Transportation Specialist, Office of Deepwater Ports and Port Conveyance, MARAD, telephone: 202–366–4839, email: *Linden.Houston@dot.gov.*

Please include ''MARAD–2019–0093, GulfLink Comment'' in the subject line of the message. For written comments and other material submissions, please follow the directions under the ''*How do I submit comments?*'' question in the Public Participation section of this notice.

SUPPLEMENTARY INFORMATION:

Prior Federal Actions

On May 30, 2019, MARAD and USCG received a license application from GulfLink for all Federal authorizations required for a license to construct, own, and operate a deepwater port for the export of oil. The proposed deepwater port would be in Federal waters approximately 26.6 nautical miles off the coast of Brazoria County, Texas. Texas was designated as the ACS for the GulfLink license application.

A Notice of Application that summarized the GulfLink Deepwater Port License Application was published in the **Federal Register** on June 26, 2019 (84 FR 30298). A Notice of Intent to Prepare an Environmental Impact Statement (EIS) and Notice of Public Scoping Meeting was published in the **Federal Register** on July 3, 2019 (84 FR 32008). A public scoping meeting in connection with the evaluation of the GulfLink license application was held in Lake Jackson, Texas on July 17, 2019. The transcript of the scoping meeting is included on the public docket located at *www.regulations.gov/document/MARAD-2019-0093-0047.* A **Federal Register** Notice was published on August 14, 2019 (84 FR 40476) to extend the public scoping comment period to August 30, 2019.

MARAD and USCG held three virtual public comment meetings to receive comments on the Draft Environmental Impact Statement (DEIS). A Notice of Availability for the DEIS and Notice of Public Meeting was published in the **Federal Register** on November 27, 2020 (85 FR 76157). The first two virtual public comment meetings were held on December 16, 2020, and December 17, 2020. The public comment period for these meetings began on November 27, 2020, and a **Federal Register** Notice was published on December 21, 2020 (85 FR 83142) to extend the comment period to January 22, 2021. Transcripts of these DEIS virtual public comment meetings are provided on the public docket at *www.regulations.gov/document/MARAD-2019-0093-0318, www.regulations.gov/document/MARAD-2019-0093-0319,* and *www.regulations.gov/document/MARAD-2019-0093-2839.* A Notice of Availability and Notice of Virtual Public Meeting was published in the **Federal Register** on September 24, 2021 (86 FR 53144). The Federal agencies held a third virtual DEIS public comment meeting to receive comments on the DEIS. The DEIS public meeting was held virtually on October 14, 2021. The purpose of the October 14, 2021, virtual public meeting was to reopen the public comment period for the DEIS and to provide affected communities, including Limited English Proficient persons, further opportunities to review and comment on the document. The transcripts from the third DEIS public comment meeting are included on the public docket at *www.regulations.gov/document/MARAD-2019-0093-2853.*

After the publication of the DEIS, GulfLink revised its deepwater license application in response to ongoing consultation with regulatory agencies and subsequently refined the design of the proposed deepwater port by adding a vapor control system into the design and operation of the proposed GulfLink deepwater port. A Notice of Availability; Notice of Virtual Public Meeting; Request for Comments for the Supplemental Draft Environmental Impact Statement (SDEIS) and was published in the **Federal Register** on September 30, 2022 (87 FR 59487) in response to proposed changes to the GulfLink deepwater port. The public meeting was held virtually on October 18, 2022. The transcripts of the SDEIS public comment meetings are also included on the public docket at

www.regulations.gov/document/MARAD-2019-0093-3097 and *www.regulations.gov/document/MARAD-2019-0093-3098.*

This Notice of Availability incorporates the aforementioned **Federal Register** notices by reference.

Summary of the License Application

GulfLink is proposing to construct, own, and operate a deepwater port terminal in the Gulf of Mexico to export domestically produced crude oil. Use of the deepwater port would include the loading of various grades of crude oil at flow rates of up to 85,000 barrels per hour (bph). The GulfLink deepwater port would allow for up to two Very Large Crude Carriers (VLCCs) or other crude oil carriers to moor at single point mooring (SPM) buoys and connect with the deepwater port via floating connecting crude oil hoses and a floating vapor recovery hose. The maximum frequency of loading VLCCs or other crude oil carriers would be one million barrels per day, 365 days per year.

The overall project would consist of offshore and marine components as well as onshore components as described below.

The GulfLink deepwater port offshore and marine components would consist of the following:

An Offshore Platform: One fixed offshore platform with piles in Outer Continental Shelf Galveston Area Lease Block GA–423, 26.6 nautical miles off the coast of Brazoria County, Texas, in a water depth of approximately 104 feet. The fixed offshore platform would have four decks comprised of personal living space, pipeline metering, a surge system, a pig receiving station, generators, lease automatic custody transfer unit, oil displacement prover loop, sample system, radar tower, electrical and instrumentation building, portal cranes, a hydraulic crane, an Operations/Traffic Room, and helicopter deck.

One 42-inch outside diameter, 28.1-nautical-mile long crude oil pipeline would be constructed from the shoreline crossing in Brazoria County, Texas, to the GulfLink deepwater port for crude oil delivery. This pipeline would connect the proposed onshore Jones Creek Terminal described below to the offshore platform.

The fixed offshore platform is connected to VLCC tankers for loading by two separate 42-inch diameter departing pipelines. Each pipeline will depart the fixed offshore platform, carrying the crude oil to a Pipeline End Manifold (PLEM) in approximately 104 feet of water depth located 1.25 nautical miles from the fixed offshore platform. Each PLEM is then connected to a Single Point Mooring (SPM) Buoy through two 24-inch cargo hoses. Two 24-inch floating cargo hoses will connect each SPM Buoy to the VLCC (or other crude oil carrier type). SPM Buoy 1 is positioned in Outer Continental Shelf Galveston Area Lease Block GA–423 and SPM Buoy 2 is positioned in Outer Continental Shelf Galveston Area Lease Block GA–A36.

Use of a dynamically positioned third-party Offshore Support Vessel, equipped with a vapor processing system to control the release of vapor emissions during the cargo loading operations of the proposed GulfLink deepwater port.

Onshore storage and supply components for the GulfLink deepwater port would consist of the following:

An Onshore Storage Terminal: The proposed Jones Creek Terminal would be in Brazoria County, Texas, on approximately 319 acres of land, consisting of eight above-ground storage tanks, each with a working storage capacity of 708,168 barrels, for a total onshore storage capacity of approximately 5,655,344 million barrels. The facility can accommodate four additional tanks, bringing the total to twelve tanks or 8,498,016 million barrels of storage capacity.

The Jones Creek Terminal also would include: Six electric-driven mainline crude oil pumps; three electric-driven booster crude oil pumps; one crude oil pipeline pig launcher; one crude oil pipeline pig receiver; two measurement skids for measuring incoming crude oil—one skid located on the Department of Energy's Bryan Mound facility, and one skid installed for the outgoing crude oil barrels leaving the tank storage to be loaded on the VLCC; and ancillary facilities to include an operations control center, electrical substation, offices, and warehouse building.

Two onshore crude oil pipelines would be constructed to support the GulfLink deepwater port and include the following:

One proposed incoming 9.1-statute mile long, 36-inch outside diameter pipeline connected to a leased 40-inch ExxonMobil pipeline originating at the Department of Energy's Bryan Mound facility with connectivity to the Houston market.

One proposed outgoing 12.1-statute mile long, 42-inch outside diameter pipeline connecting the Jones Creek Terminal to the shore crossing, where the offshore portion of this pipeline begins and supplies the proposed offshore GulfLink deepwater port.

As previously stated, the purpose of this notice is to announce the availability of the FEIS and the public comment period. Comments can be submitted through the Federal docket website: *www.regulations.gov* under docket number MARAD–2019–0093.

Purpose of the Final Environmental Impact Statement

The purpose of the FEIS is to analyze the direct, indirect, and cumulative environmental impacts of the proposed action, and to identify and analyze environmental impacts of a reasonable range of alternatives. The FEIS is currently available for public review and comment at the Federal docket website: *www.regulations.gov* under docket number MARAD–2019–0093.

Request for Comments

You are encouraged to provide comments on the proposed action and the environmental impact analysis contained in the FEIS for the proposed GulfLink deepwater port. These comments will inform MARAD's Record of Decision for the GulfLink deepwater license application. We encourage you to review the information on the project's docket located online at *www.regulations.gov* under docket number MARAD–2019–0093. It is preferred that comments be submitted electronically.

Please see the information in the ''*Public Participation*'' section below on how to properly submit comments. All comments submitted to the docket via *www.regulations.gov* or delivered to the Federal Docket Management Facility will be posted, without change, to the Federal Docket Management Facility website (*www.regulations.gov*) and will include any personal information you provide. Therefore, submitting such information makes it public. You may wish to read the Privacy and Use Notice available on the *www.regulations.gov* website and the Department of Transportation (DOT) Privacy Act Notice that appeared in the **Federal Register** on April 11, 2000 (65 FR 19477), see Privacy Act. You may view docket submissions at the DOT Docket Management Facility or electronically at the *www.regulations.gov* website.

Public Participation

How do I prepare comments?

To ensure that your comments are correctly filed in the Docket, please include the docket number (MARAD–2019–0093) shown at the beginning of this document in your comments. If you are submitting comments electronically as a .pdf (Adobe Acrobat) File, MARAD

and USCG ask that the documents be submitted using the Optical Character Recognition (OCR) process, thus allowing the agencies to search and copy certain portions of your submissions.

Please note that pursuant to the Data Quality Act, for substantive data to be relied upon and used by the agency, it must meet the information quality standards set forth in the Office of Management and Budget (OMB) and Department of Transportation (DOT) Data Quality Act guidelines. Accordingly, we encourage you to consult the guidelines in preparing your comments. OMB's guidelines may be accessed at *www.whitehouse.gov/omb/fedreg/reproducible.html.* DOT's guidelines may be accessed at *www.bts.gov/programs/statistical_policy_and_research/data_quality_guidelines.*

How do I submit comments?

You may submit comments for the GulfLink deepwater license application (identified by DOT Docket Number MARAD–2019–0093) by any one of the following methods:

Mail or Hand Delivery: The Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, MARAD–2019–0093, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590. Due to flexible work schedules in response to COVID–19, call 202–493–0402 to determine facility hours prior to hand delivery.

Federal eRulemaking Portal: Go to *www.regulations.gov.* Search ''MARAD–2019–0093'' and follow the instructions for submitting comments.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, and/or a telephone number on a cover page so that we can contact you if we have questions regarding your submission. All submissions received must include the agency name and specific docket number to ensure your comment is filed in the appropriate docket. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided.

What will happen if I submit comments in any other manner?

Comments that are not submitted directly to the Docket Management Facility using the methods specified and outlined within this **Federal Register** notice may not be considered.

How long do I have to submit comments?

We are providing a comment period for the public to submit comments, which begins with the publication of this **Federal Register** Notice and ends on Monday, August 19, 2024.

How can I be sure that my comments were received?

If you wish for Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

Will the agency consider late comments?

No. MARAD and USCG will consider all substantive comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**.

How can I read the comments submitted by other people?

You may read the comments received by Docket Management at the address given above under **ADDRESSES**. The hours of the Docket Management Unit are indicated above in the same location. You may also see the comments on the internet. To read the comments on the internet, go to *www.regulations.gov.* Search using ''MARAD–2019–0093'' and follow the online instructions.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, visit *www.transportation.gov/privacy.*

(Authority: 33 U.S.C. 1501, *et seq.;* 49 CFR 1.93(h))

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2024–14370 Filed 7–3–24; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Interest Rate Paid on Cash Deposited To Secure U.S. Immigration and Customs Enforcement Immigration Bonds

AGENCY: Departmental Offices, Treasury.

ACTION: Notice.

SUMMARY: For the period beginning July 1, 2024, and ending on September 30, 2024, the U.S. Immigration and Customs Enforcement Immigration Bond interest rate is 3 per centum per annum.

DATES: Rates are applicable July 1, 2024, to September 30, 2024.

ADDRESSES: Comments or inquiries may be mailed to Will Walcutt, Supervisor, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Services, Parkersburg, West Virginia 26106–1328.

You can download this notice at the following internet addresses: <*http://www.treasury.gov*> or <*http://www.federalregister.gov*>.

FOR FURTHER INFORMATION CONTACT: Ryan Hanna, Manager, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Service, Parkersburg, West Virginia 261006–1328; (304) 480–5120; Will Walcutt, Supervisor, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Services, Parkersburg, West Virginia 26106–1328, (304) 480–5117.

SUPPLEMENTARY INFORMATION: Federal law requires that interest payments on cash deposited to secure immigration bonds shall be ''at a rate determined by the Secretary of the Treasury, except that in no case shall the interest rate exceed 3 per centum per annum.'' 8 U.S.C. 1363(a). Related Federal regulations state that ''Interest on cash deposited to secure immigration bonds will be at the rate as determined by the Secretary of the Treasury, but in no case will exceed 3 per centum per annum or be less than zero.'' 8 CFR 293.2. Treasury has determined that interest on the bonds will vary quarterly and will accrue during each calendar quarter at a rate equal to the lesser of the average of the bond equivalent rates on 91-day Treasury bills auctioned during the preceding calendar quarter, or 3 per centum per annum, but in no case less than zero. [FR Doc. 2015–18545]. In addition to this Notice, Treasury posts the current quarterly rate in Table 2b—Interest Rates for Specific Legislation on the Treasury Direct website.

The Deputy Assistant Secretary for Public Finance, Gary Grippo, having reviewed and approved this document, is delegating the authority to electronically sign this document to Heidi Cohen, Federal Register Liaison for the Department, for purposes of publication in the **Federal Register**.

Heidi Cohen,

Federal Register Liaison.

[FR Doc. 2024–14759 Filed 7–3–24; 8:45 am]

BILLING CODE 4810–AS–P

FEDERAL REGISTER

Vol. 89 Friday,
No. 129 July 5, 2024

Part II

Environmental Protection Agency

40 CFR Part 63
National Emission Standards for Hazardous Air Pollutants for Coke Ovens: Pushing, Quenching, and Battery Stacks, and Coke Oven Batteries; Residual Risk and Technology Review, and Periodic Technology Review; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2002–0085, EPA–HQ–OAR–2003–0051; FRL–8471–02–OAR]

RIN 2060–AV19

National Emission Standards for Hazardous Air Pollutants for Coke Ovens: Pushing, Quenching, and Battery Stacks, and Coke Oven Batteries; Residual Risk and Technology Review, and Periodic Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action finalizes the residual risk and technology review conducted for the National Emissions Standards for Hazardous Air Pollutants (NESHAP) for the Coke Ovens: Pushing, Quenching, and Battery Stacks (PQBS) source category and the periodic technology review for the Coke Oven Batteries (COB) source category NESHAP. The EPA is finalizing a determination that risks due to emissions of hazardous air pollutants (HAP) from the PQBS source category are acceptable and that the current NESHAP provides an ample margin of safety to protect public health.

DATES: This final rule is effective on July 5, 2024, except for amendatory instruction 3, which is effective July 15, 2024. The incorporation by reference (IBR) of certain publications listed in the rule is approved by the Director of the Federal Register beginning July 5, 2024. The IBR of certain other material listed in the rule was approved by the Director of the Federal Register as of July 13, 2005.

ADDRESSES: The U.S. Environmental Protection Agency (EPA) has established a docket for this action under Docket ID Nos. EPA–HQ–OAR–2002–0085 for the Coke Ovens: Pushing, Quenching, and Battery Stacks (PQBS) source category and EPA–HQ–OAR–2003–0051 for the Coke Oven Batteries (COB) source category. 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 either electronically through *https://www.regulations.gov/,* or in hard copy at the EPA Docket Center, WJC West Building, Room Number 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time, Monday through Friday. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact U.S. EPA, Attn: Donna Lee Jones, Sector Policies and Programs Division (MD–243–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5251; email address: *jones.donnalee@epa.gov.* For specific information regarding the risk modeling methodology, contact U.S. EPA, Attn: Michael Moeller, Health and Environmental Impacts Division (C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2766; email address: *moeller.michael@epa.gov.*

SUPPLEMENTARY INFORMATION: Under the technology review for the PQBS NESHAP, we are finalizing new maximum achievable control technology standards for unregulated HAP or sources of HAP and a 20 percent opacity limit for bypass/waste heat stacks at heat and/or nonrecovery (HNR) facilities. Under the technology review for the COB NESHAP, we are lowering the limits for leaking doors, lids, and offtakes at by-product (ByP) facilities to reflect improvements in practices, processes, or technology, a requirement for fenceline monitoring for benzene (as a surrogate for coke oven emissions) with a requirement to conduct a root cause analysis and corrective action upon exceeding an action level of benzene; a revised equation to estimate emissions from leaks of ByP oven doors; a requirement of zero leaking oven doors at HNR facilities and pressure monitoring in either oven or common tunnels. We are finalizing the removal of exemptions for periods of startup, shutdown, and malfunction consistent with a 2008 court decision, clarifying that the standards apply at all times; and the addition of electronic reporting for performance test results and compliance reports.

Preamble acronyms and abbreviations. 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:

1–BP 1-bromopropane
ACI activated carbon injection
ANSI American National Standards Institute
APCD air pollution control device
B/W bypass/waste heat
BDL below detection limit
BTF beyond-the-floor
ByP coke production process with by-product chemical recovery
CAA Clean Air Act
CBI confidential business information
CBRP coke by-product chemical recovery plant
CDX Central Data Exchange
CEDRI Compliance and Emissions Data Reporting Interface
CFR Code of Federal Regulations
COB coke oven batteries
CE Cost Effectiveness
COE coke oven emissions
CRA Congressional Review Act
DCOT digital camera opacity technique
D/F dioxin and furans
EAV equivalent annualized value
EDL estimated level of detection
EDT Eastern Daylight Time
EIA economic impact analysis
EMPC estimated maximum potential concentration
EPA Environmental Protection Agency
ERPG emergency response planning guideline
ERT Electronic Reporting Tool
FR Federal Register
FTIR Fourier Transform Infrared Spectroscopy
gr/dscf grains per dry standard cubic feet
HAP hazardous air pollutants(s)
HCl hydrochloric acid
HCN hydrogen cyanide
HEM human exposure model
HF hydrogen fluoride
HNR heat and nonrecovery (i.e., no chemical recovery), or nonrecovery with no heat recovery
HQ hazard quotient
HRSG heat recovery steam generator
IBR incorporation by reference
ICR information collection request
km kilometer
LAER lowest achievable emissions rate
lb/ton pounds per ton
LDAR leak detection and repair
LEAN Louisiana Environmental Action Network
MACT maximum achievable control technology
MIR maximum individual risk
NA not applicable
NAICS North American Industry Classification System
ND number of doors
NESHAP national emission standards for hazardous air pollutants
NSPS New Source Performance Standards
NTTAA National Technology Transfer and Advancement Act
O2 oxygen dioxide
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget

OP Office of Policy
PAH polycyclic aromatic hydrocarbons
PDF portable document format
PLD percent leaking doors
PLD_{bench} percent leaking doors from the bench
$PLD_{bench\text{-}only}$ percent leaking doors from the bench only
PLD_{yard} percent leaking doors from the yard
PM particulate matter
PRA Paperwork Reduction Act
ppbv parts per billion by volume
ppbw parts per billion by weight
ppmv parts per million by volume
ppmw parts per million by weight
PQBS pushing, quenching, and battery stacks
RCACA root cause analysis and corrective action
REL reference exposure limit
RFA Regulatory Flexibility Act
RIN Regulatory Information Number
RTR risk and technology review
SO_2 sulfur dioxide
SSM startup, shutdown, and malfunction
SSMP site-specific monitoring plans
TBD to be determined
TOSHI target organ-specific hazard index
tpy tons per year
UMRA Unfunded Mandates Reform Act
UPL upper prediction limit
$\mu g/m^3$ microgram per cubic meter
URE unit risk estimate
U.S. United States
VCS voluntary consensus standards
VE visible emissions
VOC volatile organic compound
VOHAP volatile organic HAP
WAS wet alkaline scrubber

Background information. On August 16, 2023, the EPA proposed revisions to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pushing, Quenching, and Battery Stacks (PQBS) based on our risk and technology review (RTR), and for the Coke Oven Batteries (COB) NESHAP based on our technology review. In this action, we are finalizing decisions and revisions for the rules. We summarize some of the more significant comments we timely received regarding the proposed rule and provide our responses in this preamble. A summary of all other public comments on the proposal and the EPA's responses to those comments is available in the document, *Summary of Public Comments and Responses for Coke Ovens: Pushing, Quenching, and Battery Stacks Residual Risk and Technology Review, and Coke Oven Batteries Periodic Technology Review,*[1] hereafter referred to as the ''*Response to Comment*'' document, which is available in the dockets for this final action (Docket ID No's. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051). A ''track changes'' or ''redline strikeout'' version of the regulatory language that incorporates the changes in this action is available in the dockets.

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

I. General Information

A. Executive Summary

1. Purpose of the Regulatory Action

The Environmental Protection Agency (EPA) is finalizing amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Coke Ovens: Pushing, Quenching, and Battery Stacks (PQBS) source category and NESHAP for the Coke Oven Batteries (COB) source category. The purpose of this final action is to fulfill the EPA's statutory obligations pursuant to Clean Air Act (CAA) sections 112(d)(2), (d)(3) and (d)(6) and improve the emissions standards for the COB and PQBS source categories based on information regarding developments in practices, processes, and control technologies (''technology review'').

In addition, this action fulfills the EPA's statutory obligations pursuant to CAA section 112(f)(2) to evaluate the

[1] *Summary of Public Comments and Responses for Coke Ovens: Pushing, Quenching, and Battery Stacks Residual Risk and Technology Review, and Coke Oven Batteries Periodic Technology Review.* U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division (D243–02), Research Triangle Park, North Carolina. May 1, 2024.

maximum achievable control technology (MACT) standards for the PQBS source category to determine whether additional standards are required to address any remaining risk associated with hazardous air pollutant (HAP) emissions from this PQBS source category (''residual risk review'').

2. Summary of the Major Provisions of This Regulatory Action

Under the residual risk review for the PQBS NESHAP pursuant to CAA section 112(f)(2), the EPA estimated the inhalation maximum individual risk (MIR) for cancer (based on current actual emissions levels) due to HAP emissions from PQBS sources is 9-in-1 million, and the MIR based on allowable emissions was slightly higher (10-in-1 million). All estimated noncancer risks are below a level of concern. Based on these risk results and subsequent evaluation of potential controls (*e.g.,* costs, feasibility and impacts) that could be applied to reduce these risks even further, we are promulgating a determination that risks due to HAP emissions from the PQBS source category are acceptable and the PQBS NESHAP provides an ample margin of safety to protect public health. Therefore, we are not finalizing amendments under CAA section 112(f)(2).

Under the technology review for the PQBS NESHAP pursuant to CAA section 112(d)(6), and consistent with the Louisiana Environmental Action Network (LEAN*)* court decision,[2] the EPA is finalizing MACT standards for previously unregulated HAP emissions pursuant to CAA sections 112(d)(2) and (3), and 112(h). The EPA identified unregulated HAP and emissions source combinations from PQBS sources,as follows: acid gases (AG) (*i.e.,* the sum of hydrochloric acid and hydrofloric acid), dioxin and furans (D/F), formaldehyde, hydrogen cyanide (HCN), mercury (Hg), polycyclic aromatic hydrocarbons (PAH), and volatile organic HAP (VOHAP) from pushing operations; AG, D/F, HCN, Hg, PAH, particulate matter (PM) nonmercury HAP metals (*e.g.,* lead and arsenic), and VOHAP from by-product (ByP) coke facility battery stacks; AG, formaldehyde, Hg, PAH, and PM nonmercury metals from heat and/or nonrecovery (HNR) facilities' heat recovery steam generators (HRSG) main stacks; AG, formaldehyde, Hg, PAH, PM nonmercury metals, and VOHAP from HNR facilities' bypass/waste heat (B/W) stacks. In this action, under the authority of CAA sections 112(d)(2) and (3) and 112(h), we are finalizing MACT floor standards (*i.e.,* the minimum stringency level allowed by the CAA) for these previously unregulated HAP.

Also under the technology review for the PQBS NESHAP pursuant to CAA section 112(d)(6), the EPA also is setting a 20 percent opacity limit for HNR B/W stacks to be measured weekly. The EPA did not identify any other cost-effective options to reduce emissions from currently regulated sources under the PQBS NESHAP.

The EPA is finalizing amendments under the technology review for the COB NESHAP pursuant to CAA section 112(d)(6) to include: (1) lower emission leak limits for ByP facility coke oven doors, lids, and offtakes; (2) for ByP facilities, continuous fenceline monitoring for benzene along with an action level for benzene (as a surrogate for coke oven emissions) and a requirement for root cause analysis and corrective actions (RCACA) if the action level is exceeded; (3) for HNR facilities, a requirement to demonstrate that there are zero leaks from their oven doors, as well as to ensure negative pressure in the ovens or common tunnels; and (4) a revised equation to estimate emissions from leaks of ByP oven doors that better represents the current industry emissions. The EPA did not identify any other cost-effective options to reduce emissions from currently regulated sources under the COB NESHAP.

We conducted a demographics analysis that indicates that the population within 10 kilometers (km) of the coke oven facilities with whole facility cancer risks greater than or equal to 1-in-1 million is predominantly white (62 percent versus 60 percent nationally). The population with whole facility cancer risks greater than or equal to 1-in-1 million is 30 percent African American compared to the national average of 12 percent. The population with whole facility cancer risks greater than or equal to 1-in-1 million living within 10 km of the two facilities located in Alabama is 56 percent African American, which is significantly higher than the national average. The population with whole facility cancer risks greater than or equal to 1-in-1 million also is above the national average for the percent of the population living below poverty (17 percent versus a 13 percent national average).

In addition, we are finalizing: (1) the removal of exemptions for periods of startup, shutdown, and malfunction (SSM) consistent with a 2008 court decision, *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), and clarifying that the emissions standards apply at all times; and (2) the addition of requirements for electronic reporting of performance test results and compliance reports for both NESHAP and fenceline monitoring reports for the COB NESHAP.

3. Costs and Benefits

Cost impacts will occur due to the required source testing that includes: testing every 5 years to demonstrate compliance with the promulgated MACT floor standards for PQBS; weekly opacity testing of HNR B/W heat stacks; daily visible leak testing of HNR ovens doors; and fenceline monitoring at ByP facilities. The total costs for the rules are estimated to be $4.0 million per year for the 11 operating facilities ($2023), with $500,000 per facility, on average for the five HNR facilities and $250,000 per facility, on average, for the 6 ByP facilities. The testing to demonstrate compliance with the MACT limits is estimated to be $3.3 million total for the 11 operating facilities, with $300,000 per facility on average. The HNR B/W stack opacity testing is estimated to be $22,000 total for the five HNR facilities, with $4,400 per facility on average. The HNR daily door leak testing with EPA Method 303A is estimated to be $105,000 total for the five HNR facilities, with $21,000 per facility on average. The fenceline monitoring costs are estimated to be $640,472 for the six ByP facilities, with $107,000 per facility on average.

The EPA has not quantified any benefits associated with this final rule because all covered facilities are expected to already have HAP emissions levels that are below the final limits, based on facility data available to the EPA. However, the EPA anticipates that this final rule's new requirements will increase the likelihood of facilities successfully detecting any HAP emissions in excess of the specified limits, allowing for earlier corrective action and thus preventing pollution increases that could otherwise occur. The potential public health benefits associated with such prevention are difficult to estimate, given that they correspond to hypothetical scenarios of emissions beyond those indicated by current facility data, and are thus not quantified in EPA's analysis.

4. Community Outreach

The EPA held a virtual public hearing on August 31, 2023, from 11:00 a.m. to 3:00 p.m. eastern daylight time (EDT), where 37 speakers provided oral comments. The EPA held a virtual webinar on September 14, 2023, from 6:00 p.m. to 7:30 p.m. EDT, where 34 registrants participated.

[2] *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

B. Does this action apply to me?

Regulated entities. Categories and entities potentially regulated 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	NESHAP	NAICS [a] code
Coke Ovens: Pushing, Quenching, and Battery Stacks.	40 CFR part 63, subpart CCCCC	331110 Iron and Steel Mills and Ferroalloy Manufacturing.
Coke Oven Batteries	40 CFR part 63, subpart L	324199 All Other Petroleum and Coal Products Manufacturing.

[a] North American Industry Classification System.

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 appropriate 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.

C. 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/coke-ovens-pushing-quenching-and-battery-stacks-national-emission* and *https://www.epa.gov/stationary-sources-air-pollution/coke-ovens-batteries-national-emissions-standards-hazardous-air.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at this same website.

Additional information is available on RTR website at *https://www.epa.gov/stationary-sources-air-pollution/risk-and-technology-review-national-emissions-standards-hazardous.* This information includes an overview of the RTR program and links to project websites for the RTR source categories.

D. Judicial Review and Administrative Reconsideration

Under 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 (the Court) by September 3, 2024. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background

A. What is the statutory authority for this action?

Section 112 of the CAA establishes a two-stage regulatory process to address emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, we must identify categories of sources emitting one or more of the HAP listed in CAA section 112(b) and then promulgate technology-based NESHAP for those sources. ''Major sources'' are those that emit, or have the potential to emit, any single HAP at a rate of 10 tons per year (tpy) or more, or 25 tpy or more of any combination of HAP. For major sources, these standards are commonly referred to as MACT standards and must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). In developing MACT standards, CAA section 112(d)(2) directs the EPA to consider the application of measures, processes, methods, systems, or techniques, including, but not limited to, those that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or processes to eliminate emissions; collect, capture, or treat HAP when released from a process, stack, storage, or fugitive emissions point; are design, equipment, work practice, or operational standards; or any combination of the above.

For these MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as MACT floor requirements, and which may not be based on cost considerations. See CAA section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor under CAA section 112(d)(2). We may establish standards more stringent than the floor, referred to as ''beyond-the-floor'', based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements.

In the second stage of the regulatory process, the CAA requires the EPA to

undertake two different analyses, which we refer to as the technology review and the residual risk review. Under the technology review, we must review the technology-based standards and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years, pursuant to CAA section 112(d)(6). In conducting this review, the EPA is not required to recalculate the MACT floors that were established in earlier rulemakings. *Natural Resources Defense Council (NRDC)* v. *EPA,* 529 F.3d 1077, 1084 (D.C. Cir. 2008). *Association of Battery Recyclers, Inc.* v. *EPA,* 716 F.3d 667 (D.C. Cir. 2013). The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6). The EPA is required to address regulatory gaps, such as missing standards for listed air toxics known to be emitted from the source category, and any new MACT standards must be established under CAA sections 112(d)(2) and (3), or, in specific circumstances, CAA sections 112(d)(4) or (h).[3] Under the residual risk review, we must evaluate the risk to public health remaining after application of the technology-based standards and revise the standards, if necessary, to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. The residual risk review is required within 8 years after promulgation of the technology-based standards, pursuant to CAA section 112(f). In conducting the residual risk review, if the EPA determines that the current standards provide an ample margin of safety to protect public health, it is not necessary to revise the MACT standards pursuant to CAA section 112(f).[4] For more information on the statutory authority for this rule, see 88 FR 55858.

B. What are coke ovens, what are the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks and the NESHAP for Coke Oven Batteries source categories, and how do the NESHAP regulate HAP emissions from the source categories?

Coke ovens are chambers of brick or other heat-resistant material in which coal is heated to separate the gas, water, and tar in coal to produce coke, a fuel and source of carbon used in steelmaking. The coking process takes place at two types of facilities: (1) ByP facilities, where chemical by-products are recovered from coke oven emissions (COE), a CAA section 112(b) listed HAP, in coke oven exhaust at a co-located coke byproduct chemical recovery plant (CBRP); or (2) HNR facilities, where chemicals are not recovered (and, therefore, are called ''nonrecovery'' facilities), but heat may be recovered from the exhaust from coke ovens in a heat recovery steam generator (HRSG). There are 12 coke facilities in the United States (U.S.), with 11 of these currently operating. Seven of these facilities use the ByP process and five use the HNR process. Of the five HNR facilities, four have HRSGs and one does not. For additional background information on the source categories see the proposal preamble (88 FR 55858).

The COB NESHAP (40 CFR part 63, subpart L), promulgated in 1993, set emission limits (via limiting the number of seconds of visible emissions (VE)) from doors, lids, and offtakes at HNR facilities and any new ByP facilities to 0 percent leaking. The NESHAP for PQBS (40 CFR part 63, subpart CCCCC) were promulgated on April 14, 2003. The PQBS NESHAP established emissions standards for pushing coke out of ovens, quenching hot coke, and battery stacks of oven combustion.

For nonrecovery facilities, *i.e.,* facilities that do not recover chemicals, operating before 2004, the 1993 COB NESHAP required good operating and maintenance practices to minimize emissions during charging. The 1993 promulgated requirement for charging affected only SunCoke's Vansant (Virginia) facility, which is a nonrecovery coke facility, and also does not recover heat. For the nonrecovery facilities that recover heat that began operating after 2004, which includes the other four HNR facilities and any future HNR facilities, the NESHAP regulates charging via PM and opacity limits, requires a PM control device, and establishes work practices for minimizing VE during charging.

For ByP facilities, the COB NESHAP regulates emissions occurring during the charging of coal into the ovens and from leaking oven doors, leaking topside charging port lids, and leaking offtake ducts. The charging process for ByP facilities includes opening the lids on the charging ports on the top of the tall narrow ovens and discharging coal from hoppers of a car that positions itself over the oven port and drops coal into the oven. The COB NESHAP limits the number of seconds of VE during a charge at ByP facilities, as determined by measurements made according to EPA Method 303.

The emissions from leaks at ByP batteries are regulated under the COB NESHAP by limits on the percent of doors, lids, and offtakes that leak COE. The emissions from leaks at HNR batteries are regulated under the COB NESHAP by limits on leaks only from oven doors. At HNR facilities, coal is charged into doors on one end of a long horizontal oven and pushed out the other end through another door at the other end of the oven. The offtake system at ByP facilities includes ascension pipes and collector main offtake ducts that are located on the top of the coke oven and battery. At HNR facilities, a common tunnel collects exhaust from the batteries and also is located on the top of the coke oven and battery. The common tunnels are equipped with afterburners that burn any remaining organics in the coke oven exhaust as it travels through the common tunnel. The common tunnel routes exhaust from the batteries to either HRSG or bypass/waste heat stacks depending on whether there are HRSG at the facility and whether the HRSG are operating.

The standards for the COB NESHAP are codified at 40 CFR part 63, subpart L. The COB NESHAP limits for leaks from doors, lids, and offtakes, and the requirements for charging are based on the regulatory ''track'' of the facilities. The facilities were required by CAA section 112(i)(8) to choose either the MACT track or the lowest achievable emissions rate (LAER) track by 1993 (58 FR 57898). There are no longer any ByP facilities on the MACT track operating today. Of the eleven operating coke facilities, all seven ByP facilities are on the LAER track and one HNR facility (SunCoke's Vansant plant) is on the LAER track; the remaining four HNR facilities are on the MACT track. Any future coke facilities of any type (HNR or ByP) would be on the MACT track,[5] but no additional ByP facilities are expected in the future due to the requirement for 0 percent leaking doors, lids, and offtakes (as determined by EPA Method 303) for new facilities under the COB NESHAP. The positive pressure operation of ByP ovens likely makes it impossible to achieve zero leaks with the current ByP coke oven technology. Therefore, any new facilities would be expected to be only the HNR type, which operate under negative pressure.

The standards for the Coke PQBS NESHAP are codified at 40 CFR part 63,

[3] *Louisiana Environmental Action Network* v. *EPA*, 955 F.3d 1088 (D.C. Cir. 2020).

[4] The Court has affirmed this approach of implementing CAA section 112(f)(2)(A): *NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008) (''If EPA determines that the existing technology-based standards provide an 'ample margin of safety,' then the Agency is free to readopt those standards during the residual risk rulemaking.'').

[5] *See* CAA section 112(i)(8)(D).

subpart CCCCC and apply to both ByP and HNR facilities. The battery stacks are located only at ByP facilities. The proposed amendments to the Coke PQBS NESHAP added MACT limits for HNR HRSG main stacks and HNR B/W stacks, which are located only at HNR facilities.

C. What changes did we propose for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks and the NESHAP for Coke Oven Batteries source categories in our August 16, 2023, proposal?

On August 16, 2023, the EPA published a proposed rule in the **Federal Register** for the NESHAPs for PQBS and COB, 40 CFR part 63, subparts CCCCC and L, respectively, that took into consideration the RTR analysis for the PQBS NESHAP and technology review for the COB NESHAP. We proposed:

- 17 new MACT standards for previously-unregulated HAP pursuant to CAA sections 112(d)(2) and (3).
- Opacity limit of 10 percent for the HNR B/W stacks and requirement for daily observation of B/W stacks during charging to determine if VE are present.
- Zero leaking oven doors at HNR oven batteries, as determined by EPA Method 303A, which relies on observing VE emanating from the ovens; and also monitoring pressure both in the ovens and the common tunnel, instead of choosing one or the other points to measure pressure and instead of choosing either 0 oven door leaks or pressure monitoring, as the current rule allows.
- Fenceline monitoring for benzene (as a surrogate for COE) along with an action level for benzene and a requirement for RCACA if the action level is exceeded.
- Lower limits for allowable leaks from coke oven doors, lids, and offtakes at ByP facilities.
- Removal of exemptions for periods of SSM consistent with a 2008 court decision, *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), and clarifying that the emissions standards apply at all times.
- Addition of electronic reporting for performance test results and compliance reports for both NESHAP.

III. What is included in these final rules?

This action finalizes the EPA's determinations for: (1) the CAA sections 112(f) and 112(d)(6) residual risk and technology review for the NESHAP for the PQBS source category; (2) the CAA section 112(d)(6) technology review for the NESHAP for the COB source category; and (3) other changes to the NESHAP, including the removal of SSM exemptions and addition of electronic reporting.

A. What are the final rule amendments based on the risk review for the Coke Ovens: Pushing, Quenching, and Battery Stacks source category?

Considering the health risk information and factors discussed in the August 2023 proposed rule for the PQBS NESHAP, the EPA is finalizing a determination that the risks for this source category under the current NESHAP provisions are acceptable pursuant to CAA section 112(f). We did not identify any potential cost-effective controls or other measures to reduce risk further under our CAA section 112(f) risk review. Therefore, based on all of the information presented in the proposed rule and in this final rule preamble, we conclude that the current standards in the PQBS NESHAP provide an ample margin of safety to protect public health and are finalizing no changes based on the risk review. Furthermore, based on our screening assessment of environmental risk presented in section IV.B.4. of the August 2023 proposed rule preamble, we have determined that HAP emissions from the Coke Ovens: PQBS source category do not result in an adverse environmental effect, and we are finalizing that it is not necessary to set a more stringent standard to prevent an adverse environmental effect, taking into consideration costs, energy, safety, and other relevant factors.

B. What are the final rule amendments based on the technology reviews for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks and Coke Oven Batteries source categories?

As part of the technology review for the PQBS source category, we identified regulatory gaps (previously unregulated processes or pollutants) and are establishing new standards to fill those gaps, as described in section III.C. and IV.C. of this preamble. We also are requiring HNR B/W stacks to meet a limit of 20 percent opacity to be measured weekly at HNR B/W stacks and weekly at HRSG bypass stacks if operating.

For the COB source category, to address fugitive emissions at COB facilities as part of the technology review, we are finalizing a requirement for a work practice based on the results of fenceline monitoring for benzene at ByP facilities. The work practice has an action level of 7 microgram per cubic meter ($\mu g/m^3$) of benzene (as a surrogate for COE) with a requirement for RCACA if the action level is exceeded. We also identified improvements in control of ByP battery leaks and are finalizing reduced allowable limits for the percent of leaking doors, lids, and offtakes at ByP facilities. We are finalizing a requirement to demonstrate there are zero leaking oven doors at HNR facilities, as determined by EPA Method 303A, and requiring either oven pressure or common tunnel pressure monitoring at HNR facilities during the main parts of the oven cycle. Lastly, we are finalizing a revised equation for estimating leaks from ByP coke oven doors based on our evaluation of the historic equation developed from 1981 coke oven leak data supplemented with recent coke oven leak data, and also considering comments received.

C. What are the final rule amendments pursuant to CAA sections 112(d)(2) and (3) for the NESHAP for the Coke Ovens: Pushing, Quenching, and Battery Stacks source category?

We are finalizing 18 MACT floor standards [6] unregulated HAP and process combinations for the NESHAP for PQBS pursuant to CAA sections 112(d)(2) and (3) and 112(h) as follows: (1) MACT floor standards for AG, HCN, Hg, and PAH from pushing operations for existing and new sources; (2) MACT floor standards for AG, HCN, Hg, and PM (as a surrogate for nonmercury HAP metals), and a work practice standard for battery stacks (based on good combustion in battery waste heat flues) for PAH, D/F and VOHAP emissions from battery stacks at ByP facilities for existing and new sources; (3) MACT standards for AG, Hg, PAH, and PM (as a surrogate for nonmercury HAP metals) from HNR HRSG main stacks for existing and new sources; and (4) MACT standards for AG, formaldehyde, Hg, PAH, and PM (as a surrogate for nonmercury HAP metals) for HNR B/W stacks. More details are provided in section IV.C. of this preamble.

D. What are the final rule amendments addressing emissions during periods of startup, shutdown, and malfunction?

We are finalizing the removal of exemptions for periods of startup, shutdown, and malfunction (SSM) largely as proposed, consistent with a 2008 court decision, *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), and

[6] Note, we erroneously reported that there were 15 new MACT floor limits in the August 2023 proposal preamble. This was a typographic error. The proposed rule included 17 new MACT floor limits and 2 BTF limits; the BTF limits are not included in the final rule. However, we are adding a work practice standard in this final rule so the count of standards is now 18.

clarifying that the emissions standards apply at all times.

E. What are the final rule amendments addressing electronic reporting?

The EPA is promulgating that owners and operators of coke oven facilities, under both the PQBS NESHAP and COB NESHAP, submit electronic copies of required performance test reports, periodic reports (including fenceline monitoring reports), and periodic certifications through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). A description of the electronic data submission process is provided in the memorandum *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* available in the dockets for this action (EPA–HQ–OAR–2002–0085–0908 and EPA–HQ–OAR–2003–0051–0748). The promulgated rule requires that performance test results collected using test methods that are supported by the EPA's ERT as listed on the ERT website [7] at the time of the test be submitted in the format generated through the use of the ERT or an electronic file consistent with the *xml* schema on the ERT website, and other performance test results be submitted in portable document format (PDF) using the attachment module of the ERT.

For the quarterly and semiannual compliance reports of the PQBS NESHAP source category and the semiannual compliance certification of the COB NESHAP source category, the promulgated rule requires that owners and operators use the appropriate spreadsheet template to submit information to CEDRI. A draft version of the promulgated templates for these reports is included in the docket for this action.[8] The final version of the templates will be available at the CEDRI website *(https://www.epa.gov/electronic-reporting-air-emissions/cedri*).

The electronic submittal of the reports addressed in this final rulemaking increases the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, further assists in the protection of public health and the environment, improves compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and ultimately reduces the burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public. Moreover, electronic reporting is consistent with the EPA's plan [9] to implement Executive Order 13563 and is in keeping with the EPA's agency-wide policy [10] developed in response to the White House's Digital Government Strategy.[11] For more information on the benefits of electronic reporting, see the memorandum *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* referenced earlier in this section.

F. What are the effective and compliance dates of the final rule amendments?

These final rules are effective upon promulgation. The compliance date for the MACT standards for sources in the PQBS NESHAP is January 5, 2026. For the periodic MACT compliance testing, we are promulgating that periodic testing be conducted at the beginning of each permit cycle or every 5 years, whichever is shorter. The compliance date for opacity limits on HNR B/W stacks is July 7, 2025. The compliance date for achieving zero leaks from HNR oven doors and concurrent oven or tunnel pressure monitoring is July 7, 2025.

For fenceline monitoring provisions of the COB NESHAP, the compliance date to begin fenceline monitoring is July 7, 2025. The compliance date for complying with the revisions to the limits for allowable leaks from doors, lids, and offtakes is July 7, 2025.

The date for complying with the SSM changes is no later than July 5, 2024 with the exception of recordkeeping provisions. For recordkeeping under the SSM, facilities must comply with this requirement January 2, 2025. The date for complying with the recordkeeping provisions associated with malfunction events is January 2, 2025.

G. What are the final rule amendments addressing adding 1-bromopropane to list of HAP?

On January 5, 2022, the EPA published a final rule amending the list of HAP under the CAA to add 1-bromopropane (1–BP) in response to public petitions previously granted by the EPA. (87 FR 393). Consequently, as each NESHAP is reviewed, the EPA is evaluating whether the addition of 1–BP to the CAA section 112 HAP list impacts the source category. For the PQBS and COB source categories, we concluded that the inclusion of 1–BP as a regulated HAP would not impact the representativeness of the MACT standard because, based on available information, we have no evidence that 1–BP is emitted from this source category. No comments were received on this subject for the coke ovens NESHAP. As a result, no changes are being promulgated to the PQBS and COB NESHAP based on the January 2022 rule adding 1–BP to the list of HAP.

IV. What is the rationale for our final decisions and amendments for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks and the NESHAP for Coke Oven Batteries source categories?

For each issue, this section provides a description of what we proposed and what we are finalizing for the issue, the EPA's rationale for the final decisions and amendments, and a summary of key comments and responses. For all comments not discussed in this preamble, comment summaries and the EPA's responses can be found in the *Response to Comment* document,[12] which is available in the docket for this final action.

[7] *https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert.*

[8] See Draft Form 5900–618 Coke Ovens Part 63 Subpart L Semiannual Report.xlsx, Draft Form 5900–619 Part 63 Subpart L Fenceline Quarterly Report.xlsx, and Draft Form 5900–621 Coke Ovens Part 63 Subpart CCCCC Semiannual Report.xlsx, available at Docket ID. No EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

[9] *EPA's Final Plan for Periodic Retrospective Reviews.* August 2011. Available at: *https://www.regulations.gov/document?D=EPA-HQ-OA-2011-0156-0154.*

[10] E-Reporting Policy Statement for EPA Regulations. September 2013. Available at: *https://www.epa.gov/sites/production/files/2016-03/documents/epa-ereporting-policy-statement-2013-09-30.pdf.*

[11] Digital Government: Building a 21st Century Platform to Better Serve the American People. May 2012. Available at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/egov/digital-government/digital-government.html.*

[12] *Summary of Public Comments and Responses for Coke Ovens: Pushing, Quenching, and Battery Stacks Residual Risk and Technology Review, and Coke Oven Batteries Periodic Technology Review.* U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division (D243–02), Research Triangle Park, North Carolina. May 1, 2024.

A. Residual Risk Review for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks Source Category

1. What did we propose pursuant to CAA section 112(f) for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks source category?

Pursuant to CAA section 112(f), the EPA conducted a residual risk review of the PQBS NESHAP and presented the results of this review, along with our proposed decisions regarding risk acceptability and ample margin of safety, in the August 16, 2023, proposed rule for the PQBS source category (88 FR 55858). The results of the risk assessment for the proposal are presented in table 2 of this preamble. More detail is in the residual risk technical support document *Residual Risk Assessment for the Coke Pushing, Quenching, and Battery Stacks Source Category in Support of the 2023 Risk and Technology Review Proposed Rule.*[13]

TABLE 2—COKE OVEN PUSHING, QUENCHING, AND BATTERY STACKS SOURCE CATEGORY INHALATION RISK ASSESSMENT RESULTS IN PROPOSAL

Risk assessment	Number of facilities	Maximum individual cancer risk (in 1 million) [a]	Estimated population at increased risk of cancer ≥ 1-in-1 million	Estimated annual cancer incidence (cases per year)	Maximum chronic noncancer TOSHI	Maximum screening acute noncancer HQ
Based on Actual Emissions Level						
Source Category Emissions	14	9	2,900	0.02	0.1 (arsenic)	HQ_{REL} = 0.6 (arsenic)
Facility-Wide	14	50	2.7 million	0.2	2 (HCN)	HQ_{REL} = 0.6 (arsenic)
Based on Allowable Emissions Level						
Source Category Emissions	14	10	440,000	0.05	0.2 (arsenic).	

[a] Maximum individual excess lifetime cancer risk due to HAP emissions.

The results at proposal of the chronic baseline inhalation cancer risk assessment indicated that, based on estimates of current actual emissions, the MIR posed by the PQBS source category was 9-in-1 million driven by arsenic emissions, primarily from bypass/waste heat stacks. The total estimated cancer incidence estimated from this source category at proposal was 0.02 excess cancer cases per year, or 1 case every 50 years. No people were estimated to have inhalation cancer risks greater than 100-in-1 million; the population estimated to be exposed to cancer risks greater than or equal to 1-in-1 million was approximately 2,900. The estimated maximum chronic noncancer target organ-specific hazard index (TOSHI) from inhalation exposure for this source category was 0.1 for developmental effects from arsenic emissions The acute risk screening assessment of reasonable worst-case inhalation impacts indicated a maximum acute hazard quotient (HQ) of 0.6 based on the REL for arsenic.

The results of the inhalation risk assessment at proposal, considering MACT-allowable emissions, indicated that the cancer MIR was 10-in-1 million driven by arsenic emissions, primarily from HNR pushing and bypass/waste heat stacks. The total estimated cancer incidence from this source category based on allowable emissions was 0.05 excess cancer cases per year, or one excess case every 20 years. No people were estimated to have inhalation cancer risks above 100-in-1 million due to allowable emissions, and the population exposed to cancer risks greater than or equal to 1-in-1 million was approximately 440,000. In addition, the maximum modeled chronic noncancer TOSHI for the source category based on allowable emissions was estimated to be 0.2 (for developmental effects from arsenic emissions).

The maximum lifetime individual cancer risk at proposal posed by the 14 modeled facilities and based on whole facility emissions was 50-in-1 million, with COE from coke oven doors (a regulated source in the COB NESHAP), driving the whole facility risk. The total estimated cancer incidence based on facility-wide emission levels was 0.2 excess cancer cases per year. Regarding the noncancer risk assessment, the maximum chronic noncancer TOSHI posed by whole facility emissions was estimated to be 2 (for the neurological and thyroid systems as the target organs) driven by emissions of HCN from CBRPs, which are emissions sources not included within the source category (PQBS) addressed in the risk assessment for this rulemaking nor included in the COB NESHAP.

We weighed all health risk measures and factors, including those shown in table 2 of this preamble, in our risk acceptability determination and proposed that the risks posed by the PQBS source category under the current MACT provisions were acceptable.

Under the proposed ample margin of safety analysis, we again considered all of the health factors evaluated in the acceptability determination and evaluated the cost and feasibility of available control technologies and other measures (including the control devices and other measures examined under the technology review) that could be applied to further reduce risk. We also considered whether, taking into consideration costs, energy, safety, and other relevant factors, additional standards are required to prevent an adverse environmental effect.

We proposed that the current NESHAP provides an ample margin of safety to protect public health and that no additional standards are necessary to prevent an adverse environmental effect. Therefore, we did not propose amendments under CAA section 112(f)(2). However, we noted that the proposed beyond-the-floor (BTF) MACT limits for HNR B/W stacks would reduce the estimated MIR from 9-in-1 million to 2-in-1 million; and the population estimated to be exposed to cancer risks greater than or equal to 1-in-1 million would be reduced from approximately 2,900 to 390 with the proposed BTF MACT limits. The whole facility cancer MIR (the maximum cancer risk posed by all sources of HAP at coke oven facilities) would remain unchanged, at 50-in-1 million with BTF MACT limits, because the whole facility MIR was driven by the estimated actual

[13] *Residual Risk Assessment for the Coke Ovens: Pushing, Quenching, and Battery Stacks Source Category in Support of the 2023 Risk and Technology Review Proposed Rule.* U.S. Environmental Protection Agency, Office of Air and Radiation, Office of Air Quality Planning and Standards, Research Triangle Park, NC. May 2023. Docket No. EPA–HQ–OAR–2002–0085.

current fugitive emissions from coke oven doors and we did not expect reductions of the actual emissions from doors as a result of the proposed rule.

2. How did the risk review change for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks source category?

Changes were made to the risk emission model file used in the risk analyses which resulted in small changes in the estimated risk. These changes are listed below.

- Removed U.S. Steel Clairton batteries 1 through 3 and associated sources that were shut down in 2023.
- Removed Cleveland Cliffs' Follansbee, West Virginia, facility because it permanently closed in Spring 2022.
- Removed Cleveland Cliffs' Middletown, Ohio, facility because it permanently closed as of 2023.
- Corrected latitude and longitude values for two natural gas water heaters at Cleveland Cliffs' Warren, Ohio, facility.
- Corrected the angle of rotation for the byproduct plant fugitive source at Cleveland Cliffs' Warren, Ohio, facility.
- Replaced SunCoke's East Chicago facility's HRSG main stack (default) emissions with test data that was received too late to model for the proposal (received May 2023).
- Incorporated Hg emissions submitted for HNR HRSG main stacks from previous tests for SunCoke's Middletown and East Chicago (Cokenergy) facilities, which also changed the default average HNR HRSG main stack Hg emissions used for two other SunCoke facilities (SunCoke's Franklin Furnace and Gateway facilities).
- Incorporated Hg emissions data from previous tests submitted by SunCoke for HNR B/W stacks, which changed the Hg emissions for SunCoke's Middletown, Vansant, and East Chicago facilities.
- Revised emissions from door leaks based on revisions to new equation as a result of comments.

The results of the risk assessment performed for the final rule that incorporates the above changes are shown in table 3 of this section. The main difference in the risk estimated for the final rule and the proposed rule is the reduction in the whole facility MIR from 50 to 40-in-1 million, resulting primarily from removing two facilities (Cleveland Cliffs' Middleton, Ohio, and Follansbee, West Virginia, facilities) that shut down after years of being idle and removing three batteries (1,2,3) at U.S. Steel's facility in Clairton, Pennsylvania, that were permanently shut down. The baseline PQBS source category MIR remained at 9-in-1 million.

TABLE 3—COKE OVEN PUSHING, QUENCHING, AND BATTERY STACKS SOURCE CATEGORY INHALATION RISK ASSESSMENT RESULTS

Risk assessment scenario	Number of Facilities	Maximum individual cancer risk (in 1 million)[a]	Estimated population at increased risk of cancer ≥ 1-in-1 million	Estimated annual cancer incidence (cases per year)	Maximum chronic noncancer TOSHI	Maximum screening acute noncancer HQ
Based on Actual Emissions Level[b]						
Source Category Emissions	12	9	2,600	0.01	0.1 (arsenic)	HQ_{REL} = 0.6 (arsenic).
Facility-Wide Emissions[b]	12	40	2.4M	0.1	2 (HCN)	HQ_{REL} = 0.6 (arsenic).

[a] Maximum individual excess lifetime cancer risk due to HAP emission.
[b] See section IV.A. of this preamble for more details on the risk assessment.

As noted in the proposal, we weigh a range of health risk measures and factors in our risk acceptability determination, including the cancer MIR, the number of persons in various cancer and noncancer risk ranges, cancer incidence, the maximum noncancer TOSHI, the maximum acute noncancer HQ, and risk estimation uncertainties (54 FR 38044, September 14, 1989). Under the current MACT standards for the PQBS source category, the revised risk results indicate that the MIR is 9-in-1 million, driven by emissions of arsenic. The estimated incidence of cancer due to inhalation exposures is 0.01 excess cancer case per year. No people are estimated to have inhalation cancer risks greater than 100-in-1 million, and the population estimated to be exposed to cancer risks greater than or equal to 1-in-1 million is approximately 2,600. The estimated maximum chronic noncancer TOSHI from inhalation exposure for this source category is 0.1 for developmental effects. The acute risk screening assessment of reasonable worst-case inhalation impacts indicates a maximum acute HQ of 0.6.

We conducted a revised assessment of facility-wide (or ''whole-facility'') risk to characterize the source category risk in the context of whole-facility risk. The maximum lifetime individual cancer risk based on whole-facility emissions is 40-in-1 million with COE from coke oven doors (a regulated source in the COB NESHAP source category) driving the risk. The total estimated cancer incidence based on facility-wide emission levels is 0.1 excess cancer cases per year. No people are estimated to have inhalation cancer risks above 100–in-1 million due to facility-wide emissions, and the population exposed to cancer risk greater than or equal to 1-in-1 million is approximately 2.4 million people. The estimated maximum chronic noncancer TOSHI posed by whole facility emissions is 2 (for the neurological and thyroid systems as the target organs) driven by emissions of HCN from CBRPs, which are emissions sources not included within the source category. Approximately 10 people are estimated to be exposed to a TOSHI greater than 1 due to whole facility emissions. The acute risk screening assessment of reasonable worst-case inhalation impacts indicates a maximum acute HQ of 0.6.

We are not finalizing the proposed BTF limit for PM, as a surrogate for nonmercury HAP metals, pursuant to CAA sections 112(d)(2) and (3) for HRSG waste heat stacks in the PQBS source category for the reasons described in section IV.C.4. in this preamble, which would have achieved a reduction of the metal HAP emissions (*e.g.,* arsenic and lead) as well as a reduction in the estimated MIR due to arsenic from these units. Therefore, the overall post control MIR for this source category remains at 9-in-1 million. Additionally, the total estimated cancer incidence remains unchanged at 0.01 excess cancer cases per year, and the maximum modeled chronic noncancer

TOSHI for the source category remains unchanged at 0.1 (for respiratory effects from HCl emissions). The estimated worst-case acute exposures to emissions from the PQBS source category is a maximum acute HQ of 0.6, based on the reference exposure limit (REL) for arsenic. Considering all of the health risk information and factors discussed above, including the uncertainties discussed in the proposal preamble, the EPA is finalizing that the risks for this source category under the current NESHAP provisions are acceptable.

Under the ample margin of safety analysis, we did not change our proposal assessment that there were no cost-effective controls or measures to further reduce risks due to HAP emissions. Therefore, there are no changes for the final rule and the EPA concludes that the final rule provides an ample margin of safety to protect public health, that HAP emissions from the PQBS source category do not result in an adverse environmental effect, and that it is not necessary to set a more stringent standard to prevent an adverse environmental effect, taking into consideration costs, energy, safety, and other relevant factors.

3. What key comments did we receive on the risk review, and what are our responses?

We received a few comments on the risk review that offered other data and procedures to use rather than the EPA's protocol for risk assessment as well as comments on the risk to minority populations. The key comments on the risk review are summarized in this section along with the EPA's responses to the comments. Other comments received on the risk review are summarized along with the EPA's responses in the *Response to Comment* [14] document, and which is located in the dockets to the coke ovens rules.

Comment: A commenter stated that they believe the EPA does not consider the disproportionate exposure and resulting health impacts for African Americans and people living below the poverty level to ensure an ''ample margin of safety'' to protect public health. The commenter requested that the EPA reduce the health risks and advance environmental justice for this disproportionate exposure by setting standards to ensure an ''ample margin of safety to protect public health.'' The commenter asserted that the EPA's own demographic analysis reveals that African Americans and people living below the poverty level experience a higher level of exposure to toxic air pollution, and consequently greater health impacts, compared to their representation in the national population. This exposure, combined with other types of toxic exposure in their neighborhoods, contributes to cumulative health risks. The commenter stated that the EPA's proposal does not include any changes to mitigate these health risks or address the environmental justice implications of this disproportionate exposure. The commenter contended that this conclusion is unlawful and arbitrary and runs contrary to the Biden Administration's commitment to advancing environmental justice.

Response: The EPA is directed by Executive Order, to the greatest extent practicable and permitted by law, to make environmental justice part of its mission by identifying and addressing, as appropriate, disproportionate and adverse human health or environmental effects of its programs, policies, and activities on communities with environmental justice concerns. The EPA's environmental justice policies promote justice, including access to health impact data, by providing information on the types of environmental justice harms and risks that are prevalent in communities with environmental justice concerns. No such policies mandate consideration of any specific factors or particular outcomes from an action, but they direct that environmental justice analysis be performed as part of regulatory impact analysis, as appropriate, so that the public can have this information. The environmental justice analysis is presented for the purpose of providing the public with as full as possible an understanding of the potential impacts of this final action. The EPA notes that analysis of such impacts is distinct from the determinations finalized in this action under CAA section 112, which are based solely on the statutory factors the EPA is required to consider. The residual risk estimated for the PQBS source category, with a cancer MIR of 9-in-1 million and where 2,600 people are estimated to have a cancer risk greater than 1-in-1 million (*i.e.,* risk from 1-in-1 million up to 9-in-1 million) is considered acceptable for all populations. Also, as noted previously in this preamble, we conclude that the PQBS NESHAP provides an ample margin of safety to protect public health.

Comment: A commenter requested that the EPA include a risk review for LAER track ovens in this rulemaking. The commenter contended the EPA did not perform the required risk review in 2020 for the COB, subpart L, LAER track coke ovens. The EPA mentions in the *Technology Review Memorandum* that the LAER track RTR was to be completed by 2020, however, the commenter indicates that it was not. The Fall 2022 Regulatory Agenda contemplated a risk review for LAER track coke ovens. However, the risk review for LAER track coke ovens, which includes eight of the nine ByP facilities, is not included in this rulemaking. The commenter stated that the EPA has not delivered on its public commitments to review risks for LAER track ovens, which include almost all facilities with co-located CBRPs.

Response: The EPA was not able to complete a risk review for LAER track sources in time for the court-ordered final rule for the Coke PQBS RTR and Technology Review of the COB NESHAP. The EPA will undertake the LAER track risk review rulemaking as we plan future activities in the steel sector.

4. What is the rationale for our final approach and final decisions for the risk review?

We considered all of the health risk information and factors due to emissions from PQBS source category as well as the uncertainties in the risk assessment and have determined that the risks for this source category under the current PQBS NESHAP provisions are acceptable because the cancer MIR of 9-in-1 million is well below the presumptive level of acceptability (*i.e.,* 100-in-1 million) and because we did not identify any significant noncancer risks from the source category.

Under the ample margin of safety analysis, we again considered all of the health factors evaluated in the acceptability determination and evaluated the cost and feasibility of available control technologies and other measures that could be applied to further reduce risk. We also considered whether, taking into consideration costs, energy, safety, and other relevant factors, additional standards are required to prevent an adverse environmental effect. We determined that no additional standards are required to provide an ample margin of safety to protect public health or to prevent an adverse environmental effect.

[14] *Summary of Public Comments and Responses for Coke Ovens: Pushing, Quenching, and Battery Stacks Residual Risk and Technology Review, and Coke Oven Batteries Periodic Technology Review.* U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division (D243–02), Research Triangle Park, North Carolina. May 1, 2024.

B. Technology Review for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks and the NESHAP for Coke Oven Batteries Source Categories

1. What did we propose pursuant to CAA section 112(d)(6) for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks source category?

a. MACT Limits

To fulfill the requirements of the *LEAN* decision,[15] we proposed 17 new MACT limits [16] for unregulated HAP and processes pursuant to CAA sections 112(d)(2)/(3) based on available test data. These MACT limits along with a summary of comments and responses, changes made for the final rule, and the rationale for the final standards (*i.e.,* MACT limits) are provided in section IV.C. of this preamble.

b. Opacity Limit for HNR B/W Stacks

We proposed a 10 percent opacity limit for HNR B/W stacks during charging to be measured daily to limit the PM emissions from these sources.

c. Other Aspects of the CAA Section 112(d)(6) Technology Review for the PQBS Source Category (Subpart CCCCC)

As explained in the August 2023 proposed rule preamble, under the technology review for the PQBS NESHAP pursuant to CAA section 112(d)(6), the EPA did not identify any other cost-effective options to reduce emissions from currently regulated sources under the PQBS NESHAP apart from those requirements discussed in IV.B.1.a. and IV.B.1.b. of this section. Therefore, the EPA did not propose any other changes to the PQBS NESHAP pursuant to CAA section 112(d)(6). However, the EPA solicited comments regarding whether a 1-hour opacity standard would identify short-term periods of high opacity that are not identified from the current 24-hour standard of 15 percent opacity; and whether excessive COE are emitted from ovens after being pushed and before they are charged again (*i.e.,* ''soaking emissions'') despite work practice standards currently applicable to these emisions.

2. How did the technology review change for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks NESHAP source category?

As described in section IV.C. of this preamble, we are finalizing 17 [17] new MACT floor emissions limits pursuant to CAA sections 112(d)(2)/(3) based on available test data for previously unregulated HAP, as identified in the August 2023 proposal (see section IV.C. for details). However, some of the limits changed in the final rule to reflect additional data submitted by coke oven facilities since the limits were developed for the proposal as well as comments received to standardize limits which are in units of grains per dry standard cubic feet (gr/dscf) to 10 percent oxygen. The revised MACT limits include those for: (1) pushing for AG, HCN, and PAH; (2) battery stacks for AG, HCN, Hg, and PM to standardize to 10 percent oxygen; (3) HNR main stacks for AG, Hg, PAH, and PM (as a surrogate for non-Hg metal HAP), and to standardize all limits to 10 percent oxygen; and (4) HNR B/W stacks for Hg and PM, and to standardize all limits to 10 percent oxygen.

The EPA also is finalizing a MACT floor work practice standard based on ''good combustion,'' pursuant to CAA section 112(h), that addresses the previously unregulated organic HAP of D/F, PAH, and VOHAP from battery stacks. Details regarding the final MACT standards are described in section IV.C. of this preamble.

In addition, the EPA is finalizing surrogate determinations to address the additional unregulated HAP of D/F, formaldehyde, and VOHAP from pushing; formaldehyde from HNR main stacks; and VOHAP from HNR B/W stacks. Details regarding these surrogates are described in section IV.C. of this preamble.

We also are finalizing a requirement for 20 percent HNR B/W stack opacity to reflect current permit requirements that is to be determined weekly for HNR waste heat stacks, and weekly for HRSG bypass stacks when operating longer than an hour in any week.

We are not setting 1-hour opacity standards for battery stacks in the final rule. We did not propose a 1-hour battery stack limit for comment and because there was a wide variation in the data collected from facilities for 1-hour opacity from battery stacks, without additional information we were not able to determine a 1-hour limit that considered all the factors which may influence short-term opacity and the impacts the limit might have on facilities not meeting a new 1-hour standard. Although we received three comments in favor of a 1-hour standard, one against, and one comment recommending a work practice to be triggered by an (unspecified) 1-hour opacity value, we are not setting a 1-hour battery stack opacity standard at this time as part of the Technology Review in this rulemaking as a development in practices, processes, and control technologies. We also are not including additional work practices or new control device requirements for soaking emissions in the final rule as part of the technology review. The short-term nature of soaking fugitives emissions would prevent accurate measurement of a limit for opacity, and the addition of a second collecting duct that routes standpipe COE exhaust to a control device would present safety hazards to workers and could prove to be impractical. We received one comment in favor of setting soaking standards and two comments against. See the *Response to Comment* [18] document for this rulemaking to see details of the comments received on both of these sources and the EPA responses.

3. What did we propose pursuant to CAA section 112(d)(6) for the NESHAP for Coke Oven Batteries source category?

a. Fenceline Monitoring

We proposed a fenceline monitoring work practice standard (for benzene, as a surrogate for COE). Fenceline monitoring refers to the placement of monitors along the perimeter of a facility to measure fugitive pollutant concentrations. The proposed fenceline monitoring work practice standard would have required owners and operators to monitor for benzene and conduct RCACA upon exceeding an ''action level'' concentration of 3 $\mu g/m^3$ based on the rolling 12-month average ''*delta* c'', notated as Δc, which represents the concentration difference between the highest measured concentration and lowest measured concentration for a set of samples in one sampling period. The sampling period

[15] *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

[16] Note, we erroneously reported that there were 15 new MACT floor limits in the August 2023 proposal preamble. This was a typographic error. The proposed rule included 17 new MACT floor limits and 2 BTF limits; the BTF limits are not included in the final rule. However, we are adding a work practice standard in this final rule so the count of standards is now 18.

[17] Note, we erroneously reported that there were 15 new MACT floor limits in the August 2023 proposal preamble. This was a typographic error. The proposed rule included 17 new MACT floor limits and 2 BTF limits; the BTF limits are not included in the final rule. However, we are adding a work practice standard in this final rule so the count of standards is now 18.

[18] *Summary of Public Comments and Responses for Coke Ovens: Pushing, Quenching, and Battery Stacks Residual Risk and Technology Review, and Coke Oven Batteries Periodic Technology Review.* U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division (D243–02), Research Triangle Park, North Carolina. May 1, 2024.

Δc values are averaged over 12 months to create the rolling average. We also proposed a procedure for reduced monitoring at a particular monitoring location after consistent low measurements at that monitor. More details are provided in the August 16, 2023, proposed rule preamble.

b. Lower Leak Limits for Doors, Lids, and Offtakes

Due to improvements in leak control at coke oven facilities, we proposed to lower the allowable door leak limits in the NESHAP under the technology review for the COB source category pursuant to CAA section 112(d)(6). We proposed for facilities with coke production capacity of greater than or equal to 3 million tpy of coke to lower the allowable leaking door limit from the current limit of 4 percent to 1.5 percent for tall leaking doors and from 3.3 percent to 1.0 percent for ''not tall'' leaking doors. These proposed standards would currently only apply to the U.S. Steel Clairton facility in Pennsylvania. For COB facilities that have coke production capacity less than 3 million tpy coke, we proposed an allowable leaking door limit of 3.0 percent leaking doors for all sizes of doors that is lower than the limit currently in the NESHAP of 4.0 and 3.3 percent leaking doors for tall and not tall doors, respectively.

We also proposed to lower the lid and offtake allowable leak limits in the NESHAP due to similar improvements in operation of these sources by the coke facilities. The current NESHAP includes limits of 0.4 percent leaking lids and 2.5 percent leaking offtakes; we proposed a revised limit of 0.2 percent for leaking lids and a revised offtake limit of 1.2 percent leaking offtakes.

The proposed changes to the leak limits were meant to ensure continued low emissions from doors, lids, and offtakes and reflect improvements in performance of the facilities to minimize leaks. We estimated that there would be no reductions in actual emissions and there would be no control costs, but the lower limits would reduce the allowable emissions. More details are provided in the August 16, 2023, proposed rule preamble.

c. Zero Allowable Leaks From HNR Oven Doors, and Concurrent Oven or Common Tunnel Pressure Monitoring

The current NESHAP requires HNR facilities to demonstrate (with method 303) that facilities have zero leaks or demonstrate the ovens are under negative pressure. We proposed to revise the COB NESHAP for new and existing HNR doors (40 CFR 63.303(a)(1) and (b)(1)) to require zero leaks from oven doors at HNR coke batteries, as determined by EPA Method 303A, which relies on observing VE emanating from the ovens; and monitoring pressure both in the ovens and the common tunnel, instead of choosing one or the other points to measure pressure and instead of choosing either 0 oven leaks or pressure monitoring, as the current rule allows. We also proposed to add the requirement to measure both pressure in the ovens and common tunnels during the critical periods in the entire oven cycle to include, at minimum, during pushing, coking, and charging (but not necessarily continuously throughout the oven cycle).

d. Revised Emissions Equation for Emissions From Leaking Doors

We proposed a revised version of the equation than that historically had been used to estimate COE from leaking oven doors. The proposed revised equation provided more accurate estimates of COE from doors that reflected operation of any coke facility, not just the facility upon which the equation was derived, and includes facilities where advancements in preventing and reducing door leaks have occurred since 1981, which is when the equation was first developed. The proposed revised equation was as follows:

$$\text{COE-doors (lb/hr)} = ND \times (PLD_{yard}/100) \times (0.04 \text{ lb/hr}) + ND \times (PLD_{yard} \times 0.94_{bench\text{-}only/yard})/100) \times (0.023 \text{ lb/hr})$$

Where:
ND = number of doors
PLD = percent leaking doors
PLDbench = percent leaking doors from bench
PLDyard = percent leaking doors from yard

A summary of the proposed revised equation and the rationale for its development are provided in the August 16, 2023, preamble. A more detailed explanation can be found in the memorandum prepared for the proposal, *Revised Equation to Estimate Coke Oven Emissions from Oven Doors,*[19] located in the docket for this rule.

e. Opacity From HNR B/W Stacks

We proposed a new opacity limit of 10 percent on the HNR facilities' HNR B/W stacks and to require a daily observation of all bypass or waste heat stacks during charging to determine if VE are present.

[19] *Revised Equation to Estimate Coke Oven Emissions from Oven Doors.* D.L. Jones and K. McGinn. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. August 2021. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

4. How did the technology review change for the NESHAP for the Coke Oven Batteries source categories?

a. Fenceline Monitoring

As a result of comments, we revised the modeling procedures used to determine the fenceline action level by including additional offsite receptors in our modeling to more appropriately assess the maximum concentrations from irregular-shaped facility properties. Due to the unique layout of the coke oven sources and the elongated shape of their fencelines, the spatial resolution of the default receptor grid was not sufficient to accurately estimate the maximum ambient concentration. This change in procedures resulted in a change to the action level from 3 μg/m^3 to 7 μg/m^3 of benzene. In addition, in the final rule, we are only requiring fenceline monitoring and corrective action at ByP coke oven facilities and not at HNR facilities because the NESHAP will have sufficient monitoring of VE to ensure minimal HNR fugitive emissions and the operation of the coke ovens at HNR facilities is under negative pressure, *i.e.,* outside air and oven exhaust is pulled through ovens and into the common tunnels by suction, which effectively prevents excess fugitive emissions from these sources. Furthermore, data received from CAA section 114 information request from one HNR facility showed very low benzene at the fenceline (a maximum individual sample concentration of 0.7 μg/m^3 and an average Δc of 0.1 μg/m^3), which demonstrates the low fenceline impact from these sources. Lastly, for those facilities subject to fenceline monitoring, the EPA is providing the opportunity to develop site-specific monitoring plans (SSMP) and, when approved by the EPA, to monitor and correct for the contribution of benzene emissions from co-located sources not subject to a regulation codified in 40 CFR part 63 (such as the CBRP) and offsite emissions sources to the measured fenceline concentration. The SSMP must include: (1) identification of the near-field sources whose emissions, if approved, will be subtracted from the monitor concentrations, *i.e.,* offsite and co-located sources not subject to a regulation codified in 40 CFR part 63; (2) the impacted monitoring location(s) and the near-field source(s) that impact them; (3) the detailed data reduction criteria and calculations; (4) the details of the real-time sampling technique(s) being employed and how meteorological conditions will be measured; and (5) explanation of how monitoring data are handled during adverse conditions.

b. Lower Leak Limits for Doors, Lids, and Offtakes

We revised the proposed leak limits for doors, lids, and offtakes based on information and data obtained from a number of ByP facilities in late 2023 on the variability of leaks in daily rolling 30-day averages basis, including Cleveland Cliffs' Warren, Ohio, and Burns Harbor, Indiana, facilities, EES Coke in Michigan, and U.S. Steel Clairton in Pennsylvania; and based on additional information and data provided by email from David Alor (of COETF) on February 5, 2024 and March 22, 2024 regarding the maximum 30-day rolling averages across facilities for the period 2018–2023. These data are available in the docket for this action.

Using the available data, we compared the maximum 30-day rolling averages with the maximum annual averages and developed adjustment factors to account for variability. Then, we multiplied the adjustment factors by the maximum annual average for each door type to obtain the revised leak limits. In this final rule, we are promulgating the revised leak limits shown in table 4 and in the revised memorandum prepared for the final rule, *Technology Review for the Coke Ovens: Pushing, Quenching, and Battery Stack and Coke Oven Batteries Source Categories-Final Rule,*[20] hereafter referred to as the *Technology Review Memorandum—Final Rule.* These six revised leak limits (shown in table 4) are higher than all the maximum 30-day averages in our dataset (available in docket). Therefore, we expect facilities will be able to comply with these limits without the need for any new controls or operating costs.

TABLE 4—REVISED LEAK LIMITS FOR DOORS, LIDS, AND OFFTAKES TO ACCOUNT FOR VARIABILITY

Source, battery type, No. facilities and batteries	Current NESHAP limit	Proposed limit	Maximum annual average 2022/2023	Adjustment factor for variability	Revised leak limits for final rule	Higher or lower than proposed limit
Doors—Higher Capacity (> or = 3M ton/year), Tall Batteries [a]						
1 facility, 2 batteries	4.0%	1.5%	0.54%	4.6X	2.5%	higher.
Doors—Higher Capacity (> or = 3M ton/year), Not Tall Batteries [a]						
1 facility, 8 batteries	3.3%	1.0%	0.39%	4.4X	1.7%	higher.
Doors—Lower Capacity (< 3M ton/year), Tall Batteries						
2 facilities 3 batteries	4.0%	3.0%	2.9% [b]	1.3X	3.8%	higher.
Doors—Lower Capacity (< 3M ton/year), Not Tall Batteries						
6 facilities, 14 batteries	3.3%	3.0%	2.4%	1.3X	3.2%	higher.
Offtakes—6 facilities	2.5%	1.2%	1.3%	1.6X	2.1%	higher.
Lids—6 facilities	0.4%	0.2%	0.087%	3.7X	0.32%	higher.

[a] Tall = doors are equal to or greater than 6 meters (20 ft) in height. ''Not tall'' doors are doors that are not tall.
[b] This value is the average for 10 months of 2023.

c. Zero Allowable Leaks From HNR Oven Doors and Concurrent Oven or Common Tunnel Pressure Monitoring

We are not requiring pressure monitoring in both common tunnels and ovens in the final rule but instead are allowing a choice between the two as in the current rule because we did not receive any comments in support of requiring both and we received comments pointing out the expense and safety hazards of oven pressure monitoring. We are requiring the pressure monitoring in either ovens or tunnels to be performed at minimum during pushing, charging, and coking. For the final rule, we also are requiring zero leaks from HNR oven doors with daily leak testing, as determined by EPA Method 303A, along with pressure monitoring in either the common tunnels or the ovens during pushing, charging, and coking.

d. Revised Emissions Equation for Emissions From Leaking Doors

We revised the proposed equation to estimate COE emissions from leaking doors based on VE test data from two facilities that the EPA received in 2022 and combined these data with VE test results from 1981, which was when the original equation first was developed. The 2022 VE testing was performed at Cleveland Cliffs' Burns Harbor and U.S. Steel's Clairton facilities and included simultaneous yard and bench VE tests at the coal-side and coke-side of two batteries at each facility. The 1981 data also had been collected at U.S. Steel Clairton. In addition, we received a comment that the equation did not account for the case where no VE from oven doors is observed from the yard but VE from ovens is observed from the bench. A linear regression analysis of the combined 1981 and 2022 data provided a revised equation with an intercept that is only dependent on the number of doors (ND) and not dependent on yard observations and provides an estimate of emissions when yard VE is zero. The final equation is as follows:

$$\text{COE-doors (lb/hr)} = ND \times (PLD_{yard}/100) \times (0.04 \text{ lb/hr}) + ND \times (PLD_{yard}/100 \times 1.5 * PLD_{(bench\text{-}only\text{-}to\text{-}yard)} \times (0.023 \text{ lb/hr})) + 0.7/100 * ND \times (0.023 \text{ lb/hr}),$$

Where:

ND = number of doors
PLD = percent leaking doors

e. Opacity From HNR B/W Stacks

For the final rule, we revised the proposed 10 percent opacity limit for HNR B/W stacks during charging with daily testing to 20 percent and moved the requirement from the COB rule (subpart L) to the Coke PQBS rule (subpart CCCCC). We also changed the proposed daily testing requirement to weekly. For HNR facilities without continuous bypass, weekly opacity testing is only required if the bypass event continues for more than an hour.

[20] *Technology Review for the Coke Ovens: Pushing, Quenching, and Battery Stack and Coke Oven Batteries Source Categories—Final Rule.* D.L. Jones, U.S. Environmental Protection Agency, and G.E. Raymond, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085–0873 and EPA–HQ–OAR–2003–0051–0682.

For HNR facilities with continuous bypass, weekly testing is required.

5. What key comments did we receive on the technology review, and what are our responses?

The key comments on the proposed results of the technology review are summarized in this section along with the EPA's responses to the comments. Other comments received on the technology review not included here are summarized along with the EPA's responses in the *Response to Comment* [21] document, which is located in the dockets to the rules.

a. Fenceline Monitoring

We received many comments on fenceline monitoring with comments both in favor of the proposed requirement and comments that were opposed to the requirements or requested significant changes.

Comment: A commenter asserted the proposed rule would exceed the EPA's authority under CAA section 112 because it would impose monitoring and a work practice standard on the CBRP, which is not a source category listed pursuant to CAA section 112(c). The commenter set forth the reasons why they believe the EPA's authority to promulgate ''emission standards'' under CAA sections 112(d) and (f) are limited to source categories listed pursuant to CAA section 112(c). The commenter stated that if fenceline monitoring is required in the final rule, sampling stations should be located so as to monitor emissions only from coke oven batteries and no other sources, and the rule should provide that both offsite and onsite non-source category sources should be subtracted out in determining compliance with any corrective action level. The commenter added that such an exercise would be complicated by the fact that benzene in COE from coke oven batteries is entrained by the hot, buoyant vertical plume rise. The EPA would also need to consider the feasibility of designing and implementing such a program, given the close proximity and size of the co-located CBRP and nearby offsite sources of benzene emissions. At U.S. Steel Clairton, for example, the CBRP is located in between the coke batteries, so isolating the impacts from the category-specific sources would be difficult, and perhaps impossible.

Response: As explained in the **Federal Register** document announcing the Petroleum Refineries NESHAP final rule (80 FR 75178) and again in the Hazardous Organic NESHAP final rule (known as the ''HON''), published on May 16, 2024 (89 FR 42932), the EPA concludes that CAA section 112(d)(6) provides the EPA with the authority to require fenceline monitoring requirements in NESHAPs. Comments on the proposal did not take issue with this fundamental authority, but rather argued only that the EPA does not have the authority to apply the work practice associated with fenceline monitoring to a non-listed source category, in this case the CBRP.

The fenceline monitoring provisions in the final rule can be thought of as consisting of two elements, one being measurement and reporting of fenceline concentrations, the other being compliance with the RCACA, the latter being the work practice element of the rule. To the extent the commenters assert that the EPA's authority is lacking in regard to the requirements to measure and report fenceline concentrations resulting from emissions from CBRPs, the EPA disagrees. By its own terms, the commenter's argument regarding the limits of CAA section 112 authority to non-listed source categories pertains only to ''emission standards,'' which as defined in CAA section 302(k) are requirements that ''limit[ ] the quantity, rate, or concentration of emissions . . .'' The commenter's own reasoning, therefore, does not suggest that the EPA may not require monitoring of non-listed CBRPs.

In any case, CAA section 114 independently provides ample authority to require monitoring of CBRPs. Relevant to the fenceline monitoring provisions of this rule, CAA section 114 gives the EPA authority to require the owner or operator of a source of emissions to monitor emissions, including by periodic sampling, either for the purpose of assisting in the development of a CAA section 112 standard, or to determine compliance with an existing CAA section 112 standard. The fenceline monitoring provisions in the final rule will serve both purposes. It will inform the EPA's consideration of whether and how to further regulate emissions from CBRP. It may also provide information relevant to determining compliance with 40 CFR part 61, subpart L applicable to CBRP. Fenceline monitoring will further these goals notwithstanding that the final rule does not require corrective action at CBRP, and also notwithstanding that coke oven facilities may seek approval of an SSMP that may reduce the likelihood of needing to perform a root cause analysis at the CBRP.

Regarding requirements pertaining to the RCACA work practice element of the rule, 40 CFR 63.314(d)(3) of the final rule provides that corrective action will not be required at sources not subject to a regulation codified in part 63. At present, CBRP are not subject to a regulation codified in part 63, and as a consequence there is no requirement to conduct corrective action at CBRP until a part 63 regulation is promulgated for that source category.

The final rule also provides an opportunity for facilities to develop an SSMP, subject to review and approval by the EPA, allowing a facility to account for the contribution to measured fenceline concentrations due to benzene emissions from offsite or co-located sources not subject to a regulation codified in 40 CFR part 63 (such as CBRP). The owner/operator may choose to develop a technically-sound monitoring plan to isolate and distinguish emissions from CBRP from other emission sources. The SSMP may be used to correct the measured concentration at impacted sample locations, thereby reducing the number of exceedances of the action level caused by the CBRP, and also reducing the number of root cause investigations pointing to the CBRP. The EPA recognizes that, similar to refineries where the correction for onsite sources is also allowed, development of a monitoring program to implement the SSMP for onsite sources is expected to be complicated. We have also extended the time for the EPA to review the SSMP to 120 days from 90 days to account for the increased complexity of SSMP as a result of the inclusion of these onsite sources. Real-time monitoring techniques, such as open-path monitoring and sensor networks, could potentially be useful to characterize emissions from such proximate sources. Further, if information from a root cause investigation demonstrates that a primary or other contributing cause of an exceedance of the corrective action level are due to emissions from a CBRP, no corrective action would be required to address those causes at the non-listed CBRP operations beyond those that may be required under current regulations (40 CFR part 61, subpart L, or other applicable regulatory requirements). For example, if during the root cause investigation the primary or other contributing cause(s) is traced to a leak, as defined by 40 CFR part 61 subpart L, in the connections or seals of a control system, that leak would be required to

[21] *Summary of Public Comments and Responses for Coke Ovens: Pushing, Quenching, and Battery Stacks Residual Risk and Technology Review, and Coke Oven Batteries Periodic Technology Review.* U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division (D243–02), Research Triangle Park, North Carolina. May 1, 2024.

be repaired within 15 days as stipulated in 40 CFR 61.132(b)(3), but not as a result of the fenceline monitoring corrective action requirements. Primary and other contributing cause(s) of exceedances of the action level that are located within the facility grounds, excepting those sources not subject to a regulation codified in 40 CFR part 63, would need to be addressed. Sources that contribute to the fenceline benzene concentrations above the action level that are not subject to a regulation codified in 40 CFR part 63 may be accounted for through the SSMP.

Comment: A commenter opposed to the proposed fenceline monitoring provisions stated that they believe the proposed benzene fenceline monitoring program ''targets'' co-located CBRP and not benzene in COE from the source category coke batteries. The commenter asserts that benzene in COE from the source category coke batteries is dispersed at 90 to 200 meters above ground level due to the heat flux and vertical momentum rise (buoyancy), while benzene from CBRP operations generally remain near ground level and would more likely be measured by fenceline monitors.[22]

Response: To the extent the commenter is asserting that fenceline monitoring is not an effective means of measuring coke oven emissions, the EPA disagrees. Benzene comprises a significant portion of the COE emitted from coke oven doors, which are fugitive emissions that are released at heights considerably lower than the 90 to 200 meters mentioned by the commenter. Likewise, internal facility monitoring conducted in close proximity to the coke oven batteries at four byproduct facilities, as part of the 2022 CAA section 114 requests, identified benzene as the predominant volatile organic compound (VOC) (which includes benzene) measured in the area of the coke oven batteries and at elevated average concentrations ranging from approximately 11 $\mu g/m^3$ to 340 $\mu g/m^3$. Therefore, we maintain the position that benzene is a good surrogate for COE and that fenceline monitoring is appropriate for this type of fugitive emissions source. We also identified benzene as the predominant VOC measured in close proximity to the CBRPs at equivalent or greater concentration than was measured in close proximity to the coke oven batteries. This underscores the potential impact of these non-regulated sources such as CBRPs on the fenceline concentration at some facilities. We have revised the fenceline monitoring requirements in this final rule to provide an opportunity for a facility to develop an SSMP to determine and account for the benzene emissions from onsite sources (such as CBRPs) not currently subject to a regulation codified in 40 CFR part 63 in the calculation of Δc.

Comment: A commenter requested that the proposed fenceline monitoring requirements for HNR facilities be withdrawn and not be included in the final rule. The commenter contended that fenceline monitoring is not a new trend in facility procedures or generally in use at HNR facilities. The commenter stated that because ByP ovens operate under positive pressure, small openings or cracks in ByP ovens allow raw coke oven gas and HAPs to leak into the atmosphere. In contrast, the commenter indicated that their facility's (SunCoke's) HNR ovens operate under negative pressure and release the heat of combustion within the oven system. The commenter stated that the EPA previously acknowledged that operating the coke ovens under negative pressure virtually eliminates the risk of leakage of COE through doors or other potential leakage points. See the EPA document, ''*National Emissions Standards for Coke Oven Batteries: Background Information for Final Amendments,*'' at 21 (Mar. 31, 2005; Docket ID no. EPA–HQ–OAR–2003–0051–0232).

The commenter continued that fugitive HAP emissions monitoring conducted at one of SunCoke's plants for ten years demonstrates that there is no impact on ambient HAP levels, that any emissions are below risk-based screening levels, and that the state agency agreed with this determination. The commenter contended in determining whether to adopt fenceline monitoring requirements in the current rulemaking, the EPA selected five coke facilities—four ByP facilities and one HNR facility. The commenter asserted that the proposal inappropriately grouped ByP and HNR facilities together as subject to fenceline monitoring despite significant differences in potential for fugitive emissions.

One commenter contended the predicted maximum benzene concentrations for ByP plants range from 0.3 to 3 $\mu g/m^3$, while the predicted maximum benzene concentrations for HNR plants range from 0.00005 to 0.0003 $\mu g/m^3$. Sampling at HNR plants is predicted to yield results at about twice the MDL for the method or lower. The commenter stated that only a major malfunction at a HNR plant would ever trigger performance of a root cause analysis. The commenter stated that such an increase in emissions would be noticed by plant personnel and addressed long before the 45 days after the end of a sampling period allowed for laboratory analysis and Δc calculation. The commenter indicated that an exceedance of the proposed subpart L limits at HNR batteries, monitored by EPA Method 303A, would alert plant personnel of the need to address excess fugitive emissions in a timely manner.

Another commenter contended the EPA did not remark upon the discrepancy of benzene concentrations between ByP and HNR facilities; the benzene fenceline concentrations detected at ByP facilities were 90 to 4,000 percent higher than the levels detected at SunCoke's Haverhill facility in Franklin Furnace, Ohio. The absence of any necessity for fenceline monitoring at HNR facilities was demonstrated by the company's Haverhill facility, which performed almost 10 years of monitoring for PAH and VOCs as required by the facility's Title V operating permit. The permit called for sampling at three ambient monitoring locations near the plant (one upwind, one downwind, and one adjacent to the entry gate to the plant). The sampling was initiated when the plant was being built in late 2004, continued as the plant became operational in mid-2005, and continued until the Ohio EPA terminated the requirements for monitoring (in 2013 for PAH and in 2014 for VOC) because the HAP monitoring data demonstrated that Haverhill had no impact on ambient HAP levels and emissions were below risk-based screening levels. (Commenter cites ''Letter from Ohio EPA to Haverhill Coke Company, July 14, 2014''.)

Response: After considering these public comments and other relevant information, the EPA has decided to not finalize the requirement to require fenceline monitoring and RCACA at HNR facilities because the HNR coke ovens operate under negative pressure, *i.e.,* under suction, which causes any leaks to consist of outside air moving into the ovens rather than coke oven exhaust leaking out, and, as a result, have negligible fugitive benzene emissions. Fenceline monitoring data collected through the 2022 CAA section 114 request, which can be found in the memorandum *Fugitive Monitoring at Coke Oven Facilities,*[23] showed an HNR

[22] See email from D. Ailor, ACCCI/COETF, to D.L. Jones, EPA OAQPS, (Mar. 26, 2021, available in the docket for this rule *https://www.regulations.gov/document/EPA-HQ-OAR-2002-0085-0605.*

[23] *Fugitive Monitoring at Coke Oven Facilities.* D.L. Jones, K. Boaggio, K. McGinn, and N. Shappley, U.S. Environmental Protection Agency; and G.E. Raymond, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. July 1, 2023. Docket

facility's fenceline benzene concentrations to be very low (a maximum individual sample concentration of 0.7 μg/m³ and an average Δc of 0.1 μg/m³ of benzene) during the 3 months of fenceline monitoring, especially as compared to the ByP fenceline average delta Δc values at four facilities that ranged from 3 μg/m³ to 33 μg/m³. Additionally, the total estimated benzene emissions from the 5 HNR facilities are quite low, estimated at 2.3 tpy year, which equates to an average of 0.5 tpy benzene per facility, on average, based on all sources at the facilities, both category and noncategory. This compares to ByP facilities that are estimated to emit 25 tpy, which equates to 3.6 tpy per facility, on average, also based on all sources at the facilities, both category and noncategory.

Comment: A commenter stated that coke plants cover large areas with substantial fenceline/perimeters where some portions when located close to communities may be more critical, and therefore, the SSMP should address certain specific information. The commenter said that the EPA should require plants to develop a SSMP that at a minimum addresses the following items:

- Physical plant boundary including each fenceline ''reach'' on a properly-drawn scaled map, showing all coke-making and related operations as well as the land uses beyond the plant, adjacent to each reach of the fenceline.
- Types of pollutants emitted by the plant—for which the starting point is the collection of 2016 and 2022 (ICR) data, as supplemented by ongoing testing. This will include a range of VOCs and HAPs, PAHs, $PM_{2.5}$ (as a surrogate for nonmercury metals), Hg, AG, etc.
- Sampling approach to initially measure all potential HAP emissions at each fenceline reach, and especially for those reaches where there is potential for community exposure if pollutants escape the plant boundary—at least for a period of 1 year.
- Potential reduction of the list of measured HAP that are potentially emitted at each fenceline reach, as needed, based on the first year of data collection.
- Proper frequency of sampling at the critical fenceline reaches. For example, if benzene or naphthalene are identified as the potential pollutants for adjacent community exposures, the plan should include continuous measurements using open path methods as opposed to periodic sorbent tube collection. Continuous measurements will provide the data on short-term variability of such impacts as opposed to a 2-week or similar average using sorbent tubes. Refineries in California have successfully implemented such continuous fenceline monitoring for many years and the EPA can readily access how these have been implemented.
- Collection of continuous meteorological data in order to assist in data evaluation—*i.e.,* to determine if the coke plant or some other source may have been the likely cause of a spike in emissions. This would eliminate the need to address upwind corrections since, depending on the meteorological data, the upwind fenceline can always be readily identified, making this correction defensible and simple.

Another commenter asked how the monitoring requirements that support the exclusion of benzene from offsite sources can be made more transparent and enforceable, particularly if the SSMP is the method for excluding benzene from offsite sources. The commenter requested that the EPA revise the proposed rule text for fenceline monitoring (40 CFR 63.314(i)(1)(ii)) accordingly to make this requirement more transparent and enforceable. The commenter suggested the following text as a replacement: ''. . . . . identify the location of the additional monitoring stations that must be used to determine the uniform background concentration and the near-field source concentration contribution. Modeling may not be used in lieu of monitoring to identify near-field sources that an SSMP applicant alleges contribute significantly to fenceline benzene levels at the applicant's facility.''

Response: The EPA disagrees with the commenter that SSMP are necessary for every facility. In the proposed rule, the EPA stipulated that an EPA-approved SSMP is required if a facility wants to account for near-field offsite upwind sources in their determination of Δc. In the final rule, this requirement is extended to accounting for onsite sources not subject to a regulation codified in 40 CFR part 63. The EPA disagrees that the additional elements suggested by the commenter are necessary for the correct implementation of fenceline monitoring. The siting criteria of EPA Method 325A are specified based on the size and shape of facility, and the location of monitors are detailed in each quarterly report. It is unclear from the comment what is meant by fenceline ''reach.'' Land uses outside of the fenceline of the facility are not necessarily known by the facility, since they are outside the control of the facility. Benzene is being used as a surrogate for COE, which encompasses many different HAP and of which benzene is the dominant HAP as indicated by fenceline monitoring and the interior facility monitoring conducted through the CAA section 114 information collection request. Continuous meteorological data is already required to be collected to correct the measured concentration to standard temperature and pressure and depending on the locality, it can be used in locating potential sources of any emissions. When an SSMP has been developed, the meteorological data can be used to account for up-wind or onsite benzene contributions. To achieve this, the meteorological data must be collected at an onsite location when an SSMP is implemented.

The EPA acknowledges the feedback from the commenter about making the language for near field source correction of upwind contributions more transparent and enforceable in the final rule. The rule requires an owner or operator to submit a SSMP to the EPA for review and approval when near-field offsite upwind sources or certain onsite sources are being accounted for. The EPA will approve or disapprove the SSMP in writing within 120 days of receiving a complete SSMP submittal. The EPA agrees with the commenter that more specificity should be provided in the SSMP and has chosen to revise the final rule to include more prescriptive language to define the requirements of the SSMP and to harmonize the approach for this rule with other NESHAPs.

Comment: Commenters stated that the EPA needs to include a more comprehensive suite of pollutants for fenceline monitoring, not just one surrogate parameter. The commenters requested that the EPA expand the initial set of target analytes.

One commenter stated the proposed rule does not include hydrogen sulfide fenceline monitoring. The commenter argued that the EPA has failed to account for its own data about how damaging these facilities are. The commenter stated that in 2018, the EPA produced a ''Geospatial Monitoring of Air Pollution Report'' (October 31, 2018) after conducting some fenceline monitoring over 6 days along one side of Middletown Works (which then had an operating coke plant). The commenter indicated that the EPA concluded ''These mobile and stationary data indicate a potential acute human health hazard.'' The commenter asserted that these hydrogen sulfide results show

ID Nos. EPA–HQ–OAR–2002–0085–0880 and EPA–HQ–OAR–2003–0051–0735.

the need for far more comprehensive fenceline monitoring.

Another commenter stated that benzene is an adequate surrogate for some HAP, but not for inorganic compounds, and indicated that the EPA should require fenceline monitoring of arsenic. This commenter requested that the EPA add a requirement for fenceline monitoring of arsenic. The commenter contended that while benzene seems to be a good indicator for hydrocarbons such as BTEX or PAH, it is not clear that it is also a surrogate for inorganic pollutants. The commenter stated that the U.S. Geological survey examined arsenic levels in coal, finding a broad range of mean concentrations from 1.5 ppm to 71 ppm, depending on the source (*https://pubs.usgs.gov/fs/2005/3152/fs2005-3152.pdf*). The commenter stated that wide differences in arsenic content were also found in a review article by Yudovich and Ketris (*https://www.sciencedirect.com/science/article/pii/S0166516204001673*). The commenter stated such differences in arsenic coal content are reflected in emission levels: A study of trace metal elements released during coal coking found differences of 600 percent in arsenic levels between different facilities, stating ''This is obvious owing to the different levels of trace elements contents in coals, depending on the coal type, origin, basin, and other factors.'' (Konieczynski J, Zajusz-Zubek E, Jablonska M. *The release of trace elements in the process of coal coking.* (*Scientific World Journal.* 2012;2012:294927. Doi: 10.1100/2012/294927). While this study refers to different facilities, such variability is expected to apply to different times within a given facility as well.

The commenter stated that the EPA identified arsenic as the leading cause for cancer and chronic health risks from COE but benzene has not been proven to be an adequate surrogate for arsenic levels. According to the commenter, adding a fenceline monitoring requirement for arsenic would be feasible and simple to implement. The commenter said that the EPA has a number of methods to determine metal concentration in ambient air that could be used for the fenceline monitoring (see *https://www.epa.gov/amtic/compendium-methods-determination-inorganic-compounds-ambient-air*). The commenter said there are a number of EPA-certified ambient air monitoring methods for metals, including arsenic, that could easily be installed and sampled on the same deployment and retrieval data collection schedule as the fenceline benzene monitors.

Response: The EPA required some facilities in the industry to conduct comprehensive fenceline monitoring as part our 2022 CAA section 114 request, which included measurement of a suite of organic HAPs. The results of this monitoring can be found in the memorandum *Fugitive Monitoring at Coke Oven Facilities*[24] The monitoring identified benzene as the most common organic HAP measured above detection level and the organic HAP with the highest concentration, making it an appropriate surrogate for fugitive emissions from coke ovens and COE. For fugitive leaks of COE, the intended use of fenceline monitoring, benzene is the chemical best suited as a surrogate for COE.

Arsenic requires a different monitoring approach with much higher costs, both for the analytical tests and for installation, and requires electricity at each sampling location. Benzene also is present in much higher concentrations in COE than arsenic; therefore, any leaking coke oven gas contains benzene and at much higher concentrations than arsenic. The EPA did not evaluate arsenic (or any other metal HAP) as part of the information requests related to fenceline monitoring. Instead, fenceline monitoring was performed at these sites to evaluate VOC/HAP emissions from fugitive sources. Although we recognize that arsenic is emitted from these facilities, the arsenic emissions are typically hot and emitted from ducted sources such as stacks at much higher elevations than the ground level of the fenceline. Therefore, we do not expect arsenic to be detected at the fenceline. The emissions from elevated, ducted sources regulated under subpart CCCCC that do not directly impact the fenceline measurements are measured at the source through periodic compliance testing required to demonstrate compliance with the MACT standards.

Lastly, hydrogen sulfide is not currently a listed HAP under CAA section 112, and so could not be considered in this rulemaking unless the EPA determined that it was a surrogate for one or more HAP emitted as fugitives from the category. We have not made such a determination.

Comment: A commenter said that the ''Δc'' calculation is not sufficient to account for offsite sources of benzene when there are significant offsite sources or when wind direction information demonstrates the impact of offsite sources on monitoring locations. The commenter requested that the EPA redesign the Δc element of the fenceline monitoring program. The commenter provided, as an example, the CAA section 114 fenceline monitoring data for the Cleveland Cliffs' Burns Harbor facility, which demonstrated that the highest benzene concentrations are associated with sources at the adjacent port facility and are not located near the coke facility.

Response: The EPA disagrees that the final rule should provide a mechanism in addition to that already incorporated in the proposed rule to take into account the impact of offsite sources. As proposed, the final rule accomplishes this not just through the Δc calculation methodology, but also through allowing the use of an SSMP. The rule states that an owner or operator may elect to submit an SSMP (for EPA review and approval), which could allow for the subtraction of upwind contributions. The final rule includes more prescriptive language to define the requirements of the SSMP. This is consistent with fenceline monitoring provisions in other NESHAPs.

Comment: Commenters stated that they believe the fenceline monitor data should be made available to the public to improve transparency. The commenters requested that the EPA provide public access to the fenceline data as it is being collected and reviewed so people can be aware of their exposure risks. A commenter requested that the fenceline data be put on a website that is easily accessible to a layperson or community member near a facility who is not aware of and has not had training on that portal. A commenter contended when action levels are exceeded, the community must be provided immediate notification of such exceedances and that reporting through the EPA's electronic reporting and data retrieval portal is not sufficient and is confusing to use. Making pollution data readily available to the public is a low-cost, efficient way to drive pollution reduction.

A commenter contended the EPA does not specify when fenceline monitoring data submitted via CEDRI will be made available to the public. The commenter said that public access to fenceline data will allow regulators to detect non-compliance earlier, and that communities would be simultaneously informed of dangerous, higher concentrations of chromium (and for lead, if the EPA includes lead in the

[24] *Fugitive Monitoring at Coke Oven Facilities.* D.L. Jones, K. Boaggio, K. McGinn, and N. Shappley, U.S. Environmental Protection Agency; and G.E. Raymond, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. July 1, 2023. Docket ID Nos. EPA–HQ–OAR–2002–0085–0880 and EPA–HQ–OAR–2003–0051–0735.

fenceline standard, as they should) with less delay. The commenter contended that prompt public disclosure of benzene monitoring data will make the failure to collect and report such information more visible, will give regulators and communities quicker access to information about dangerous spikes in benzene levels, and will give companies a ''real time'' incentive to move quickly to clean up emission sources causing the problem.

Response: As described in the proposed rule preamble and in this preamble, the EPA is only requiring fenceline monitoring for benzene in this final rule. We decided it is not necessary or appropriate to require fenceline monitoring for lead, arsenic or any other metal HAP as part of this rulemaking. See other responses in this section for more details on this topic.

Regarding the public availability of data and monitoring locations, we are finalizing, as proposed, the requirement that the exact location of each sampling location (latitude and longitude) as well as the individual sampling results (both original results and corrected results if a monitoring location result is modified as a result of an SSMP) are included in the quarterly report at 40 CFR 63.311(j)(3) and (5). These quarterly fenceline reports will be submitted to CEDRI and subsequently be available to the public via the Web Factor Information Retrieval System (WebFIRE) (*https://www.epa.gov/electronic-reporting-air-emissions/webfire*). The fenceline monitoring data is released to WebFIRE 30 days after submittal to CEDRI to allow time for the EPA and any delegated authority to review the data prior to release. For a general discussion on the electronic reporting process, see the memorandum *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* available in the dockets for this action (EPA–HQ–OAR–2002–0085–0908 and EPA–HQ–OAR–2003–0051–0748).

To search for a fenceline monitoring report required by this rule, begin at the WebFIRE home page, *https://cfpub.epa.gov/webfire,* and select ''Search for Reports.'' On the following page, select ''Air Emissions Reports'' and click ''Submit Search.'' From the ''Search Criteria,'' select ''Part 63—NESHAP'', and ''NESHAP—L: Coke Oven Batteries'' from the list and click ''Submit Search''. From this page, additional search criteria can be used to narrow the search to a specific facility, either through ''Submitting Organization and/or Facility Name,'' the ''Facility Location,'' or Federal Registry Service identification ''FRS ID'', which can be found at *https://www.epa.gov/frs/frs-query.* From the results screen, individual reports can be selected or multiple reports may be selected for a bulk download, either through the link at the top of the page for all reports matching the search criteria, or for a smaller subset of results through selecting multiple reports in the ''Include Report in Bulk Download'' and clicking ''Bulk Download Selected Reports'' on the bottom of the page. Depending on the overall file size, this may take some time to download.

b. Lowered Leak Limits for Doors, Lids, and Offtakes

We received a few comments on the proposed lowered leak limits for doors, lids, and offtakes with comments both in favor of the proposed requirement and comments that were opposed to the requirements or requested significant changes.

Comment: Commenters stated that they believe the leak rate data used for new limits are not a ''development in practices, processes, and control technologies.'' Commenters requested that the EPA not finalize the proposed leak limits because the proposed rule fails to demonstrate that there have been any new cost-effective developments in leak control practices, processes, or control technologies for doors, lids, and offtakes. Further, one commenter stated they believe that the EPA does not demonstrate why coke facility production capacity is a factually sound basis for establishing differing door leak limits. The commenter requested that the EPA not finalize the proposed leak limits for doors, lids, and offtakes based on capacity. This commenter also stated they believed that the EPA offers no basis for its conclusion that ''tall'' and ''not tall'' doors should have the same leak limits at facilities with less than 3 million tpy production capacity. The commenter requested that the EPA use door height for setting door limits as in current rule for lower production capacity facilities.

Commenters contended that across the cokemaking industry, leak control for doors, lids, and offtakes is achieved through operational and maintenance work practices, not through add-on pollution controls or other equipment; and the current leak control methods existed and were considered during development of the original MACT standards [for subpart L, in 1993]. The EPA's use of new leak rate data for coke battery facilities is not based on any previously unidentified leak control work practices, operational procedures, process changes, add-on controls, or pollution prevention alternatives. Leak rate data, like other forms of emissions data, are simply information about a practice, process, or control technology. The commenters stated the EPA's approach improperly equates data showing overcompliance with existing standards as ''developments'' in leak control practices and processes. Nothing in the language of CAA section 112(d)(6) gives the EPA authority to rachet-down existing MACT floor limits based solely on data showing overcompliance with those existing limits. The commenter contended there is no explanation for why the EPA selected a 3 million tpy threshold versus some other level of coke production capacity. It is counterintuitive to presume that higher coke production capacity correlates to lower leak rates. The existing subpart L door leak standards are not based on coke production capacity; and one would expect that higher production facilities have a larger number of ovens in operation, with more cycles of charges and pushes, *etc.* All of these factors would be expected to correlate with similar or higher leak rates compared to smaller capacity facilities.

The commenter also stated that since promulgation in 1993, the subpart L door leak limits have been based on the height of the door (*i.e.,* ''tall'' doors (6 meters and taller) and ''not tall'' doors) because taller doors are more correlated with the occurrence of leaks. ''Tall'' doors have a longer perimeter length compared to ''not tall'' doors, and longer perimeters have more area where leaks can occur. For example, a 6-meter ''tall'' battery door has 43 percent more perimeter length compared to a 4.3-meter ''not tall'' door. Therefore, ''tall'' doors are expected to have higher leak rates compared to ''not tall'' doors, and the existing door leak limits reflect these differences.

The commenter contended the EPA seemingly acknowledges this by proposing different leak limits for ''tall'' and ''not tall'' doors for facilities with greater than 3 million tpy production capacity. However, the EPA offers no explanation why size of the door matters for leak limits at higher production facilities but size does not matter for lower production facilities.

Response: The EPA disagrees with the commenter that the leak rate data used for new limits are not a development in ''practices, processes, and control technologies.'' The EPA believes there is a strong basis to infer that the data acquired by the EPA in CAA section 114 requests from current coke facilities in 2016 and 2022, which showed fewer leaking doors, lids, and offtakes than

that allowed under the rule, reflects improved performance due to improved work practices for observing leaks during operations, and more quickly and efficiently sealing and adjusting doors, or other practices related to door leaks. We also received additional leak data in 2023 and 2024 from a number of facilities that provide further evidence that there has been improved performance. These data are available in the docket for the final rule. There is no other known factor that correlates to reduced leak frequency or duration. As a commenter points out, these practices, broadly described, are not necessarily new. However, CAA section 112(d)(6) does not require that practices be either recently invented or recently identified. The CAA section 112(d)(6) gives the EPA authority to revise standards based upon ''developments'' in practices, which clearly can include improvements in previously existing practices and new information about the performance of those improvements. Here there is no apparent reason for lower leak rate values other than positive developments in work practices concerning detection and minimization of leaks. Industry commenters have not suggested any alternative explanation. It is therefore reasonable to infer that lower leak rate values reflect developments in work practices to control leaks. See the response to the next comment in regard to the data supporting this statement.

The lower leak rate standard for larger capacity facilities reflects the lower leak rates shown in the recent EPA Method 303 data for those operations. The commenter correctly notes that oven leak rates are not functionally related to the number of ovens at a facility; rather, leak rates depend on whether each oven is well-sealed or not. As noted above, the primary determinant of leak rates is the effectiveness of work practices to detect and minimize leaks. There is not an apparent reason for why larger capacity facilities are attaining lower leak rates other than that they are more effectively employing work practices to control leaks. Industry commenters have not suggested an alternative explanation. In this situation, the distinction based on facility size (as allowed by CAA section 112(d)(1)) reflects more effective work practices at the larger facilities. There may be, for instance, cost-related reasons why smaller capacity facilities have not employed the same work practices as larger facilities. It is reasonable to infer that a larger capacity facility may be able to invest more resources in leak control practices. Lacking a firm basis for concluding that smaller facilities can reasonably achieve the same performance as larger facilities, the EPA is finalizing the capacity-based distinction in leak rate limits supported by current measurement data.

That leak rates are primarily determined by work practices, and that work practices are not restricted to facility capacity, if anything, suggests that the lower leak rates achieved at larger capacity facilities should be achievable at smaller facilities as well. Notwithstanding such a possible inference, the EPA is setting leak rate limits at levels demonstrated to be achievable by the available data.

The EPA selected a 3 million tpy production of coke production capacity because the production of the facility in this category (nearly 5 million tpy capacity) is more than twice the capacity of the next highest facility (<2 million tons coke capacity). This is a clear break point in size between larger and smaller capacity facilities, and that break point aligns with the data showing lower leak rates at the larger facility.

Regarding the commenter's request to use door height for setting door limits for lower production capacity facilities, the EPA agrees with the commenter and is finalizing allowable door limits for both ''tall'' and ''not tall'' batteries, as described in section IV.B.4.b. of this preamble and in the *Technology Review Memorandum-Final Rule,*[25] and which reflect the current rule. Also, see the EPA's response to other comments on the revised leak limits in this section.

Comment: A commenter stated that they believed the EPA has not provided adequate information regarding what data were used and how the EPA calculated the proposed leak limits for doors, lids, and offtakes. The commenter requested that the EPA provide rationale for new leak limits for doors, lids, and offtakes. The commenter contended the *Technology Review Memorandum* identifies the proposed limits but provides little information on how the EPA derived the limits. Beyond a sentence stating that ''[t]he 2022 facility-average data showed a high of 46 percent of the standard for tall doors (standard 4.0 percent); a high of 52 percent of the standard for all other doors, *i.e.,* not tall (standard 3.3 percent); and a high of only 36 percent of the standard for foundry (standard 4.0 percent) . . .'' it is not apparent how the EPA derived any of the proposed leak limits, including the averaging time the EPA used. It is not clear if the EPA used or disregarded the 2022 ICR data in developing the proposed limits, which makes it difficult to verify the EPA's claim regarding the facility-average data.

Response: The EPA agrees with the commenter and has revised the proposed leak limits. The proposed limits were based on data described in the memorandum prepared for the proposal *Technology Review for the Coke Ovens: Pushing, Quenching, and Battery Stack and Coke Oven Batteries Source Categories,*[26] hereafter referred to as the ''*Proposal Technology Review Memorandum,*'' and specifically, Section 3.2 Current Leak Control at ByP Coke Oven Facilities and ''Table 5. Summary of ByP Facility Method 303 Performance and COE Emissions Data from 2022 Coke Section 114 Request.'' The EPA developed an annual average for 2022 each facility and each battery from the submitted monthly averages for 2022. However, we used a different approach for the final rule limits. The revised limits are based on consideration of public comments and additional facility data for rolling 30-day average leak rates received after the publication of the proposed rule, as described in section IV.B.4.b. of this preamble (*e.g.,* see table 4 in section IV.B.4.b.) and in the *Technology Review Memorandum-Final Rule.*[27]

c. Zero Allowable Leaks From HNR Oven Doors and Concurrent Oven or Common Tunnel Pressure Monitoring

We received 2 comments on requiring both zero leaks from HNR oven doors and concurrent oven and common tunnel pressure monitoring. Both commenters were not in favor of the proposed amendments to require pressure monitoring in ovens. No comments in support were received.

[25] *Technology Review for the Coke Ovens: Pushing, Quenching, and Battery Stack and Coke Oven Batteries Source Categories—Final Rule.* D.L. Jones, U.S. Environmental Protection Agency, and G.E. Raymond, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085–0873 and EPA–HQ–OAR–2003–0051–0682.

[26] *Technology Review for the Coke Ovens: Pushing, Quenching, and Battery Stack and Coke Oven Batteries Source Categories.* D.L. Jones, U.S. Environmental Protection Agency, and G.E. Raymond, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2023. Docket ID Nos. EPA–HQ–OAR–2002–0085–0873 and EPA–HQ–OAR–2003–0051–0682.

[27] *Technology Review for the Coke Ovens: Pushing, Quenching, and Battery Stack and Coke Oven Batteries Source Categories—Final Rule.* D.L. Jones, U.S. Environmental Protection Agency, and G.E. Raymond, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085–0873 and EPA–HQ–OAR–2003–0051–0682.

Comment: A commenter stated that costly and onerous HNR oven pressure monitoring is unnecessary, burdensome, and unsafe. The commenter explained that if pressure monitors are located in the ovens, they must be manually cleaned out by maintenance personnel 2 to 3 times per week. The commenter requested that the EPA not require HNR oven pressure monitoring (in 40 CFR 63.303(a)(1)(i)) in addition to VE monitoring. The commenter contended the EPA lacks authority to require costly and onerous oven pressure monitoring for HNR oven door leaks. The commenter noted that the EPA had stated in the proposal that it ''did not identify any developments in practices, processes or control technologies,'' (88 FR 55883) and acknowledged that ''[VE] monitoring has been used as an effective surrogate for monitoring door leaks in the past.'' The commenter asserted the EPA incorrectly assumes that increased pressure monitoring is necessary to establish negative oven pressure. The EPA's proposed requirement ''to measure pressure in the ovens during the main points in the entire oven cycle to include, at minimum, during pushing, coking, and charging,'' (88 FR 55884), is inconsistent with its findings that for pushing and charging, ''no technology has been identified that demonstrates reduced emissions . . . beyond the current control technology in use.''

The commenter continued that installing and maintaining pressure monitors in each oven would be exorbitantly expensive, challenging, and unreliable. The commenter estimated costs of $3 to 4 million for every 100 ovens subject to this requirement. In addition, pressure monitors located in the ovens must be manually cleaned out by maintenance personnel 2 to 3 times per week, exposing personnel to excessive heat, which is an unnecessary safety risk. The commenter stated that SunCoke's heat recovery facilities already monitor negative pressure in the common tunnel electronically on a continuous basis and have one pressure transmitter for every seven (7) ovens in the battery on average. Monitoring for negative pressure in the common tunnel, in conjunction with monitoring for coke oven leaks throughout all stages of coking as previously described, accurately captures any time that an oven is experiencing positive pressure and allows personnel to take action in a timely and safe manner when necessary. Therefore, the commenter states that the EPA should not include these proposed changes to pressure monitoring in 40 CFR 63.303(a)(i) in the final rule.

Another commenter also stated that the EPA proposed rule includes unnecessary and redundant instrumentation to monitor HNR oven operational pressure continuously.

In regard to the proposed requirement to require zero leaks from HNR oven doors, as determined by EPA Method 303A, a commenter notes that SunCoke's work practices are already consistent with 40 CFR 63.303(c)(2) in that SunCoke monitors the ovens for the entirety of the coking cycle and responds to any observed door leaks to make adjustments to the ovens by reviewing electronic data and physically walking the coke oven batteries. Any door leaks due to positive pressure are corrected by adjusting oven uptakes, dampers, and/or sole flues, and are then recorded, and reported as required under 40 CFR 63.303(c)(2).

Response: In response to what the EPA believes to be credible concerns regarding safety hazards and costs, the EPA is not finalizing a requirement for both HNR oven and common tunnel pressure monitoring in 40 CFR 63.303(a)(1)(i). The costs of requiring both oven pressure monitoring and common tunnel monitoring would not be justifiable given the already low leak emissions from HNR ovens that will be complying with the 0 percent leaking oven doors requirement in the final rule, and the common tunnel pressure monitoring already in place at HNR facilities.

Because of the commenter's statements that due to another part of the COB rule, 40 CFR 63.303(c)(2), HNR facilities are already required to respond to oven leaks, and that all HNR facilities already ''monitor the ovens for the entirety of the coking cycle and respond to any observed door leaks to make adjustments to the ovens by reviewing electronic data and physically walking the coke oven batteries,'' we are promulgating the requirement for zero leaks from oven doors, with daily monitoring using EPA Method 303A, so that the current SunCoke practice to observe oven doors to maintain zero leaks is codified in the rule.

Therefore, in the final rule, a HNR facility is required to demonstrate and maintain zero leaks from HNR oven doors, and measure pressure in either the ovens or common tunnels to demonstrate negative pressure, minimally during charging, coking, and pushing.

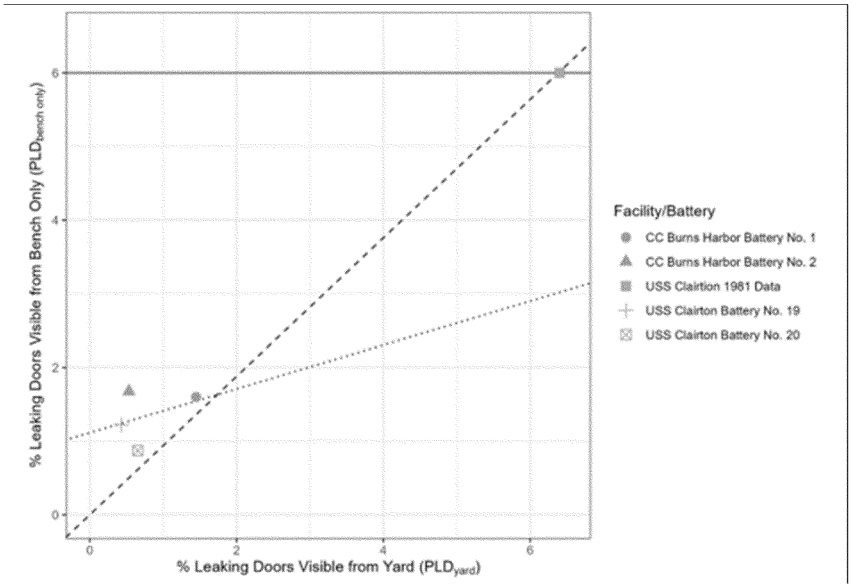
d. Revised Emissions Equation for Emissions From Leaking Doors

We received one comment on the revised emissions equation for emissions from leaking doors which suggested corrections to the equation.

Comment: A commenter stated they believe the EPA's proposed change to the equation for estimating leaks would underestimate PLD_{bench} and thus COE, and proposed an alternative equation. To test the EPA's proposed change, the commenter plotted PLD_{bench} versus PLD_{yard} (shown in this section as Commenter's Figure 1). The commenter asserted that for a valid equation the points should fall along a line with a slope of 0.94 and intercept of 0, and that because data for these four batteries in Commenter's Figure 1 are above this line, the EPA's proposed equation underestimates PLD_{bench} and thus COE.

The commenter continued that another issue is that the EPA's proposed change assumes that PLD_{bench} is zero when PLD_{yard} is zero. However, even when there are no leaks visible from the yard, there will still likely be leaks visible only from the bench. It appears a more appropriate method for estimating PLD_{bench} from PLD_{yard} is to fit a line to the data with a non- zero intercept. Doing so yields the following equation for estimating PLD_{bench} from PLD_{yard}:

$$PLD_{bench} = 0.30 * PLD_{yard} + 1.11 \quad \text{(Equation 1)}$$



Commenter's Figure 1: Plot of door leak data from the EPA's CAA section 114 request with assumed current and proposed values of PLD_{bench} only.

The commenter asserted the EPA should estimate PLD_{bench} using Equation 1 ($PLD_{bench\ only} = 0.30 * PLD_{yard} + 1.11$), resulting in a more accurate estimate of PLD_{bench} only and presumably of COE.

Response: We agree with the commenter that there could be PLD from the bench, *i.e.,* PLD bench-only emissions, when PLD from the yard is zero. However, the term PLD_{bench} in the equation in the proposal materials represented emissions from the PLD from bench-only, see pg. 2 of the *Revised Equation to Estimate Coke Oven Emissions from Oven Doors* prepared for the proposal,[28] as well as the memorandum prepared for the final rule titled *Revised Equation to Estimate Coke Oven Emissions from Oven Doors-Final Rule,*[29] where it was stated that the PLD_{bench} term was the ''percent of doors with leaks only visible from the bench, assumed [previously] to be 6%''. The PLD-bench total is equal to ''PLD-bench only'' plus PLD visible from both the bench and the yard (PLD-yard). We have added subscripts for all the terms in the equation in the memorandum prepared for the final rule (and in this section) so that it is clear what emissions are being referenced.

The 2022 CAA section 114 test data submitted included only PLD from the bench, *i.e.,* bench total, and PLD from the yard. PLD-Bench-only is obtained from the PLD-Bench Total leak data, obtained via the 2022 CAA section 114 request, minus the PLD yard. To evaluate the door leak equation, the comparison should be between the ratio of PLD bench-only to the PLD yard.

The results of the analysis of CAA section 114 data submitted by Cleveland Cliffs' Burns Harbor and U.S. Steel's Clairton facilities are shown in table 5 of this section. Similar to the commenter, we combined the 1981 leak data with the 2022 leak data so as to have a more robust data set. We first determined the average ratio of PLD-bench-only to PLD-yard for both batteries from each facility, and from both coal and coke sides in the 1981 and 2022 data. These ratios were averaged together to produce a revised PLD bench-only/PLD yard ratio of 1.5 to use in the leak emissions equation. See table 6 of this section.

TABLE 5—SUMMARY OF DOOR LEAK STUDY AT CLEVELAND CLIFFS BURNS HARBOR AND U.S. STEEL'S CLAIRTON FACILITIES SUBMITTED FOR 2022 CAA SECTION 114 REQUEST

Facility	Battery ID	Coke side			Coal side		
		Average PLD			Average PLD		
		Bench (%)	Bench-only (%)	Yard (%)	Bench (%)	Bench-only (%)	Yard (%)
CC Burns Harbor	2	3.8	2.7	1.1	0.61	0.61	0.0
	1	4.4	2.6	1.8	1.7	0.61	1.1
	Facility Avg	4.1	2.7	1.4	1.1	0.61	0.53
U.S. Steel Clairton	20	1.1	0.38	0.72	1.9	1.3	0.57
	19	1.6	1.03	0.57	1.7	1.4	0.29
	Facility Avg	1.4	0.71	0.60	1.8	1.4	0.40

[28] *Revised Equation to Estimate Coke Oven Emissions from Oven Doors.* D.L. Jones and K. McGinn. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. August 2021. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

[29] *Revised Equation to Estimate Coke Oven Emissions from Oven Doors-Final Rule.* D.L. Jones and K. McGinn. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

TABLE 6—RATIOS OF PLD-YARD TO PLD-BENCH-ONLY IN 1981 AND 2022 DATA SETS AND OVERALL AVERAGES

Facility	Battery ID	Ratio PLD bench-only/PLD yard		
		Coke side	Coal side	Average
CC-Burns Harbor	2	2.6	NA [a]	
	1	1.4	0.57	
	Facility Avg	2.0	0.57	1.3
U.S. Steel Clairton	20	0.53	2.3	
	19	1.8	4.9	
	Facility Avg	1.2	3.6	2.4
1981 Data [b]				0.94
Overall Average				1.5

[a] Coal-side ratio can't be calculated because coal-side yard PLD is zero.
[b] Ratio was determined from bench-only value of 6.0 and PLD yard of 6.4 (6.0/6.4 = 0.94).

In order to determine the value for PLD-bench only when PLD yard is equal to zero, we plotted PLD yard by PLD bench-only, similar to the commenter's approach but using PLD bench-only instead of PLD bench-total. The intercept of the regression line with the y-axis is the value for PLD-bench-only when PLD yard is 0, at 0.7 percent (or a factor of 0.007). The correlation coefficient (r^2) of the regression line is 0.84, which is considered a good fit.[30] See Figure 2 in this section.

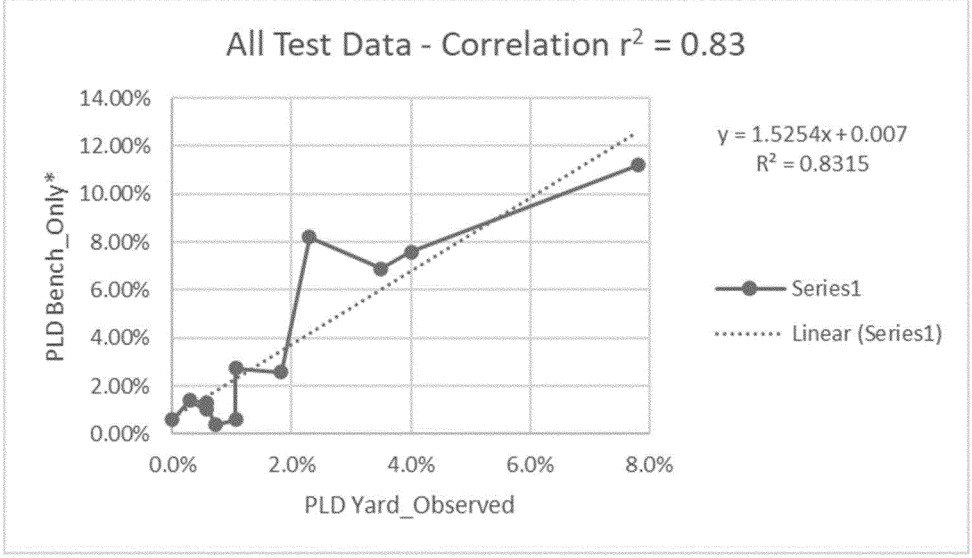


Figure 2. Regression Of 1981 And 2022 Coke Oven Method 303 Leak Data From Bench-Only And Yard

The revised door leak equation using the revised ratio of PLD-bench-only to PLD yard of 1.5 and adding a third term in the equation to represent the case where PLD-yard is equal to zero is shown below:

$$\text{COE-doors (lb/hr)} = N_D \times (PLD_{yard}/100) \times (0.04 \text{ lb/hr}) + N_D \times ((PLD_{yard} \times 1.5_{PLDbench\text{-}only/PLDyard})/100) \times (0.023 \text{ lb/hr}) + N_D \times 0.007 \times (0.023 \text{ lb/hr})$$

See the *Revised Equation to Estimate Coke Oven Emissions from Oven Doors—Final Rule* [31] for documentation of the revised leak limit equation for the final rule that reflects comments received and additional analyses.

e. Opacity Testing of HNR B/W Stacks

We received one comment on the proposed opacity limit for HNR B/W stacks that objected to the numerical value, the frequency of the proposed limit, and the coke NESHAP (COB) in which the limit was proposed. The comment is summarized below along with the EPA response.

Comment: The commenter stated that the EPA's redline version of its proposed amendments to subpart L includes a proposed change to 40 CFR 63.303(d)(3) to impose a 10 perent opacity limit on HNR B/W stacks. The commenter contends they are not aware of any coke plant that could meet the proposed limit. According to the commenter, the permits and state

[30] Davide, C., M.J. Warrens, and G. Jurman. *The coefficient of determination R-squared is more informative than SMAPE, MAE, MAPE, MSE and RMSE in regression analysis evaluation. PeerJ Comput Sci.* 2021; 7: e623. Published online 2021 Jul 5. doi: 10.7717/peerj-cs.623. July 5, 2021. *https://peerj.com/articles/cs-623/.*

[31] *Revised Equation to Estimate Coke Oven Emissions from Oven Doors-Final Rule.* D.L. Jones and K. McGinn. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

regulatory authorities already limit VE from the HNR B/W stacks to 20 percent opacity. As demonstrated by the performance testing conducted and the deviation reports submitted in response to the EPA's CAA section 114 request, the commenter stated that SunCoke is in substantial compliance with the existing opacity limits for the HNR B/W stacks. When this equipment is in operation, SunCoke personnel monitor opacity from the HNR B/W stacks and adjust oven dampers to minimize or eliminate VE if present to ensure compliance with the existing opacity limits. At SunCoke's Jewell facility, which is the only facility where the waste heat stacks operate on a continuous basis, an equivalent weekly monitoring requirement is already established by its CAA Title V requirement. The commenter stated more frequent monitoring is not necessary, citing Jewell's vast history of complying with its opacity limit.

The commenter also stated that it would not be appropriate to establish a daily [opacity] observation requirement at heat recovery facilities because the bypass stacks do not operate on a continuous basis. Because venting at SunCoke's heat recovery facilities can be brief and intermittent, imposing such a requirement any time the bypass vent stacks are in operation would result in greater environmental harm because it would extend the duration of venting to allow SunCoke sufficient time to dispatch certified personnel to the appropriate location in the plant to conduct readings per EPA Method 9. The commenter, therefore, urged the EPA to not include its proposed changes to 40 CFR 63.303(d)(3) in the final rule, and stated that including these changes would be unnecessary, arbitrary and capricious. Moreover, SunCoke notes that the EPA is attempting to regulate the same source—bypass/HNR B/W stacks—as part of two different source categories, subparts L and CCCCC. The commenter also stated that the EPA lacks authority to impose the proposed new opacity limit and the related requirements, arguing that the EPA had not shown these requirements are ''necessary,'' taking into account developments in practices, processes, and control technologies. See 42 U.S.C. 7412(d)(6) (requiring the EPA to ''review, and revise as necessary (taking into account developments in practices, processes, and control technologies), emission standards promulgated under this section''); 88 FR 55883 (the EPA ''did not identify any developments in practices, processes or control technologies'') (emphasis added).

Response: We agree with the commenter that daily testing from HNR bypass to achieve 10 percent opacity is not demonstrated and that 20 percent opacity is a limit that has been established as a feasible limit for HNR B/W stacks via an existing facility's permit. We also agree that the intermittent nature of the HNR B/W events could prevent HNR facilities from testing under EPA Method 9 and also could unnecessarily extend the bypass event in order to perform the testing.

Based on the comments received, we are finalizing a 20 percent opacity limit for HNR B/W stack, pursuant to a CAA section 112(d)(6) technology review of the PQBS NESHAP, to be measured weekly when a bypass event occurs for more than one continuous hour to allow sufficient time to ascertain whether the bypass event will last long enough to test opacity with EPA Method 9 and, if so, to dispatch personnel qualified to perform EPA Method 9 to the B/W stack. When there is at least one bypass event during any week that last for at least one hour, the weekly opacity testing requirement applies. This condition is important for the four HNR facilities that do not have continuous bypass. The one HNR facility with continuous bypass will be able to test anytime during each week. We agree with the commenter that the revised opacity requirements for HNR B/W stacks should be included as part of the technology review pursuant to CAA section 112(d)(6) under 40 CFR part 63, subpart CCCCC.

6. What is the rationale for our final approach for the technology review?

a. Coke Oven Leak Limits

The leak limits being finalized for doors, lids, and offtakes reflect changes from the proposed rule based on information obtained from a number of ByP facilities on the variability of leaks on daily rolling 30-day average basis. Using the available data, we compared the maximum 30-day rolling averages with the maximum annual averages and developed adjustment factors to account for variability. Then, we multiplied the adjustment factors by the maximum annual average for each leak type. We are promulgating these revised leak limits (shown in table 4 of this preamble). Available data demonstrate that these limits reflect current performance of facilities and are, therefore, achievable. The current performance reflects improvements in work practices, specifically practices designed to enhance prevention, detection, and remediation of leaks and, therefore, constitute a ''development'' for purposes of CAA section 112(d)(6).

b. Fenceline Monitoring Requirements

We revised the modeling procedures to incorporate irregular-shaped facility properties after considering public comments. This resulted in a change in the action level from 3 μg/m^3 to 7 μg/m^3. This action level reflects emissions from the whole site and takes into account all emissions from the coke oven facilities. In addition, in the final rule we are requiring fenceline monitoring and corrective action only at ByP coke oven facilities and not at HNR facilities because the HNR facilities operate under negative pressure, already have very low fugitive benzene emissions, and the NESHAP requires monitoring to ensure no fugitive emissions at HNR facilities. Furthermore, in this final rule, the EPA is providing an opportunity for facilities to develop SSMPs to account for the contribution to the fenceline monitoring by benzene emissions from co-located sources that are not currently subject to regulation under CAA section 112 (such as the non-listed CBRPs).

c. Zero Allowable Leaks From HNR Oven Doors and Negative Pressure Monitoring in Ovens or Tunnels

We are not requiring pressure monitoring in both ovens and common tunnels in the final rule for COB because we did not receive any comments in support of requiring both and we received information on the cost and other problems with installing and maintaining oven monitors. We received two comments describing the redundance of requiring both as well as description of the safety problems with using pressure monitors within ovens. In the final rule, we are requiring both zero leaks from HNR oven doors and pressure monitoring in either ovens or common tunnels. From the comments received, we learned that HNR facilities already monitor ovens to ensure there are no leaks, so the final rule codifies this practice. The compliance date for zero leaking oven doors and pressure monitoring at HNR facilities is July 7, 2025.

d. Revised Emissions Equation for Doors

We revised the proposed equation to estimate COE emissions from leaking doors based on VE test data received from two facilities that was obtained by the EPA in 2022 and combined these data with VE test results from 1981, which was when the equation first was developed. In addition, we received a comment that the equation did not account for the case where no VE from

oven doors is observed from the yard but VE from ovens is observed from the bench. A linear regression analysis of the combined 1981 and 2022 data provided a revised equation that reflects these data and addresses the comments.

e. Opacity Limits for HNR B/W Stacks

We are finalizing a 20 percent opacity limit for HNR B/W stacks under the PQBS NESHAP because this limit is currently required and achieved at the one HNR facility with continuous bypass and because the opacity limit in the rule will ensure continued compliance for this source as well as the other HNR B/W sources with intermittent bypass. We are requiring weekly testing for HNR waste heat stacks, which operate continuously. For HNR bypass stacks, which operate intermittently, testing is required weekly if and when bypass occurs longer than one hour so as to enable testing using the procedures in EPA Method 9 and so as to not prolong emitting bypass exhaust solely for the purpose of testing. The compliance date for opacity limit on HNR B/W stacks is July 7, 2025.

C. CAA Sections 112(d)(2) and (3) for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks Source Category

1. What did we propose pursuant to CAA sections 112(d)(2) and (3) for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks source category?

a. MACT Limits

Consistent with the *LEAN* decision,[32] we proposed 17 [33] new MACT floor limits for unregulated HAP and processes based on available test data, as follows:

- Pushing: AG, HCN, Hg, PAHs;
- ByP battery combustion: AG, HCN, Hg, nonmercury HAP metals;
- HNR HRSG main stack: AG, Hg, nonmercury HAP metals, PAHs; and
- HNR HRSG bypass/waste heat stacks: AG, Hg, formaldehyde, nonmercury HAP metals, and PAHs.

Based on the data we had at proposal, we expected all sources could meet the 17 [34] new MACT floor limits without additional controls. Compliance testing was the only costs that EPA anticipated would be associated with the proposed rule for testing. More details are provided in the August 16, 2023, proposed rule preamble (88 FR 55858).

b. BTF Standards at HNR Facilities Without HRSG

We proposed BTF limits for Hg and non-Hg particulate matter (PM) HAP metals at HNR facilities without HRSG based the addition of baghouses and activated carbon injection (ACI). More details are provided in the August 16, 2023, proposed rule preamble.

2. How did the amendments pursuant to CAA sections 112(d)(2) and (3) change for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks and the NESHAP for Coke Oven Batteries source categories?

a. MACT Limits

We are finalizing 17 new MACT floor-based standards [35] for unregulated HAP and processes that were previously identified in the August 2023 proposed rule. Some of the proposed 17 emission limits changed in the final rule to reflect additional data submitted by coke oven facilities since the limits were developed for the August 2023 proposal, and also from comments received on standardizing limits in gr/dscf to a specific oxygen concentration. The MACT limits, as revised, include: (1) HNR main stack limits for AG, Hg, PAH, and PM (as a surrogate for non-Hg metal HAP) based on additional data, and to standardize all limits to 10 percent oxygen; (2) HNR Bypass stack limits based on additional data for Hg and PM, and to standardize all limits to 10 percent oxygen; (3) revised limits for battery stacks based on additional data for AG, HCN, and Hg, and to standardize the proposed PM limits to 10 percent oxygen; and (4) revised limits for AG, HCN, and PAH for pushing based on additional data.

In addition to the 17 MACT floor limits described above, during the EPA's review of this Coke Ovens RTR final rule, we realized that we did not propose standards for eight additional HAP and process combinations. As a result, the EPA also is finalizing a MACT work practice standard based on ''good combustion practices'' in battery waste heat flues to address the organic HAP emissions of D/F, PAH, and VOHAP from battery stacks. In addition, we are finalizing surrogate standards for five additional HAP and process combinations for which many, but not all, test runs were below the detection limits (BDL), as follows: D/F, formaldehyde, and VOHAP from pushing; formaldehyde from HNR main stacks; and VOHAP from HNR B/W stacks.

The additional eight unregulated HAP and process described in this section were documented in the memorandum *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Coke Ovens Facilities under 40 CFR part 63, Subpart CCCCC* prepared for the proposal, hereafter called the ''*Proposal MACT/BTF Memorandum,*'' [36] which was located in the docket for the proposed rule (Docket ID Item No. EPA–HQ–OAR–2002–0085–0859) and has been available since publication of the proposal in August 2023.

Although the test data for the 17 HAP [37] for which MACT floor emissions limits were proposed included some measurements that were BDL, the majority of test runs were above the detection limits. With regard to the eight additional HAP and process combinations identified for this final rule, many of the test runs were BDL and seven of the eight had a majority of test runs BDL. For all eight HAP and process combinations, emissions are low.

To address this issue, we are promulgating work practice standards pursuant to CAA section 112(h) for battery stacks based on ensuring good combustion in battery waste heat flues for D/F, PAH, and VOHAP emissions from battery stacks since it is not economically and technically feasible to

[32] *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

[33] Note, we erroneously reported that there were 15 new MACT floor limits in the August 2023 proposal preamble. This was a typographic error. The proposed rule included 17 new MACT floor limits and 2 BTF limits; the BTF limits are not included in the final rule. However, we are adding a work practice standard in this final rule so the count of standards is now 18.

[34] Note, we erroneously reported that there were 15 new MACT floor limits in the August 2023 proposal preamble. This was a typographic error. The proposed rule included 17 new MACT floor limits and 2 BTF limits; the BTF limits are not included in the final rule. However, we are adding a work practice standard in this final rule so the count of standards is now 18.

[35] Note, we erroneously reported that there were 15 new MACT floor limits in the August 2023 proposal preamble. This was a typographic error. The proposed rule included 17 new MACT floor limits and 2 BTF limits; the BTF limits are not included in the final rule. However, we are adding a work practice standard in this final rule so the count of standards is now 18.

[36] *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Coke Ovens Facilities under 40 CFR part 63, Subpart CCCCC—Proposed Rule.* D. L. Jones, U.S. Environmental Protection Agency, and G. Raymond, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2023. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

[37] Note, we erroneously reported that there were 15 new MACT floor limits in the August 2023 proposal preamble. This was a typographic error. The proposed rule included 17 new MACT floor limits and 2 BTF limits; the BTF limits are not included in the final rule. However, we are adding a work practice standard in this final rule so the count of standards is now 18.

reliably measure emissions of these HAP, as evidenced by the large percent of test runs that are BDL. For the other five HAP and process combinations, we are finalizing a determination that three of the 17 MACT floor emission limits serve as surrogates for these five HAP and process combinations, and that the five HAP are subject to these surrogate limits. This is shown in table 7. The limits themselves are not changing otherwise as a result of this surrogacy determination. The EPA has used all data available to set valid and appropriate standards and address these eight unregulated HAP. Recognizing that additional data would further support appropriate regulation of these HAP, the Agency intends to obtain additional data, and in a separate, future action use that data to ensure the appropriateness of these standards.

The three additional emission standards and one work practice standard apply as follows: (1) the final limits for PAH for pushing serve as a surrogate for all other organic HAP for pushing, including D/F, VOHAP, and formaldehyde (all had greater than 55 percent of test runs BDL); (2) the final limits for PAH from HNR HRSG main stacks serve as a surrogate for all organic HAP from this source, including formaldehyde, for which greater than 25 percent of test runs were BDL and from very limited data (only one test report from one facility); (3) the final limits for formaldehyde from HNR HRSG B/W stacks serve as a surrogate for VOHAP from B/W stacks (for which greater than 55 percent of test runs were BDL); and (4) a work practice standard of ''good combustion practices'' during ByP waste heat combustion in battery flues to minimize organic HAP emissions from battery stacks, including PAH, D/F and VOHAP.

The good combustion work practice standards require owners or operators to identify and implement a set of site-specific good combustion work practices for each battery. These good combustion work practices should correspond to the facility's standard operating procedures for maintaining the proper and efficient combustion within battery waste heat flues. Good combustion work practices include, but are not limited to, the following:

- Proper operating conditions for each battery (*e.g.,* minimum combustion temperature, burner alignment, or proper fuel-air distribution/mixing).
- Routine inspection and preventative maintenance and corresponding schedules of each battery.
- Performance analyses of each battery.
- Maintaining applicable operator logs.
- Maintaining applicable records to document compliance with each element.

The work practice standards to minimize organic HAP emissions from battery stacks are being finalized under CAA section 112(h) because the EPA has determined that it is not feasible to prescribe or enforce an emissions standard. Sections 112(h)(1) and (h)(2)(B) of the CAA provide the EPA with the discretion to adopt a work practice standard rather than a numeric standard when ''the application of measurement methodology to a particular class of sources is not practicable due to technological and economic limitations.'' The ''application of measurement methodologies'' (described in CAA section 112(h)(2)(B)) means not only conducting a measurement, but also that a measurement has some reasonable relation to what the source is emitting (*i.e.,* that the measurement yields a meaningful value). That is not the case here, where a clear majority of values are BDL using best available technology.

With regard to surrogacy limits, we conclude that PAHs are a good surrogate for the other organic HAP (including D/F, VOHAP and formaldehyde) for the pushing operation because the relative amount of emissions of the other organic HAP due to the high temperature thermal distillation process in coke ovens which are expected to be emitted at a similar degree as PAHs. Regarding the HNR HRSG main stacks, PAHs are a good surrogate for formaldehyde and other organic HAP because the afterburners that facilities use to combust any remaining organic HAP in the oven exhaust are expected to control these organic HAP to similar levels as PAH. Likewise, formaldehyde is a good surrogate for VOHAP for HNR B/W stacks for the same reason (*i.e.,* the afterburners are expected to control VOHAP to a similar degree as formaldehyde).

We also conclude that the additional work practice standard and surrogacy determinations will not result in any new control costs or compliance testing costs.

The 17 MACT floor emissions limits,[38] one MACT work practice standard based on good combustion practices, and five HAP and process combinations for which surrogacy determinations have been made are shown in table 7 of this section. For additional discussion and documentation of these final MACT standards, see the memorandum *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Coke Ovens Facilities under 40 CFR part 63, subpart CCCCC—Final Rule,*[39] hereafter referred to as the ''*Final Rule MACT/BTF Memorandum,*'' which is available in the docket for this rule.

TABLE 7—MACT STANDARDS FOR PQBS SOURCES IN THIS FINAL RULE

Source or process	Pollutant	Type of affected source (new or existing)	
		Existing	New
Pushing	AG	0.013 lb/ton coke [UPL]	5.3E–04 lb/ton coke [3xRDL].
	HCN	0.0015 lb/ton coke [UPL]	3.8E–05 lb/ton coke [UPL].
	Hg	8.9E–07 lb/ton coke [UPL]	5.1E–07 lb/ton coke [3xRDL].
	PAH[a]	4.0E–04 lb/ton coke [UPL]	1.4E–05 lb/ton coke [UPL].

[38] Note, we erroneously reported that there were 15 new MACT floor limits in the August 2023 proposal preamble. This was a typographic error. The proposed rule included 17 new MACT floor limits and 2 BTF limits; the BTF limits are not included in the final rule. However, we are adding a work practice standard in this final rule so the count of standards is now 18.

[39] *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Coke Ovens Facilities under 40 CFR part 63, subpart CCCCC—Final Rule.* D. L. Jones, U.S. Environmental Protection Agency, and G. Raymond and Michael Laney, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

TABLE 7—MACT STANDARDS FOR PQBS SOURCES IN THIS FINAL RULE—Continued

Source or process	Pollutant	Type of affected source (new or existing)	
		Existing	New
	D/F, formaldehyde, VOHAP.	Meet applicable PAH limits and requirements of 40 CFR 63.7290(e).	
Battery Stack	AG	0.160 lb/ton coke [UPL]	0.013 lb/ton coke [UPL].
	D/F, PAH, VOHAP.	''Good combustion'' work practices in battery waste heat combustion flues and meet requirements of 40 CFR 63.7300(c)(4).	
HNR HRSG Main Stack	HCN	0.032 lb/ton coke [UPL]	7.4E–04 lb/ton coke [UPL].
	Hg	4.5E–05 lb/ton coke [UPL]	7.1E–06 lb/ton coke [UPL].
	PM	0.13 PM gr/dscf @10% O_2 [UPL]	0.013 gr/dscf @10% O_2 [UPL].
	AG	0.049 gr/dscf @10% O_2 [UPL]	0.0034 gr/dscf @10% O_2 [UPL].
	Formaldehyde	Meet applicable PAH limit and requirements of 40 CFR 63.7297(d).	
HNR B/W Stack	Hg	3.0E–06 gr/dscf @10% O_2 [UPL]	1.5E–06 gr/dscf @10% O_2 [UPL].
	PAH[b]	4.8E–07 gr/dscf @10% O_2 [UPL]	4.7E–07 gr/dscf @10% O_2 [UPL].
	PM	0.0049 gr/dscf @10% O_2 [UPL]	8.8E–04 gr/dscf @10% O_2 [UPL].
	AG	0.12 gr/dscf @10% O_2 [UPL]	0.093 gr/dscf [UPL].
	Formaldehyde[c]	0.0012 gr/dscf @10% O_2 [UPL]	1.8E–05 gr/dscf @10% O_2 [UPL].
	Hg	1.2E–05 gr/dscf @10% O_2 [UPL]	8.6E–06 gr/dscf @10% O_2 [UPL].
	PAH	2.7E–06 gr/dscf @10% O_2 [UPL]	2.7E–06 gr/dscf @10% O_2 [UPL].
	PM	0.032 gr/dscf @10% O_2 [UPL]	0.022 gr/dscf @10% O_2 [UPL].
	VOHAP	Meet applicable formaldehyde limits and requirements of 40 CFR 63.7298(e).	

[a] Serves as a surrogate for other organic HAP including D/F, formaldehyde and VOHAP.
[b] Serves as a surrogate for other organic HAP including formaldehyde.
[c] Serves as a surrogate for VOHAP.
Note: gr/dscf = grains per dry standard cubic feet. RDL = representative detection level. UPL = upper prediction limit.

Based on consideration of public comments and our revised cost estimates, the EPA is not promulgating the BTF standards for HNR facilities without HRSG. Instead, these units will need to comply with the same MACT floor standards that the EPA is promulgating for HNR HRSG bypass stacks for facilities with HRSG.

3. What key comments did we receive on the amendments pursuant to CAA sections 112(d)(2) and (3), and what are our responses?

We received many comments on the proposed MACT and BTF standards with comments in favor of the proposed limits, comments requesting more stringent limits, and comments that were opposed to the proposed requirements. The key comments on the proposed amendments developed pursuant to CAA sections 112(d)(2) and (3) are summarized in this section along with the EPA's responses to the comments. Other comments received on these proposed amendments are summarized along with the EPA's responses in the *Response to Comment*[40] document, which is located in the dockets for these rules.

Comment: A commenter stated that they believe the EPA is not required by CAA section 112(d) or by the *LEAN*[41] court decision to set new ''gap filling'' MACT floors when the cost of control is extreme and the benefit of further emission reduction is minimal due to very low risk to public health. The commenter requested the EPA consider the cost of meeting the proposed MACT standards as well as the non-air quality health and environmental impacts and energy requirements of doing so. The commenter asserted the following reasons for why they believe the EPA is not required to set new ''gap filling'' MACT floors for existing sources:

- Further reductions of these pollutants are not necessary due to very low risk of the source category;
- Controlling these pollutants has not been demonstrated for sources like ByP battery stacks;
- The cost of adding controls would be exorbitant; and
- The new standards would not be cost effective due to the extreme cost of controls and the minimal reductions in these pollutants that would be achieved.

The commenter urged the EPA to reconsider its long-held interpretation that costs are not considered in setting the MACT floor. The commenter argued that interpretation is not reasonable in the context of a setting *LEAN*[42] ''gap-filling'' MACT standards where the cost of control is extreme and the benefit of further emission reduction is minimal due to very low risk to public health. The commenter believes all relevant factors should be considered in that context, including ''the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements.''

The commenter also asserted that the EPA erred in calculating MACT floors for existing sources based on actual emissions performance rather than on enforceable limitations to which existing sources are subject. The commenter argues this contravenes the plain language of CAA section 112(d)(3), which requires the MACT floor to be based on the ''average emission limitation achieved ''by the best performing sources.''

Response: Regarding the assertion that the assessment of risk should affect

[40] *Summary of Public Comments and Responses for Coke Ovens: Pushing, Quenching, and Battery Stacks Residual Risk and Technology Review, and Coke Oven Batteries Periodic Technology Review.* U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division (D243–02), Research Triangle Park, North Carolina. May 1, 2024.

[41] *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

[42] *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

whether gap-filling standards are required consistent with the *LEAN*[43] decision, the EPA disagrees. The EPA has an independent statutory authority and obligation to conduct the technology review separate from the EPA's authority to conduct a residual risk review. The EPA's finding that there is an ample margin of safety under the residual risk review in no way obviates the EPA's obligation to require more stringent standards under the technology review where developments warrant such standards. The D.C. Circuit has recognized the CAA section 112(d)(6) technology review and 112(f)(2) residual review are ''distinct, parallel analyses'' that the EPA undertakes ''[s]eparately.'' *Nat'l Ass'n for Surface Finishing* v. *EPA,* 795 F.3d 1, 5 (D.C. Cir. 2015). In other recent residual risk and technology reviews, the EPA determined additional controls were warranted under technology reviews pursuant to CAA section 112(d)(6) although the Agency determined additional standards were not necessary to maintain an ample margin of safety under CAA section 112(f)(2).[44] The EPA has also made clear that the Agency ''disagree[s] with the view that a determination under CAA section 112(f) of an ample margin of safety and no adverse environmental effects alone will, in all cases, cause us to determine that a revision is not necessary under CAA section 112(d)(6).''[45] While the EPA has considered risks as a factor in some previous technology reviews,[46] that does not compel the Agency to do so in this rulemaking. Indeed, in other instances, the EPA has adopted the same standards under both CAA sections 112(f)(2) and 112(d)(6) based on independent rationales where necessary to provide an ample margin of safety and because it is technically appropriate and necessary to do so, emphasizing the independent authority of the two statutory provisions.[47]

The language and structure of CAA section 112 further underscores the independent nature of these two provisions. While the EPA is only required to undertake the risk review once (8 years after promulgation of the original MACT standards), it is required to undertake the technology review multiple times (every 8 years after promulgation of the original MACT standard). That Congress charged the EPA to ensure an ample margin of safety through the risk review, yet still required the technology review to be conducted on a periodic basis, demonstrates that Congress anticipated that the EPA would strengthen standards based on technological developments even after it had concluded that the revision was not warranted under CAA section 112(f) . This provision's CAA section 112's overarching charge to the EPA to ''require the maximum degree of reduction in emissions of the hazardous air pollutants subject to this section (including a prohibition on such emissions)'' further demonstrates that Congress sought to minimize the emission of hazardous air pollution wherever feasible independent of a finding of risk.

When the EPA sets MACT standards pursuant to the *LEAN*[48] decision to fill regulatory gaps during a CAA section 112(d)(6) technology review, it must do so without consideration of risk. To the extent the commenter asserts that considerations of risk are relevant at this stage and that the process for setting MACT standards should be approached differently in the CAA section 112(d)(6) context than during the initial promulgation of standards for a source category, we disagree. The CAA section 112(d) clearly outlines the approach the EPA must follow in setting MACT standards. The EPA is finalizing 23 MACT standards that address 25 previously unregulated pollutants and source combinations at the MACT floor level of control pursuant to CAA section 112(d)(3) or 112(h), and as discussed elsewhere in the preamble and in the preamble to the proposal, Congress set forth a prescriptive and clear process that the EPA must follow in determining the MACT floor; that process does not include consideration of risk. Nothing in either the statute or the *LEAN*[49] decision suggests that MACT floors are to be calculated differently subsequent to a CAA section 112(f) risk review.

The EPA also disagrees that the CAA allows the EPA to take costs into consideration in determining MACT floors. The D.C. Circuit has ruled that costs are not to be considered when setting MACT floor standards. In *Nat'l Lime Ass'n* v. *EPA,* 233 F.3d 625 (D.C. Cir. 2000) (''*Nat'l Lime*''), the Court clearly stated that cost should only be considered when evaluating whether ''beyond the floor'' emission standards should be adopted: . ''*Cost, however, may be taken into account only in considering beyond-the-floor emissions limitations,*'' and that ''*cost may not influence the determination of a MACT floor,*'' which depends exclusively upon the emissions reductions achieved by the best-performing sources. *Id.* at 640 (emphasis added).

Requiring the consideration of costs in setting the MACT floor would conflict with the plain language of CAA section 112(d)(3). Section 112(d)(3) of the CAA provides that the emission standards developed under this section ''*shall* not be less stringent than'' the emission performance of the best controlled similar source, for new sources; and ''*shall* not be less stringent, and may be more stringent than'' the emission performance of the top 12% of existing sources for categories with more than 30 sources, or the top 5 sources for categories with fewer than 30 sources, for existing sources. This language provides a clear mandate and does not indicate discretion to consider cost.

We note in this context that for the Coke PQBS source category, based on the data submitted to the EPA by the industry, all facilities should be able to meet the MACT floor limits developed for the previously unregulated HAP and unregulated sources of HAP without the installation of additional controls. Commenters who raised claims of exorbitant costs to meet the new MACT floors did not provide any additional data contradicting the EPA's findings; thus, the EPA does not find any support for these claims.

Regarding the commenter's claim that the MACT floors must be based on emissions legally allowed rather than actual performance, the D.C. Circuit has spoken to this issue several times, including in *Nat'l Lime,* where the court stated that the MACT floor depends exclusively on the emissions reductions ''achieved'' by the best-performing

[43] *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

[44] See, *e.g., National Emission Standards for Hazardous Air Pollutants: Refractory Products Manufacturing Residual Risk and Technology Review.* (86 FR 66045). November 19, 2021; *National Emission Standards for Hazardous Air Pollutants: Generic Maximum Achievable Control Technology Standards; and Manufacture of Amino/Phenolic Resins.* (79 FR 60898, 60901). October 8, 2014.

[45] *National Emission Standards for Hazardous Air Pollutant Emissions: Group I Polymers and Resins; Marine Tank Vessel Loading Operations; Pharmaceuticals Production; and the Printing and Publishing Industry.* (76 FR 22566, 22577). April 21, 2011.

[46] See, *e.g., National Emission Standards for Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry.* (71 FR 76603, 76606). December 21, 2006. *See also Proposed Rules: National Emission Standards for Halogenated Solvent Cleaning.* (73 FR 62384, 62404). October 20, 2008.

[47] *National Emissions Standards for Hazardous Air Pollutants: Secondary Lead Smelting,* 77 FR 556, 564). January 5, 2012.

[48] *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

[49] *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

sources rather than the standard of ''achievability.'' In *Sierra Club* v. *EPA*, 167 F.3d 658, 662–64 (D.C. Cir 1999), the court found that the individual emission levels set by EPA for MACT standards pursuant to CAA section 129 could not be supported because the emissions limitations that the EPA relied upon to set the numeric floor for each pollutant did not appear to reflect the actual individual pollutant emission levels being achieved by the best performing sources.[50] The court remanded the standards to better explain how the emissions limitations represented the actual performance of the best units or to, instead, use more reliable data. Because the EPA could not explain the original use of the emission limitations, on remand, the agency used actual performance data to establish the final standards. When the D.C. Circuit reviewed the EPA's approach in response to the remand, it found the Agency's use of the actual emissions data in lieu of the permit limits reasonable. *See Medical Waste Inst.* v. *EPA,* 645 F.3d 420 426 (D.C. Cir. 2011). The D.C. Circuit in *Northeast Maryland Waste Disposal Authority* v. *EPA* evaluated this same issue, again in the context of the analogous CAA section 129, determining that ''actual'' emissions, not a ''reasonable estimate,'' should be utilized to develop a standard. *See,* generally, 358 F.3d 936 (D.C. Cir. 2004) (''*Northeast Maryland*''). Thus, MACT standards should be based on measurements that represent actual performance, not regulatory limits.

The D.C. Circuit in *Northeast Maryland* squarely rejected EPA's attempt to base MACT floors on ''emission limits'' set forth in state permits.[51] Petitioners specifically contended that ''there is nothing in the record to demonstrate that a state permit limits . . . reflect 'the average emissions limitation achieved' '' by the best performing units; environmental petitioners in *Northeast Maryland* claimed that it was likely that sources were overachieving beyond their permit limits, arguing that ''the regulatory limits are in fact much higher than the emissions that units achieve in practice.'' *Id.* at 954. The court held that ''[g]iven the absence of evidence that the permit levels reflect the emission levels of the best-performing [units] . . . we cannot uphold the MACT floors.'' *Id.* at 954. Thus, the court specifically held that the establishment of a CAA section 129 MACT standard based on state permit limits (*i.e.,* an ''emission limitation'')—alone and otherwise refraining from measuring ''actual'' emissions—was insufficient to meet the purposes of the statute. Other courts have likewise declined to impute the definition of ''emission limitation'' found in CAA section 302(k) to signify that EPA should ignore actual emission statistics. *See Cement Kiln Recycling Coalition* v *EPA,* 255 F.3d 855, 860–61 (D.C. Cir. 2001).

Comment: A commenter contended that the EPA found through its RTR that risks due to the HAP emissions from coke ovens' PQBS are ''acceptable''; that the existing PQBS rule ''provides an ample margin of safety to protect public health''; and that there ''are no developments in practices, processes or control technologies that necessitate revision of standards for this source category'' (citing 88 FR 55858, 55858). The commenter argued that the EPA's sole reason for proposing the new MACT limits is to comply with its interpretation of *LEAN* v. *EPA,*[52] but that while *LEAN* requires that the EPA ''address'' all HAPs known to be emitted by a source category, it does not mandate that the EPA set numerical MACT floors for every HAP, particularly those that are already controlled to an adequate margin of safety. In support of this argument, the commenter quoted language from the *LEAN* decision that ''an emission standard includes *as many limits as needed* to control all the emitted air toxics of a particular source category'' (emphasis added by commenter). The commenter asserts that, given a finding that risks are acceptable pursuant to CAA section 112(f)(2), the EPA should conclude, consistent with the commenter's interpretation of the *LEAN* decision, that it is not ''necessary'' to amend the MACT standard to include these limits.

Response: The EPA disagrees with the commenter's reading of the *LEAN*[53] decision. The Court in *LEAN* did not consider the relationship of risk review under CAA section 112(f)(2) and technology review under CAA section 112(d)(6). Nor did the Court have occasion to consider whether a standard for a pollutant previously unregulated at a source category must consider costs. The language quoted by the commenter regarding ''as many limits as needed'' thus could not be related to either consideration. The context of quoted language is that the Court was rejecting an argument that CAA section 112(d)(6) technology review could be completed without regulating all previously unregulated pollutants. *LEAN* thus requires that the EPA promulgate ''as many limits as needed'' so that all pollutants from a source category are regulated.

Comment: One commenter expressed concern that the MACT floors for PQBS sources were not developed with enough data, resulting in an invalid upper prediction limit (UPL) calculation. The commenter stated that more data would result in lower MACT limits. The commenter contended that a MACT floor based on a UPL calculation is, by design, very susceptible to variability in the underlying dataset, in addition to the average or mean value [of the data]. In other words, a data set with a high variance will result in a larger UPL than one with a lower variance for the same mean value. Thus, the variability in the dataset significantly influences the estimated UPL and the MACT floor in almost every instance. The commenter continued that an examination of the details of several calculations in the proposal illustrates the unreliability of the calculations underlying the MACT floors established in the proposed rule. For each MACT floor pool, there were at best four or five sources, and in some instances, there were just two sources that provided data—a small pool of data with high variability. The commenter requested that the EPA collect additional data to increase the data pool, to conduct proper validation of the data to eliminate any outliers, and take other measures necessary to improve the data set. The commenter is hopeful that a larger data pool will the lower the variance and result in more meaningful MACT floors. The commenter also requested that the EPA reassess the MACT floor calculations which resulted in MACT floors with higher levels than most if not all individual test data runs from which they were based.

Response: The EPA disagrees with the commenter's assertion that the MACT floor determinations are based on insufficient data. Emission limits based on testing are necessarily an extrapolation from data that does not account for operations in all circumstances at all times. Each MACT

[50] The CAA section 129 is highly analogous to CAA section 112 because the language found in both sections specifies that the respective ''degree of reduction in emissions'' cannot be less stringent than the ''emissions control that is achieved in practice by the best controlled similar unit.'' *See* CAA sections,129(A)(2) and 112(d)(3).

[51] Note that in *Northeast Maryland,* the EPA tried to justify basing CAA section 129 standards on state permit ''emission limitations,'' not through the argument currently presented by the commenter (*i.e.,* that 302(k) is a narrow definition that precludes utilizing ''actual'' emissions) but, rather, because ''[p]ermit limits and regulatory limits provide a reasonable estimate of the actual performance [].'' [*Northeast* Maryland, 358 F.3d 936, at 954].

[52] *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

[53] *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

standard is based on limited data from sources whose emissions are expected to vary over their long-term performance. For this reason, and because sources must comply with the MACT standards at all times, consideration of variability is a key factor in establishing these standards. This variability in emissions is due to numerous factors, including operation of control technologies, variation in combustion materials and combustion conditions, variation in operation of the unit itself, and variation associated with the emission measurement techniques. In order to account for variability that is reflected in the available data that we use to calculate MACT floors, we use the UPL, which represents the average emissions achieved by the best performing sources considering variability.

In defining the parameters for the MACT floor, Congress recognized that standards will necessarily be based on data that does not account for all operating scenarios. Section 112(d)(3)(A) of the CAA provides that MACT standards shall reflect the average of the best performing sources ''for which the Administrator has emissions information.'' For categories comprised of five or fewer sources, standards shall reflect the best performing sources ''for which the Administrator has or could reasonably obtain emissions information.''

The MACT standards being promulgated in this rule reflect available information, including additional information brought forward by industry during the comment period. The EPA sent 2 CAA section 114 testing requests to coke oven companies in 2016 and 2022 to collect test data to be used in the MACT determinations. The data used for the proposed MACT limits were all the data that were available to the EPA at that time. The EPA used these data to calculate the proposed limits. However, as explained in responses to previous comments in this section, the EPA revised some of these limits after incorporating additional data received after publication of the proposed rule. These changes are described in the *Final Rule MACT/BTF Memorandum,*[54] available in the docket for this rule. Though the coke oven companies did not in all instances provide the data sought by the EPA in its 2016 and 2022 information requests, the data collection effort demonstrates that the EPA made reasonable efforts to obtain a broad set of data. The requirement for establishing the minimum stringency level under CAA section 112(d)(3) for categories or subcategories with fewer than 30 sources is that the EPA base those standards on ''the average emission limitation achieved by the best performing 5 sources (for which the Administrator has or could reasonably obtain emissions information).'' These final standards meet that requirement as explained above.

As noted above, it is not uncommon for MACT standards to be based on data sets that are comprised of test results and therefore do not represent all known operating scenarios. Some data sets are more limited than others, and the EPA has explained its approach to the more limited data sets in memoranda *Approach for Applying the Upper Prediction Limit to Limited Datasets,* versions of which are tailored to promulgation of each MACT standard as appropriate. A version of this memorandum is included in the docket for these rules.[55] The D.C. Circuit has upheld the EPA's approach to basing MACT standards on limited data sets. See *Sierra Club* v. *EPA,* 895 F.3d 1, 14 (D.C. Circuit, 2018). The approach to MACT floor calculation used here is substantially the same as that which was upheld in *Sierra Club.*

Comment: Commenters expressed concern that the lack of data used to develop MACT floors for PQBS sources (pushing, battery stacks, main stacks, HNR B/W stacks) do not show the variability in operation of the coke units taking into account the operating coke units not included in the dataset. The commenters stated that due to the lack of sufficient data, the MACT limits are lower than they would be with more data and, therefore, may require application of control technology that is not feasible or cost-effective.

One commenter asserted that the limited amount of test data does not accurately represent emissions because the data do not account for normal variability in operations, variability of coal blends and suppliers, and seasonal effects. Without additional test data, the commenter expects the proposed limits will be regularly exceeded, forcing facilities to install expensive controls or curtail operations to meet the limits.

The commenter asserted it is critical that any standards be established using complete data and UPL methodologies that adequately account for variability in operating conditions (*e.g.,* normal and extended coking times) and in raw materials (*e.g.,* coal content). Referring to the *Technology Review* and *Cost* memoranda, the commenter asserted the lack of demonstrated technical feasibility and the extremely high cost of add-on controls highlights the importance of setting standards that can be achieved by the MACT floor facilities under various operating conditions and accounting for variation in raw materials. The commenter contended that if the EPA proceeds to finalize the proposed MACT floor emission limits, it first should revise the limits by employing an additional UPL adjustment factor to account for variability that is not adequately reflected in the current data. The commenter claimed that the EPA has made such an adjustment in other rules.

The commenter contended that a single test covering less than a handful of operating hours does not represent normal emissions from a unit at all times over the range of normal operating conditions during a typical year. Actual emissions will vary from time to time not only due to normal variations in process operations (differing coking times, variability in composition of feed materials and fuels, process operating conditions, *etc.*), but also due to seasonal variations in ambient weather conditions such as temperature, precipitation, and humidity (and corresponding impacts on fuel heat input, feed materials temperatures, *etc.*). For example, emissions of Hg are highly dependent on chemical content within the raw materials (*e.g.,* Hg in coal). Mercury and chloride content in coal varies not only between coal mines, but also within a coal seam at the same mine. The commenter asserted that for these reasons, the variability of emissions is under-represented in the calculated UPLs for the proposed rule, resulting in emission limits that cannot be achieved with the EPA's stated confidence and frequency. As such, the commenter stated it is not appropriate to establish standards using such limited emissions performance data as used in the proposed rule.

One commenter noted that in section 2.1.2 of the *Technology Review for the Coke Ovens: Pushing, Quenching, and Battery Stack and Coke Oven Batteries Source Categories,* the EPA identifies potential additional control technologies for pushing including ACI

[54] *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Coke Ovens Facilities under 40 CFR part 63, subpart CCCCC—Final Rule.* D. L. Jones, U.S. Environmental Protection Agency, and G. Raymond and Michael Laney, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

[55] *Approach for Applying the Upper Prediction Limit to Limited Datasets.* D.L. Jones, U.S. Environmental Protection Agency. Research Triangle Park, NC. May 1, 2023. Docket ID Nos. EPA–HQ–OAR–2002–0085–0891 and EPA–HQ–OAR–2003–0051–0664.

for Hg and PAHs, and wet alkaline scrubbers (WAS) for AG and HCN. But based on its review, the EPA concludes that ''[n]o capture technology has been identified that demonstrates reduced emissions from pushing beyond the current technologies in use; therefore, no recommendations are made to pushing capture or control technology under this review.''

The commenter noted that in section 2.3.2 of the *Technology Review Memorandum,* the EPA identifies potential additional control technologies for battery stacks including ACI for Hg, and WAS for AG, HCN, and non-Hg HAP metals. The EPA similarly concludes that ''[b]ecause no other add-on control technology was identified, a control strategy based on control device technology for battery stacks is not recommended at this time.''

The commenter asserted the lack of demonstrated technical feasibility and the extremely high cost of add-on controls in the *Cost Memorandum* highlights the importance of setting standards that can be achieved by the MACT floor facilities under various operating conditions and accounting for variation in raw materials. The MACT floor test data sets are too limited and do not represent normal variability in emissions and operating conditions. The commenter asserted it is critical that any standards be established using complete data and UPL methodologies that adequately account for variability in operating conditions (*e.g.,* normal and extended coking times) and in raw materials (*e.g.,* coal content). Without additional test data to revise the limits, the commenter expects the proposed limits, which are based on inadequate data according to the commenter, will be regularly exceeded, forcing facilities to install expensive controls or curtail operations in order to meet the limits.

Another commenter asserted the EPA incorrectly established the proposed HNR HRSG main stack emission limits using only a limited subset of the available data, thus, the data set is incomplete and not representative of HNR operating conditions. The commenter described the test data from the 2016 ICR and the 2022 ICR, on which the MACT floor calculations are based, as ''very limited.'' The commenter contended a much larger dataset that more accurately represents trial-to-trial and plant-to-plant variations is available from compliance tests conducted on these sources in prior years, yet the EPA provides no explanation for why it excluded this larger body of stack test data from its MACT floor calculations.

The commenter asserted the EPA's use of the limited data set and its UPL approach for setting MACT limits did not reasonably account for variability. The commenter contended there are too few data points for a statistically valid analysis and limit. The UPL calculation relies upon estimating the true average and true variance. While the estimation of the average can be confidently done with a small number of samples, the estimation of the variance requires a substantially larger number of samples and in particular samples that cover the range of varying factors.

The commenter asserted the EPA's decision to base the proposed rule requirements on limited data is arbitrary and capricious, and that the EPA gave no explanation for its decision to ignore relevant information provided by the types of facilities to which the proposed limits would apply. The commenter cited language from a court case holding that agencies ''must *examine the relevant data* and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.' '' *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Ins. Co.,* 463 U.S. 29, 43 (1983). The commenter also cited the EPA's *Guidelines for MACT Determinations under Section 112(j) Requirements* (Feb. 2002) (''It is not necessary for the MACT floor to be determined based on emissions information from every existing source in the source category or subcategory if such information is not available. The permitting authority, however, should check with the EPA Regional Offices and the EPA Headquarters for any available information that could be used in determining the MACT floor'').

The commenter asserted the EPA must recalculate the HNR HRSG main stack limits using all available stack test data from 2006 through 2022 from SunCoke HNR HRSG main stacks at Haverhill, Middletown, and Granite City, and the Cokenergy HRSG main stack at Indiana Harbor. The commenter argued the 45-day comment period did not provide sufficient time for them to fully evaluate and propose more appropriate and accurate revised limits. Nonetheless, the commenter noted their preliminary estimates (correcting for the arbitrarily confined dataset used) demonstrate that the UPL calculations used must be revised significantly.

The commenter noted the EPA expects their facilities (with the exception of the Jewell coke plant) to meet the proposed bypass vent stack limits with no additional controls. However, the commenter asserted, this expectation may be wrong as the emission limits are based on a very limited data set. The commenter contended additional controls may be required to meet the proposed bypass vent limits at some or all of their heat recovery facilities. (The commenter discussed controls needed for SunCoke's Jewell facility separately in their comment letter). The commenter explained that waste gases exiting the bypass vent stacks are typically in the 1300 °F to 2000 °F temperature range. To install any kind of additional pollution control equipment on the bypass vent stacks would first require cooling the high temperature waste gases significantly, using HRSGs or similar equipment, to a level that is appropriate for the specific control equipment. The current layout of their plants and the limited space available in and around the bypass vent stacks make it extremely challenging to design and install additional HRSGs, route additional ductwork, and install any additional control equipment for the bypass vent stacks. The commenter asserted, even if this could be engineered, the cost effectiveness ($/ton removed) would be extremely high considering the bypass vent stacks are used and open for venting only a fraction of the time on an annual basis. Even then, any time that bypass venting was required for any reason, the source would not be able to meet the proposed limits because it is not technically feasible to install controls directly on waste heat stacks.

Other commenters stated the proposed amendments to 40 CFR part 63 subpart CCCCC and subpart L are based on limited data that were not peer-reviewed data and do not consider operational variations. Additional commenters stated any amendments made to the existing regulations should be consistent with the CAA and based on sound science.

Response: The EPA disagrees with the commenter that the number of runs in the MACT dataset was insufficient to develop MACT standards. As an example that supports this point, new source MACT limits are commonly developed from data for a single test at the one top performing facility, which typically includes three test runs.

The EPA disagrees with the commenter's statement that UPL calculations do not incorporate variability into the UPL-based limit. The use of the UPL to account for variability was upheld in *U.S. Sugar* v. *EPA,* 830 F.3d 579 (D.C. Circuit, 2016). That the UPL already incorporates variability into the calculated value is explained in the memorandum, *Use of the Upper Prediction Limit for Calculating MACT*

Floors,[56] hereafter referred to as the ''*UPL Memorandum,*'' located in the docket for this rule, as follows: ''There are several key points, addressed in more detail below, that underlie the EPA's methodology for calculating MACT floor standards through the use of the UPL. First, the floor standards reasonably account for variability in the emissions of the sources used to calculate the standards. This variability occurs due to a number of factors, including measurement variability (both sampling and analysis) and short term fluctuations in the emission levels that result from short-term changes in fuels, processes, combustion conditions, and controls. Second, because the emissions data available to the EPA is in the form of short-term stack tests and the standards must be complied with at all times, the agency uses the UPL to estimate the average emissions performance of the units used to establish the MACT floor standards at times other than when the stack tests were conducted. Thus, the UPL results in a limit that represents the average emissions limitation achieved by the best performing sources over time, accounting for variability in emissions performance.''

In addition, the EPA disagrees with the commenter that the standards should be revised to use a larger pool of test data to account for variability in operating conditions. It is incorrect to assume that including more data will cause the average or UPL to reflect more variability. Depending on the additional data, the increase in the size of the dataset may outweigh any additional variability and lower the UPL limit. That the UPL represents the average emission performance is described in the second point in the previous paragraph citing the *UPL Memorandum.*[57]

Additionally, the EPA handled the limited datasets used to set the MACT limits (pushing new source limits: Hg, AG, HCN, and PAH and battery stack new source limits: Hg, PM, AG, HCN) as per the procedures in the memorandum *Approach for Applying the Upper Prediction Limit to Limited Datasets.*[58] In *Sierra Club* v. *EPA* 895 F.3d 1, 14 (D.C. Circuit, 2018), the Court decided that the EPA had sufficiently explained the general application of the UPL to small/limited datasets and denied the petition for review as to the general application of the upper prediction limit to limited datasets as defined by the EPA: ''We deny the Environmental Petitioner's petition for review as to the general application of the upper prediction limit to limited datasets as defined by the EPA.''

The EPA did not have data for each existing pushing technology as shown in table 8, which lists the existing NESHAP PM pushing limits by technology, and as compared to table 9, which shows the data collected as part of the CAA section 114 request for this rulemaking, with pushing technology identified. Therefore, separate MACT limits were not developed for each pushing technology from the data submitted to the EPA. In addition, any MACT limits that might be set for subcategories would have less variability than the data in the pooled MACT limit for all pushing technologies.

TABLE 8—EXISTING 40 CFR PART 63 SUBPART CCCCC PM PUSHING LIMITS

Source	Pollutant	gr/dscf	lb/ton
Cokeside shed	PM	0.01	
Cokeside shed vented to CD	PM	0.01	
Moveable shed/hood&CD	PM		0.02
Mobile scrubber car: Short battery	PM		0.03
Mobile scrubber car: Tall battery	PM		0.01
Mobile scrubber car: Mobile CD	PM		0.04

TABLE 9—AVAILABLE PUSHING DATA BY FACILITY AND PUSHING EQUIPMENT TYPE

Facility	Unit description	Facility type	CAA section 114 data	HAP data collected for MACT limits
CC-Burnsharbor-IN	moveable shed/hood&baghouse	ByP	2016	Hg, AG, HCN, PAH.
CC-Middletown-OH	moveable shed/hood&baghouse	ByP	2016	Hg, AG, HCN, PAH.
CC-Monessen-PA	moveable shed/hood&baghouse	ByP	2016	Hg, AG, HCN, PAH.
SC-GraniteCity-IL	flat push hot car mobile scrubber car&multiclone	HNR	2016	Hg.
SC-Middletown-OH	flat push hot car mobile scrubber car&multiclone	HNR	2016	AG, HCN, Hg, PAH.
ABC-Tarrant-AL	moveable shed/hood&baghouse	ByP		none.
CC-Warren-OH	mobile scrubber car—short battery	ByP		none.
BLU-Birmingham-AL	moveable shed/hood&baghouse	ByP		none.
EES-RiverRouge-MI	moveable shed/hood&baghouse	ByP		AG, HCN, PAH.
SC-EastChicago-IN	moveable shed/hood&baghouse	HNR		none.
SC-FranklinFurnace-OH	mobile scrubber car with multiclone	HNR		none.
SC-Vansant-VA	cokeside shed	HNR		none.
USS-Clairton-PA	moveable shed/hood&baghouse	ByP		none.

[56] *Use of the Upper Prediction Limit for Calculating MACT Floors.* Memorandum from D. L Jones, EPA/OAQPS/SPPD, Research Triangle Park, North Carolina, to Docket No. EPA–HQ–OAR–2002–0085–0890. September 2, 2021.

[57] *Use of the Upper Prediction Limit for Calculating MACT Floors.* Memorandum from D. L Jones, EPA/OAQPS/SPPD, Research Triangle Park, North Carolina, to Docket No. EPA–HQ–OAR–2002–0085–0890. September 2, 2021.

[58] *Approach for Applying the Upper Prediction Limit to Limited Datasets.* D.L. Jones, U.S. Environmental Protection Agency. Research Triangle Park, NC. May 1, 2023. Docket ID Nos. EPA–HQ–OAR–2002–0085–0891 and EPA–HQ–OAR–2003–0051–0664.

For the proposal, the EPA evaluated potential control technologies for pushing sources as documented in the *Proposal Technology Review Memorandum.*[59] The EPA found that the add-on controls for pushing were not cost effective and, therefore, we did not propose BTF limits for pushing sources. However, the EPA also estimated that the coke ovens pushing sources would be able to meet the MACT limits developed from the 2016 CAA section 114 data with no additional controls, as documented in the *Proposal MACT/BTF Memorandum.*[60]

The EPA collected test data from the 2016 CAA section 114 test requests for HNR HRSG main stacks. The EPA conducted a second CAA section 114 testing request in 2022 for additional stack testing data from HNR HRSG main stacks. The EPA used the available data to calculate the MACT limits, as described in the *Proposal MACT/BTF Memorandum.*[61]

SunCoke provided the EPA with previous stack test data from 2006–2022 with their 2016 CAA section 114 submission. After the August 2023 proposal, the EPA reviewed the previous test reports submitted that were within five years prior to 2016 and that matched the requirements for testing in the CAA section 114 requests to add to the MACT data pool. We determined that there were four test reports listed in table 10 of this section, three for HNR HRSG main stacks and one for HNR B/W stacks, that were applicable to sources and pollutants in the CAA section 114 requests and, therefore, we have incorporated these data into a revised MACT floor calculation for the final rule.

We received test data from Cokenergy, Inc., for HNR HRSG main stacks at the SunCoke facility in Indiana Harbor in 2022, but these data were received too late to incorporate into the proposed rule. These data also are included in the MACT limits for HNR HRSG main stacks for the final rule.

In addition, we received test data from EES Coke on April 24, 2024, that included HAP test data from a February 21, 2024, emission test for pushing and battery stacks. We determined that of the HAP tested, the data for AG, HCN, and PAH for pushing and AG, HCN, and Hg from battery stacks were valid. Therefore, these data also were incorporated into the MACT limits.

The additional test data added to the final MACT data pool that were not reflected in the proposed MACT limits are shown in table 10. The results of these additions to the MACT data pool are shown in table 7 and documented in the *Final Rule MACT/BTF Memorandum.*[62]

TABLE 10—ADDITIONAL DATA RECEIVED AFTER PROPOSAL

Facility ID	Unit type	Unit tested	Pollutant	Test date
SC-GraniteCity-IL	HNR HRSG main stack	main baghouse stack	PM	8/25/2011
SC-GraniteCity-IL	HNR HRSG main stack	main baghouse stack	PM	5/30/2012
SC-Middletown-OH	HNR HRSG main stack	main baghouse stack	PM, Hg	4/1/2015
SC-Middletown-OH	HNR HRSG B/W stack	HRSG bypass stack #4	PM, Hg	6/26/2012
Cokenergy	HNR main stack	HRSG main stack	AG, Hg, nonmercury HAP, PAH.	2/2/2023
EES-RiverRouge-MI	pushing	pushing emission control system stack.	AG, HCN, PAH	2/21/2024
EES-RiverRouge-MI	battery stacks	underfire combustion stack	AG, HCN, Hg	2/21/2024

For the August 2023 proposal, the EPA estimated the costs for additional controls that would be used at the HNR facility without a HRSG to meet the proposed BTF limits for Hg and PM at HNR B/W stacks at this facility. The EPA has re-evaluated the proposed costs for the BTF limits based on comments received and revised the cost estimates for the HNR facility without HRSG. The revised costs are much higher than the costs at proposal ($7.5M capital and $4.6M annual costs ($2022) v. revised costs of capital $340M capital and $56M annual costs ($2023)). We also received comments that it would be infeasible to construct controls at this facility given the configuration of the facility between the bordering roads, rivers, and train tracks on all sides. Therefore, due to the physical constraints and high costs, the EPA is not finalizing the BTF standards for Hg and PM for HNR B/W stacks at facilities with no HRSG. As such, revised MACT standards for HNR B/W stacks were determined by incorporating the previous SunCoke Hg and PM test data described above and the data for the HNR facility without HRSG (previously used in the BTF analysis). The revised MACT limits for final rule apply to all HNR B/W stacks, *i.e.,* HNR facilities with and without HRSG.

The EPA agrees that the MACT standards should be consistent with the CAA and based on ''sound science'' as the commenter describes. The EPA utilized data conducted and submitted in compliance with two CAA section 114 requests, in 2016 and 2022, and additional valid data received after the proposed rule was published. The EPA developed the standards according to well-established CAA section 112(d)(2) and (3) procedures, established EPA methods and policy, and case law and incorporated operational variability by applying a UPL to the MACT floors. See

[59] *Technology Review for the Coke Ovens: Pushing, Quenching, and Battery Stack and Coke Oven Batteries Source Categories.* D.L. Jones, U.S. Environmental Protection Agency, and G.E. Raymond, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2023. Docket ID Nos. EPA–HQ–OAR–2002–0085–0873 and EPA–HQ–OAR–2003–0051–0682.

[60] *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Coke Ovens Facilities under 40 CFR part 63, Subpart CCCCC—Proposed Rule.* D.L. Jones, U.S. Environmental Protection Agency, and G. Raymond, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2023. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

[61] *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Coke Ovens Facilities under 40 CFR part 63, Subpart CCCCC—Proposed Rule.* D. L. Jones, U.S. Environmental Protection Agency, and G. Raymond, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2023. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

[62] *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Coke Ovens Facilities under 40 CFR part 63, subpart CCCCC—Final Rule.* D.L. Jones, U.S. Environmental Protection Agency, and G. Raymond and Michael Laney, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

the *UPL Memorandum*[63] and *Final Rule MACT/BTF Memorandum*[64] for details of the MACT standards development.

In regard to the comment that the proposed amendments to PQBS and COB NESHAP are based on ''limited data'' that were not peer-reviewed, the EPA notes that it would be out of the ordinary to subject data used to support a CAA regulation to a scientific peer review process. The methods used to collect data are peer reviewed, and the EPA engaged in a dialogue with the coke oven plants regarding the data produced in response to a CAA section 114 request to ensure that data was representative. Finally, the notice and comment process to promulgate a rule is an opportunity for interested parties to raise issues regarding the data relied upon by the EPA. These measures typically relied upon by the EPA to ensure the quality of data were followed in this rule process.

Finally, the requirement for establishing the minimum stringency level under CAA section 112(d)(3) for categories or subcategories with fewer than 30 sources is that the EPA base those standards on ''the average emission limitation achieved by the best performing 5 sources (for which the Administrator has or could reasonably obtain emissions information).'' These final standards meet that requirement.

Comment: One commenter asserted that the EPA has not justified their decision to set BTF limits for their Jewell facility, nor has the EPA demonstrated that the limits are ''achievable'' as required by the CAA. The commenter argued the BTF limits are far from technically, physically, and economically achievable, however, even if they were, meeting the limits would have significant energy requirements and non-air quality health and environmental impacts that the EPA insufficiently considered. Additionally, the EPA's determination that the BTF measures were ''cost-effective'' was based on erroneous data concerning not only the costs of such measures, but also their effectiveness at reducing Hg and other HAP emissions.

The commenter said the EPA's costs are underestimated for other reasons as well, including the following:

- The EPA miscalculated the emissions reductions of the proposed BTF limits at their Jewell facility because they wrongly assumed the feasible reductions of a baghouse and ACI system on a long-term basis. According to the commenter, 99 percent removal for the baghouse is a more realistic assumption of long-term removal than the 99.9 percent removal assumed by the EPA. Similarly, for Hg, a baghouse with ACI combination can only reasonably provide 80 percent Hg removal on a long-term basis versus the 90 percent reduction assumed by the EPA.
- The EPA's estimates did not include cooling before subjecting the 1,600 °F exhaust from the HNR B/W stacks to emissions controls, as would be necessary for the baghouse to function. The oven exhaust must be cooled from 1,600 °F or more to a maximum of 400 °F for high temperature bag material to function. And an air quench, as opposed to a water quench, would be required because the enormous water volumes otherwise required would far exceed the limitations of Dismal Creek, the source of plant cooling water. The air quench would result in a constant steam cloud within the valley. The commenter contended these two factors alone make a baghouse and an ACI system technically infeasible for this site.
- The ductwork costs assume only a nominal length of unlined, galvanized steel duct between the battery stacks and the air emission controls. No provision for refractory lining, and ductwork foundations, structural support, access platforms, and underground routing of the duct were considered.
- The assumed height of the exhaust stack was too low. Given the valley location of the Jewell facility, an exhaust stack of significant height should have been considered.
- A shaker baghouse—notably the lowest capital cost baghouse type—was assumed. Shaker baghouses are old technology no longer used in industry because of high maintenance requirements, challenges with operation, and degradation of removal efficiency over time. A compartmentalized, pulse jet baghouse is the industry standard for this application.
- The EPA failed to consider the characteristics of the exhaust gases and the requisite materials of construction.
- The EPA incorrectly assumed the volume of flue gas that would need to be treated based on arbitrary data from a single stack at a different plant.
- The EPA failed to consider the unique retrofit requirements that would be necessary given the age, configuration, layout, and underground utilities existing at the Jewell facility.
- The EPA significantly underestimated the amount of electricity usage and hazardous waste that would be generated.
- The EPA used an incorrect algorithm to calculate the total capital investment for ACI (Sargent & Lundy 2011).
- The EPA used an incorrect methodology to calculate the ACI rates. Based on the methodology included in a later study by the same authors (Sargent & Lundy 2017), the rate should be 699 lbs/hr rather than 50 lbs/hr, as the EPA assumed.
- The EPA did not sufficiently consider the infrastructure upgrades that would be needed to install controls to meet BTF limits at their Jewell facility.
- The EPA wrongly calculated the increased energy costs to meet the BTF limits for their Jewell facility. The commenter noted they have not been able to locate the EPA's energy analysis.
- The EPA underestimated the tons of hazardous dust disposal at 761 tpy.

The commenter contended that their Jewell facility, which is in a river valley with rivers, a state road, railroad tracks, and extremely steep gradients on two sides, does not have sufficient space to install the size of baghouse(s) needed to control the exhaust from the COB. The commenter contended installing the infrastructure could require surfaces to be levelled and forested areas to be cleared. These electrical upgrades would likely impact wetlands, visual resources, soils, and/or vegetation and wildlife species in the affected areas, which the EPA does not appear to have considered.

Response: The EPA agrees with some of the commenter's points and suggested revisions and has incorporated them into revised air pollution control device (APCD) costs and BTF Hg and PM HAP metals cost effectiveness, as described below. Details of the revised cost estimates can be found in the *Final Rule MACT/BTF Memorandum*.[65]

[63] *Use of the Upper Prediction Limit for Calculating MACT Floors.* Memorandum from D.L Jones, EPA/OAQPS/SPPD, Research Triangle Park, North Carolina, to Docket No. EPA–HQ–OAR–2002–0085–0890. September 2, 2021.

[64] *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Coke Ovens Facilities under 40 CFR part 63, Subpart CCCCC—Final Rule.* D.L. Jones, U.S. Environmental Protection Agency, and G. Raymond and Michael Laney, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

[65] *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Coke Ovens Facilities under 40 CFR part 63, Subpart CCCCC—Final Rule.* D.L. Jones, U.S. Environmental Protection Agency, and G. Raymond and Michael Laney, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

• The EPA revised the BTF cost estimates developed by the EPA for proposal using some, but not all, of SunCoke's suggestions submitted with their comments, such that the EPA's cost and cost effectiveness (CE) estimates now include the following SunCoke costs/procedures that the EPA agrees are better estimates, as described in the *Final Rule MACT/BTF Memorandum;*[66] increased duct length based on SunCoke provided values; increased the stack flowrates based on SunCoke provided values; added 1 baghouse for a total of 3 baghouses; decreased the operating hours; lowered Hg control efficiency based on SunCoke's comment about long-term removal efficiency; lowered baghouse control efficiency based on SunCoke's comment about long-term removal efficiency; different units of measurement for ACI injection rate (lb/hr) based on SunCoke provided estimates; and itemized direct and indirect capital costs for installing baghouses. The estimated CE for Hg and non-Hg metals control were revised to $51K/lb and $14M/ton, respectively.

• The EPA did not use SunCoke's values/estimates/procedures for: ACI 2017 cost equation; estimating ductwork costs; 5 percent interest rate; and $44.25 labor rate. Instead, we used the EPA's previous method of estimating ACI control costs from 1996 proposed hazardous waste incineration NESHAP[67] (using SunCoke's ACI lb/hr injection rates), the EPA Cost Manual for ductwork costs (using SunCoke's length of ductwork), 2022 interest rate of 7.5 percent, and a labor rate of $29.44/hr from U.S. Bureau of Labor Statistics.

The result of revising the costs components are as follows: estimated capital costs are $340M, estimated annual costs are $56M, with cost-effectiveness of $14M/ton non-Hg metals and $51,000/lb Hg. Based on these cost considerations along with concerns raised by the commenter above regarding infeasibility to install these controls, the EPA has decided to not promulgate the BTF standards. Therefore, the MACT floor emission limits will apply to all HNR waste heat stacks, including the SunCoke Vansant, Virginia waste heat stacks, regardless of the presence of HRSGs. See the *Final Rule MACT/BTF Memorandum*[68] for details.

The EPA agrees that the calculation for the increased electricity use was not explicitly documented in the information used for proposal. The values can be calculated using data in the attachment to the *Proposal MACT/BTF Memorandum*[69] ''*Appendix_D_BTFCosts_Bypass_ACI–PBH*'' excel file, in the tab 'BH-duct8V', as follows:

(1) Using cell B129 value of electricity 514,816 $/yr;

(2) Divide by cell D112 electricity price 0.0671 $/kWh; and

(3) Multiply by 2 for the two APCD configurations to obtain a total of 15.3 million kilowatt-hours of increased electricity use [Note, the preamble to the proposed rule erroneously cited 15.1 million kilowatt-hour, due to rounding differences].

4. What is the rationale for our final approach for the amendments pursuant to CAA sections 112(d)(2) and (3)?

As mandated by the *LEAN*[70] court decision, the EPA is finalizing MACT standards for previously unregulated HAP emissions pursuant to CAA sections 112(d)(2) and (3). The final MACT limits were developed using the valid data available to the EPA according to established procedures for development of MACT limits which includes accounting for operation variability with use of UPL procedures[71] and accounting for small datasets.[72] Based on the available data, we expect all facilities to be able to meet these MACT floor limits without the need for additional controls. These MACT floor-based limits are based on the UPL calculated with available data. All the test data results we have (based on 2- or 3-run averages) are below the promulgated MACT floor limits. The UPLs account for variability and provide limits that reflect the requirements of the statute.

D. Periods of Startup, Shutdown, and Malfunction (SSM) for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks and the NESHAP for Coke Oven Batteries

1. What did we propose pursuant to SSM for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks and the NESHAP for Coke Oven Batteries source categories?

We proposed the removal of exemptions for periods of startup, shutdown, and malfunction (SSM) consistent with a 2008 court decision, *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), and that the emissions standards apply at all times. In establishing the standards in this rule, the EPA has taken into account startup and shutdown periods and, for the reasons explained in the proposal preamble, has not established alternate standards for those periods.

2. How did the amendments pursuant to SSM change in the final rule for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks and the NESHAP for Coke Oven Batteries source categories?

Only minor changes from those proposed were made for SSM for the NESHAP for PQBS and COB source categories.

3. What key comments did we receive on SSM and what are our responses?

We received a few comments on SSM, with some in favor of the removal and some that were not. The key comments on SSM are summarized in this section along with the EPA's responses to the comments. Other comments received on SSM are summarized along with the EPA's responses in the *Response to Comment*[73] document, which is located in the dockets to the rules.

[66] *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Coke Ovens Facilities under 40 CFR part 63, Subpart CCCCC—Final Rule.* D.L. Jones, U.S. Environmental Protection Agency, and G. Raymond and Michael Laney, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

[67] Revised Standards for Hazardous Waste Combustors. Proposed Rule. U.S. Environmental Protection Agency, Washington, DC. 61 FR 17358. April 19, 1996. Docket Number EPA–HQ–OAR–2004–0022. *https://www.govinfo.gov/content/pkg/FR-1996-04-19/pdf/96-7872.pdf.*

[68] *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Coke Ovens Facilities under 40 CFR part 63, subpart CCCCC—Final Rule.* D.L. Jones, U.S. Environmental Protection Agency, and G. Raymond and Michael Laney, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

[69] *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Coke Ovens Facilities under 40 CFR part 63, subpart CCCCC—Proposed Rule.* D.L. Jones, U.S. Environmental Protection Agency, and G. Raymond, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2023. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

[70] *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

[71] *Use of the Upper Prediction Limit for Calculating MACT Floors.* Memorandum from D.L Jones, EPA/OAQPS/SPPD, Research Triangle Park, North Carolina, to Docket No. EPA–HQ–OAR–2002–0085–0890. September 2, 2021.

[72] *Approach for Applying the Upper Prediction Limit to Limited Datasets.* D.L. Jones, U.S. Environmental Protection Agency. Research Triangle Park, NC. May 1, 2023. Docket ID Nos. EPA–HQ–OAR–2002–0085–0891 and EPA–HQ–OAR–2003–0051–0664.

[73] *Summary of Public Comments and Responses for Coke Ovens: Pushing, Quenching, and Battery Stacks Residual Risk and Technology Review, and Coke Oven Batteries Periodic Technology Review.* U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division (D243–02), Research Triangle Park, North Carolina. May 1, 2024.

Comment: A commenter said that eliminating the SSM provisions subjects coke manufacturers to penalties based on events that cannot be avoided. The commenter requested the EPA to develop work practice standards to address SSM and/or allow facilities to follow a SSM plan during SSM events. Two commenters said they disagreed with the EPA's proposal to eliminate the SSM provisions and that the emission standards applying during these periods. The commenters said that alternate limits must be established for emissions during these periods because the proposed limits in 40 CFR 63.7297 (''What emission limitations must I meet for HRSG main stacks?'') would be impossible to meet otherwise. The commenter continued that they believed the EPA should evaluate the need for a work practice standard that would allow coke facility owners/operators to address major malfunctions following a site-specific plan, in lieu of normal emission standards, and use the facilities' SSM plans to develop work practices. The commenter stated that the EPA has discretion to account for emissions that occur during malfunctions and set separate work practice standards where (1) sufficient information is available, and (2) the circumstances indicate that treating malfunction periods the same as normal operating periods would not be appropriate. The commenters noted that emissions during malfunction periods may increase until it is possible to complete repairs safely and restart the equipment and that coke facilities should have an option to meet work practice requirements for malfunction periods or meet the requirements applicable to normal operating periods. If a facility chooses to meet the requirements applicable to malfunction periods, then the work practice standard could require that the facility create and follow a malfunction work plan with site-specific operating conditions, unless doing so would not be possible due to safety considerations. A commenter disagreed with the EPA's proposal to eliminate the requirement to have a written SSM plan, and thus eliminate the ability of facilities to demonstrate compliance if the regulated entity complies with the plan during SSM.

Response: The EPA expects control devices to be operating during startup and shutdown (SS); therefore, no additional requirements should be needed for startup or shutdown. The EPA asked for comments on whether any situations exist where separate standards, such as work practices, would be more appropriate during periods of SS rather than the current standard. The commenters did not provide a description of specific situations where work practice standards, or any specific work practices, would be more appropriate than the numerical emissions standards we are finalizing in this rule (or standards that were already in the NESHAP) that would be appropriate during startup or shut down.

In regard to the commenter's statement that ''coke facilities should have an option to meet work practice requirements for malfunction periods or meet the requirements applicable to normal operating periods,'' the EPA notes that facilities always have the option of complying with the applicable limits and using work practices, even during a malfunction. As stated in the proposal preamble [88 FR 55890]: '' the standards that apply during normal operation apply during periods of malfunction.'' As the EPA has consistently explained, in the event that a source fails to comply with the applicable CAA section 112 standards, the EPA would determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during the violative period, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. Additionally, the EPA will continue to evaluate violations on a case-by-case basis and determine whether an enforcement action is appropriate.'' The D.C. Circuit upheld the EPA's general approach to malfunctions in *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (2016) (CAA section 112 ''permits the EPA to ignore malfunctions in its standard setting and account for them instead through its regulatory discretion'').

With regard to commenters statements addressing the removal of SSM plan requirements, note that affected units are subject to emission standards at all times. The applicability of a standard during any SSM event will ensure that sources have ample incentive to plan for and achieve compliance and thus the SSM plan requirements are no longer necessary.

Comment: A commenter agreed with removal of the SSM provisions because the EPA now lacks the authority to retain SSM exemptions. The commenter contended the EPA correctly proposed to remove SSM loopholes from Subparts L and CCCCC. The commenter explained that the CAA directs the EPA to set emission standards for all HAP emitted by a source category, and such emission standards must apply continuously. The [previous] existing emission standards allowed a general exemption during SSM periods. This general exemption is inconsistent with the Act's mandate that standards apply continuously, and as such, the D.C. Circuit struck it down in 2008, in *Sierra Club* v. *EPA.* The EPA thus lacks any authority to retain such an exemption when it reviews standards under CAA section 112(d)(6): ''The obligatory periodic review and revision of 'emission standards' thus must ensure that each source category's standard imposes appropriate limits. . . .'' Standards that violate the Act because they include SSM exemptions cannot be appropriate. Commenter stated that the EPA correctly declines to factor malfunction emissions into standards. The EPA's position is not only reasonable, but the only one consistent with the Act. Congress rewrote CAA section 112 in 1990 to ensure that emissions of HAPs would be controlled. During malfunctions, by definition, emission controls fail. Incorporating such emissions into standards would thus allow uncontrolled emissions, contrary to Congress's intent and binding D.C. Circuit precedent.

Response: We acknowledge the support by the commenter. We note that malfunctions can include malfunction of process operations or monitoring equipment as well as failure of emission controls.

4. What is the rationale for our final approach for the amendments pursuant to SSM?

Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. Malfunctions, in contrast, are neither predictable nor routine. Instead, they are by definition, sudden infrequent and not reasonably preventable failures of emissions control, process, or monitoring equipment (40 CFR 63.2) (definition of malfunction). Nor are emissions during a malfunction able to be reliably measured with EPA methods which specify that these methods are only to be used during normal operations. The EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards (either numerical or as work practices)and this reading has been upheld as reasonable in *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (2016). The D.C. Circuit agreed with the EPA's approach, as it relates to the difficulties in determining an appropriate numerical standard that

would reflect the MACT limits required by CAA section 112 and the immense spread of variability that would ensue if the EPA were to include conditions during a malfunction. In essence, the D.C. Circuit concluded that any such standard would be too broad and would be meaningless with respect to the intent of CAA section 112 MACT standards.

We are finalizing the removal of exemptions for periods of SSM consistent with a 2008 court decision, *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), and clarifying that the emissions standards apply at all times. We are not promulgating any separate standards for startup or shut down because the control devices in use in the industry operate at all times.

In its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), the United States Court of Appeals for the District of Columbia Circuit (the Court) vacated portions of two provisions in the EPA's CAA section 112 regulations governing the emissions of HAP during periods of SSM. Specifically, the Court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some CAA section 112 standards apply continuously.

With the issuance of the mandate in *Sierra Club* v. *EPA,* the exemptions that were in 40 CFR 63.6(f)(1) and (h)(1) are null and void. The EPA amended 40 CFR 63.6(f)(1) and (h)(1)) on March 11, 2021, to reflect the Court order and correct the CFR to remove the SSM exemption. In this action, we are eliminating any cross-reference to the vacated provisions in the regulatory text including 40 CFR 63.7310(a) and table 1 of the PQBS NESHAP and 40 CFR 63.300(e) and 63.310 for the COB NESHAP. Consistent with *Sierra Club* v. *EPA,* we are promulgating standards in these rules that apply at all times. We are also promulgating several revisions to table 1 of the PQBS NESHAP (the General Provisions applicability table) as is explained in more detail below and in the proposal preamble. For example, we are eliminating the incorporation of the General Provisions' requirement that the source develop an SSM plan. We also are eliminating or revising certain recordkeeping and reporting requirements related to the SSM exemption as further described as follows.

The EPA has attempted to ensure that the provisions we are promulgating to eliminate are inappropriate, unnecessary, or redundant in the absence of the SSM exemption. In promulgating the standards in this rule, the EPA has taken into account SS periods and, for the reasons explained as follows, has not promulgated alternate standards for those periods: The coke oven industry has not identified (and there are no data indicating) any specific problems with removing the SSM provisions due to the nature of the coke process to operate continuously. If an oven is shut down (cold), it often has to be significantly repaired before it can be restored to operational status before starting back up, which is the reason why coke ovens instead are put in (hot) idle mode when not operating.

For all the above these reasons, we are finalizing that the standards for PQBS NESHAP and the COB NESHAP apply at all times including startup, shut down, and malfunction.

E. Other Issues

1. What did we propose?

We did not propose any amendments that were expected to force facilities to close, as described in the economic analysis performed for the proposed rule. We also did not propose to list CBRP facilities under CAA section 112.

2. How did the amendments pursuant to Other Issues change for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks and the NESHAP for Coke Oven Batteries source categories?

a. Facility Closures

We did not finalize any amendments that were expected to force facilities to close, as described in the economic analysis for the final rule. See section V.D.

b. Listing CBRP Facilities Under CAA Section 112

In the final rules as in the proposal, we are not listing CBRP facilities under CAA section 112 but we intend to list CBRP operations as a source category under CAA section 112(c) in a separate, future regulatory action. We intend to provide the EPA's rationale for such listing in the future action along with details of the EPA's regulatory activities in regard to the CBRP facility. We will perform data gathering to support the listing using a CAA section 114 request that we intend to distribute by the end of the 2024 calendar year and that will request information related to CAA section 112 requirements.

3. What key comments did we receive on the Other Issues and what are our responses?

The key comments on the Other Issues are summarized in this section along with the EPA's responses to the comments. Other comments received on these issues are summarized along with the EPA's responses in the *Response to Comment* [74] document, which is located in the dockets to the rules.

a. Facility Closures

We received a few comments on the potential for facility closures as a result of the proposed amendments. These comments are summarized below along with the EPA responses.

Comment: Commenters stated that they believe the EPA's proposed changes would cause additional coke plant closures or curtailments, leading to a decline in domestic steel and cast iron production. Commenters further stated that regulations rendering domestic cokemaking infeasible would further cripple the domestic steel and iron foundry industries, increase the necessity to import these products, hinder the U.S. transition to a low-carbon economy, and cause job loss in economically distressed areas. Commenters requested that the current proposal be modified to minimize impact to industry.

One commenter stated that there are only two remaining blast furnace steelmakers in the U.S., namely Cleveland-Cliffs, Inc., and U.S. Steel, both of whom rely heavily on the coke industry to provide them millions of tons of coke annually. The commenter asserted that should SunCoke be forced to curtail or cease coke production to meet the new limits as required by the EPA rulemaking, SunCoke may be unable to meet its contractual obligations and be unable to supply steelmakers with the quantities of coke necessary to fuel the domestic steel industry.

The commenter emphasized that a strong domestic steel industry is vital to national and economic security, the U.S. clean energy transition and decarbonization strategy, critical infrastructure, and the competitiveness of many domestic manufacturing industries. The domestic steel industry is the cleanest and most energy-efficient in the world; steel production in the

[74] *Summary of Public Comments and Responses for Coke Ovens: Pushing, Quenching, and Battery Stacks Residual Risk and Technology Review, and Coke Oven Batteries Periodic Technology Review.* U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division (D243–02), Research Triangle Park, North Carolina. May 1, 2024.

United States has the lowest GHG emissions intensity of the nine largest steel producing countries and the EU–27. The commenter contended that the curtailment of domestic steel production due to a coke supply shortage would make the U.S. dependent on imports of steel from countries where GHG emissions from steel production are substantially higher, not to mention the environmental emissions associated with shipping millions of tons of coke across the world. The commenter also asserted that their cokemaking process creates higher quality, higher strength coke that results in steelmakers using less coke in their blast furnaces and thereby lowering their GHG emissions. The commenter stated that SunCoke invests in maintaining and improving its cokemaking plants with environmentally superior technology and younger cokemaking assets.

Other commenters contended our national security, in both the economic and military senses, depends on being able to convert iron ore into a usable product for our nation. Our manufacturing, transportation, construction, energy, and military all require steel. The U.S. steel industry cannot be 100 percent recycled steel as it needs new iron units for quality and quantity reasons. Coke batteries make coke, coke reduces iron oxide from in the ground to usable pig iron, and pig iron makes steel. It is fundamental to so much of the U.S. economy and we need U.S. Steel's coke batteries to remain operational and competitive.

Several commenters contended the U.S. Department of Commerce has recognized that the domestic steel industry is vital to assuring our national security and maintaining critical infrastructure. It is crucial that we continue to maintain the balance of environmental responsibility and economic opportunity for our country. We should not risk the future of our remaining manufacturing jobs and national security. The U.S. Steel facilities are very important to our region and country. Working together, we can accomplish three important goals for future generations: protect our region's jobs, preserve our environment in which we work and live, and preserve our ability to convert iron ore into steel for national economic and military security.

One commenter stated the proposed EPA rule threatens to make coke production uneconomical (through the cost of controls) and impractical (through compliance with the new standards that, as written, is a practical impossibility). If implemented, the proposed EPA rule will reduce coke reduction in the U.S. at a time when domestic steel production is more important than ever.

Another commenter stated the proposed amendments could be detrimental to the coke industry and reduce U.S. production, with potentially negative ramifications for the U.S. economy.

Another commenter stated over the past decade, numerous coke plants have been forced to close due to aging assets and increasing facility costs to meet existing environmental requirements. The EPA's proposed rule would only further this trend, by imposing unattainable emission limits, extensive compliance tests, and costly surveillance for all coke facilities. These new standards would cost coke plants millions of dollars in compliance and force many to shutter their doors due to the stringent and impractical demands.

Response: The EPA disagrees with the commenter that the rule would cause additional coke plant closures or curtailments, leading to a decline in domestic steel and cast iron production. The EPA estimated that all sources can meet the MACT floor standards and would not have to install controls to meet the limits. Note, the EPA is not finalizing the BTF Hg and PM standards for HNR B/W stacks proposed for facilities with no HRSG.

As explained in the memorandum *Coke Ovens Risk and Technology Review: Compliance Costs*[75] prepared for the proposal, costs for fenceline monitoring were estimated at about $101,496 per facility including recordkeeping and reporting ($2022); costs for MACT compliance testing including recordkeeping and reporting for ByP facilities were estimated to range from $151,802 to $442,414; costs for MACT compliance testing for HNR facilities was estimated to range from $291,285 to $823,767. The MACT compliance testing is required in the final rule to be performed every 5 years or every permit cycle (at the beginning of the permit cycle), whichever period is shorter.

As documented in the *Economic Impact Analysis* (EIA)[76] prepared for the proposed rule, based on the Small Business Association (SBA) standards and the company employment figures (shown in table 3–1 of the EIA), none of the firms that own affected coke facilities are small businesses and the compliance costs are small relative the revenues of the steel industry.

All previous coke plant closures have been due to a combination of market reductions in demand for steel and, therefore, coke, and multiple noncompliance issues with their states for sources that were not Coke PQBS or COB mission sources but which required significant upgrades and cleanup costs.

There currently are three ByP companies producing blast furnace coke at five facilities (two facilities recently shut down). There was an acquisition by Cleveland Cliffs, Inc., of AK Steel and ArcelorMittal in 2020 that reduced the number of companies but not the number of facilities. There is one HNR company producing blast furnace coke at five facilities and two ByP companies producing foundry coke at two facilities (one is cold idle).

See sections V.C. and V.D. of this preamble for more information about the costs and economic impacts of these rules.

b. Listing CBRP Facilities Under CAA Section 112

We received a few comments on listing CBRP facilities under CAA section 112. All except one were in favor of listing. These comments are summarized below along with the EPA response.

Comment: Commenters stated that they believe the EPA should list the CBRP under CAA section 112 so that the standards can be updated in an RTR. The commenters requested that the EPA list the co-located CBRPs as a source category under CAA section 112. The commenters support the EPA's intentions to list co-located CBRP at ByP facilities as a source category under CAA section 112(c)(5). However, where the EPA has not fulfilled its duty to revise technology and risk standards for ByP recovery plants, the EPA must approach listing co-located CBRP with an increased sense of urgency. The commenters asserted the risk and technology review for CBRP was completed prior to the 1990 CAA Amendment framework and is due to be revised. Another commenter requested the EPA update standards on CBRP,

[75] *Coke Ovens Risk and Technology Review: Compliance Costs.* D. L. Jones, U.S. Environmental Protection Agency and G.E. Raymond, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2023. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

[76] *Economic Impact Analysis for the Proposed National Emission Standards for Hazardous Air Pollutants for Coke Ovens: Pushing, Quenching, and Battery Stacks, Residual Risk and Technology Review; National Emission Standards for Hazardous Air Pollutants for Coke Oven Batteries, Technology Review* (EPA–452/R–23–005). U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Health and Environmental Impacts Division, Research Triangle Park, NC. May 2023.

which are not included in this rulemaking but are sources of HAP at coke facilities. One commenter disagrees with the EPA's decision not to revise the standards for the CBRP. The commenter contends that the EPA must list co-located CBRP as a source under CAA section 112(c)(5) and issue standards.

Response: We agree with the commenters that CBRP should be listed under CAA section 112. However, we need to gather information to support both listing and regulation and intend to do that by end of 2024. In order to evaluate the CBRP effectively under CAA section 112, the EPA would need to use a CAA section 114 request to obtain additional data, which could include requests for testing, to enhance the quality of data used to develop the MACT standards, especially considering the complexity of the sources and the need for quantitative testing. The EPA would not be able to finalize a sound and appropriate rule within 2 years; we estimate that the EPA would need about 3 years or more to complete such a final rule. We intend to send a CAA section 114 information request in 2024 to gather data for the future CAA section 112 regulation.

Comment: A commenter addressed the history of CBRPs as a source category listed and the later de-listing pursuant to CAA section 112(c), and the steps they believe necessary to re-list. The commenter noted that the 40 CFR part 61 subpart L NESHAP limits HAP emissions at CBRPs through equipment leak detection and repair (LDAR) work practice standards. The commenter continued that, based upon the 40 CFR part 61, subpart L requirements, in 2001, the EPA published a document delisting CBRP as a source category under CAA section 112(c). The commenter stated that the delisting decision was based on an EPA study where the EPA concluded that the benzene standard, applicable to all CBRP in the listed source category, would determine the floor for any CAA section 112(d) standard; that the EPA did not know of any realistic ''beyond the floor'' options at the time of the de-listing; that the EPA believed that further rulemaking would result in no accompanying benefits; and that any new standard that the EPA would develop under CAA section 112(d) would be based on and be comparable to the existing standard both in terms of application and level of stringency. The commenter concluded that in order for the EPA to list CBRP as a new CAA section 112 source category, the Agency must first re-evaluate its earlier delisting decision and provide a rational basis for reversing this longstanding regulatory determination; and explain why regulating CBRP under multiple sets of standards would be authorized and technically sound.

Response: We are not listing the CBRP source category as part of this final rule. As noted in the August 2023 proposed rule preamble, we intend to list CBRP operations, elements of which currently are addressed in the 40 CFR part 61 regulation, as a source category under CAA section 112(c)(5) in a future action. We plan to issue a CAA section 114 request for information regarding the CBRPs in calendar year 2024.

4. What is the rationale for our final approach for the amendments pursuant to these Other Comments?

a. Facility Closures

There are no amendments included in this final rule that were expected to force facilities to close. The BTF standards for HNR facilities without HRSG are not included in this final rule. We are extending the compliance date for the MACT standards by 6 months, for a total of 18 months after publication of the final rule in the **Federal Register**, which should give facilities the time to prepare for the new standards.

b. Listing CBRP Facilities Under CAA Section 112

We did not list CBRP facilities under CAA section 112 in this final rule because we need to gather information to support both listing and regulation and intend to do that by end of 2024. Gathering additional data will enhance the quality of data used to develop the MACT standards, especially considering the complexity of the sources and the need for testing. We intend to list CBRP operations as a source category under CAA section 112(c)(5) in a separate, future regulatory action. We also intend to provide the EPA's rationale for such listing in this separate future action with details of the EPA's plan for future regulatory activities for the CBRP. We intend to send a CAA section 114 information request by end of 2024 to gather data for the future CAA section 112 regulation.

F. Compliance

1. What did we propose?

The proposed compliance date for the new MACT limits in the PQBS NESHAP was 1 year after publication of the final rule. The proposed compliance date for the two BTF emission limits for HNR B/W stack in the PQBS NESHAP was 3 years after publication of the final rule to allow time for the installation of ductwork and control devices. We estimated that the facility would need 3 years to complete this work and comply with the new PM limit due to the unique configuration of the facility. The proposed requirement for periodic compliance testing after the initial compliance demonstration with the required MACT standards was ''at the end of each permit cycle.''

The proposed compliance date to begin fenceline monitoring under the COB NESHAP was 1 year after the publication date of the final rule; facilities must perform root cause analysis and apply corrective action requirements upon exceedance of an annual average concentration action level starting 3 years after the publication date of the final rule. The proposed compliance date under the COB NESHAP for the revisions to the limits for allowable leaks from doors, lids, and offtakes was 1 year after publication of the final rule.

We proposed the date for complying with the proposed SSM changes to be no later than the effective date of the final rule with the exception of recordkeeping provisions. For recordkeeping under the SSM, we proposed that facilities must comply with this requirement 180 days after the effective date of the final rule. Recordkeeping provisions associated with malfunction events would be effective no later than 180 days after the effective date of the final rule. The EPA proposed to require additional information for recordkeeping of malfunction events, so the additional time was necessary to permit sources to read and understand the new requirements and adjust record keeping systems to comply. The proposed reporting provisions were in accordance with the reporting requirements during normal operations and the semi-annual report of excess emissions.

The proposed date for complying with the proposed electronic reporting submission requirements was 60 days after publication of the final rule for performance tests and 1 year after publication of the final rule or the date the template is made available on the CEDRI website for compliance reports.

2. How did the amendments related to compliance change for the NESHAP for Coke Ovens: Pushing, Quenching, and Battery Stacks and the NESHAP for Coke Oven Batteries source categories?

We changed the required initial MACT compliance in the final rule to be 18 months after publication of the final rule for all MACT emissions limits in the final rule. For the periodic MACT compliance testing, we are promulgating that periodic testing be conducted ''at

the beginning of each permit cycle or every 5 years, whichever is shorter.'' The remaining final promulgation compliance dates for the PQBS and COB NESHAP are unchanged from proposal and are as follows: 1 year after the publication date of the final rule to begin fenceline monitoring; 1 year after publication of the final rule for complying with the revisions to the limits for allowable leaks from doors, lids, and offtakes; 1 year after publication of the final rule for compliance with the 20 percent opacity limit for HNR B/W stacks; and 1 year after publication of the final rule for compliance with the zero leaks from HNR oven doors and pressure monitoring in either ovens or tunnels.

For SSM, the final promulgation compliance dates also are unchanged from proposal and are as follows: no later than the publication date of the final rule except for the recordkeeping provisions, which for startup and shutdown are 180 days after the effective date of the final rule and for malfunction events, the recordkeeping requirements are effective no later than 180 days after publication date of the final rule.

3. What key comments did we receive on compliance and what are our responses?

We received a number of comments on compliance deadlines and compliance methods. Some commenters wanted shorter time periods for the deadlines and some wanted longer time periods. In regard to methods, some commenters wanted to use methods not included in the rules and some commenters wanted methods in the rules removed. The key comments on compliance are summarized in this section along with the EPA's responses to the comments. Other comments received on compliance are summarized along with the EPA's responses in the *Response to Comment*[77] document, which is located in the dockets to the rules.

Comment: A commenter stated they believe that, because Title V permits for coke plants can take years, based on the proposed rule text, facilities can delay the PM test indefinitely based on the timing of a Title V reissuance. The commenter requested that the EPA specify intervals to conduct performance testing in months or years rather than relative to the permit cycle. The commenter also requested that citations 40 CFR 63.7321(a) and 63.7333(a)(2) specify performance testing intervals in months or years to avoid facilities indefinitely delaying the PM emission limits test.

Response: We agree with the commenter and instead have required testing ''at the beginning of each permit cycle or every 5 years, whichever is shorter'' instead of only every ''permit cycle.''

Comment: Two commenters stated that because the EPA does not have enough data to calculate representative limits, facilities may not be able to meet limits without installing new controls. Therefore, facilities need 3 years to comply instead of proposed one year to allow facilities to do testing to evaluate the need for additional controls and to design, purchase, and install new equipment, if needed.

Response: Based on available data, we estimate all facilities will be able to meet MACT floor limits without new controls. We looked at all the data available to the EPA and found that only one test run was slightly higher than the MACT floor for one HAP, but compliance is demonstrated a 3-run average and all the 3-run averages for all the HAP are below the MACT floor limits. These limits are based on the UPL calculated with available data. All the test data results we have (based on 3-run averages) are below the promulgated MACT floor limits. The UPL accounts for variability and provides upper bound limits based on available HAP emissions data for these sources. We have no evidence that indicates these facilities will need to install additional controls to meet these MACT floor limits, and the commenters requesting the full 3 years allowed by the statute did not provide such evidence. Rather, these commenters base their request on the assertion that because, in their view, there is not enough data to prove that additional controls are not needed, the compliance date should be set based on the assumption that they will be. The EPA does not believe this rationale is sufficient to justify delaying compliance for 3 years. In the final rule, the EPA is allowing 18 months to comply with the MACT standards to allow sufficient time for the facilities to conduct the compliance emissions testing and in acknowledgement of the remote possibility that some additional action may be needed by facilities to confirm compliance. In that unlikely event, 18 months will allow additional time for the facility to confirm that they can meet the limit.

4. What is the rationale for our final approach for the amendments related to compliance?

Based on consideration of comments and other relevant information, we are promulgating the same compliance dates as proposed for fenceline monitoring, revised leak limits, SSM, and ERT submissions. We conclude that the final compliance dates and timelines for these requirements are appropriate as described previously in this section of the preamble. However, we are promulgating that periodic testing for the MACT limits be conducted ''at the beginning of each permit cycle or every 5 years, whichever is shorter,'' to account for permit periods that can extend for many years beyond 5 years due to delays in permit reviews and to establish compliance at the beginning of the permit cycle because permit conditions may change from the previous permit cycle.

For the MACT standards, as described in responses in previous subsection of this preamble, we made some adjustments to the dates and timelines based on consideration of comments. We conclude that the final compliance dates and timelines for the MACT standards are appropriate as described previously in this section of the preamble.

V. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted

The following analyses of costs and benefits, and environmental, economic, and environmental justice impacts are presented for the purpose of providing the public with an understanding of the potential consequences of this final action. The EPA notes that analysis of such impacts is distinct from the determinations finalized in this action under CAA section 112, which are based on the statutory factors the EPA discussed in sections II.A., IV.B.1., and IV.C.

A. What are the affected facilities?

The affected sources are facilities in the Coke PQBS source category and the COB source category. These sources include any facility engaged in producing coke from coal, where either the ByP process or the HNR process is used. The coke production processes include pushing coke out of ovens, quenching hot coke with water; and, for HNR facilities only, also recovering heat from hot coke oven exhaust to produce steam and, in some cases, also power. In the coke-making process, the production

[77] *Summary of Public Comments and Responses for Coke Ovens: Pushing, Quenching, and Battery Stacks Residual Risk and Technology Review, and Coke Oven Batteries Periodic Technology Review.* U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division (D243–02), Research Triangle Park, North Carolina. May 1, 2024.

of coke is achieved by the thermal distillation of coal in oven chambers made of brick or other heat-resistant material at temperatures approaching 2,000 °F (1,100 °C) to separate the gas, water, and tar in coal. The coke product is used as a fuel and source of carbon used in steelmaking. Based on the information we have, there are 11 operating coke manufacturing facilities subject to these NESHAP and one idle facility.

B. What are the air quality impacts?

There are no measurable air quality impacts from this rule that can be guaranteed. However, the promulgated 21 new MACT floor standards for the PQBS NESHAP source category will ensure that emissions of these HAP do not increase and help ensure that air quality in the vicinity of coke oven facilities does not degrade over time. In addition, the promulgated reduction in allowable emissions from coke oven doors, lids, and offtakes in the COB source category will ensure that emissions of HAP do not increase and that air quality does not degrade over time. We also are promulgating fenceline monitoring, which would improve compliance assurance and potentially result in some unquantified additional emission reductions. Lastly, we also are requiring that standards apply during periods of SSM.

The EPA has not quantified any benefits associated with this final rule, because all covered facilities are expected to already have HAP emissions levels that are below the final limits, based on facility data available to the EPA. However, the EPA anticipates that this final rule's new requirements will increase the likelihood of facilities successfully detecting any HAP emissions in excess of the specified thresholds, allowing for earlier corrective action and thus preventing pollution increases that could otherwise occur. The potential public health benefits associated with such prevention are difficult to estimate, given that they correspond to hypothetical scenarios of emissions beyond those indicated by current facility data, and are thus not quantified in the EPA's analysis

C. What are the cost impacts?

Cost impacts are due to the required source testing that includes: testing every 5 years to demonstrate compliance with the promulgated MACT floor standards for PQBS; weekly opacity testing of HNR B/W heat stacks; daily visible leak testing of HNR ovens doors; and fenceline monitoring at ByP facilities. The total costs for the rules are estimated to be $4.0 million per year for the 11 operating facilities ($2023), with $500,000 per facility, on average for the five HNR facilities and $250,000 per facility, on average, for the 6 ByP facilities. The compliance testing is estimated to cost $3.3 million total for the 11 operating facilities, with $300,000 per facility on average. The HNR B/W stack opacity testing is estimated to be $22,000 total for the five HNR facilities, with $4,400 per facility on average. The HNR daily door leak testing with EPA Method 303A is estimated to be $105,000 total for the five HNR facilities, with $21,000 per facility on average. The fenceline monitoring costs are estimated to be $640,472 for the six ByP facilities, with $107,000 per facility on average.[78]

D. What are the economic impacts?

The EPA prepared an EIA for the final rule,[79] which is available in the docket for this action. This final rule is not a significant regulatory action under Executive Order 12866 section 3(f)(1), as amended by Executive Order 14094, since it is not likely to 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. The EIA analyzed the potential cost impacts under the promulgated requirements, and the projected impacts are presented for the 2025–2036 time period. The EIA analyzes the projected impacts of the final rule in order to better inform the public about its potential effects.

If the compliance costs, which are key inputs to an EIA, are small relative to the receipts of the affected industries, then the impact analysis may consist of a calculation of annual (or annualized) costs as a percent of sales for affected parent companies. This type of analysis is often applied when a partial equilibrium or more complex EIA approach is deemed unnecessary given the expected size of the impacts. The annualized cost per sales for a company represents the maximum price increase in the affected product or service needed for the company to completely recover the annualized costs imposed by the regulation. We conducted a cost-to-sales analysis to estimate the economic impacts of this promulgation, given that the equivalent annualized value (EAV), which represents a flow of constant annual values that would yield a sum equivalent to the present value of the compliance costs over the period 2025–2036. The EAV is estimated at $3.9 million using a 2 percent discount rate, $3.9 million using a 3 percent discount rate, and $3.7 million using a 7 percent discount rate in 2022 dollars, which is small relative to the revenues of the steel industry (of which the coke industry is a part).

There are five parent companies that operate active coke facilities: Cleveland-Cliffs, Inc. U.S. Steel, SunCoke Energy, Inc., DTE Energy Company (EES Coke in River Rouge (Detroit), Michigan), and the Drummond Company (ABC Coke in Tarrant City, Alabama). Each reported greater than $1 billion in revenue in 2021. The EPA estimated the annualized compliance cost each firm is expected to incur and determined the estimated cost-to-sales ratio for each firm is less than 0.2 percent. James C. Justice Companies owns the idled Bluestone Coke facility, and the EPA estimated the compliance cost-to-sales ratio, if the facility were to resume operations, would be less than 0.1 percent. Therefore, the projected economic impacts of the expected compliance costs of the promulgation are likely to be small. The EPA also conducted a small business screening to determine the possible impacts of the promulgated rule on small businesses. Based on the Small Business Administration size standards and business information gathered by the EPA, this source category has one small business, which would not be subject to significant cost by the promulgated requirements.

In this section of the preamble and in the EIA [80] for this final rule, we focus on the compliance cost impacts to the firms who own affected facilities. Other than the simple cost-to-sales analysis described earlier in this section, we do

[78] *Coke Ovens Risk and Technology Review: Compliance Costs.* D.L. Jones, U.S. Environmental Protection Agency and G.E. Raymond, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

[79] *Economic Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants for Coke Ovens: Pushing, Quenching, and Battery Stacks, Residual Risk and Technology Review; National Emission Standards for Hazardous Air Pollutants for Coke Oven Batteries, Technology Review* (EPA–452/R–23–005). U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Health and Environmental Impacts Division, Research Triangle Park, NC. May 2024.

[80] *Economic Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants for Coke Ovens: Pushing, Quenching, and Battery Stacks, Residual Risk and Technology Review; National Emission Standards for Hazardous Air Pollutants for Coke Oven Batteries, Technology Review* (EPA–452/R–23–005). U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Health and Environmental Impacts Division, Research Triangle Park, NC. May 2024.

not have the data or methods to assess potential price impacts or distributional consequences of the potential pass-through of regulatory costs to consumers of intermediate and final products for which coke is an input.

With regard to emissions reductions, this rule has no quantifiable emission reductions. At this time, since these impacts are uncertain and not quantifiable, the EPA is unable to assess the total costs, benefits, and distributional consequences of these actions at the community level.

For more information on the potential benefits of this rulemaking, see section V.E. of this preamble. For additional discussion on the environmental justice analyses conducted and their results, see section V.F.

E. What are the benefits?

The promulgated amendments revise the standards such that they apply at all times, which includes periods of SSM, and may result in some unquantified additional emissions reductions (and associated potential public health benefits) compared to historic or current emissions (*i.e.,* before the SSM exemptions were removed). Additional elements of the promulgated amendments, including MACT standards for previously unregulated HAP emissions, lower ByP coke oven emission leak limits, ensuring zero HNR door leaks, and HNR B/W stack opacity limits also may result in unquantified additional emissions reductions (and associated potential public health benefits) that improve accountability and compliance assurance. Also, the promulgated fenceline monitoring will improve compliance assurance and potentially result in some unquantified additional emission reductions (and associated public health benefits).

The EPA has not quantified any benefits associated with this final rule because all covered facilities are expected to already have HAP emissions levels that are below the final limits, based on facility data available to the EPA. However, the EPA anticipates that this final rule's new requirements will increase the likelihood of facilities successfully detecting any HAP emissions in excess of the specified thresholds, allowing for earlier corrective action and thus preventing pollution increases that could otherwise occur. The potential public health benefits associated with such prevention are difficult to estimate, given that they correspond to hypothetical scenarios of emissions beyond those indicated by current facility data, and are thus not quantified in EPA's analysis.

F. What analysis of environmental justice did we conduct?

For purposes of analyzing regulatory impacts, the EPA relies upon its June 2016 ''*Technical Guidance for Assessing Environmental Justice in Regulatory Analysis*,'' [81] which provides recommendations that encourage analysts to conduct the highest quality analysis feasible, recognizing that data limitations, time, resource constraints, and analytical challenges will vary by media and circumstance. The *Technical Guidance* [82] states that a regulatory action may involve potential environmental justice concerns if it could: (1) create new disproportionate impacts on communities with environmental justice concerns; (2) exacerbate existing disproportionate impacts on communities with environmental justice concerns; or (3) present opportunities to address existing disproportionate impacts on communities with environmental justice concerns through this action under development.

The EPA's environmental justice *Technical Guidance* [83] states that ''[t]he analysis of potential environmental justice concerns for regulatory actions should address three questions: (A) Are there potential environmental justice concerns associated with environmental stressors affected by the regulatory action for population groups of concern in the baseline? (B) Are there potential environmental justice concerns associated with environmental stressors affected by the regulatory action for population groups of concern for the regulatory option(s) under consideration? (C) For the regulatory option(s) under consideration, are potential environmental justice concerns created or mitigated compared to the baseline?''

The environmental justice analysis is presented for the purpose of providing the public with as full as possible an understanding of the potential impacts of this final action. The EPA notes that analysis of such impacts is distinct from the determinations finalized in this action under CAA sections 112, which are based solely on the statutory factors the EPA is required to consider.

1. Coke Ovens: Pushing, Quenching, and Battery Stacks Source Category Demographics

The EPA examined the potential for the 12 coke oven facilities to disproportionately impact residents in certain demographic groups living in proximity to the facilities. Specifically, the EPA analyzed how demographics and risk are distributed under the PQBS NESHAP. The methodology and detailed results of the demographic analysis are presented in the document titled *Analysis of Demographic Factors for Populations Living Near Coke Oven Facilities—Final,*[84] which is available in the docket for this action.

To examine the potential for disproportionate impacts on certain population groups, the EPA conducted a proximity demographic analysis and a risk-based demographic analysis. A proximity demographic analysis is an assessment of individual demographic groups in the total population living within 10 km (~6.2 miles) and 50 km (~31 miles) of the affected facilities. A risk-based demographic analysis is an assessment of risks to individual demographic groups in the population living within 10 km and 50 km of the facilities. In this preamble, we focus on the 10 km radius for the demographic analysis because it encompasses all the facility MIR locations and captures 99 percent of the population with cancer risks greater than or equal to 1-in-1 million from coke ovens PQBS source category emissions. The results of the proximity analysis for populations living within 50 km are included in the document titled *Analysis of Demographic Factors for Populations Living Near Coke Oven Facilities—Final,*[85] which is available in the docket for this action (EPA–HQ–OAR–2002–0085).

The total population, population percentages, and population count for each demographic group for the entire U.S. population is shown in the column titled ''Nationwide Average for Reference'' in table 11 of this preamble.

[81] *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis.* U.S. Environmental Protection Agency. June 2016. Quote is from Section 3—Key Analytic Considerations, page 11. *https://www.epa.gov/sites/default/files/2016-06/documents/ejtg_5_6_16_v5.1.pdf.*

[82] *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis.* U.S. Environmental Protection Agency. June 2016. Quote is from Section 3—Key Analytic Considerations, page 11. *https://www.epa.gov/sites/default/files/2016-06/documents/ejtg_5_6_16_v5.1.pdf.*

[83] *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis.* U.S. Environmental Protection Agency. June 2016. Quote is from Section 3—Key Analytic Considerations, page 11. *https://www.epa.gov/sites/default/files/2016-06/documents/ejtg_5_6_16_v5.1.pdf.*

[84] *Analysis of Demographic Factors for Populations Living Near Coke Oven Facilities—Final.* U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

[85] *Analysis of Demographic Factors for Populations Living Near Coke Oven Facilities—Final.* U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

These national data are provided as a frame of reference to compare to the results of the proximity analysis and the risk-based analysis.

The results of the category proximity demographic analysis (see table 11, column titled ''Proximity Analysis for Pop. Living within 10 km of Coke Oven Facilities'') indicate that a total of 1.3 million people live within 10 km of the 12 coke oven facilities. The percent of the population that is African American is more than double the national average (28 percent versus 12 percent). The percent of people living below the poverty level is almost double the national average (21 percent versus 13 percent) and the percent of people living below twice the poverty level is above the national average (41 percent versus 30 percent).

The PQBS source category risk-based demographic analysis (see table 11 in this preamble), which focuses on populations that have higher cancer risks, indicates that there are approximately 2,500 people with cancer risks greater than or equal to 1-in-1 million living around two PQBS facilities, one in Pennsylvania and one in Virginia. Over 99 percent of the population with cancer risks greater than or equal to 1-in-1 million are living around the Virginia facility; therefore, the demographics for the population living around this facility dominates the risk-based demographics. The population with cancer risks greater than or equal to 1-in-1 million due to emissions from the PQBS source category is predominantly white (83 percent versus 60 percent nationally).[86] The population with cancer risks greater than or equal to 1-in-1 million for emissions from the PQBS source category also are above the national average for: (1) the percent of the population living below poverty (15 percent versus 13 percent); (2) the percent of the population living below twice the poverty level (34 percent versus 30 percent); and (3) the percent of the population that is over 25 without a high school diploma (23 percent versus 12 percent). Note that no reduction in actual emissions or risk is expected for the PQBS source category as a result of these final actions.

TABLE 11—SOURCE CATEGORY: DEMOGRAPHICS OF POPULATIONS LIVING WITHIN 10 km OF FACILITIES WITH CANCER RISK GREATER THAN OR EQUAL TO 1-IN-1 MILLION FROM EMISSIONS FROM THE PQBS SOURCE CATEGORY COMPARED TO THE NATIONAL AVERAGE AND PROXIMITY DEMOGRAPHICS

Demographic group	Nationwide average for reference	Proximity analysis for population living within 10 km of coke oven facilities	Cancer risk ≥1-in-1 million within 10 km of coke oven facilities
Total Population	330M	1.3M	2.5K
Number of Facilities	.....	12	2
Race and Ethnicity by Percent/Number of People			
White	60%	58%	83%
	196M	737K	2K
African American	12%	28%	10%
	40M	359K	300
Native American	0.6%	0.2%	0%
	2M	3K	0
Hispanic or Latino (includes white and nonwhite)	19%	10%	2%
	63M	133K	<100
Other and Multiracial	9%	4%	5%
	29M	47K	100
Income by Percent/Number of People			
Below Poverty Level	13%	21%	15%
	42M	267K	400
Below 2x Poverty Level	30%	41%	34%
	100M	524K	900
Education by Percent/Number of People			
Over 25 and without a High School Diploma	12%	12%	23%
	38M	152K	600
Over 25 and with a High School Diploma	88%	88%	77%
	292M	1.1M	2K
Linguistically Isolated by Percent/Number of People			
Linguistically Isolated	5%	3%	2%

[86] Note, since there are fewer than 100 people with a noncancer hazard index greater than or equal to 1 living around one facility, we did not conduct risk-based demographics for noncancer.

TABLE 11—SOURCE CATEGORY: DEMOGRAPHICS OF POPULATIONS LIVING WITHIN 10 km OF FACILITIES WITH CANCER RISK GREATER THAN OR EQUAL TO 1-IN-1 MILLION FROM EMISSIONS FROM THE PQBS SOURCE CATEGORY COMPARED TO THE NATIONAL AVERAGE AND PROXIMITY DEMOGRAPHICS—Continued

Demographic group	Nationwide average for reference	Proximity analysis for population living within 10 km of coke oven facilities	Cancer risk ≥1-in-1 million within 10 km of coke oven facilities
	17M	33K	<100

Notes: The nationwide population count and all demographic percentages are based on the Census' 2016–2020 American Community Survey five-year block group averages and include Puerto Rico. Demographic percentages based on different averages may differ. The total population counts are based on the 2020 Decennial Census block populations. To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category for these analyses. A person is identified as one of five racial/ethnic categories above: White, African American, Native American, Other and Multiracial, or Hispanic/Latino. A person who identifies as Hispanic or Latino is counted as Hispanic/Latino for this analysis, regardless of what race this person also may have identified as in the Census.

2. Coke Oven Whole-Facility Demographics

As described in section IV.B.5. of this preamble, we assessed the facility-wide (or ''whole-facility'') risks for 12 coke oven facilities in order to compare the PQBS NESHAP source category risk to the whole facility risks. This whole-facility demographic analysis characterizes the risks communities face from all HAP sources at coke oven facilities. The whole facility risk assessment includes all sources of HAP emissions at each facility (described in the memorandum *HAP Emissions from Coke Oven Facilities—Final Rule* [87]). Note, no reduction in actual emissions or risk is expected at the whole facility level.

The whole-facility demographic analysis is an assessment of individual demographic groups in the total population living within 10 km (~6.2 miles) and 50 km (~31 miles) of the facilities. In this preamble, we focus on the 10 km radius for the demographic analysis because it encompasses all the facility MIR locations and captures 99 percent of the population with cancer risks greater than or equal to 1-in-1 million from the PQBS NESHAP source category emissions. The results of the whole-facility demographic analysis for populations living within 50 km are included in the document titled *Analysis of Demographic Factors for Populations Living Near Coke Oven Facilities—Final,*[88] which is available in the docket for this action.

While the source category population with risks ≥ 1-in-1 million (shown in table 11 of this preamble) is disproportionately White (83 percent living within 10 km of coke oven facilities *v.* 60 percent nationally), the whole-facility population with risks ≥ 1-in-1 million (shown in table 12 of this section) is disproportionately African American (30 percent living within 10 km of coke oven facilities *v.* 12 percent nationally). Specifically, the whole-facility population with risk greater than 1-in-1 million is 30 percent African American compared to the national average of 12 percent. In addition, the percentage of the whole-facility population living within 10 km of coke oven facilities with cancer risks ≥ 1-in1 million that is living below the poverty level (17 percent) and also the population living below two times the poverty level (36 percent) are above the corresponding national average (13 percent and 30 percent).

TABLE 12—WHOLE-FACILITY: DEMOGRAPHICS OF POPULATIONS LIVING WITHIN 10 km OF FACILITIES WITH CANCER RISK GREATER THAN OR EQUAL TO 1-IN-1 MILLION FROM COKE OVEN WHOLE-FACILITY EMISSIONS COMPARED TO THE NATIONAL AVERAGE AND PROXIMITY DEMOGRAPHICS

Demographic group	Nationwide average for reference	Proximity analysis for pop. living within 10 km of coke oven facilities	Cancer risk ≥1-in-1 million within 10 km of coke oven facilities
Total Population	330M	1.3M	491K
Number of Facilities	.....	12	7
Race and Ethnicity by Percent/Number of People			
White	60%	58%	62%
	196M	737K	303K
African American	12%	28%	30%
	40M	359K	149K
Native American	0.6%	0.2%	0.1%
	2M	3K	500
Hispanic or Latino (includes white and nonwhite)	19%	10%	4%
	63M	133K	21K
Other and Multiracial	9%	4%	3%

[87] *HAP Emissions from Coke Oven Facilities—Final Rule.* D.L. Jones, U.S. Environmental Protection Agency; and G.E. Raymond and E. Kerr, RTI International. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 1, 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

[88] *Analysis of Demographic Factors for Populations Living Near Coke Oven Facilities—Final.* U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

TABLE 12—WHOLE-FACILITY: DEMOGRAPHICS OF POPULATIONS LIVING WITHIN 10 km OF FACILITIES WITH CANCER RISK GREATER THAN OR EQUAL TO 1-IN-1 MILLION FROM COKE OVEN WHOLE-FACILITY EMISSIONS COMPARED TO THE NATIONAL AVERAGE AND PROXIMITY DEMOGRAPHICS—Continued

Demographic group	Nationwide average for reference	Proximity analysis for pop. living within 10 km of coke oven facilities	Cancer risk ≥1-in-1 million within 10 km of coke oven facilities
	29M	47K	17K
Income by Percent/Number of People			
Below Poverty Level	13%	21%	17%
	42M	267K	84K
Below 2x Poverty Level	30%	41%	36%
	100M	524K	176K
Education by Percent/Number of People			
Over 25 and without a High School Diploma	12%	12%	8%
	38M	152K	40K
Over 25 and with a High School Diploma	88%	88%	92%
	292M	1.1M	451K
Linguistically Isolated by Percent/Number of People			
Linguistically Isolated	5%	3%	1%
	17M	33K	6K

Notes: The nationwide population count and all demographic percentages are based on the Census' 2016–2020 American Community Survey five-year block group averages and include Puerto Rico. Demographic percentages based on different averages may differ. The total population counts are based on the 2020 Decennial Census block populations. To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category for these analyses. A person is identified as one of five racial/ethnic categories above: White, African American, Native American, Other and Multiracial, or Hispanic/Latino. A person who identifies as Hispanic or Latino is counted as Hispanic/Latino for this analysis, regardless of what race this person may have also identified as in the Census.

G. What analysis of children's environmental health did we conduct?

This action is not subject to Executive Order 13045 because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The EPA's assessment of the potential impacts to human health from emissions at existing coke ovens sources in the PQBS source category are discussed in section IV.B. and IV.C. of this preamble.

A total of 281,000 children ages 0–17 live within 10 km of Coke Oven facilities, which is 22 percent of the total population within 10 km of Coke Ovens. This percentage is the same as the national percentage for children ages 0–17 (22 percent). Due to emissions from the PQBS source category, there are approximately 200 children (0–17 years) with increased lifetime cancer risks of greater than or equal to 1-in-1 million. This represents 8 percent of the total population living of 2,500 people within 10 km of coke ovens that have an increased lifetime cancer risk greater than or equal to 1-in-1 million due to PQBS emissions (see Table 11). Therefore, the number of children ages 0–17 living near these facilities is not disproportionately high.

Children breathe more air per unit of body weight than adults and are more susceptible to the impacts of mutagenic carcinogens and neurodevelopmental toxicants, both of which are found in COE. Because this action sets MACT standards for Hg, which is a known neurodevelopmental toxicant and was previously unregulated for this source category, and because the rule includes lower leak limits for coke ovens to minimize fugitive releases of COE, the final standards will prevent, and possibly reduce, the exposure of children to both cancer and noncancer health effects. In addition, the fenceline monitoring work practice required in the final rule, where benzene is used as a surrogate for COE, also may prevent and possibly reduce exposure of children to mutagenic carcinogens and neurodevelopmental toxicants.

The methodology and detailed results of the demographic analysis are presented in a technical report, *Analysis of Demographic Factors for Populations Living Near Coke Oven Facilities—Final,*[89] available in the docket for this action.

[89] *Analysis of Demographic Factors for Populations Living Near Coke Oven Facilities—Final.* U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 2024.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a ''significant regulatory action'' as defined under Executive Order 12866, as amended by Executive Order 14094. Accordingly, the EPA submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. The EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis, *Economic Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants for Coke Ovens: Pushing, Quenching, and Battery Stacks, Residual Risk and Technology Review; National Emission Standards for Hazardous Air Pollutants for Coke*

Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

Oven Batteries Technology Review,[90] is available in the dockets EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

B. Paperwork Reduction Act (PRA)

The information collection activities in this promulgated rule have been submitted for approval to OMB under the PRA. The ICR documents that the EPA prepared have been assigned EPA ICR numbers 1995.10 and 1362.15. You can find a copy of the ICRs in the dockets for this rule, and they are briefly summarized here.

We are promulgating amendments to the PQBS NESHAP that require compliance testing for 17 MACT limits and to the COB NESHAP that require fenceline monitoring. Furthermore, the amendments also require electronic reporting and remove the SSM exemptions in both NESHAP. We are also incorporating other revisions (*e.g.,* facility counts) that affect reporting and recordkeeping for coke oven facilities. This information would be collected to assure compliance with the CAA.

For ICR: NESHAP for PQBS (40 CFR part 63, subpart CCCCC) (OMB Control Number 2060–0521)

Respondents/affected entities: PQBS source category.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart CCCCC).

Estimated number of respondents: 12 facilities.

Frequency of response: One time.

Total estimated burden: 26,800 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $3,490,000 (per year), which includes $107,000 annualized capital, or operation and maintenance costs. Of the total cost, $950,000 (per year) is for this promulgation, and $2,433,000 is for other costs related to continued compliance with the NESHAP and the operation and maintenance of leak detectors and continuous opacity monitors. The total rule costs reflect an overall increase of $540,000 (per year) from the previous ICR due to the compliance with 17 additional MACT floor emission limits, transition to electronic reporting, and elimination of SSM requirements.

For ICR: NESHAP for COB (40 CFR part 63, subpart L) (OMB Control Number 2060–0253)

Respondents/affected entities: COB source category.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart L).

Estimated number of respondents: 12 facilities.

Frequency of response: One time.

Total estimated burden: The annual recordkeeping and reporting burden for facilities to comply with all of the requirements in the NESHAP is estimated to be 2,800 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $6,650,000 (per year), which includes $0 annualized capital, or operations and maintenance costs. Of the total cost, $270,000 (per year) is for this promulgation and $6,380,000 is for other costs related to continued compliance with the NESHAP. The total rule costs reflect a decrease of $230,000 (per year) from the previous ICR, due to revised HNR facility counts, transition to electronic reporting, addition of fenceline monitoring, and elimination of SSM requirements.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. Small entities that may be impacted by this rulemaking include Coke facilities located within an integrated iron and steel manufacturing facility under NAICS 331110 (Iron and Steel Mills and Ferroalloy Manufacturing) with 1500 or fewer employees, or facilities under NAICS 324199 (All Other Petroleum and Coal Products Manufacturing, with 500 or fewer workers. None of the facilities currently in operation that are potentially affected by this rulemaking promulgation under these size definitions are ''small businesses'' and therefore will not have a significant economic impact. Additional details of the analysis can be found in the EIA [91] prepared for this rule.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. While this action creates an enforceable duty on the private sector, the cost does not exceed $100 million or more.

E. Executive Order 13132: Federalism

This 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 action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, 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. No tribal governments own facilities subject to these NESHAP. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 directs federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments for PQBS source category are contained in section IV. of this preamble and further documented in *The Residual Risk Assessment for the Coke Ovens: Pushing, Quenching, and Battery Stack Source Category in Support of the 2024 Risk and Technology Review Final*

[90] *Economic Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants for Coke Ovens: Pushing, Quenching, and Battery Stacks, Residual Risk and Technology Review; National Emission Standards for Hazardous Air Pollutants for Coke Oven Batteries, Technology Review* (EPA–452/R–23–005). U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Health and Environmental Impacts Division, Research Triangle Park, NC. May 2024.

[91] *Economic Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants for Coke Ovens: Pushing, Quenching, and Battery Stacks, Residual Risk and Technology Review; National Emission Standards for Hazardous Air Pollutants for Coke Oven Batteries, Technology Review* (EPA–452/R–23–005). U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Health and Environmental Impacts Division, Research Triangle Park, NC. May 2024.

Rule,[92] available in the docket for this action (EPA–HQ–OAR–2002–0085).

The EPA's *Policy on Children's Health* [93] applies to this action. Although we did not perform a risk assessment of the COB source category in this action, we note that COE, which is primarily emitted from this source category, has a mutagenic mode of action; therefore, changes to the standards for the COB NESHAP under the technology review could reduce the exposure of children to mutagens. In addition, this action sets MACT standards for Hg, which is a known neurodevelopmental toxicant and was previously unregulated for this source category; therefore, the new Hg standards will provide additional protection for the exposure of children to noncancer impacts as well. Additional information on how the Policy was applied is available under ''Children's Environmental Health'' in the **SUPPLEMENTARY INFORMATION** section of this preamble.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. We have concluded this action is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action involves technical standards. Therefore, the EPA conducted searches for the RTR for the PQBS NESHAP and the NESHAP for COB through the Enhanced National Standards Systems Network Database managed by the American National Standards Institute (ANSI). We also contacted voluntary consensus standards (VCS) organizations and accessed and searched their databases. For COB NESHAP, we conducted searches for EPA Methods 1, 2, 2F, 2G, 3, 3A, 3B, 4, 5, 5D, 9, 18, 22 of 40 CFR part 60, appendix A, EPA Methods 303, 303A of 40 CFR part 63, appendix A. No applicable VCS were identified for EPA Methods 2F, 2G, 5D, 22, 303, and 303A. For PQBS NESHAP, searches were conducted for EPA Methods 1, 2, 2F, 2G, 3, 3A, 3B, 4, 5, 5D, 9, 23, 26, 26A, 29 of 40 CFR part 60, appendix A, EPA Methods 316 and 320 40 CFR part 63, appendix A. No applicable VCS were identified for EPA Methods 2F, 2G, 5D, and 316.

During the EPA's VCS search, if the title or abstract (if provided) of the VCS described technical sampling and analytical procedures that are similar to the EPA's reference method, the EPA reviewed it as a potential equivalent method. We reviewed all potential standards to determine the practicality of the VCS for this rule. This review requires significant method validation data that meet the requirements of EPA Method 301 for accepting alternative methods or scientific, engineering and policy equivalence to procedures in the EPA reference methods. The EPA may reconsider determinations of impracticality when additional information is available for a particular VCS.

The EPA incorporates by reference, for 40 CFR part 63, subpart CCCCC, the VCS ANSI/ASME PTC 19.10–1981 Part 10, ''Flue and Exhaust Gas Analyses,'' a method for quantitatively determining the gaseous constituents of exhausts resulting from stationary combustion and includes a description of the apparatus, and calculations which are used in conjunction with Performance Test Codes to determine quantitatively, as an acceptable alternative to EPA Method 3B of appendix A to 40 CFR part 60 for the manual procedures only and not the instrumental procedures. The manual method segment of the oxygen determination is performed through the absorption of oxygen. This VCS may be obtained from *https://webstore.ansi.org/*or from the ANSI Headquarters at 1899 L Street NW, 11th floor, Washington, DC 20036.

The EPA previously received approval to incorporate this method in § 63.309 (subpart L), where it appears in the amendatory text of this rule.

The EPA promulgates to incorporate by reference, for 40 CFR part 63, subparts CCCCC and L, the VCS ASTM D7520–16, ''Standard Test Method for Determining the Opacity of a Plume in the Outdoor Ambient Atmosphere'' is an acceptable alternative to EPA Method 9 with the following caveats:

- During the digital camera opacity technique (DCOT) certification procedure outlined in section 9.2 of ASTM D7520–16, you or the DCOT vendor must present the plumes in front of various backgrounds of color and contrast representing conditions anticipated during field use such as blue sky, trees, and mixed backgrounds (clouds and/or a sparse tree stand).
- You must also have standard operating procedures in place including daily or other frequency quality checks to ensure the equipment is within manufacturing specifications as outlined in section 8.1 of ASTM D7520–16.
- You must follow the record keeping procedures outlined in 40 CFR 63.10(b)(1) for the DCOT certification, compliance report, data sheets, and all raw unaltered JPEGs used for opacity and certification determination.
- You or the DCOT vendor must have a minimum of four (4) independent technology users apply the software to determine the visible opacity of the 300 certification plumes. For each set of 25 plumes, the user may not exceed 15 percent opacity of any one reading and the average error must not exceed 7.5 percent opacity.

This approval does not provide or imply a certification or validation of any vendor's hardware or software. The onus to maintain and verify the certification and/or training of the DCOT camera, software and operator in accordance with ASTM D7520–16 and this letter is on the facility, DCOT operator, and DCOT vendor.

The ASTM D7520–16 method describes procedures to determine the opacity of a plume, using digital imagery and associated hardware and software, where opacity is caused by PM emitted from a stationary point source in the outdoor ambient environment. The opacity of emissions is determined by the application of a DCOT that consists of a digital still camera, analysis software, and the output function's content to obtain and interpret digital images to determine and report plume opacity.

The EPA promulgates to incorporate by reference for 40 CFR part 63, subpart L, the VCS ASTM D6420–18, ''Test Method for Determination of Gaseous Organic Compounds by Direct Interface Gas Chromatography/Mass Spectrometry'' is an acceptable alternative to EPA Method 18 only when the target compounds are all known and the target compounds are all listed in ASTM D6420 as measurable. This method should not be used for methane and ethane because atomic mass is less than 35. ASTM D6420 should never be specified as a total VOC method. This test method employs a direct interface gas chromatograph/mass spectrometer to identify and quantify 36 volatile organic compounds, however, the use of the method in this rule is only applicable to benzene, toluene, and xylene.

[92] *Residual Risk Assessment for the Coke Ovens: Pushing, Quenching, and Battery Stacks Source Category in Support of the 2024 Risk and Technology Review Final Rule.* U.S. Environmental Protection Agency, Office of Air and Radiation, Office of Air Quality Planning and Standards, Research Triangle Park, NC. May 2024. Docket No. EPA–HQ–OAR–2002–0085.

[93] See *https://www.epa.gov/children/childrens-health-policy-and-plan#A1.*

The EPA promulgates to incorporate by reference, for 40 CFR part 63, subpart CCCCC, the VCS ASTM D6784–16, ''Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro 3 Method)'' is an acceptable alternative to EPA Method 29 (portion for Hg only) as a method for measuring Hg. This method applies to concentrations of approximately 0.5–100 $\mu g/Nm^3$. This test method describes equipment and procedures for obtaining samples from effluent ducts and stacks, equipment and procedures for laboratory analysis, and procedures for calculating results.

The EPA promulgates to incorporate by reference, for 40 CFR part 63, subpart CCCCC, the VCS ASTM D6348–12 (2020), ''Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy,'' as an acceptable alternative to EPA Method 320 of appendix A to 40 CFR part 63 with caveats requiring inclusion of selected annexes to the standard as mandatory. The ASTM D6348–12 (2020) method is an extractive FTIR spectroscopy-based field test method and is used to quantify gas phase concentrations of multiple target compounds in emission streams from stationary sources. This field test method provides near real time analysis of extracted gas samples. In the September 22, 2008, NTTAA summary, ASTM D6348–03(2010) was determined equivalent to EPA Method 320 with caveats. ASTM D6348–12 (2020) is a revised version of ASTM D6348–03(2010) and includes a new section on accepting the results from direct measurement of a certified spike gas cylinder, but still lacks the caveats we placed on the D6348–03(2010) version. We are finalizing that the test plan preparation and implementation in the Annexes to ASTM D 6348–12 (2020), annexes Al through A8 are mandatory; and in ASTM D6348–12 (2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (Equation A5.5). We are finalizing that, in order for the test data to be acceptable for a compound, %R must be 70% > R ≤ 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 by using the following equation:

$$Reported\ Results = \frac{Stack\ Concentration}{\%R} = 100$$

The ASTM methods are available at ASTM International at *www.astm.org* or 1100 Barr Harbor Drive, West Conshohocken, PA 19428–2959, telephone number: (610) 832–9500, fax number: (610) 832–9555 at *service@astm.org*.

Additional information for the VCS search and determinations can be found in the memorandum *Voluntary Consensus Standard Results for Coke Ovens: Pushing, Quenching and Battery Stacks: National Emission Standards for Hazardous Air Pollutants* and *Voluntary Consensus Standard Results for Coke Oven Batteries: National Emission Standards for Hazardous Air Pollutants for Coke Oven Batteries,* available in the EPA–HQ–OAR–2002–0085, EPA–HQ–OAR–2003–0051 dockets for the promulgated rule.

The EPA is also incorporating by reference, for 40 CFR part 63, subpart L, the Quality Assurance Handbook for Air Pollution Measurement Systems, Volume IV: Meteorological Measurements, Version 2.0 (Final), March 2008 (EPA–454/B–08–002). The Quality Assurance Handbook for Air Pollution Measurement Systems; Volume IV: Meteorological Measurements is an EPA developed guidance manual for the installation, operation, maintenance and calibration of meteorological systems including the wind speed and direction using anemometers, temperature using thermistors, and atmospheric pressure using aneroid barometers, as well as the calculations for wind vector data for on-site meteorological measurements. This VCS may be obtained from the EPA's National Service Center for Environmental Publications (*https://www.epa.gov/nscep*).

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

The EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with environmental justice concerns.

As discussed in section V.F. of this preamble, the population with risks greater than or equal to 1-in-1 million due to emissions from all sources of HAP at coke oven facilities is disproportionately (30 percent) African American compared to the national average (12 percent African American). About 83 percent of the 491,000 people with a cancer risk greater than or equal to 1-in-1 million live within 10 km of 3 facilities—two in Alabama and one in Pennsylvania. The population with cancer risks greater than or equal to 1-in-1 million living within 10 km of the two facilities in Alabama is 56 percent African American, which is significantly higher than the national average of 12 percent. In addition, the population with risks ≥ 1-in-1 million due to emissions from all sources of HAP at coke oven facilities that is below the poverty level (17 percent) is above the national average (13 percent).

The EPA believes that this action is not likely to change existing disproportionate and adverse effects on communities with environmental justice concerns. Although the promulgated measures are not estimated to decrease actual emissions or the number of people who have risks greater than or equal to 1-in-1 million due to HAP emissions (see table 12 of this preamble), this action will limit allowable emissions from coke ovens sources in 40 CFR part 63, subparts CCCCC and L. The EPA also is promulgating that coke oven facilities conduct fenceline monitoring for benzene and report these data electronically to the EPA. The fenceline monitoring requirements will help ensure that emissions from sources listed under CAA section 112 are being appropriately controlled. The fenceline monitoring results will be publicly available on a quarterly basis to ensure transparency and, consequently, provide fenceline communities with greater access to information about potential exposures.

The information supporting this Executive Order review is described in section V.F. of this preamble and in the document *Analysis of Demographic*

Factors for Populations Living Near Coke Oven Facilities—Final [94] located in the docket for this rule (EPA–HQ–OAR–2002–0085).

K. Congressional Review Act (CRA)

This action is subject to the CRA, 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).

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is amended 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 A—General Provisions

■ 2. Section 63.14 is amended by revising paragraphs (f)(1), (i)(88), (96), (105), and (110), the introductory text of paragraph (o), and paragraph (o)(3) to read as follows:

§ 63.14 Incorporation by reference.

* * * * *

(f) * * *

(1) ANSI/ASME PTC 19.10–1981, Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus], issued August 31, 1981; IBR approved for §§ 63.309(k); 63.365(b); 63.457(k); 63.772(e) and (h); 63.865(b); 63.997(e); 63.1282(d) and (g); 63.1450(a), (b), (d), (e), and (g); 63.1625(b); table 5 to subpart EEEE; §§ 63.3166(a); 63.3360(e); 63.3545(a); 63.3555(a); 63.4166(a); 63.4362(a); 63.4766(a); 63.4965(a); 63.5160(d); table 4 to subpart UUUU; table 3 to subpart YYYY; table 4 to subpart AAAAA; § 63.7322(b); table 5 to subpart DDDDD; §§ 63.7822(b); 63.7824(e); 63.7825(b); 63.8000(d); table 4 to subpart JJJJJ; table 4 to subpart KKKKK; §§ 63.9307(c); 63.9323(a); 63.9621(b) and (c);table 4 to subpart SSSSS; tables 4 and 5 of subpart UUUUU; table 1 to subpart ZZZZZ; §§ 63.11148(e); 63.11155(e); 63.11162(f); 63.11163(g); table 4 to subpart JJJJJJ; §§ 63.11410(j); 63.11551(a); 63.11646(a); 63.11945.

* * * * *

(i) * * *

(88) ASTM D6348–12 (Reapproved 2020), Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform Infrared (FTIR) Spectroscopy, Approved February 1, 2012; IBR approved for §§ 63.365(b); 63.7322(d), (e), and (g); 63.7825(g) and (h).

* * * * *

(96) ASTM D6420–18, Standard Test Method for Determination of Gaseous Organic Compounds by Direct Interface Gas Chromatography-Mass Spectrometry, approved November 1, 2018, IBR approved for §§ 63.305(c); 63.987(b); 63.997(e); 63.2354(b); table 5 to subpart EEEE; §§ 63.2450(j); 63.8000(d).

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(105) ASTM D6784–16, Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method), Approved March 1, 2016; IBR approved for §§ 63.1450(d); 63.9621; table 5 to subpart UUUUU; appendix A to subpart UUUUU; § 63.7322(c).

* * * * *

(110) ASTM D7520–16, Standard Test Method for Determining the Opacity of a Plume in the Outdoor Ambient Atmosphere, approved April 1, 2016; IBR approved for §§ 63.301; 63.305(c) and (f); 63.309(d), (j), and (m); 63.311(d); 63.1450(c) (e), and (g); 63.1453(h); 63.1625(b); 63.7334(a); §§ 63.7823(c) through (f), 63.7833(g); table 3 to subpart LLLLL; § 63.11423(c).

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(o) * * *

(3) EPA–454/B–08–002, Quality Assurance Handbook for Air Pollution Measurement Systems, Volume IV: Meteorological Measurements, Version 2.0 (Final), March 2008, IBR approved for §§ 63.314(b); 63.7792(b).

* * * * *

■ 3. Effective July 15, 2024, § 63.14 is amended by revising paragraphs (f)(1) and (i)(89) and (96) to read as follows:

§ 63.14 Incorporations by reference.

* * * * *

(f) * * *

(1) ANSI/ASME PTC 19.10–1981, Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus], issued August 31, 1981; §§ 63.116(c) and (h); 63.128(a); 63.145(i); 63.309(k); 63.365(b); 63.457(k); 63.490(g); 63.772(e) and (h); 63.865(b); 63.997(e); 63.1282(d) and (g); 63.1450(a), (b), (d). (e), (g); 63.1625(b); table 5 to subpart EEEE; §§ 63.3166(a); 63.3360(e); 63.3545(a); 63.3555(a); 63.4166(a); 63.4362(a); 63.4766(a); 63.4965(a); 63.5160(d); table 4 to subpart UUUU; table 3 to subpart YYYY; table 4 to subpart AAAAA; § 63.7322(b); table 5 to subpart DDDDD; §§ 63.7822(b); 63.7824(e); 63.7825(b); 63.8000(d); table 4 to subpart JJJJJ; table 4 to subpart KKKKK; §§ 63.9307(c); 63.9323(a); 63.9621(b) and (c);table 4 to subpart SSSSS; tables 4 and 5 of subpart UUUUU; table 1 to subpart ZZZZZ; §§ 63.11148(e); 63.11155(e); 63.11162(f); 63.11163(g); table 4 to subpart JJJJJJ; §§ 63.11410(j); 63.11551(a); 63.11646(a); 63.11945.

* * * * *

(i) * * *

(89) ASTM D6348–12 (Reapproved 2020), Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform Infrared (FTIR) Spectroscopy, Approved February 1, 2012; IBR approved for §§ 63.109(a); 63.365(b); 63.509(a); 63.7322(d), (e), and (g); 63.7825(g) and (h).

* * * * *

(96) ASTM D6420–18, Standard Test Method for Determination of Gaseous Organic Compounds by Direct Interface Gas Chromatography-Mass Spectrometry, approved November 1, 2018' IBR approved for §§ 63.101(b); 63.115(g); 63.116(c); 63.126(d); 63.128(a); 63.139(c); 63.145(d) and (i); 63.150(g); 63.180(d; 63.305(c); 63.482(b); 63.485(t); 63.488(b); 63.490(c) and (e); 63.496(b); 63.500(c); 63.501(a); 63.502(j); 63.503(a) and (g); 63.525(a) and (e); 63.987(b); 63.997(e); 63.2354(b); table 5 to subpart EEEE; §§ 63.2450(j); 63.8000(d).

* * * * *

Subpart L—National Emission Standards for Coke Oven Batteries

■ 4. Section 63.300 is amended by revising paragraphs (b) and (e) to read as follows:

§ 63.300 Applicability.

* * * * *

(b) The provisions for new sources in §§ 63.302(b) and (c) and 63.303(b) apply to each greenfield coke oven battery and to each new or reconstructed coke oven battery at an existing coke plant if the changes to or addition of a coke oven battery results in an increase in the design capacity of the coke plant as of

[94] *Analysis of Demographic Factors for Populations Living Near Coke Oven Facilities—Final.* U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. May 2024. Docket ID Nos. EPA–HQ–OAR–2002–0085 and EPA–HQ–OAR–2003–0051.

November 15, 1990, (including any capacity qualifying under § 63.304(b)(6), and the capacity of any coke oven battery subject to a construction permit on November 15, 1990, which commenced operation before October 27, 1993.

* * * * *

(e) The emission limitations set forth in this subpart shall apply at all times. At all times, the owner or operator must 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 a source is operating in compliance with operation and maintenance requirements 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.

* * * * *

■ 5. Section 63.301 is amended by:
■ a. Adding a definition in alphabetical order for ''Bypass stack'';
■ b. Revising the definitions for ''By-product coke oven battery'' and ''Certified observer'';
■ c. Adding definitions in alphabetical order for ''Corrective action'', ''Day'', ''Fenceline'', ''Heat and/or nonrecovery coke oven battery'', ''Heat recovery steam generator'', ''Heat recovery steam generator bypass/waste heat stack'', ''Heat recovery steam generator main stack'';
■ d. Revising the definition for ''Nonrecovery coke oven battery'';
■ e. Adding definitions in alphabetical order for ''Not tall oven battery'';
■ f. Revising the definition for ''Pushing'';
■ g. Adding definitions in alphabetical order for ''Pushing/charging machine (PCM)'' and ''Root cause analysis'';
■ h. Revising the definition for ''Short coke oven battery''; and
■ i. Adding a definition in alphabetical order for ''Waste heat stack''.

The additions and revisions read as follows:

§ 63.301 Definitions.

* * * * *

Bypass stack at a heat recovery facility means a stack through which emissions are discharged from a common tunnel that collects gases from a coke oven battery. and where the emissions are not passed through a heat recovery unit. Common tunnels typically are equipped with afterburners to further reduce organic emissions in the coke oven gas.

By-product coke oven battery means a source consisting of a group of ovens connected by common walls, where coal undergoes destructive distillation under positive pressure to produce coke and coke oven gas, from which by-products are recovered.

Certified observer means a visual emission observer, certified under (if applicable) Method 303 and Method 9 or ASTM D7520–16 (if applicable; see § 63.14 for availability) and employed by the Administrator, which includes a delegated enforcement agency or its designated agent. For the purpose of notifying an owner or operator of the results obtained by a certified observer, the person does not have to be certified.

* * * * *

Corrective action means the design, operation and maintenance changes that one takes consistent with good engineering practice to reduce or eliminate the likelihood of the recurrence of the primary cause and any other contributing cause(s) of an event identified by a root cause analysis as having resulted in a discharge of gases from an affected facility in excess of specified thresholds.

Day for monitoring purposes means any operation of the unit of more than three hours total for any time in the 24-hour period between 12:00 a.m. on one calendar day and 12:00 a.m. on the next calendar day.

* * * * *

Fenceline is a location on the border of the coke oven manufacturing facility property.

* * * * *

Heat and/or nonrecovery coke oven battery means a group of ovens, connected by common side walls, in which coal undergoes destructive distillation under negative pressure to produce coke and coke oven gas and from which by-products are not recovered. The common tunnels typically contain afterburners to further reduce organic emissions in the coke oven gas. For nonrecovery plants (*i.e.,* no chemical recovery) with heat recovery, the oven gases are vented through common tunnels to a heat recovery steam generator that produces steam. Heat recovery coke oven batteries may release oven gases through common tunnels and then into the atmosphere through bypass stacks when the heat recovery steam generators are not available due to maintenance or repair. For nonrecovery coke oven batteries (*i.e.,* no chemical recovery) without heat recovery, oven gases are vented through common tunnels and then released to the atmosphere through waste heat stacks.

Heat recovery steam generator is a process unit that recovers heat from coke oven gas in order to produce steam. Units typically are equipped with desulfurization units and baghouses to remove pollutants from the exhaust gases.

Heat recovery steam generator bypass/waste heat stack means a stack that allows coke oven gas to be vented from the coke oven batteries through common tunnels and into the atmosphere when there are no heat recovery steam generator units available for heat recovery. Common tunnels typically are equipped with afterburners to further reduce organic emissions in the coke oven gas.

Heat recovery steam generator main stack means the stack that is the point of final discharge to the atmosphere of the gases emanating from a heat recovery steam generator and its control devices, which typically are desulfurization units and baghouses.

* * * * *

Nonrecovery coke oven battery means a source consisting of a group of ovens connected by common walls, where coal undergoes destructive distillation under negative pressure to produce coke, and which is designed for the combustion of the coke oven gas from which by-products are not recovered. Also known as a heat and/or nonrecovery battery. Nonrecovery coke oven battery refers to units from which heat is recovered from the coke oven gas exhaust as well as units where heat is not recovered. Both heat and/or nonrecovery batteries are connected by common tunnels that typically include afterburners to further reduce organic emissions in the coke oven gas.

Not tall oven battery means a coke oven battery with ovens less than 6 meters (20 feet) in height.

* * * * *

Pushing, for the purposes of § 63.305, means the coke oven operation that commences when the pushing ram starts into the oven to push out coke that has completed the coking cycle and ends when the quench car is clear of the coke side shed.

Pushing/charging machine (PCM) means the combined coke oven pushing and charging machine operated on rail tracks to open an oven door, push the finished coke from the open oven, and

close the oven door, and to charge the adjacent oven with coal to start the coking cycle. Typically used with horizontal ovens such as those at nonrecovery coke facilities.

Root cause analysis is an assessment conducted through a process of investigation to determine the primary underlying cause and all other contributing causes to an exceedance of an action level set forth in this rule.

* * * * *

Short coke oven battery means a coke oven battery with ovens less than 6 meters (20 feet) in height. Also called a ''not tall'' oven battery.

* * * * *

Waste heat stack at a heat and/or nonrecovery facility means a stack that allows coke oven gas to be vented from the coke oven batteries through common tunnels and into the atmosphere when there are no units available for heat recovery. Common tunnels typically contain afterburners to further reduce organic emissions in coke oven gas.

■ 6. Section 63.302 is amended by:
■ a. Adding paragraph (a)(4); and
■ b. Revising paragraph (d).

The addition and revision read as follows:

§ 63.302 Standards for by-product coke oven batteries.

(a) * * *

(4) On and after July 7, 2025:

(i) for facilities with coke production capacity more than or equal to 3 million tpy coke and as determined by the procedures in § 63.309(d)(1), 2.5 percent leaking coke oven doors for each tall by-product coke oven battery and 1.7 percent leaking coke oven doors for each not tall by-product coke oven battery;

(ii) for facilities with coke production capacity less than 3 million tpy coke and as determined by the procedures in § 63.309(d)(1), 3.8 percent leaking coke oven doors for each tall by-product coke oven battery and 3.2 percent leaking coke oven doors for each not tall by-product coke oven battery;

(iii) 0.32 percent leaking topside port lids, as determined by the procedures in § 63.309(d)(1);

(iv) 2.1 percent leaking offtake system(s), as determined by the procedures in § 63.309(d)(1); and

(v) 12 seconds of visible emissions per charge, as determined by the procedures in § 63.309(d)(2).

* * * * *

(d) Emission limitations and requirements applied to each coke oven battery utilizing a new recovery technology shall be less than the following emission limitations or shall result in an overall annual emissions rate for coke oven emissions for the battery that is lower than that obtained by the following emission limitations on and after July 7, 2025:

(1) Coke oven doors on by-product coke oven batteries at facilities with production capacity more than or equal to 3 million tpy coke:

(i) 2.5 percent leaking coke oven doors on tall by-product coke oven batteries, as defined in § 63.301 and as determined by the procedures in § 63.309(d)(1); and

(ii) 1.7 percent leaking coke oven doors for each not tall by-product coke oven battery, as determined by the procedures in § 63.309(d)(1);

(2) For coke oven doors on by-product coke oven batteries at facilities with coke production capacity less than 3 million tpy coke:

(i) 3.8 percent leaking coke oven doors on tall by-product coke oven batteries, as determined by the procedures in § 63.309(d)(1); and

(ii) 3.2 percent leaking coke oven doors on not tall by-product coke oven batteries, as determined by the procedures in § 63.309(d)(1);

(3) 2.1 percent leaking offtake system(s), as determined by the procedures in § 63.309(d)(1);

(4) 0.32 percent leaking topside port lids, as determined by the procedures in § 63.309(d)(1); and

(5) 12 seconds of visible emissions per charge, as determined by the procedures in § 63.309(d)(2).

■ 7. Section 63.303 is amended by revising paragraphs (a)(1), (b)(1), and (c) introductory text to read as follows:

§ 63.303 Standards for nonrecovery coke oven batteries.

(a) * * *

(1) For coke oven doors and common tunnels;

(i) 0.0 percent leaking coke oven doors, as determined by the procedures in § 63.309(d)(1); and

(ii) The owner or operator shall monitor and record, once per day for each day of operation, the pressure in each oven or in each common battery tunnel during pushing, charging, and coking to ensure that the ovens are operated under a negative pressure.

(iii) The date for compliance with (a)(1)(i) and (ii) of this section is on and after July 7, 2025.

* * * * *

(b) * * *

(1) For coke oven doors and common tunnels;

(i) 0.0 percent leaking coke oven doors, as determined by the procedures in § 63.309(d)(1); and

(ii) The owner or operator shall monitor and record, once per day for each day of operation, the pressure in each oven or in each common battery tunnel during pushing, charging, and coking to ensure that the ovens are operated under a negative pressure.

(iii) The date for compliance with (b)(1)(i) and (ii) of this section is on and after July 7, 2025, or upon initial startup, whichever is later.

* * * * *

(c) Except as provided in § 63.304(a), (b), and (d), the owner or operator of any nonrecovery coke oven battery shall meet the work practice standards in paragraphs (c)(1) and (2) of this section.

* * * * *

■ 8. Section 63.304 is amended by:
■ a. Revising paragraph (b)(6);
■ b. Designating the undesignated paragraph following paragraph (b)(6)(v) as (b)(7)
■ c. Adding paragraph (b)(8).

The revision and addition read as follows:

§ 63.304 Standards for compliance date extension.

* * * * *

(b) * * *

(6) The owner or operator of a cold-idle coke oven battery that shut down prior to November 15, 1990, shall submit a written request to the Administrator to include the battery in the design capacity of a coke plant as of November 15, 1990. A copy of the request shall also be sent to Director, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711. The Administrator will review and approve or disapprove a request according to the following procedures:

(i) Requests will be reviewed for completeness in the order received. A complete request shall include:

(A) Battery identification;

(B) Design information, including the design capacity and number and size of ovens; and

(C) A brief description of the owner or operator's plans for the cold-idle battery, including a statement whether construction of a padup rebuild or a brownfield coke oven battery is contemplated.

(ii) A complete request shall be approved if the design capacity of the battery and the design capacity of all previous approvals does not exceed the capacity limit in paragraph (b)(6)(i)(C) of this section.

(iii) The total nationwide coke capacity of coke oven batteries that receive approval under paragraph (b)(6) of this section shall not exceed 2.7 million Mg/yr (3.0 million ton/yr).

(iv) If a construction permit is required, an approval shall lapse if a construction permit is not issued within 3 years of the approval date, or if the construction permit lapses.

(v) If a construction permit is not required, an approval will lapse if the battery is not restarted within 2 years of the approval date.

(7) The owner or operator of a by-product coke oven battery with fewer than 30 ovens may elect to comply with an emission limitation of 2 or fewer leaking coke oven doors, as determined by the procedures in § 63.309(d)(4), as an alternative to the emission limitation for coke oven doors in paragraphs (b)(2)(i), (b)(3) (i) through (ii), (b)(4)(i), (b)(5), and (b)(6) of this section.

(8) On and after July 7, 2025:

(i) 2.5 percent leaking coke oven doors on each tall by-product coke oven battery and for each by-product coke oven battery owned or operated by a foundry coke producer, as determined by the procedures in § 63.309(d)(1) for facilities with production capacity greater than 3 million tpy coke or 1.7 percent leaking coke oven doors for each not tall by-product coke oven battery and for each by-product coke oven battery owned or operated by a foundry coke producer, as determined by the procedures in § 63.309(d)(1) for facilities with production capacity greater than 3 million tpy coke; and

(ii) 3.8 percent leaking coke oven doors on each tall by-product coke oven battery and for each by-product coke oven battery owned or operated by a foundry coke producer, as determined by the procedures in § 63.309(d)(1) for facilities with production capacity less than 3 million tpy coke or 3.2 percent leaking coke oven doors for each not tall by-product coke oven battery and for each by-product coke oven battery owned or operated by a foundry coke producer, as determined by the procedures in § 63.309(d)(1) for facilities with production capacity less than 3 million tpy coke.

* * * * *

■ 9. Section 63.305 is amended by:
■ a. Adding paragraph (c)(3)(iii); and.
■ b. Revising paragraphs (c)(5)(ii)(A) and (f)(4).

The addition and revisions read as follows:

§ 63.305 Alternative standards for coke oven doors equipped with sheds.

* * * * *

(c) * * *

(3) * * *

(iii) Alternatively, ASTM D7520–16, (incorporated by reference, see § 63.14) may be used with the following conditions:

(A) During the digital camera opacity technique (DCOT) certification procedure outlined in section 9.2 of ASTM D7520–16 (incorporated by reference, see § 63.14), the owner or operator or the DCOT vendor must present the plumes in front of various backgrounds of color and contrast representing conditions anticipated during field use such as blue sky, trees, and mixed backgrounds (clouds and/or a sparse tree stand).

(B) The owner or operator must also have standard operating procedures in place including daily or other frequency quality checks to ensure the equipment is within manufacturing specifications as outlined in section 8.1 of ASTM D7520–16 (incorporated by reference, see § 63.14).

(C) The owner or operator must follow the recordkeeping procedures outlined in § 63.10(b)(1) for the DCOT certification, compliance report, data sheets, and all raw unaltered JPEGs used for opacity and certification determination.

(D) The owner or operator or the DCOT vendor must have a minimum of four independent technology users apply the software to determine the visible opacity of the 300 certification plumes. For each set of 25 plumes, the user may not exceed 15 percent opacity of anyone reading and the average error must not exceed 7.5 percent opacity.

(E) Use of this approved alternative does not provide or imply a certification or validation of any vendor's hardware or software. The onus to maintain and verify the certification and/or training of the DCOT camera, software, and operator in accordance with ASTM D7520–16 (incorporated by reference, see § 63.14) and these requirements is on the facility, DCOT operator, and DCOT vendor.

* * * * *

(5) * * *

(ii) * * *

(A) Measure the total emission rate of benzene, toluene, and xylene exiting the control device using Method 18 in appendix A–6 to 40 CFR part 60 and the emission rate of benzene soluble organics entering the control device as described in the test plan submitted pursuant to paragraph (b) of this section. The voluntary consensus standard ASTM D6420–18, (incorporated by reference, see § 63.14) is an acceptable alternative to EPA Method 18 for benzene, toluene, and xylene; or

* * * * *

(f) * * *

(4) The opacity of emissions from the control device for the shed shall be monitored in accordance with the requirements of either paragraph (f)(4)(i) or (ii) of this section, at the election of the owner or operator.

(i) The owner or operator shall install, operate, and maintain a continuous opacity monitor, and record the output of the system, for the measurement of the opacity of emissions discharged from the emission control system per §§ 63.300(e) and 63.8(d)(1) and (2).

(A) Each continuous opacity monitoring system shall meet the requirements of Performance Specification 1 in appendix B to 40 CFR part 60; and

(B) Each continuous opacity monitoring system shall be operated, calibrated, and maintained according to the procedures and requirements specified in 40 CFR part 52; and

(C) The owner or operator shall keep the written procedures required by § 63.8(d)(1) and (2) on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan is revised, the owner or operator shall keep previous (*i.e.,* superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to the plan. The program of corrective action should be included in the plan required under § 63.8(d)(2); or

(ii) A certified observer shall monitor and record at least once each day during daylight hours, opacity observations for the control device for the shed using Method 9 in appendix A–4 to 40 CFR part 60. Alternatively, ASTM D7520–16, (incorporated by reference, see § 63.14) may be used with the following conditions:

(A) During the digital camera opacity technique (DCOT) certification procedure outlined in section 9.2 of ASTM D7520–16 (incorporated by reference, see § 63.14), the owner or operator or the DCOT vendor must present the plumes in front of various backgrounds of color and contrast representing conditions anticipated during field use such as blue sky, trees, and mixed backgrounds (clouds and/or a sparse tree stand).

(B) The owner or operator must also have standard operating procedures in place including daily or other frequency quality checks to ensure the equipment is within manufacturing specifications as outlined in section 8.1 of ASTM D7520–16 (incorporated by reference, see § 63.14).

(C) The owner or operator must follow the recordkeeping procedures outlined

in § 63.10(b)(1) for the DCOT certification, compliance report, data sheets, and all raw unaltered JPEGs used for opacity and certification determination.

(D) The owner or operator or the DCOT vendor must have a minimum of four independent technology users apply the software to determine the visible opacity of the 300 certification plumes. For each set of 25 plumes, the user may not exceed 15 percent opacity of anyone reading and the average error must not exceed 7.5 percent opacity.

(E) Use of this approved alternative does not provide or imply a certification or validation of any vendor's hardware or software. The onus to maintain and verify the certification and/or training of the DCOT camera, software, and operator in accordance with ASTM D7520–16 (incorporated by reference, see § 63.14) and these requirements is on the facility, DCOT operator, and DCOT vendor.

* * * * *

■ 10. Section 63.309 is amended by revising paragraphs (a) introductory text, (d)(1), (2), and (5), (g), (j)(1), (k) introductory text, (k)(1) introductory text, (k)(1)(iii), and (m) to read as follows:

§ 63.309 Performance tests and procedures.

(a) Except as otherwise provided, a daily performance test shall be conducted each day, 7 days per week for each new and existing coke oven battery, the results of which shall be used in accordance with procedures specified in this subpart to determine compliance with each of the applicable visible emission limitations for coke oven doors, topside port lids, offtake systems, and charging operations in this subpart. If a facility pushes and charges only at night, then that facility must, at its option, change their schedule and charge during daylight hours or provide adequate lighting so that visible emission inspections can be made at night. ''Adequate lighting'' will be determined by the enforcement agency. The performance test should be based on representative performance (*i.e.,* performance based on the entire range of normal operating conditions) of the affected source for the period being tested. Representative conditions exclude periods of startup and shutdown. You may not conduct performance tests during periods of malfunction. You 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 the entire range of normal operations, including operational conditions for maximum emissions if such emissions are not expected during maximum production. You shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

* * * * *

(d) * * *

(1) The 30-run rolling average of the percent leaking coke oven doors, topside port lids, and offtake systems on each coke oven battery, using the equations in sections 12.5, 12.6, and 12.7 of Method 303 (or section 12 of Method 303A) in appendix A to this part;

(2) For by-product coke oven battery charging operations, the logarithmic 30-day rolling average of the seconds of visible emissions per charge for each battery, using the equation in section 12.4 of Method 303 in appendix A to this part;

* * * * *

(5) For an approved alternative emission limitation for coke oven doors according to § 63.305, the weekly or monthly observation of the percent leaking coke oven doors using Method 303 in appendix A to this part, the percent opacity of visible emissions from the control device for the shed using Method 9 in appendix A–4 to 40 CFR part 60 or ASTM D7520–16 (incorporated by reference, see § 63.14), and visible emissions from the shed using Method 22 in appendix A–7 to 40 CFR part 60;

* * * * *

(g) Compliance with the alternative standards for nonrecovery coke oven batteries in § 63.303; shed inspection, maintenance requirements, and monitoring requirements for parameters affecting the shed exhaust or pushing/charging machine or equivalent device flow rate for batteries subject to alternative standards for coke oven doors under § 63.305; work practice emission control plan requirements in § 63.306; standards for bypass/bleeder stacks in § 63.307; and standards for collecting mains in § 63.308 is to be determined by the enforcement agency based on review of records and inspections.

* * * * *

(j) * * *

(1) Using a certified observer, determine the average opacity of five consecutive charges per week for each charging emissions capture system if charges can be observed according to the requirements of Method 9 in appendix A–4 to 40 CFR part 60 or ASTM D7520–16 (as applicable; incorporated by reference, see § 63.14), except as specified in paragraphs (j)(1)(i) and (ii) of this section.

(i) Instead of the procedures in section 2.4 of Method 9 in appendix A–4 to 40 CFR part 60 or section 8.4 of ASTM D7520–16 (as applicable; incorporated by reference, see § 63.14), record observations to the nearest 5 percent at 15-second intervals for at least five consecutive charges.

(ii) Instead of the procedures in section 2.5 of Method 9 in appendix A–4 to 40 CFR part 60 or section 8.5 of ASTM D7520–16 (as applicable; incorporated by reference, see § 63.14), determine and record the highest 3-minute average opacity for each charge from the consecutive observations recorded at 15-second intervals.

* * * * *

(k) The owner or operator of a new nonrecovery coke oven battery shall conduct a performance test to demonstrate initial compliance with the emission limitations for a charging emissions control device in § 63.303(d)(2) within 180 days of the compliance date that is specified for the affected source in § 63.300(a)(4) and report the results in the notification of compliance status. The owner or operator shall prepare a site-specific test plan according to the requirements in § 63.7(c) and shall conduct each performance test according to the requirements in paragraphs (a) and (k)(1) through (4) of this section.

(1) Determine the concentration of PM according to the following test methods in appendices A–1 through A–3 to 40 CFR part 60

* * * * *

(iii) Method 3, 3A, or 3B to determine the dry molecular weight of the stack gas. You may also use as an alternative to Method 3B, the manual method (but not instrumental procedures) for measuring the oxygen, carbon dioxide, and carbon monoxide content of exhaust gas, ANSI/ASME PTC 19.10–1981 (incorporated by reference, see § 63.14).

* * * * *

(m) Visible emission observations of a charging emissions control device required by § 63.303(d)(3)(iii) must be performed by a certified observer according to Method 9 in appendix A–4 to 40 CFR part 60 or ASTM D7520–16 (as applicable; incorporated by reference, see § 63.14) for one 6-minute period.

■ 11. Remove and reserve § 63.310.

§ 63.310 [Removed and Reserved]

■ 12. Section 63.311 is amended by:

■ a. Removing paragraphs (b)(2) and (5).

■ b. Redesignating paragraphs (b)(3) and (4) as paragraphs (b)(2) and (3), and paragraphs (b)(6) and (7) as paragraphs (b)(4) and (5);
■ c. Revising and republishing paragraphs (d);
■ d. Revising paragraphs (e), (f) introductory text, (f)(1)(iv), and (f)(2)(ii)(A);
■ e. Removing paragraph (f)(6).
■ f. Adding a paragraph heading to paragraph (g);
■ g. Revising paragraph (g)(1); and
■ h. Adding paragraphs (h) through (l).

The revisions and additions read as follows:

§ 63.311 Reporting and recordkeeping requirements.

* * * * *

(d) *Semiannual compliance certification.* The owner or operator of a coke oven battery shall include the following information in the semiannual compliance certification:

(1) Certification, signed by the owner or operator, that no coke oven gas was vented, except through the bypass/bleeder stack flare system of a by-product coke oven battery during the reporting period or that a venting report has been submitted according to the requirements in paragraph (e) of this section.

(2) Certification, signed by the owner or operator, that work practices were implemented if applicable under § 63.306.

(3) Certification, signed by the owner or operator, that all work practices for nonrecovery coke oven batteries were implemented as required in § 63.303(b)(3).

(4) Certification, signed by the owner or operator, that all coke oven door leaks on a nonrecovery battery were stopped according to the requirements in § 63.303(c)(2) and (3). If a coke oven door leak was not stopped according to the requirements in § 63.303(c)(2) and (3), or if the door leak occurred again during the coking cycle, the owner or operator must report the information in paragraphs (d)(4)(i) through (iv) of this section.

(i) The oven number of each coke oven door for which a leak was not stopped according to the requirements in § 63.303(c)(2) and (3) or for a door leak that occurred again during the coking cycle.

(ii) The total duration of the leak from the time the leak was first observed.

(iii) The cause of the leak (including unknown cause, if applicable), any actions taken to minimize emissions in accordance with and § 63.300(e), the corrective action taken to stop the leak.

(iv) Whether the failure occurred during a period of startup, shutdown or malfunction.

(5) Certification, signed by the owner or operator, that the opacity of emissions from charging operations for a new nonrecovery coke oven battery did not exceed 20 percent. If the opacity limit in § 63.303(d)(1) was exceeded, the owner or operator must report the number, duration, and cause of the deviation (including unknown cause, if applicable), and the corrective action taken

(6) Before September 3, 2024, report the results of any PM performance test for a charging emissions control device for a new nonrecovery coke oven battery conducted during the reporting period as required in § 63.309(l). Beginning on September 3, 2024, report PM performance test results according to paragraph (i) of this section.

(7) Certification, signed by the owner or operator, that all work practices for a charging emissions control device for a new nonrecovery coke oven battery were implemented as required in § 63.303(d)(3). If a Method 9 in appendix A–4 to 40 CFR part 60 or ASTM D7520–16 (as applicable; incorporation by reference, see § 63.14) visible emissions observation exceeds 10 percent, the owner or operator must report the duration and cause of the deviation (including unknown cause, if applicable), and the corrective action taken.

(8) Certification, signed by the owner or operator, that all work practices for oven dampers on a new nonrecovery coke oven battery were implemented as required in § 63.303(d)(4).

(9) Facility name and address (including the county) and the beginning and ending date of the reporting period.

(e) *Report for the venting of coke oven gas other than through a flare system.* The owner or operator shall report any venting of coke oven gas through a bypass/bleeder stack that was not vented through the bypass/bleeder stack flare system to the Administrator as soon as practicable but no later than 24 hours after the beginning of the event. A written or electronic report shall be submitted within 30 days of the event and shall include a description of the event and, if applicable, a copy of the notification for a hazardous substance release required pursuant to 40 CFR 302.6.

(f) *Recordkeeping.* The owner or operator shall maintain files of all required information in a permanent form suitable for inspection at an onsite location for at least 1 year and must thereafter be accessible within 3 working days to the Administrator for the time period specified in 40 CFR 70.6(a)(3)(ii)(B). Copies of the work practice plan developed under § 63.306 shall be kept onsite at all times. The owner or operator shall record the occurrence and duration of each startup, shutdown, or malfunction of process, air pollution control, and monitoring equipment, and maintain the following information:

(1) * * *

(iv) Records to demonstrate compliance with the work practice requirement for door leaks in § 63.303(c). These records must include the oven number of each leaking door, total duration of the leak from the time the leak was first observed, the cause of the leak (including unknown cause, if applicable), the corrective action taken to return the affected unit to its normal or usual manner operation, and the amount of time taken to stop the leak from the time the leak was first observed. Beginning on January 2, 2025, an estimate of the quantity of each regulated pollutant emitted over any emission limit, a description of the method used to estimate the emissions, and whether the failure occurred during a period of startup, shutdown or malfunction. If you failed to meet an applicable standard, the compliance report must include the start date, start time, cause, and duration (in hours) of each failure. For each failure, beginning on January 2, 2025, the compliance report must include a list of the affected sources or equipment, actions taken to minimize emissions, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

* * * * *

(2) * * *

(ii) * * *

(A) Records of opacity readings from the continuous opacity monitor for the control device for the shed. Beginning on January 2, 2025, if you failed to meet an applicable standard, the compliance report must include whether the failure occurred during a period of startup, shutdown, or malfunction of process, air pollution control, and monitoring equipment; the start date, start time, and duration (in hours) of each failure; and any corrective actions taken to return the affected unit to its normal or usual manner of operation. For each failure, beginning on January 2, 2025, the compliance report must include a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the

method used to estimate the emissions; and

* * * * *

(g) *Record availability.* * * *

(1) Requests under paragraph (g) of this section shall be submitted in writing or electronically, and shall identify the records or reports that are subject to the request with reasonable specificity;

* * * * *

(h) *Electronic reporting of compliance certification reports.* Beginning on July 7, 2025, or once the report template for this subpart has been available on the EPA's Compliance and Emissions Data Reporting Interface (CEDRI) website for one year, whichever date is later, submit all subsequent reports to the EPA via the CEDRI according to § 63.9(k) except that confidential business information (CBI) should be submitted according to paragraph (k) of this section.

(i) *Electronic Reporting of Performance Tests.* Beginning on September 3, 2024, within 60 days after the date of completing each performance test required by this subpart, you must submit the results of the performance test following the procedure specified in § 63.9(k) except that CBI should submitted be according to paragraph (k) of this section. Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (*https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert*) at the time of the test must be submitted in a file format generated using the EPA's ERT. Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on the EPA's ERT website. Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test must be included as an attachment in the ERT or alternate electronic file. If a performance test consists only of opacity or EPA Method 303 measurements, reporting using the ERT and CEDRI is not required.

(j) *Fenceline monitoring reporting.* For fenceline monitoring systems subject to § 63.314 of this subpart, each owner or operator must submit fenceline monitoring reports on a quarterly basis using the appropriate electronic template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/cedri*) for this subpart and following the procedure specified in § 63.9(k), except any medium submitted through mail must be sent to the attention of the Coke Ovens Sector Lead. The first quarterly report must cover the period beginning on the compliance date that is specified in § 63.314(a) of this subpart and ending on March 31, June 30, September 30 or December 31, whichever date is the first date that occurs after the owner or operator has completed at least one sampling period. Each subsequent quarterly report must cover one of the following reporting periods: Quarter 1 from January 1 through March 31; Quarter 2 from April 1 through June 30; Quarter 3 from July 1 through September 30; and Quarter 4 from October 1 through December 31. Each quarterly report must be electronically submitted no later than 45 calendar days following the end of the reporting period.

(1) Facility name and address (including the county).

(2) Year and reporting quarter (*i.e.,* Quarter 1, Quarter 2, Quarter 3, or Quarter 4).

(3) For each passive tube monitor: The latitude and longitude location coordinates; the sampler name; and identification of the type of sampler (*i.e.,* regular monitor, extra monitor, duplicate, field blank, inactive). Coordinates must be in decimal degrees with at least five decimal places.

(4) The beginning and ending dates for each sampling period.

(5) Individual sample results for benzene reported in units of micrograms per cubic meter ($\mu g/m^3$) for each monitor for each sampling period that ends during the reporting period. Results below the method detection limit shall be flagged as below the detection limit and reported at the method detection limit. Where individual sample results are corrected according to a site specific monitoring plan according to § 63.314(f), both the original and the corrected results are reported.

(6) Data flags that indicate each monitor that was skipped for the sampling period, if the owner or operator uses an alternative sampling frequency under § 63.314(a)(2)(iii).

(7) Data flags for each outlier determined in accordance with section 9.2 of Method 325A in appendix A to this part. For each outlier, the owner or operator must submit the individual sample result of the outlier, as well as the evidence used to conclude that the result is an outlier.

(8) The biweekly concentration difference (Δc) for benzene for each sampling period and, beginning the first quarterly report with sufficient data to calculate an annual average, the annual average Δc for benzene for each sampling period.

(9) Indication of whether the owner or operator was required to develop a corrective action plan under § 63.314(e) of this subpart.

(k) *Confidential business information (CBI).* For notifications and reports required to be submitted to CEDRI:

(1) The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim for some of the information submitted under paragraphs (h) or (i) of this section, you must submit a complete file, including information claimed to be CBI, to the EPA.

(2) For performance test reports according to paragraph (j) of this section, the file must be generated using the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website.

(3) Clearly mark the part or all of the information that you claim to be CBI. Information not marked as CBI may be authorized for public release without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

(4) The preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol, or other online file sharing services. Electronic submissions must be transmitted directly to the OAQPS CBI Office at the email address *oaqpscbi@epa.gov,* and as described above, should include clear CBI markings. For performance test reports, the CBI should be flagged to the attention of the Group Leader, Measurement Policy Group; for all other reports and notifications, to the attention of the Coke Ovens Sector Lead. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email *oaqpscbi@epa.gov* to request a file transfer link.

(5) If you cannot transmit the file electronically, you may send CBI information through the postal service to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Group Leader, Measurement Policy Group or Coke Oven Sector Lead as indicated in paragraph (k)(4) of this section. The mailed CBI material should be double wrapped and clearly marked. Any CBI

markings should not show through the outer envelope.

(6) All CBI claims must be asserted at the time of submission. Anything submitted using CEDRI cannot later be claimed CBI. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(7) You must submit the same file submitted to the CBI office with the CBI omitted to the EPA via the EPA's CDX as described in paragraphs (h), (i), or (j) of this section.

(l) *Fenceline monitoring recordkeeping.* For fenceline monitoring systems subject to § 63.314, each owner or operator shall keep the records specified in paragraphs (l)(1) through (10) of this section on an ongoing basis.

(1) Coordinates of all fenceline monitors, including co-located samplers and field blanks, and if applicable, the meteorological station. The owner or operator shall determine the coordinates using an instrument with an accuracy of at least 3 meters. The coordinates shall be in decimal degrees with at least five decimal places.

(2) The start and stop times and dates for each sample, as well as the tube identifying information.

(3) Sampling period average temperature and barometric pressure measurements.

(4) For each outlier determined in accordance with Section 9.2 of Method 325A in appendix A to this part, the sampler location of and the concentration of the outlier and the evidence used to conclude that the result is an outlier.

(5) For samples that will be adjusted for a background, the location of and the concentration measured simultaneously by the background sampler(s), and the perimeter samplers to which it applies.

(6) Individual sample results, the calculated Δc for benzene for each sampling period and the two samples used to determine it, whether background correction was used, and the annual average Δc calculated after each sampling period.

(7) Method detection limit for each sample, including co-located samples and blanks.

(8) Documentation of the root cause analysis and any corrective action taken each time the action level was exceeded, including the dates the root cause analysis was initiated and the resulting correction action(s) were taken.

(9) Any corrective action plan developed under § 63.314(e).

(10) Other records as required by Methods 325A and 325B in appendix A to this part.

(11) If a near-field source correction is used as provided in § 63.314(f), or if an alternative test method is used that provides time-resolved measurements, records of hourly meteorological data, including temperature, barometric pressure, wind speed and wind direction, calculated daily unit vector wind direction and daily sigma theta, and other records specified in the site-specific monitoring plan.

■ 13. Section 63.313 is amended by adding paragraph (d)(6) to read as follows:

§ 63.313 Implementation and enforcement.

* * * * *

(d) * * *

(6) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

■ 14. Add § 63.314 to subpart L to read as follows:

§ 63.314 Fenceline monitoring provisions.

For each by-product coke oven battery facility as defined in § 63.301 of this subpart, beginning no later than July 7, 2025, the owner or operator of a coke manufacturing facility shall conduct sampling along the facility property boundary and analyze the samples in accordance with paragraphs (a) through (g) of this section.

(a) The owner or operator must conduct sampling along the facility property boundary and analyze the samples in accordance with Methods 325A and 325B in appendix A to this part and paragraphs (a)(1) through (a)(2) of this section. The monitoring perimeter may be located within the facility, inside the facility property boundary. However, the monitoring perimeter must encompass all potential sources of benzene that are located within the facility's property boundary.

(1) The target analyte is benzene. The owner or operator must follow the procedure in section 9.6 of Method 325B in appendix A to this part to determine the detection limit of benzene for each sampler used to collect samples and blanks.

(2) The owner or operator must use a sampling period and sampling frequency as specified in paragraphs (a)(2)(i) through (a)(2)(iii) of this section.

(i) A 14-day sampling period must be used unless a shorter sampling period is determined to be necessary under paragraph (e) or (g) of this section. A sampling period is defined as the period during which a sampling tube is deployed at a specific sampling location with the diffusive sampling end cap in-place and does not include the time required to analyze the sample. For the purpose of this subpart, a 14-day sampling period may be no shorter than 13 calendar days and no longer than 15 calendar days, but the routine sampling period must be 14 calendar days.

(ii) Except as provided in paragraph (a)(2)(iii) of this section, the frequency of sample collection must be once each contiguous 14-day sampling period, such that the beginning of the next 14-day sampling period begins immediately upon the completion of the previous 14-day sampling period.

(iii) When an individual monitor consistently achieves results for benzene at or below the level specified in paragraph (a)(3) of this section, the owner or operator may elect to use the applicable minimum sampling frequency specified in paragraphs (a)(2)(iii)(A) through (E) of this section for that monitoring site. When calculating Δc for the monitoring period when using this alternative for burden reduction, use zero for the lowest sampling result for each monitoring period where one or more samples was not taken and/or analyzed for benzene.

(A) If every sample at a monitoring site is at or below the level specified in paragraph (a)(3) of this section for 2 years (52 consecutive samples), every other sampling period can be skipped for that monitoring site, *i.e.,* sampling will occur approximately once per month.

(B) If every sample at a monitoring site that is monitored at the frequency specified in paragraph (a)(2)(iii)(A) of this section is at or below the level specified in paragraph (a)(3) of this section for 2 years (*i.e.,* 26 consecutive ''monthly'' samples), five 14-day sampling periods can be skipped for that monitoring site following each period of sampling, *i.e.,* sampling will occur approximately once per quarter.

(C) If every sample at a monitoring site that is monitored at the frequency specified in paragraph (a)(2)(iii)(B) of this section is at or below the level specified in paragraph (a)(3) of this section for 2 years (*i.e.,* 8 consecutive quarterly samples), twelve 14-day sampling periods can be skipped for that monitoring site following each period of sampling, *i.e.,* sampling will occur twice a year.

(D) If every sample at a monitoring site that is monitored at the frequency specified in paragraph (a)(2)(iii)(C) of this section is at or below the level specified in paragraph (a)(3) of this section for 2 years (*i.e.,* 4 consecutive semiannual samples), only one sample per year is required for that monitoring site. For yearly sampling, samples shall

occur at least 10 months but no more than 14 months apart.

(E) If at any time a sample for a monitoring site that is monitored at the frequency specified in paragraph (a)(2)(iii)(A) through (D) of this section returns a result that is above the level specified in paragraph (a)(3) of this section, the sampling site must return to the original sampling requirements of contiguous 14-day sampling periods with no skip periods for one quarter (six 14-day sampling periods). If every sample collected during this quarter is at or below the level specified in paragraph (a)(3) of this section, the owner or operator may revert back to the reduced monitoring schedule applicable for that monitoring site prior to the sample reading exceeding the level specified in paragraph (a)(3) of this section. If any sample collected during this quarter is above the level specified in paragraph (a)(3) of this section, that monitoring site must return to the original sampling requirements of contiguous 14-day sampling periods with no skip periods for a minimum of two years. The burden reduction requirements can be used again for that monitoring site once the requirements of paragraph (a)(2)(iii)(A) of this section are met again, *i.e.,* after 52 contiguous 14-day samples with no results above the level specified in paragraph (a)(3) of this section.

(3) To use the alternative sampling frequency outlined in paragraph (a)(2) of this section, an individual monitor must consistently achieve results for benzene at or below 0.7 $\mu g/m^3$.

(b) The owner or operator shall collect and record meteorological data according to the applicable requirements in paragraphs (b)(1) through (3) of this section.

(1) If a near-field source correction is used as provided in paragraph (f)(2) of this section and/or if an alternative test method is used that provides time-resolved measurements, the owner or operator must use an on-site meteorological station in accordance with section 8.3 of Method 325A in appendix A to this part. Collect and record hourly average meteorological data, including temperature, barometric pressure, wind speed and wind direction, and calculate daily unit vector wind direction and daily sigma theta.

(2) For cases other than those specified in paragraph (b)(1) of this section, the owner or operator shall collect and record sampling period average temperature and barometric pressure using either an on-site meteorological station in accordance with section 8.3 of Method 325A in appendix A to this part or, alternatively, using data from a National Weather Service (NWS) meteorological station provided the NWS meteorological station is within 40 kilometers (25 miles) of the coke manufacturing facility.

(3) If an on-site meteorological station is used, the owner or operator shall follow the calibration and standardization procedures for meteorological measurements in EPA–454/B–08–002 (incorporated by reference, see § 63.14).

(c) Within 45 days of completion of each sampling period, the owner or operator shall determine whether the results are above or below the action level as follows.

(1) The owner or operator must determine the facility impact on the benzene concentration (Δc) for each sampling period according to either paragraph (c)(1)(i) or (ii) of this section, as applicable.

(i) Except when near-field source correction is used as provided in paragraph (c)(1)(ii) of this section, the owner or operator shall determine the highest and lowest sample results for benzene concentrations from the sample pool and calculate Δc as the difference in these concentrations. Co-located samples must be averaged together for the purposes of determining the benzene concentration for that sampling location, and, if applicable, for determining Δc. The owner or operator shall adhere to the following procedures when one or more samples for the sampling period are below the method detection limit for benzene:

(A) If the lowest detected value of benzene is below detection, the owner or operator shall use zero as the lowest sample result when calculating Δc.

(B) If all sample results are below the method detection limit, the owner or operator shall use the method detection limit as the highest sample result and zero as the lowest sample result when calculating Δc.

(C) In the case of co-located samples, if one sample is above the method detection limit while the other sample is below the method detection limit, the owner or operator must use the method detection limit as the result for the sample that is below the method detection limit for purposes of averaging the results to determine the concentration at a particular sampling location, and, if applicable, for determining Δc.

(ii) When near-field source correction is used as provided in paragraph (f)(2) of this section, the owner or operator must determine Δc using the calculation protocols outlined in paragraph (c)(1)(i) of this section except as provided in this paragraph (c)(1)(ii), and the additional requirements in paragraph (f)(2) of this section, as well as any additional requirements outlined in the approved site-specific monitoring plan. The Δc for the sampling period is equal to the higher of the values in paragraphs (c)(1)(ii)(A) and (B) of this section.

(A) The highest corrected sample result from a sampling location where near-field source correction is used during the sampling period.

(B) The difference in concentration between the highest sample result that was not corrected for a near-field source during the sampling period and the lowest sample result for the sampling period.

(2) The owner or operator must calculate the annual average Δc based on the average of the 26 most recent 14-day sampling periods. The owner or operator must update this annual average value after receiving the results of each subsequent 14-day sampling period.

(3) The action level for benzene is 7 $\mu g/m^3$ on an annual average basis. If the annual average Δc value for benzene is greater than 7 $\mu g/m^3$, the concentration is above the action level, and the owner or operator must conduct a root cause analysis and corrective action in accordance with paragraph (d) of this section.

(d) Once the action level in paragraph (c)(3) of this section has been exceeded, the owner or operator must take the following actions to bring the annual average Δc back below the action level.

(1) Within 5 days of updating the annual average value as required in paragraph (c)(2) of this section and determining that the action level in paragraph (c)(3) of this section has been exceeded (*i.e.,* in no case longer than 50 days after completion of the sampling period), the owner or operator must initiate a root cause analysis to determine appropriate corrective action. A root cause analysis is an assessment conducted through a process of investigation to determine the primary underlying cause and all other contributing causes to an exceedance of the action level set forth in paragraph (c)(3) of this section.

(i) Root cause analysis may include, but is not limited to:

(A) Leak inspection using Method 21 in appendix A–7 to 40 CFR part 60, optical gas imaging, or handheld monitors.

(B) Visual inspection to determine the cause of the high benzene emissions.

(C) Employing progressively more frequent sampling, analysis and meteorology (*e.g.,* using shorter

sampling periods for Methods 325A and 325B in appendix A to this part, or using active sampling techniques, like those utilized as part of a site-specific monitoring plan).

(D) Operator knowledge of process changes (*e.g.,* a malfunction or release event).

(ii) If the root cause cannot be identified using the type of techniques described in paragraph (d)(1)(i) of this section, the owner or operator must employ more frequent sampling and analysis to determine the root cause of the exceedance.

(A) The owner or operator may first employ additional monitoring points and shorter sampling periods for Methods 325A and 325B in appendix A to this part for benzene to determine the root cause of the exceedance.

(B) If the owner or operator has not determined the root cause of the exceedance within 30 days of determining that the action level has been exceeded, the owner or operator must employ the appropriate real-time sampling techniques (*e.g.,* mobile gas chromatographs, optical spectroscopy instruments, sensors) to locate the cause of the exceedance. If the root cause is not identified after 48 hours, either the real-time monitor must be relocated or an additional real-time monitor must be added. Relocation or addition of extra real-time monitors must continue after each 48-hour period of nonidentification until the owner or operator can identify the root cause of the exceedance.

(2) If either the underlying primary or other contributing causes of the exceedance are deemed to be under the control of the owner or operator and subject to a regulation codified in 40 CFR part 63, except as provided in paragraph (c)(3) of this section, the owner or operator must take appropriate corrective action as expeditiously as possible to bring annual average fenceline concentrations back below the action level set forth in paragraph (c)(3) of this section and to prevent future exceedances from the same underlying cause(s).

(3) If the underlying primary or other contributing cause of the exceedance is under the control of the owner or operator but not subject to a regulation codified in 40 CFR part 63, as evidenced through the root cause analysis in paragraph (d)(1) of this section and supported by appropriate real-time sampling techniques consistent with paragraph (d)(1)(ii)(B) of this section, the owner or operator is not required to take corrective action under this subpart at any portion of the facility not subject to a regulation codified in 40 CFR part 63. However, the owner or operator must add additional monitoring locations in accordance with section 8.2.1.3 of EPA Method 325A in appendix A to this part or update their site-specific monitoring plan to add additional real-time monitors to account and correct for this near-field source of emissions not subject to a regulation codified in 40 CFR part 63 within 60 days of determining the underlying cause.

(4) The root cause analysis must be completed and initial corrective actions, if applicable, taken no later than 45 days after determining there is an exceedance of an action level.

(5) Except as noted in paragraph (d)(6) of this section, until the annual average Δc is below the action level again, following the completion of the initial corrective action, the owner or operator must conduct a new root cause analysis according to this paragraph (d), and if required, submit a corrective action plan under paragraph (e) of this section following any sampling period for which the Δc for the sampling period is greater than the action level in paragraph (c)(3) of this section.

(6) This paragraph applies when an owner or operator is required under paragraph (d)(3) of this section to update the site-specific monitoring plan to account for an additional near-field emission source. Until the annual average Δc is below the action level again, following implementation of the approved revision to the site-specific monitoring plan, the owner or operator must conduct a new root cause analysis according to this paragraph (d), and if required, submit a corrective action plan under paragraph (e) of this section following any sampling period for which the Δc for the sampling period is greater than the action level in paragraph (c)(3) of this section.

(e) An owner or operator must develop a corrective action plan if any of the conditions in paragraphs (e)(1) through (e)(3) of this section are met. The corrective action plan must describe the corrective action(s) completed to date, additional measures that the owner or operator proposes to employ to reduce annual average fenceline concentrations below the action level set forth in paragraph (c)(3) of this section, and a schedule for completion of these measures. The corrective action plan does not need to be approved by the Administrator. However, if upon review, the Administrator disagrees with the additional measures outlined in the plan, the owner or operator must revise and resubmit the plan within 7 calendar days of receiving comments from the Administrator.

(1) Except as noted in paragraph (e)(3) of this section, if upon completion of the root cause analysis and initial corrective actions required under paragraph (d) of the section, the Δc value for the next sampling period, for which the sampling start time begins after the completion of the initial corrective actions, is greater than the level specified in paragraph (c)(3) of this section. The corrective action plan must include the implementation of real-time sampling techniques to locate the primary and other contributing causes of the exceedance. The owner or operator must submit the corrective action plan to the Administrator within 60 days after receiving the analytical results indicating that the Δc value for the sampling period following the completion of the initial corrective action is greater than the level specified in paragraph (c)(3) of this section.

(2) The owner or operator must develop a corrective action plan if complete implementation of all corrective measures identified in the root cause analysis required by paragraph (e) of this section will require more than 45 days. The owner or operator must submit the corrective action plan to the Administrator no later than 60 days following the completion of the root cause analysis required in paragraph (d) of this section.

(3) The owner or operator must develop a corrective action plan if upon completion of the root cause analysis and following implementation of the approved revision to the site-specific monitoring plan required under paragraph (d)(3) of this section, the Δc value for the next sampling period, for which the sampling start time begins after implementation of the approved revision to the site-specific monitoring plan, is greater than the level specified in paragraph (c)(3) of this section. The corrective action plan must include the implementation of real-time sampling techniques to locate the primary and other contributing causes of the exceedance. The owner or operator must submit the corrective action plan to the Administrator within 60 days after receiving the analytical results indicating that the Δc value for the sampling period following the implementation of the approved revision to the site-specific monitoring plan is greater than the level specified in paragraph (c)(3) of this section.

(f) An owner or operator may request approval from the Administrator for a site-specific monitoring plan to account for offsite upwind sources or onsite sources not subject to a regulation

codified in 40 CFR part 63 according to the requirements in paragraphs (f)(1) through (4) of this section.

(1) The owner or operator must prepare and submit a site-specific monitoring plan and receive approval of the site-specific monitoring plan prior to using the near-field source alternative calculation for determining Δc provided in paragraph (f)(2) of this section. The site-specific monitoring plan shall include, at a minimum, the elements specified in paragraphs (f)(1)(i) through (v) of this section. The procedures in section 12 of Method 325A in appendix A to this part are not required, but may be used, if applicable, when determining near-field source contributions.

(i) Identification of the near-field source or sources. For onsite sources, specify that the onsite source is not subject to a regulation codified in 40 CFR part 63 and identify any federal regulation or federally enforceable permit condition the source is subject to.

(ii) Identification of the fenceline monitoring locations impacted by the near-field source. If more than one near-field source is present, identify the near-field source or sources that are expected to contribute to the concentration at each monitoring location.

(iii) A description of (including sample calculations illustrating) the planned data reduction; treatment of invalid data and data below detection limits; and calculations to determine the near-field source concentration contribution for each monitoring location.

(iv) A detailed description of the measurement technique, measurement location(s), the standard operating procedures, measurement frequency, recording frequency, measurement detection limit, and data quality indicators to ensure accuracy, precision, and validity of the data. If you are accounting for on-site sources, you must use a real-time sampling technique (*e.g.,* mobile gas chromatographs, optical spectroscopy instruments, sensors).

(v) A detailed description of how data will be handled during periods of calm wind conditions (*i.e.,* less than 2 miles per hour).

(2) When an approved site-specific monitoring plan is used, the owner or operator shall determine Δc for comparison with action level according to paragraph (c) of this section. When determining the sample results for use in the Δc calculation, the concentration for any monitor that has been corrected using an approved site-specific monitoring plan will be corrected according to the procedures specified in paragraphs (f)(2)(i) and (ii) of this section.

(i) For each monitoring location corrected using the site-specific monitoring plan, the corrected fenceline concentration at that monitoring station will be equal to the fenceline concentration measured with Methods 325A and 325B in appendix A to this part minus the near-field source contributing concentration at the measurement location determined using the additional measurements and calculation procedures included in the approved site-specific monitoring plan.

(ii) If the fenceline concentration at the monitoring station is below the method detection limit for Methods 325A and 325B in appendix A to this part, no near-field source contribution can be subtracted from that monitoring station for that sampling period.

(3) The site-specific monitoring plan shall be submitted and approved as described in paragraphs (f)(3)(i) through (iv) of this section.

(i) The site-specific monitoring plan must be submitted to the Administrator for approval.

(ii) The site-specific monitoring plan shall also be submitted to the following address: U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, U.S. EPA Mailroom (D243–02), Attention: Metals and Inorganic Chemicals Group, 109 T.W. Alexander Drive, Research Triangle Park, NC 27711. Electronic copies in lieu of hard copies also may be submitted to *fencelineplan@epa.gov.*

(iii) The Administrator shall approve or disapprove the plan in 120 days. The plan shall be considered approved if the Administrator either approves the plan in writing or fails to disapprove the plan in writing. The 120-day period shall begin when the Administrator confirms receipt of a complete site-specific monitoring plan.

(iv) If the Administrator finds any deficiencies in the site-specific monitoring plan and disapproves the plan in writing, the owner or operator may revise and resubmit the site-specific monitoring plan following the requirements in paragraphs (f)(3)(i) and (ii) of this section. The 120-day period starts over with the resubmission of the revised monitoring plan. The Administrator may indicate in writing that a submitted plan is incomplete and specify the information necessary for completeness.

(4) The approval by the Administrator of a site-specific monitoring plan will be based on the completeness, accuracy and reasonableness of the request for a site-specific monitoring plan. Factors that the Administrator will consider in reviewing the request for a site-specific monitoring plan include, but are not limited to, those described in paragraphs (f)(4)(i) through (v) of this section.

(i) The identification of the near-field source or sources and evidence of how the sources impact the fenceline concentration.

(ii) The location(s) selected for additional monitoring to determine the near-field source concentration contribution.

(iii) The identification of the fenceline monitoring locations impacted by the near-field source or sources.

(iv) The appropriateness of the planned data reduction and calculations to determine the near-field source concentration contribution for each monitoring location, including the handling of invalid data, data below the detection limit, and data during calm periods.

(v) The adequacy of the description of and the rationale for the measurement technique, measurement location(s), the standard operating procedure, the measurement and recording frequency, measurement detection limit, and data quality indicators proposed to ensure accuracy, precision, and validity of the data.

(g) The owner or operator shall comply with the applicable recordkeeping and reporting requirements in § 63.311.

(h) As outlined in § 63.7(f), the owner or operator may submit a request for an alternative test method. At a minimum, the request must follow the requirements outlined in paragraphs (h)(1) through (7) of this section.

(1) The alternative method may be used in lieu of all samplers or a partial number of the passive samplers required in Method 325A in appendix A to this part.

(2) The alternative method must be validated according to Method 301 in appendix A of this part or contain performance-based procedures and indicators to ensure self-validation.

(3) The method detection limit must nominally be at least one-third of the action level. The alternate test method must describe the procedures used to provide field verification of the detection limit in the sample matrix being measured.

(4) If the alternative test method will be used to replace some or all passive samplers required under paragraph (a) of this section, the spatial coverage must be equal to or better than the spatial coverage provided in Method 325A in appendix A to this part.

(i) For path average concentration open-path instruments, the physical path length of the measurement shall be no more than a passive sample footprint (the spacing that would be provided by the sorbent traps when following Method 325A). For example, if Method 325A requires spacing monitors A and B 610 meters (2000 feet) apart, then the physical path length limit for the measurement at that portion of the fenceline shall be no more than 610 meters (2000 feet).

(ii) For range resolved open-path instrument or approach, the instrument or approach must be able to resolve an average concentration over each passive sampler footprint within the path length of the instrument.

(iii) The extra samplers required in sections 8.2.1.3 of Method 325A may be omitted when they fall within the path length of an open-path instrument.

(5) At a minimum, non-integrating alternative test methods must provide a minimum of one cycle of operation (sampling, analyzing, and data recording) for each successive 15-minute period.

(6) For alternative test methods capable of real time measurements (less than a 5-minute sampling and analysis cycle), the alternative test method may allow for elimination of data points corresponding to outside emission sources for purpose of calculation of the high point for the two-week average. The alternative test method approach must have wind speed, direction and stability class of the same time resolution and within the footprint of the instrument.

(7) For purposes of averaging data points to determine the Δc for the 14-day average high sample result, all results measured under the method detection limit must use the method detection limit. For purposes of averaging data points for the 14-day average low sample result, all results measured under the method detection limit must use zero.

Subpart CCCCC—National Emission Standards for Hazardous Air Pollutants for Coke Ovens: Pushing, Quenching, and Battery Stacks

■ 15. Section 63.7280 is revised to read as follows:

§ 63.7280 What is the purpose of this subpart?

This subpart establishes national emission standards for hazardous air pollutants (NESHAP) for pushing, soaking, quenching, battery stacks, heat and/or nonrecovery (HNR) heat recovery steam generator (HRSG) main stacks, and HNR HRSG bypass/waste heat stacks at facilities that produce coke in coke oven batteries and facilities that recover heat from coke oven gas. This subpart also establishes requirements to demonstrate initial and continuous compliance with all applicable emission limitations, work practice standards, and operation and maintenance requirements in this subpart.

■ 16. Section 63.7282 is revised to read as follows:

§ 63.7282 What parts of my plant does this subpart cover?

(a) This subpart applies to each new or existing affected source at your coke plant. The affected source is each coke oven battery and units that recover heat from coke oven gas from the coke batteries.

(b) This subpart covers emissions from pushing, soaking, quenching, by-product battery stacks, HNR HRSG main stacks, and HNR HRSG bypass/waste heat stacks from each affected source, as applicable to the coke oven facility.

(c) An affected source at your coke plant is existing if you commenced construction or reconstruction of the affected source before July 3, 2001.

(d) An affected source at your coke plant is new if you commenced construction or reconstruction of the affected source on or after July 3, 2001. An affected source is reconstructed if it meets the definition of ''reconstruction'' in § 63.2. This paragraph (d) does not apply to the emission limitations listed in §§ 63.7290(b) through (d), 63.7296(c) through (f), 63.7297(a) through (d), and 63.7298(a) through (e) for capture systems and control devices applied to pushing emissions, battery stacks, HNR HRSG main stacks, and HNR HRSG bypass/waste heat stacks, respectively.

(e) An affected source at your coke plant is existing for the emissions limitations listed in §§ 63.7290(b) through (d), 63.7296(c) through (f), 63.7297(a) through (d), and 63.7298(a) through (e) for capture systems and control devices applied to pushing emissions, battery stacks, HNR HRSG main stacks, and HNR HRSG bypass/waste heat stacks, respectively if you commenced construction or reconstruction of the affected source before August 16, 2023.

(f) An affected source at your coke plant is new for the emissions limitations listed in §§ 63.7290(b) through (d), 63.7296(c) through (f), 63.7297(a) through (d), and 63.7298(a) through (e) for capture systems and control devices applied to pushing emissions, battery stacks, HNR HRSG main stacks, and HNR HRSG bypass/waste heat stacks, respectively if you commenced construction or reconstruction of the affected source on or after August 16, 2023.

■ 17. Section 63.7283 is revised to read as follows:

§ 63.7283 When do I have to comply with this subpart?

(a) If you have an existing affected source, you must comply with each emission limitation, work practice standard, and operation and maintenance requirement in this subpart that applies to you no later than April 14, 2006. This paragraph does not apply to the emission limitations listed in §§ 63.7290(b) through (d), 63.7296(c) through (f), 63.7297(a) through (d), and 63.7298(a) through (e) for capture systems and control devices applied to pushing emissions, battery stacks, HNR HRSG main stacks, and HNR HRSG bypass/waste heat stacks, respectively.

(b) If you have a new affected source and its initial startup date is on or before April 14, 2003, you must comply with each emission limitation, work practice standard, and operation and maintenance requirement in this subpart that applies to you by April 14, 2003. This paragraph does not apply to the emission limitations listed in §§ 63.7290(b) through (d), 63.7296(c) through (f), 63.7297(a) through (d), and 63.7298(a) through (e) for capture systems and control devices applied to pushing emissions, battery stacks, HNR HRSG main stacks, and HNR HRSG bypass/waste heat stacks, respectively.

(c) If you have a new affected source and its initial startup date is after April 14, 2003, you must comply with each emission limitation, work practice standard, and operation and maintenance requirement in this subpart that applies to you upon initial startup. This paragraph does not apply to the emission limitations listed in §§ 63.7290(b) through (d), 63.7296(c) through (f), 63.7297(a) through (d), and 63.7298(a) through (e) for capture systems and control devices applied to pushing emissions, battery stacks, HNR HRSG main stacks, and HNR HRSG bypass/waste heat stacks, respectively.

(d) With regard to the §§ 63.7290(b) through (d), 63.7296(c) through (f), 63.7297(a) through (d), and 63.7298(a) through (e) emission limitations for capture systems and control devices applied to pushing emissions, battery stacks, HNR HRSG main stacks, and HNR HRSG bypass/waste heat stacks, respectively:

(1) If you have an existing affected source or a new or reconstructed affected source for which construction or reconstruction commenced on or before August 16, 2023, you must be in

compliance no later than January 5, 2026.

(2) If you have a new or reconstructed affected source for which construction or reconstruction commenced after August 16, 2023, you must be in compliance no later than January 5, 2026 or upon startup, whichever is later.

(e) With regard to the § 63.7299 opacity limitations for HNR HRSG bypass/waste heat stacks:

(1) If you have an existing affected source or a new or reconstructed affected source for which construction or reconstruction commenced on or before August 16, 2023, you must be in compliance no later than July 7, 2025.

(2) If you have a new or reconstructed affected source for which construction or reconstruction commenced after August 16, 2023, you must be in compliance no later than July 7, 2025, or upon initial startup, whichever is later.

(f) You must meet the notification and schedule requirements in § 63.7340. Several of these notifications must be submitted before the compliance date for your affected source.

■ 18. Section 63.7290 is revised to read as follows:

§ 63.7290 What emission limitations must I meet for capture systems and control devices applied to pushing emissions?

(a) You must not discharge to the atmosphere emissions of particulate matter from a control device applied to pushing emissions from a new or existing coke oven battery that exceed the applicable limit in paragraphs (a)(1) through (4) of this section:

(1) 0.01 grain per dry standard cubic foot (gr/dscf) if a cokeside shed is used to capture emissions;

(2) 0.02 pound per ton (lb/ton) of coke if a moveable hood vented to a stationary control device is used to capture emissions;

(3) If a mobile scrubber car that does not capture emissions during travel is used:

(i) 0.03 lb/ton of coke for a control device applied to pushing emissions from a short battery, or

(ii) 0.01 lb/ton of coke for a control device applied to pushing emissions from a tall battery; and

(4) 0.04 lb/ton of coke if a mobile control device that captures emissions during travel is used.

(b) You must not discharge to the atmosphere emissions of mercury from a control device applied to pushing emissions from a new coke oven battery that exceeds 5.1E–07 lb/ton coke or existing coke oven battery that exceeds 8.9E–07 lb/ton coke.

(c) You must not discharge to the atmosphere emissions of total acid gases from a control device applied to pushing emissions from a new coke oven battery that exceeds 5.3E–04 lb/ton coke or existing coke oven battery that exceeds 0.013 lb/ton coke.

(d) You must not discharge to the atmosphere emissions of hydrogen cyanide from a control device applied to pushing emissions from a new coke oven battery that exceeds 3.8E–05 lb/ton coke or existing coke oven battery that exceeds 0.0015 lb/ton coke.

(e) You must not discharge to the atmosphere emissions of total polycyclic aromatic hydrocarbons (PAH) from a control device applied to pushing emissions from a new coke oven battery that exceeds 1.4E–05 lb/ton coke or existing coke oven battery that exceeds 4.0E–04 lb/ton coke.

(f) You must meet each operating limit in paragraphs (f)(1) through (4) of this section that applies to you for a new or existing coke oven battery.

(1) For each venturi scrubber applied to pushing emissions, you must maintain the daily average pressure drop and scrubber water flow rate at or above the minimum levels established during the initial performance test.

(2) For each hot water scrubber applied to pushing emissions, you must maintain the daily average water pressure and water temperature at or above the minimum levels established during the initial performance test.

(3) For each capture system applied to pushing emissions, you must maintain the daily average volumetric flow rate at the inlet of the control device at or above the minimum level established during the initial performance test; or

(i) For each capture system that uses an electric motor to drive the fan, you must maintain the daily average fan motor amperes at or above the minimum level established during the initial performance test; and

(ii) For each capture system that does not use a fan driven by an electric motor, you must maintain the daily average static pressure at the inlet to the control device at an equal or greater vacuum than the level established during the initial performance test or maintain the daily average fan revolutions per minute (RPM) at or above the minimum level established during the initial performance test.

(4) For each multicyclone, you must maintain the daily average pressure drop at or below the minimum level established during the initial performance test.

■ 19. Section 63.7293 is revised to read as follows:

§ 63.7293 What work practice standards must I meet for fugitive pushing emissions if I have a nonrecovery coke oven battery?

(a) You must meet the requirements in paragraphs (a)(1) and (2) of this section for each new and existing nonrecovery coke oven battery.

(1) You must visually inspect each oven prior to pushing by opening the door damper and observing the bed of coke.

(2) Do not push the oven unless the visual inspection indicates that there is no smoke in the open space above the coke bed and that there is an unobstructed view of the door on the opposite side of the oven.

(b) As provided in § 63.6(g), you may request to use an alternative to the work practice standard in paragraph (a) of this section.

■ 20. Section 63.7296 is revised to read as follows:

§ 63.7296 What emission limitations must I meet for battery stacks?

You must not discharge to the atmosphere any emissions from any battery stack at a new or existing by-product coke oven battery that exhibit an opacity greater than the applicable limits in paragraphs (a) and (b) of this section and emissions greater than the applicable limits in paragraphs (c) through (f) of this section.

(a) Daily average of 15 percent opacity for a battery on a normal coking cycle.

(b) Daily average of 20 percent opacity for a battery on batterywide extended coking.

(c) Emissions of particulate matter from a new by-product coke oven battery stack that exceeds 0.013 gr/dscf at 10 percent oxygen or existing by-product coke oven battery stack that exceeds 0.13 gr/dscf at 10 percent oxygen.

(d) Emissions of mercury from a new by-product coke oven battery stack that exceeds 7.1E–06 lb/ton coke or existing by-product coke oven battery stack that exceeds 4.5E–05 lb/ton coke.

(e) Emissions of total acid gases from a new by-product coke oven battery stack that exceeds 0.013 lb/ton coke or existing by-product coke oven battery stack that exceeds 0.16 lb/ton coke.

(f) Emissions of hydrogen cyanide from a new by-product coke oven battery stack that exceeds 7.4E–04 lb/ton coke or existing by-product coke oven battery stack that exceeds 0.032 lb/ton coke.

■ 21. Sections 63.7297 through 63.7299 are added to read as follows:

Sec.

§ 63.7297 What emission limitations must I meet for HNR HRSG main stacks?

You must not discharge to the atmosphere any emissions from any HNR HRSG main stack at a new or existing HNR coke oven battery that exhibit emissions greater than the applicable limits in paragraphs (a) through (d) of this section.

(a) Emissions of particulate matter from any HNR HRSG main stack at a new HNR coke oven battery that exceeds 8.8E–04 gr/dscf at 10 percent oxygen or any HNR HRSG main stack at an existing HNR coke oven battery that exceeds 0.0049 gr/dscf at 10 percent oxygen.

(b) Emissions of mercury from any HNR HRSG main stack at a new HNR coke oven battery that exceeds 1.5E–06 gr/dscf at 10 percent oxygen or any HNR HRSG main stack at an existing HNR coke oven battery that exceeds 3.0E–06 gr/dscf at 10 percent oxygen.

(c) Emissions of total acid gases from any HNR HRSG main stack at a new HNR coke oven battery that exceeds 0.0034 gr/dscf at 10 percent oxygen or any HNR HRSG main stack at an existing HNR coke oven battery that exceeds 0.049 gr/dscf at 10 percent oxygen.

(d) Emissions of total PAHs from any HNR HRSG main stack at a new HNR coke oven battery that exceeds 4.7E–07 gr/dscf at 10 percent oxygen or any HRSG main stack at existing HNR coke oven battery that exceeds 4.8E–07 gr/dscf at 10 percent oxygen.

§ 63.7298 What emission limitations must I meet for HNR HRSG bypass/waste heat stacks?

You must not discharge to the atmosphere any emissions from any HNR HRSG bypass/waste heat stack at a new or existing HNR coke oven battery that exhibit emissions greater than the applicable limits in paragraphs (a) through (e) of this section.

(a) Emissions of particulate matter from any HNR HRSG bypass/waste heat stack at a new HNR coke oven battery that exceeds 0.022 gr/dscf at 10 percent oxygen or any HNR HRSG bypass/waste heat stack at an existing HNR coke battery that exceeds 0.032 gr/dscf at 10 percent oxygen.

(b) Emissions of mercury from any HNR HRSG bypass/waste heat stack at a new HNR coke oven battery that exceeds 8.6E–06 gr/dscf at 10 percent oxygen or any HNR HRSG bypass/waste heat stack at an existing HNR coke oven battery that exceeds 1.2E–05 gr/dscf at 10 percent oxygen.

(c) Emissions of total acid gases from any HNR HRSG bypass/waste heat stack at a new HNR coke oven battery that exceeds 0.12 gr/dscf at 10 percent oxygen or any HNR HRSG bypass/waste heat stack at an existing HNR coke battery that exceeds 0.095 gr/dscf at 10 percent oxygen.

(d) Emissions of total PAHs from any HNR HRSG bypass/waste heat stack at a new or existing HNR coke oven battery that exceeds 2.7E–06 gr/dscf at 10 percent oxygen.

(e) Emissions of formaldehyde from any HNR HRSG bypass/waste heat stack at a new HNR coke oven battery that exceeds 1.8E–05 gr/dscf at 10 percent oxygen or any HNR HRSG bypass/waste heat stack at an existing HNR coke oven battery that exceeds 0.0012 gr/dscf at 10 percent oxygen.

§ 63.7299 What opacity limitations must I meet for HNR HRSG bypass/waste heat stacks?

The owner or operator shall observe the exhaust stack of each bypass or waste heat stacks once each week that exhaust is emitted through each stack continuously for more than an hour. The observation shall be made when exhaust is being emitted through the bypass or waste heat stack to determine if opacity, as a 6-minute average measured according to EPA Method 9 in appendix A–4 to 40 CFR part 60, exceeds 20 percent opacity. The owner or operator shall record the results of each observation. If a bypass event does not occur during a week or does not exceed one hour in duration, then no measurement is required for that week. If exhaust is emitted through any bypass or waste heat stack continuously for more than an hour during a week and no opacity measurement has been performed, the owner or operator shall record in the operating record the reason why conditions did not permit an opacity observation. If opacity greater than 20 percent opacity is observed during any weekly measurement, the owner or operator must:

(a) Take corrective action to reduce the emissions contributing to the opacity;

(b) Record the cause of opacity exceeding 20 percent and the corrective action taken; and

(c) Report opacity exceedances in any HNR HRSG bypass or HNR waste heat stacks in the quarterly semiannual compliance report required by § 63.7341.

■ 22. Section 63.7300 is amended by revising paragraph (a) and (c) to read as follows:

§ 63.7300 What are my operation and maintenance requirements?

(a) As required by § 63.7310(a) you must always operate and maintain your affected source, including air pollution control and monitoring equipment, in a manner consistent with good air pollution control practices for minimizing emissions at least to the levels required by this subpart.

* * * * *

(c) You must prepare and operate at all times according to a written operation and maintenance plan for each capture system and control device applied to pushing emissions from a new or existing coke oven battery. Each plan must address at a minimum the elements in paragraphs (c)(1) through (4) of this section.

(1) Monthly inspections of the equipment that are important to the performance of the total capture system (*e.g.,* pressure sensors, dampers, and damper switches). This inspection must include observations of the physical appearance of the equipment (*e.g.,* presence of holes in ductwork or hoods, flow constrictions caused by dents or accumulated dust in ductwork, and fan erosion). In the event a defect or deficiency is found in the capture system (during a monthly inspection or between inspections), you must complete repairs within 30 days after the date that the defect or deficiency is discovered. If you determine that the repairs cannot be completed within 30 days, you must submit a written request for an extension of time to complete the repairs that must be received by the permitting authority not more than 20 days after the date that the defect or deficiency is discovered. The request must contain a description of the defect or deficiency, the steps needed and taken to correct the problem, the interim steps being taken to mitigate the emissions impact of the defect or deficiency, and a proposed schedule for completing the repairs. The request shall be deemed approved unless and until such time as the permitting authority notifies you that it objects to the request. The permitting authority may consider all relevant factors in deciding whether to approve or deny the request (including feasibility and safety). Each approved schedule must provide for completion of repairs as expeditiously as practicable, and the permitting authority may request modifications to the proposed schedule as part of the approval process.

(2) Preventative maintenance for each control device, including a preventative maintenance schedule that is consistent with the manufacturer's instructions for routine and long-term maintenance.

(3) Corrective action for all baghouses applied to pushing emissions. In the event a bag leak detection system alarm is triggered, you must initiate corrective action to determine the cause of the alarm within 1 hour of the alarm, initiate corrective action to correct the cause of the problem within 24 hours of the alarm, and complete the corrective action as soon as practicable. Actions may include, but are not limited to:

(i) Inspecting the baghouse for air leaks, torn or broken bags or filter media, or any other condition that may cause an increase in emissions.

(ii) Sealing off defective bags or filter media.

(iii) Replacing defective bags or filter media or otherwise repairing the control device.

(iv) Sealing off a defective baghouse compartment.

(v) Cleaning the bag leak detection system probe, or otherwise repairing the bag leak detection system.

(vi) Shutting down the process producing the particulate emissions.

(4) Beginning January 5, 2026, you must identify and implement a set of site-specific good combustion practices for each battery. These good combustion practices should correspond to your standard operating procedures for maintaining the proper and efficient combustion within battery waste heat flues. Good combustion practices include, but are not limited to, the elements listed in paragraphs (c)(4)(i) through (v) of this section.

(i) Proper operating conditions for each battery (*e.g.,* minimum combustion temperature, burner alignment, or proper fuel-air distribution/mixing).

(ii) Routine inspection and preventative maintenance and corresponding schedules of each battery.

(iii) Performance analyses of each battery.

(iv) Maintaining applicable operator logs.

(v) Maintaining applicable records to document compliance with each element.

* * * * *

■ 23. Section 63.7310 is revised to read as follows:

§ 63.7310 What are my general requirements for complying with this subpart?

(a) You must be in compliance with the emission limitations, work practice standards, and operation and maintenance requirements in this subpart at all times. At all times, you must 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 further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements 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.

(b) During the period between the compliance date specified for your affected source in § 63.7283 and the date upon which continuous monitoring systems have been installed and certified and any applicable operating limits have been set, you must maintain a log detailing the operation and maintenance of the process and emissions control equipment.

■ 24. Section 63.7320 is amended by revising paragraph (a) to read as follows:

§ 63.7320 By what date must I conduct performance tests or other initial compliance demonstrations?

(a) As required in § 63.7(a)(2), you must conduct a performance test to demonstrate compliance with each limit in:

(1) Section 63.7290(a) through (e) for emissions of particulate matter, mercury, total acid gases, HCN, and total PAH from a control device applied to pushing emissions that applies to you within 180 calendar days after the compliance date that is specified in § 63.7283.

(2) Section 63.7296(c) through (f) for emissions of particulate matter, mercury, total acid gases, and HCN from a battery stack that applies to you within 180 calendar days after the compliance date that is specified in § 63.7283.

(3) Section 63.7297(a) through (d) for emissions of mercury, particulate matter, total acid gases, and total PAH from a HNR HRSG main stack that applies to you within 180 calendar days after the compliance date that is specified in § 63.7283.

(4) Section 63.7298(a) through (e) for emissions of mercury, particulate matter, total acid gases, total PAH, and formaldehyde from a HNR HRSG bypass/waste heat stack that applies to you within 180 calendar days after the compliance date that is specified in § 63.7283.

* * * * *

■ 25. Section 63.7321 is revised to read as follows:

§ 63.7321 When must I conduct subsequent performance tests?

(a) For each control device subject to an emission limit for particulate matter in § 63.7290(a), you must conduct subsequent performance tests no less frequently than once every 5 years or at the beginning of each term of your title V operating permit, whichever is less.

(b) For each source subject to emission limits in §§ 63.7290(b) through (d), 63.7296(c) through (f), 63.7297(a) through (d), and 63.7298(a) through (e) for capture systems and control devices applied to pushing emissions, battery stacks, HNR HRSG main stacks, and HNR HRSG bypass/waste heat stacks sources, respectively, you must conduct subsequent performance tests once every five years.

■ 26. Section 63.7322 is revised to read as follows:

§ 63.7322 What test methods and other procedures must I use to demonstrate initial compliance with the emission limits?

(a) You must conduct each performance test that applies to your affected source based on representative performance (*i.e.,* performance based on the entire range of normal operating conditions) of the affected source for the period being tested, according to the requirements in paragraph (b) through (g) of this section. Representative conditions exclude periods of startup and shutdown. You shall not conduct performance tests during periods of malfunction. You 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 the entire range of normal operation, including operational conditions for maximum emission if such emissions are not expected during maximum production. You shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(b) To determine compliance with the emission limit for particulate matter from a control device applied to pushing emissions where a cokeside shed is the capture system, battery stack, HNR HRSG main stack, and HNR HRSG bypass/waste heat stack, follow the test methods and procedures in paragraphs (b)(1) and (2) of this section.

To determine compliance with a process-weighted mass rate of particulate matter (lb/ton of coke) from a control device applied to pushing emissions where a cokeside shed is not used, follow the test methods and procedures in paragraphs (b)(1) through (4) of this section.

(1) Determine the concentration of particulate matter according to the following test methods in appendices A–1 through A–3 to 40 CFR part 60.

(i) Method 1 to select sampling port locations and the number of traverse points. Sampling sites must be located at the outlet of the control device and prior to any releases to the atmosphere.

(ii) Method 2, 2F, or 2G to determine the volumetric flow rate of the stack gas.

(iii) Method 3, 3A, or 3B to determine the dry molecular weight of the stack gas. You may also use as an alternative to Method 3B, the manual method (but not instrumental procedures) for measuring the oxygen, carbon dioxide, and carbon monoxide content of exhaust gas, ANSI/ASME PTC 19.10–1981 (incorporated by reference, see § 63.14).

(iv) Method 4 to determine the moisture content of the stack gas.

(v) Method 5 or 5D, as applicable, to determine the concentration of filterable particulate matter in the stack gas.

(2) Collect a minimum sample volume of 30 dry standard cubic feet of gas during each test run. Three valid test runs are needed to comprise a performance test. During each particulate matter test run to meet the emission limitations in § 63.7290, sample only during periods of actual pushing when the capture system fan and control device are engaged. For capture systems and control devices applied to pushing emissions each run must start at the beginning of a push and finish at the end of a push (*i.e.,* sample for an integral number of pushes).

(3) Determine the total combined weight in tons of coke pushed during the duration of each test run according to the procedures in your source test plan for calculating coke yield from the quantity of coal charged to an individual oven.

(4) Compute the process-weighted mass emissions ($E_{p,\ PM}$) for each test run using equation 1 to this paragraph (b)(4) as follows:

Equation 1 to Paragraph (b)(4)

$$E_{p,PM}=(C_{PM}\times Q\times \Theta)/(P\times K) \quad \text{(Eq. 1)}$$

Where:

$E_{p,\ PM}$ = Process weighted mass emissions of particulate matter, lb/ton;

C_{PM} = Concentration of particulate matter, gr/dscf;

Q = Volumetric flow rate of stack gas, dscf/hr;

Θ = Total sampling run time; the time during a run that a sample is withdrawn from the stack during pushing, hr;

P = Total amount of coke pushed during the test run, tons; and

K = Conversion factor, 7,000 gr/lb.

(c) To determine compliance with the emission limit for mercury from a control device applied to pushing emissions where a cokeside shed is the capture system, battery stack, HNR HRSG main stack, and HNR HRSG bypass/waste heat stack, follow the test methods and procedures in paragraphs (c)(1) and (2) of this section. To determine compliance with a process-weighted mass rate of mercury (lb/ton of coke) from a control device applied to pushing emissions and battery stack, follow the test methods and procedures in paragraphs (c)(1) through (4) of this section.

(1) Determine the concentration of mercury according to the following test methods.

(i) The methods specified in sections (b)(1)(i) through (iv) of this section.

(ii) Method 29 in appendix A–8 to 40 CFR part 60, to determine the concentration of mercury in the stack gas. The voluntary consensus standard ASTM D6784–16 (incorporated by reference, see § 63.14) is an acceptable alternative to EPA Method 29 (portion for mercury only) as a method for measuring mercury, note: applies to concentrations approximately 0.5—100 µg/Nm3.

(2) Collect a minimum sample volume of 70 dry standard cubic feet of gas during each mercury test run. Three valid test runs are needed to comprise a performance test. During each mercury test run to meet the emission limitations in § 63.7290, sample only during periods of actual pushing when the capture system fan and control device are engaged. For capture systems and control devices applied to pushing emissions each run must start at the beginning of a push and finish at the end of a push (*i.e.,* sample for an integral number of pushes).

(3) Determine the total combined weight in tons of coke pushed during the duration of each test run according to the procedures in your source test plan for calculating coke yield from the quantity of coal charged to an individual oven.

(4) Compute the process-weighted mass emissions ($E_{p,Hg}$) for each test run using equation 2 to this paragraph (c)(4) as follows:

Equation 2 to Paragraph (c)(4)

$$E_{p,Hg}=(C_{Hg}\times Q\times \Theta)/(P\times K) \quad \text{(Eq. 2)}$$

Where:

$E_{p,Hg}$ = Process weighted mass emissions of mercury, lb/ton;

C_{Hg} = Concentration of mercury, gr/dscf;

Q = Volumetric flow rate of stack gas, dscf/hr;

Θ = Total sampling run time; the time during a run that a sample is withdrawn from the stack, for capture systems and control devices applied to pushing emissions, total time during a run that a sample is withdrawn from the stack during pushing, hr;

P = Total amount of coke pushed during the test run, tons; and

K = Conversion factor, 7,000 gr/lb.

(d) To determine compliance with the emission limit for total acid gases from a HNR HRSG main stack and HNR HRSG bypass/waste heat stack, follow the test methods and procedures in paragraphs (d)(1) and (2) of this section. To determine compliance with a process-weighted mass rate of total acid gases (lb/ton of coke) from a control device applied to pushing emissions and battery stack, follow the test methods and procedures in paragraphs (d)(1) through (4) of this section.

(1) Determine the concentration of total acid gases according to the following test methods.

(i) The methods specified in sections (b)(1)(i) through (iv) of this section.

(ii) Methods 26 or 26A in appendix A–8 to 40 CFR part 60, or Method 320 in appendix A to this part, to determine the concentration of total acid gases in the stack gas. The voluntary consensus standard ASTM D6348–12 (Reapproved 2020) (incorporated by reference, see § 63.14) is an acceptable alternative to Method 320 at this time with caveats requiring inclusion of selected annexes to the standard as mandatory. When using ASTM D6348–12 (Reapproved 2020), the following conditions must be met:

(A) The test plan preparation and implementation in the Annexes to ASTM D6348–12 (Reapproved 2020), Annexes A1 through A8 are mandatory; and

(B) In ASTM D6348–12 (Reapproved2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (Equation A5.5).

(C) In order for the test data to be acceptable for a compound, % R must be greater than or equal to 70% and less than or equal to 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 by using equation 3 to this paragraph (d)((1)(ii)(C):

Equation 3 to Paragraph (d)((1)(ii)(C)

Reported Results = ((Measured Concentration in Stack)/(% R)) × 100.

(2) Collect a minimum sample volume of 35 dry standard cubic feet of gas during each test run for Method 26 and 26A in appendix A–8 to 40 CFR part 60. For Method 320 in appendix A to this part and ASTM D6348–12 (Reapproved 2020) (incorporated by reference, see § 63.14), each test run must be a minimum of one hour in duration. Three valid test runs are needed to comprise a performance test. During each total acid gases test run to meet the emission limitations in § 63.7290, sample only during periods of pushing when the capture system fan and control device are engaged. For capture systems and control devices applied to pushing emissions each run must start at the beginning of a push and finish at the end of a push (*i.e.,* sample for an integral number of pushes).

(3) Determine the total combined weight in tons of coke pushed during the duration of each test run according to the procedures in your source test plan for calculating coke yield from the quantity of coal charged to an individual oven.

(4) Compute the process-weighted mass emissions ($E_{p,AG}$) for each test run using equation 4 to this paragraph (d)(4) as follows:

Equation 4 to Paragraph (d)(4)

$$E_{p,AG}=(C_{AG}\times Q\times \Theta)/(P\times K) \quad \text{(Eq. 4)}$$

Where:

$E_{p,AG}$ = Process weighted mass emissions of total acid gases, lb/ton;
C_{AG} = Concentration of total acid gases, gr/dscf;
Q = Volumetric flow rate of stack gas, dscf/hr;
Θ = Total sampling run time; the time during a run that a sample is withdrawn from the stack, for capture systems and control devices applied to pushing emissions, total time during a run that a sample is withdrawn from the stack during pushing, hr;
P = Total amount of coke pushed during the test run, tons; and
K = Conversion factor, 7,000 gr/lb.

(e) To determine compliance with a process-weighted mass rate of hydrogen cyanide (lb/ton of coke) from a control device applied to pushing emissions and battery stack, follow the test methods and procedures in paragraphs (e)(1) through (4) of this section.

(1) Determine the concentration of hydrogen cyanide according to the following test methods.

(i) The methods specified in sections (b)(1)(i) through (iv) of this section.

(ii) Method 320 in appendix A to this part, to determine the concentration of hydrogen cyanide in the stack gas. The voluntary consensus standard ASTM D6348–12 (Reapproved 2020) (incorporated by reference, see § 63.14) is an acceptable alternative to Method 320 at this time with caveats requiring inclusion of selected annexes to the standard as mandatory. When using ASTM D6348–12 (Reapproved 2020), the following conditions must be met:

(A) The test plan preparation and implementation in the Annexes to ASTM D6348–12 (Reapproved 2020), Annexes A1 through A8 are mandatory; and

(B) In ASTM D6348–12 (Reapproved 2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (Equation A5.5).

(C) In order for the test data to be acceptable for a compound, % R must be greater than or equal to 70% and less than or equal to 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 by using equation 5 to this paragraph (e)(1)(ii)(C):

Equation 5 to Paragraph (e)(1)(ii)(C)

Reported Results = ((Measured Concentration in Stack)/(% R)) × 100.

(2) Collect a minimum of eight spectra for each of six runs (or hours) evenly spaced over the test period for Method 320 in appendix A to this part or alternatively ASTM D6348–12 (Reapproved 2020) (incorporated by reference, see § 63.14). Three valid test runs are needed to comprise a performance test. During each hydrogen cyanide test run to meet the emission limitations in § 63.7290, sample only during periods of actual pushing when the capture system fan and control device are engaged. For capture systems and control devices applied to pushing emissions each run must start at the beginning of a push and finish at the end of a push (*i.e.,* sample for an integral number of pushes).

(3) Determine the total combined weight in tons of coke pushed during the duration of each test run according to the procedures in your source test plan for calculating coke yield from the quantity of coal charged to an individual oven.

(4) Compute the process-weighted mass emissions ($E_{p,HCN}$) for each test run using equation 6 to this paragraph (e)(4) as follows:

Equation 6 to Paragraph (e)(4)

$$E_{p,HCN}=(C_{HCN}\times Q\times \Theta)/(P\times K) \quad \text{(Eq. 6)}$$

Where:

$Ep_{,HCN}$ = Process weighted mass emissions of hydrogen cyanide, lb/ton;
C_{HCN} = Concentration of hydrogen cyanide, gr/dscf;
Q = Volumetric flow rate of stack gas, dscf/hr;
Θ = Total sampling run time; the time during a run that a sample is withdrawn from the stack, for capture systems and control devices applied to pushing emissions, total time during a run that a sample is withdrawn from the stack during pushing, hr;
P = Total amount of coke pushed during the test run, tons; and
K = Conversion factor, 7,000 gr/lb.

(f) To determine compliance with the emission limit for total PAH from a HNR HRSG main stack and HNR HRSG bypass/waste heat stack, follow the test methods and procedures in paragraphs (f)(1) and (2) of this section. To determine compliance with a process-weighted mass rate of total PAH (lb/ton of coke) from a control device applied to pushing emissions, follow the test methods and procedures in paragraphs (f)(1) through (4) of this section.

(1) Determine the concentration of total PAH, the sum of 17 PAH compounds listed at § 63.7290(e), according to the following test methods.

(i) The methods specified in sections (b)(1)(i) through (iv) of this section.

(ii) Method 23 in appendix A–7 to 40 CFR part 60, to determine the concentration of total PAH in the stack gas.

(2) Collect a minimum sample volume of 105 dry standard cubic feet of gas during each test run for total PAH. Three valid test runs are needed to comprise a performance test. During each total PAH test run to meet the emission limitations in § 63.7290, sample only during periods of actual pushing when the capture system fan and control device are engaged. For capture systems and control devices applied to pushing emissions each run must start at the beginning of a push

and finish at the end of a push (*i.e.,* sample for an integral number of pushes). When calculating total PAH, the estimated level of detection (EDL) shall be used for each PAH measured below the EDL.

(3) Determine the total combined weight in tons of coke pushed during the duration of each test run according to the procedures in your source test plan for calculating coke yield from the quantity of coal charged to an individual oven.

(4) Compute the process-weighted mass emissions ($E_{p,PAH}$) for each test run using equation 7 to this paragraph (f)(4) as follows:

Equation 7 to Paragraph (f)(4)

$$E_{p,PAH}=(\Sigma(C_{PAH}\times Q\times \Theta))/(P\times K) \quad \text{(Eq. 7)}$$

Where:

$E_{p,PAH}$ = Process weighted mass emissions of total PAH, lb/ton;
C_{PAH} = Concentration of each PAH, gr/dscf;
Q = Volumetric flow rate of stack gas, dscf/hr;
Θ = Total sample run time; the time during a run that a sample is withdrawn from the stack during pushing, hr;
P = Total amount of coke pushed during the test run, tons; and
K = Conversion factor, 7,000 gr/lb.

(g) To determine compliance with the emission limit for formaldehyde from a HNR HRSG bypass/waste heat stack, follow the test methods and procedures in paragraphs (h)(1) and (2) of this section.

(1) Determine the concentration of formaldehyde according to the following test methods.

(i) The methods specified in sections (b)(1)(i) through (iv) of this section.

(ii) Method 316 or Method 320 in appendix A to this part, to determine the concentration of formaldehyde in the stack gas. The voluntary consensus standard ASTM D6348–12 (Reapproved 2020) (incorporated by reference, see § 63.14) is an acceptable alternative to Method 320 at this time with caveats requiring inclusion of selected annexes to the standard as mandatory. When using ASTM D6348–12 (Reapproved 2020), the following conditions must be met:

(A) The test plan preparation and implementation in the Annexes to ASTM D6348–12 (Reapproved 2020), Annexes A1 through A8 are mandatory; and

(B) In ASTM D6348–12 (Reapproved 2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (Equation A5.5).

(C) In order for the test data to be acceptable for a compound, % R must be greater than or equal to 70% and less than or equal to 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 by using equation 8 to this paragraph (g)(1)(ii)(C):

Equation 8 to Paragraph (g)(1)(ii)(C)

Reported Results = ((Measured Concentration in Stack)/(% R)) × 100.

(2) Sample time should ensure that minimum quantification levels have been met under the methods used during each test run, for Method 320 in appendix A to this part or ASTM D6348–12 (Reapproved 2020) (incorporated by reference, see § 63.14), each test run must be at least one hour in duration. Three valid test runs are needed to comprise a performance test.

■ 27. Section 63.7323 is amended by revising paragraphs (c)(1) through (3) to read as follows:

§ 63.7323 What procedures must I use to establish operating limits?

* * * * *

(c) * * *

(1) If you elect the operating limit in § 63.7290(f)(3) for volumetric flow rate, measure and record the total volumetric flow rate at the inlet of the control device during each push sampled for each particulate matter test run. Your operating limit is the lowest volumetric flow rate recorded during any of the three runs that meet the emission limit.

(2) If you elect the operating limit in § 63.7290(f)(3)(i) for fan motor amperes, measure and record the fan motor amperes during each push sampled for each particulate matter test run. Your operating limit is the lowest fan motor amperes recorded during any of the three runs that meet the emission limit.

(3) If you elect the operating limit in § 63.7290(f)(3)(ii) for static pressure or fan RPM, measure and record the static pressure at the inlet of the control device or fan RPM during each push sampled for each particulate matter test run. Your operating limit for static pressure is the minimum vacuum recorded during any of the three runs that meets the emission limit. Your operating limit for fan RPM is the lowest fan RPM recorded during any of the three runs that meets the emission limit.

* * * * *

■ 28. Section 63.7324 is amended by revising paragraph (a) to read as follows:

§ 63.7324 What procedures must I use to demonstrate initial compliance with the opacity limits?

(a) You must conduct each performance test that applies to your affected source based on representative performance (*i.e.,* performance based on the entire range of normal operating conditions) of the affected source for the period being tested, according to the requirements in paragraph (b) of this section. Representative conditions exclude periods of startup and shutdown. You shall not conduct performance tests during periods of malfunction. You 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 the entire range of normal operation, including operational conditions for maximum emissions if such emissions are not expected during maximum production. You shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

* * * * *

■ 29. Section 63.7325 is amended by revising paragraph (a) introductory text to read as follows:

§ 63.7325 What test methods and other procedures must I use to demonstrate initial compliance with the TDS or constituent limits for quench water?

(a) If you elect the TDS limit for quench water in § 63.7295(a)(1)(i), you must conduct each performance test that applies to your affected source based on representative performance (*i.e.,* performance based on the entire range of normal operating conditions) of the affected source for the period being tested, according to the conditions in paragraphs (a)(1) and (2) of this section. Representative conditions exclude periods of startup and shutdown. You shall not conduct performance tests during periods of malfunction. You 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 the entire range of normal operation, including operational conditions for maximum emissions if such emissions are not expected during maximum production. You shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

* * * * *

■ 30. Section 63.7326 is revised to read as follows:

§ 63.7326 How do I demonstrate initial compliance with the emission limitations that apply to me?

(a) For each coke oven battery subject to the emission limits from a control device applied to pushing emissions, you have demonstrated initial compliance if you meet the requirements in paragraphs (a)(1) through (9) of this section that apply to you.

(1) The concentration of particulate matter, measured in accordance with the performance test procedures in § 63.7322(b)(1) and (2), did not exceed 0.01 gr/dscf for a control device where a cokeside shed is used to capture pushing emissions or the process-weighted mass rate of particulate matter (lb/ton of coke), measured in accordance with the performance test procedures in § 63.7322(b)(1) through (4), did not exceed:

(i) 0.02 lb/ton of coke if a moveable hood vented to a stationary control device is used to capture emissions;

(ii) If a mobile scrubber car that does not capture emissions during travel is used, 0.03 lb/ton of coke from a control device applied to pushing emissions from a short coke oven battery or 0.01 lb/ton of coke from a control device applied to pushing emissions from a tall coke oven battery; and

(iii) 0.04 lb/ton of coke if a mobile control device that captures emissions during travel is used.

(2) The process-weighted mass rate of mercury (lb/ton of coke), measured in accordance with the performance test procedures in § 63.7322(c)(1) through (4), did not exceed 3.4E–07 lb/ton coke for pushing emissions from a new coke oven battery or 8.9E–07 lb/ton coke for pushing emissions from an existing coke oven battery.

(3) The process-weighted mass rate of total acid gases, the sum of hydrochloric acid and hydrofluoric acid (lb/ton of coke), measured in accordance with the performance test procedures in § 63.7322(d)(1) through (4), did not exceed 5.1E–04 lb/ton coke for pushing emissions from a new coke oven battery or 0.0052 lb/ton coke for pushing emissions from an existing coke oven battery.

(4) The process-weighted mass rate of hydrogen cyanide (lb/ton of coke), measured in accordance with the performance test procedures in § 63.7322(e)(1) through (4), did not exceed 3.8E–05 lb/ton coke for pushing emissions from a new coke oven battery or 0.0011 lb/ton coke for pushing emissions from an existing coke oven battery.

(5) The process-weighted mass rate of total PAH (lb/ton of coke), measured in accordance with the performance test procedures in § 63.7322(f)(1) through (4), did not exceed 1.4E–05 lb/ton coke for pushing emissions from a new coke oven battery or 3.4E–04 lb/ton coke for pushing emissions from an existing coke oven battery.

(6) For each venturi scrubber applied to pushing emissions, you have established appropriate site-specific operating limits and have a record of the pressure drop and scrubber water flow rate measured during the performance test in accordance with § 63.7323(a).

(7) For each hot water scrubber applied to pushing emissions, you have established appropriate site-specific operating limits and have a record of the water pressure and temperature measured during the performance test in accordance with § 63.7323(b).

(8) For each capture system applied to pushing emissions, you have established an appropriate site-specific operating limit, and:

(i) If you elect the operating limit in § 63.7290(f)(3) for volumetric flow rate, you have a record of the total volumetric flow rate at the inlet of the control device measured during the performance test in accordance with § 63.7323(c)(1); or

(ii) If you elect the operating limit in § 63.7290(f)(3)(i) for fan motor amperes, you have a record of the fan motor amperes during the performance test in accordance with § 63.7323(c)(2); or

(iii) If you elect the operating limit in § 63.7290(f)(3)(ii) for static pressure or fan RPM, you have a record of the static pressure at the inlet of the control device or fan RPM measured during the performance test in accordance with § 63.7323(c)(3).

(9) For each multicyclone applied to pushing emissions, you have established an appropriate site-specific operating limit and have a record of the pressure drop measured during the performance test in accordance with § 63.7323(d).

(b) For each new or existing by-product coke oven battery subject to the emission limits in § 63.7296, you have demonstrated initial compliance if you meet the requirements in paragraphs (b)(1) through (5) of this section.

(1) The opacity limit for stacks in § 63.7296(a), you have demonstrated initial compliance if the daily average opacity, as measured according to the performance test procedures in § 63.7324(b), is no more than 15 percent for a battery on a normal coking cycle or 20 percent for a battery on batterywide extended coking.

(2) The concentration of particulate matter, measured in accordance with the performance test procedures in § 63.7322(b)(1) and (2), did not exceed 0.013 gr/dscf at 10 percent oxygen from a battery stack at a new by-product coke oven battery or 0.13 gr/dscf at 10 percent oxygen from a battery stack at an existing by-product coke oven battery.

(3) The process-weighted mass rate of mercury (lb/ton of coke), measured in accordance with the performance test procedures in § 63.7322(c)(1) through (4), did not exceed 7.1E–06 lb/ton coke from a battery stack at a new by-product coke oven battery or 4.5E–05 lb/ton coke from a battery stack at an existing by-product coke oven battery.

(4) The process-weighted mass rate of total acid gases (lb/ton of coke), measured in accordance with the performance test procedures in § 63.7322(d)(1) through (4), did not exceed 0.013 lb/ton coke from a battery stack at a new by-product coke oven battery or 0.16 lb/ton coke from a battery stack at an existing by-product coke oven battery.

(5) The process-weighted mass rate of hydrogen cyanide (lb/ton of coke), measured in accordance with the performance test procedures in § 63.7322(e)(1) through (4), did not exceed 7.4E–04 lb/ton coke from a battery stack at a new by-product coke oven battery or 0.032 lb/ton coke from a battery stack at an existing by-product coke oven battery.

(c) For each new or existing by-product coke oven battery subject to the TDS limit or constituent limits for quench water in § 63.7295(a)(1),

(1) You have demonstrated initial compliance with the TDS limit in § 63.7295(a)(1)(i) if the TDS concentration, as measured according to the performance test procedures in § 63.7325(a), does not exceed 1,100 mg/L.

(2) You have demonstrated initial compliance with the constituent limit in § 63.7295(a)(1)(ii) if:

(i) You have established a site-specific constituent limit according to the procedures in § 63.7325(b); and

(ii) The sum of the constituent concentrations, as measured according to the performance test procedures in § 63.7325(c), is less than or equal to the site-specific limit.

(d) For each new or existing HNR HRSG main stack subject to the emission limits in § 63.7297, you have demonstrated initial compliance if you meet the requirements in paragraphs (d)(1) through (4) of this section.

(1) The concentration of particulate matter, measured in accordance with the performance test procedures in § 63.7322(b)(1) and (2), did not exceed 8.8E–04 gr/dscf at 10 percent oxygen from a HNR HRSG main stack at a new HNR coke battery or 0.0049 gr/dscf at 10 percent oxygen at a HNR HRSG main stack at an existing HNR coke oven battery.

(2) The concentration of mercury, measured in accordance with the performance test procedures in § 63.7322(c)(1) and (2), did not exceed 1.5E–06 gr/dscf at 10 percent oxygen from a HNR HRSG main stack at a new HNR coke battery or 3.0E–06 gr/dscf at 10 percent oxygen at a HNR HRSG main stack at an existing HNR HRSG.

(3) The concentration of total acid gases, measured in accordance with the performance test procedures in § 63.7322(d)(1) and (2), did not exceed 3.4E–03 gr/dscf at 10 percent oxygen from a HNR HRSG main stack at a new coke oven battery or 4.9E–02 gr/dscf at 10 percent oxygen at a HNR HRSG main stack at an existing HNR coke oven battery.

(4) The concentration of total PAHs, measured in accordance with the performance test procedures in § 63.7322(f)(1) and (2), did not exceed 4.7E–07 gr/dscf at 10 percent oxygen from a HNR HRSG main stack at a new coke oven battery or 4.8E–07 gr/dscf at 10 percent oxygen at a HNR HRSG main stack at an existing HNR coke oven battery.

(e) For each HNR HRSG bypass/waste heat stack through which emissions are discharged from a new or existing coke oven battery subject to the emission limits in § 63.7298, you have demonstrated initial compliance if you meet the requirements in paragraphs (e)(1) through (5) of this section.

(1) The concentration of particulate matter, measured in accordance with the performance test procedures in § 63.7322(b)(1) and (2), did not exceed 0.022 gr/dscf at 10 percent oxygen from a HNR HRSG bypass/waste heat stack at a new HNR coke oven battery or 0.032 gr/dscf at 10 percent oxygen from a HNR HRSG bypass/waste heat stack at an existing HNR coke oven battery.

(2) The concentration of mercury, measured in accordance with the performance test procedures in § 63.7322(c)(1) and (2), did not exceed 8.6E–06 gr/dscf at 10 percent oxygen from a HNR HRSG bypass/waste heat stack at a new HNR coke oven battery or 1.2E–05 gr/dscf at 10 percent oxygen from a HNR HRSG bypass/waste heat stack at an existing HNR coke battery.

(3) The concentration of total acid gases, measured in accordance with the performance test procedures in § 63.7322(d)(1) and (2), did not exceed 0.12 gr/dscf at 10 percent oxygen from a HNR HRSG bypass/waste heat stack at a new HNR coke oven battery or 0.095 gr/dscf at 10 percent oxygen from a HNR HRSG bypass/waste heat stack at an existing HNR coke oven battery.

(4) The concentration of total PAHs, measured in accordance with the performance test procedures in § 63.7322(f)(1) and (2), did not exceed 2.7E–06 gr/dscf at 10 percent oxygen from a HNR HRSG bypass/waste heat stack at a new coke oven battery or existing HNR coke oven battery.

(5) The concentration of formaldehyde, measured in accordance with the performance test procedures in § 63.7322(g)(1) and (2), did not exceed 1.8E–05 gr/dscf at 10 percent oxygen from a HNR HRSG bypass/waste heat stack at a new HNR coke oven battery or 0.0012 gr/dscf at 10 percent oxygen from a HNR HRSG bypass/waste heat stack at an existing HNR coke oven battery.

(f) For each by-product coke oven battery stack subject to an opacity limit in § 63.7296(a) and each by-product coke oven battery subject to the requirements for quench water in § 63.7295(a)(1), you must submit a notification of compliance status containing the results of the COMS performance test for battery stacks and the quench water performance test (TDS or constituent limit) according to § 63.7340(e)(1). For each particulate matter, mercury, total acid gases, hydrogen cyanide, total PAHs, or formaldehyde emission limitation that applies to you, you must submit a notification of compliance status containing a summary of the results of the performance test according to § 63.7340(e)(2).

■ 31. Section 63.7327 is amended by revising paragraph (c) to read as follows:

§ 63.7327 How do I demonstrate initial compliance with the work practice standards that apply to me?

* * * * *

(c) For each nonrecovery coke oven battery subject to the work practice standards for fugitive pushing emissions in § 63.7293(a), you have demonstrated initial compliance if you certify in your notification of compliance status that you will meet each of the work practice requirements beginning no later than the compliance date that is specified in § 63.7283.

* * * * *

■ 32. Section 63.7331 is amended by revising paragraphs (b)(4) through (6) and (g) through (i) to read as follows:

§ 63.7331 What are the installation, operation, and maintenance requirements for my monitors?

* * * * *

(b) * * *

(4) Ongoing operation and maintenance procedures in accordance with the general requirements of § 63.8(c)(1)(ii), (3), (4)(ii), (7), and (8);

(5) Ongoing data quality assurance procedures in accordance with the general requirements of §§ 63.8(d)(1) and (2) and 63.7342(b)(3); and

(6) Ongoing recordkeeping and reporting procedures in accordance the general requirements of § 63.10(c)(1) through (14) and (e)(1) and (2)(i).

* * * * *

(g) If you elect the operating limit in § 63.7290(f)(3) for a capture system applied to pushing emissions, you must install, operate, and maintain a device to measure the total volumetric flow rate at the inlet of the control device.

(h) If you elect the operating limit in § 63.7290(f)(3)(i) for a capture system applied to pushing emissions, you must install, operate, and maintain a device to measure the fan motor amperes.

(i) If you elect the operating limit in § 63.7290(f)(3)(ii) for a capture system applied to pushing emissions, you must install, operate and maintain a device to measure static pressure at the inlet of the control device or the fan RPM.

* * * * *

■ 33. Section 63.7333 is revised to read as follows:

§ 63.7333 How do I demonstrate continuous compliance with the emission limitations that apply to me?

(a) For each control device applied to pushing emissions and subject to the emission limit in § 63.7290(a), you must demonstrate continuous compliance by meeting the requirements in paragraphs (a)(1) and (2) of this section:

(1) Maintaining emissions of particulate matter at or below the applicable limits in paragraphs § 63.7290(a)(1) through (4); and

(2) Conducting subsequent performance tests to demonstrate continuous compliance no less frequently than at the beginning of your title V operating permit or every 5 years, whichever is less.

(b) For each control device applied to pushing emissions and subject to the emission limits in § 63.7290(b) through (e), you must demonstrate continuous compliance by meeting the requirements in paragraphs (b)(1) through (5) of this section:

(1) Maintaining emissions of mercury at or below the applicable limits in § 63.7290(b);

(2) Maintaining emissions of total acid gases at or below the applicable limits in § 63.7290(c);

(3) Maintaining emissions of hydrogen cyanide at or below the applicable limits in § 63.7290(d);

(4) Maintaining emissions of total PAHs at or below the applicable limits in § 63.7290(e); and

(5) Conducting subsequent performance tests to demonstrate continuous compliance once every five years.

(c) For each venturi scrubber applied to pushing emissions and subject to the operating limits in § 63.7290(f)(1), you must demonstrate continuous compliance by meeting the requirements in paragraphs (c)(1) through (3) of this section.

(1) Maintaining the daily average pressure drop and scrubber water flow rate at levels no lower than those established during the initial or subsequent performance test.

(2) Operating and maintaining each CPMS according to § 63.7331(b) and recording all information needed to document conformance with these requirements.

(3) Collecting and reducing monitoring data for pressure drop and scrubber water flow rate according to § 63.7331(e)(1) through (3).

(d) For each hot water scrubber applied to pushing emissions and subject to the operating limits in § 63.7290(f)(2), you must demonstrate continuous compliance by meeting the requirements in paragraphs (d)(1) through (3) of this section.

(1) Maintaining the daily average water pressure and temperature at levels no lower than those established during the initial or subsequent performance test.

(2) Operating and maintaining each CPMS according to § 63.7331(b) and recording all information needed to document conformance with these requirements.

(3) Collecting and reducing monitoring data for water pressure and temperature according to § 63.7331(f).

(e) For each capture system applied to pushing emissions and subject to the operating limit in § 63.7290(f)(3), you must demonstrate continuous compliance by meeting the requirements in paragraph (e)(1), (2), or (3) of this section:

(1) If you elect the operating limit for volumetric flow rate in § 63.7290(f)(3):

(i) Maintaining the daily average volumetric flow rate at the inlet of the control device at or above the minimum level established during the initial or subsequent performance test; and

(ii) Checking the volumetric flow rate at least every 8 hours to verify the daily average is at or above the minimum level established during the initial or subsequent performance test and recording the results of each check.

(2) If you elect the operating limit for fan motor amperes in § 63.7290(f)(3)(i):

(i) Maintaining the daily average fan motor amperages at or above the minimum level established during the initial or subsequent performance test; and

(ii) Checking the fan motor amperage at least every 8 hours to verify the daily average is at or above the minimum level established during the initial or subsequent performance test and recording the results of each check.

(3) If you elect the operating limit for static pressure or fan RPM in § 63.7290(f)(3)(ii):

(i) Maintaining the daily average static pressure at the inlet to the control device at an equal or greater vacuum than established during the initial or subsequent performance test or the daily average fan RPM at or above the minimum level established during the initial or subsequent performance test; and

(ii) Checking the static pressure or fan RPM at least every 8 hours to verify the daily average static pressure at the inlet to the control device is at an equal or greater vacuum than established during the initial or subsequent performance test or the daily average fan RPM is at or above the minimum level established during the initial or subsequent performance test and recording the results of each check.

(f) Beginning on the first day compliance is required under § 63.7283, you must demonstrate continuous compliance for each by-product coke oven battery subject to the opacity limit for battery stacks in § 63.7296(a) by meeting the requirements in paragraphs (f)(1) and (2) of this section:

(1) Maintaining the daily average opacity at or below 15 percent for a battery on a normal coking cycle or 20 percent for a battery on batterywide extended coking; and

(2) Operating and maintaining a COMS and collecting and reducing the COMS data according to § 63.7331(j).

(g) For each battery stack subject to the emission limits in § 63.7296(c) through (f), you must demonstrate continuous compliance by meeting the requirements in paragraphs (g)(1) through (5) of this section:

(1) Maintaining emissions of particulate matter at or below the applicable limits in § 63.7296(c);

(2) Maintaining emissions of mercury at or below the applicable limits in § 63.7296(d);

(3) Maintaining emissions of total acid gases at or below the applicable limits in § 63.7296(e);

(4) Maintaining emissions of hydrogen cyanide at or below the applicable limits in § 63.7296(f); and

(5) Conducting subsequent performance tests to demonstrate continuous compliance once every five years.

(h) Beginning on the first day compliance is required under § 63.7283, you must demonstrate continuous compliance with the TDS limit for quenching in § 63.7295(a)(1)(i) by meeting the requirements in paragraphs (h)(1) and (2) of this section:

(1) Maintaining the TDS content of the water used to quench hot coke at 1,100 mg/L or less; and

(2) Determining the TDS content of the quench water at least weekly according to the requirements in § 63.7325(a) and recording the sample results.

(i) Beginning on the first day compliance is required under § 63.7283, you must demonstrate continuous compliance with the constituent limit for quenching in § 63.7295(a)(1)(ii) by meeting the requirements in paragraphs (i)(1) and (2) of this section:

(1) Maintaining the sum of the concentrations of benzene, benzo(a)pyrene, and naphthalene in the water used to quench hot coke at levels less than or equal to the site-specific limit approved by the permitting authority; and

(2) Determining the sum of the constituent concentrations at least monthly according to the requirements in § 63.7325(c) and recording the sample results.

(j) For each multicyclone applied to pushing emissions and subject to the operating limit in § 63.7290(f)(4), you must demonstrate compliance by meeting the requirements in paragraphs (j)(1) through (3) of this section.

(1) Maintaining the daily average pressure drop at a level at or below the level established during the initial or subsequent performance test.

(2) Operating and maintaining each CPMS according to § 63.7331(k) and recording all information needed to document conformance with these requirements.

(3) Collecting and reducing monitoring data for pressure drop according to § 63.7331(e)(1) through (3).

(k) For each HNR HRSG main stack subject to the emission limits in § 63.7297(a) through (d), you must demonstrate continuous compliance by

meeting the requirements in paragraphs (k)(1) through (5) of this section:

(1) Maintaining emissions of particulate matter at or below the applicable limits in § 63.7297(a);

(2) Maintaining emissions of mercury at or below the applicable limits in § 63.7297(b);

(3) Maintaining emissions of total acid gases at or below the applicable limits in § 63.7297(c);

(4) Maintaining emissions of total PAHs at or below the applicable limits in § 63.7297(d); and

(5) Conducting subsequent performance tests to demonstrate continuous compliance once every five years.

(l) For each HNR HRSG bypass/waste heat stack subject to the emission limits in § 63.7298(a) through (e), you must demonstrate continuous compliance by meeting the requirements in paragraphs (l)(1) through (6) of this section:

(1) Maintaining emissions of particulate matter at or below the applicable limits in § 63.7298(a);

(2) Maintaining emissions of mercury at or below the applicable limits in § 63.7298(b);

(3) Maintaining emissions of total acid gases at or below the applicable limits in § 63.7298(c);

(4) Maintaining emissions of total PAHs at or below the applicable limits in § 63.7298(d);

(5) Maintaining emissions of total formaldehyde at or below the applicable limits in § 63.7298(e); and

(6) Conducting subsequent performance tests to demonstrate continuous compliance once every five years.

■ 34. Section 63.7334 is amended by revising paragraphs (a)(3), (4), and (c) to read as follows:

§ 63.7334 How do I demonstrate continuous compliance with the work practice standards that apply to me?

(a) * * *

(3) Make all observations and calculations for opacity observations of fugitive pushing emissions in accordance with Method 9 in appendix A–4 to 40 CFR part 60 using a Method 9 certified observer unless you have an approved alternative procedure under paragraph (a)(7) of this section. Alternatively, ASTM D7520–16, (incorporated by reference, see § 63.14) may be used with the following conditions:

(i) During the digital camera opacity technique (DCOT) certification procedure outlined in section 9.2 of ASTM D7520–16 (incorporated by reference, see § 63.14), the owner or operator or the DCOT vendor must present the plumes in front of various backgrounds of color and contrast representing conditions anticipated during field use such as blue sky, trees, and mixed backgrounds (clouds and/or a sparse tree stand).

(ii) The owner or operator must also have standard operating procedures in place including daily or other frequency quality checks to ensure the equipment is within manufacturing specifications as outlined in section 8.1 of ASTM D7520–16 (incorporated by reference, see § 63.14).

(iii) The owner or operator must follow the recordkeeping procedures outlined in § 63.10(b)(1) for the DCOT certification, compliance report, data sheets, and all raw unaltered JPEGs used for opacity and certification determination.

(iv) The owner or operator or the DCOT vendor must have a minimum of four independent technology users apply the software to determine the visible opacity of the 300 certification plumes. For each set of 25 plumes, the user may not exceed 15 percent opacity of anyone reading and the average error must not exceed 7.5 percent opacity.

(v) Use of this approved alternative does not provide or imply a certification or validation of any vendor's hardware or software. The onus to maintain and verify the certification and/or training of the DCOT camera, software, and operator in accordance with ASTM D7520–16 (incorporated by reference, see § 63.14) and these requirements is on the facility, DCOT operator, and DCOT vendor.

(4) Record pushing opacity observations at 15-second intervals as required in section 2.4 of Method 9 in appendix A–4 to 40 CFR part 60. The requirement in section 2.4 of Method 9 for a minimum of 24 observations does not apply, and the data reduction requirements in section 2.5 of Method 9 do not apply. The requirement in § 63.6(h)(5)(ii)(B) for obtaining at least 3 hours of observations (thirty 6-minute averages) to demonstrate initial compliance does not apply. Alternatively, ASTM D7520–16, (incorporated by reference, see § 63.14) may be used with the following conditions:

(i) During the digital camera opacity technique (DCOT) certification procedure outlined in section 9.2 of ASTM D7520–16 (incorporated by reference, see § 63.14), the owner or operator or the DCOT vendor must present the plumes in front of various backgrounds of color and contrast representing conditions anticipated during field use such as blue sky, trees, and mixed backgrounds (clouds and/or a sparse tree stand).

(ii) The owner or operator must also have standard operating procedures in place including daily or other frequency quality checks to ensure the equipment is within manufacturing specifications as outlined in section 8.1 of ASTM D7520–16 (incorporated by reference, see § 63.14).

(iii) The owner or operator must follow the recordkeeping procedures outlined in § 63.10(b)(1) for the DCOT certification, compliance report, data sheets, and all raw unaltered JPEGs used for opacity and certification determination.

(iv) The owner or operator or the DCOT vendor must have a minimum of four independent technology users apply the software to determine the visible opacity of the 300 certification plumes. For each set of 25 plumes, the user may not exceed 15 percent opacity of anyone reading and the average error must not exceed 7.5 percent opacity.

(v) Use of this approved alternative does not provide or imply a certification or validation of any vendor's hardware or software. The onus to maintain and verify the certification and/or training of the DCOT camera, software, and operator in accordance with ASTM D7520–16 (incorporated by reference, see § 63.14) and these requirements is on the facility, DCOT operator, and DCOT vendor.

* * * * *

(c) For each nonrecovery coke oven battery subject to the work practice standards in § 63.7293(a), you must demonstrate continuous compliance by maintaining records that document each visual inspection of an oven prior to pushing and that the oven was not pushed unless there was no smoke in the open space above the coke bed and there was an unobstructed view of the door on the opposite side of the oven.

* * * * *

■ 35. Section 63.7336 is revised to read as follows:

§ 63.7336 What other requirements must I meet to demonstrate continuous compliance?

You must report each instance in which you did not meet each emission limitation in this subpart that applies to you. This includes periods of startup, shutdown, and malfunction. You must also report each instance in which you did not meet each work practice standard or operation and maintenance requirement in this subpart that applies to you. These instances are deviations from the emission limitations (including operating limits), work practice

standards, and operation and maintenance requirements in this subpart. These deviations must be reported according to the requirements in § 63.7341.

(a) In the event that an affected unit fails to meet an applicable standard, record the number of failures. For each failure, record the start date, start time and duration (in hours) of each failure.

(b) For each failure to meet an applicable standard, record and retain a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit and a description of the method used to estimate the emissions.

(c) Record actions taken to minimize emissions in accordance with § 63.7310(a), and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

■ 36. Section 63.7340 is amended by revising paragraph (e)(2) to read as follows:

§ 63.7340 What notifications must I submit and when?

* * * * *

(e) * * *

(2) For each initial compliance demonstration that does include a performance test, you must submit the notification of compliance status, including a summary of the performance test results, before the close of business on the 60th calendar day following completion of the performance test according to § 63.10(d)(2).

* * * * *

■ 37. Section 63.7341 is revised to read as follows:

§ 63.7341 What reports must I submit and when?

(a) *Compliance report due dates.* Unless the Administrator has approved a different schedule, you must submit quarterly compliance reports for battery stacks and semiannual compliance reports for all other affected sources to your permitting authority according to the requirements in paragraphs (a)(1) through (4) of this section.

(1) The first quarterly compliance report for battery stacks must cover the period beginning on the compliance date that is specified for your affected source in § 63.7283 and ending on the last date of the third calendar month. Each subsequent compliance report must cover the next calendar quarter.

(2) The first semiannual compliance report must cover the period beginning on the compliance date that is specified for your affected source in § 63.7283 and ending on June 30 or December 31, whichever date comes first after the compliance date that is specified for your affected source. Each subsequent compliance report must cover the semiannual reporting period from January 1 through June 30 or the semiannual reporting period from July 1 through December 31.

(3) All quarterly compliance reports for battery stacks must be postmarked or delivered no later than one calendar month following the end of the quarterly reporting period. All semiannual compliance reports must be postmarked or delivered no later than July 31 or January 31, whichever date is the first date following the end of the semiannual reporting period.

(4) For each affected source that is subject to permitting regulations pursuant to 40 CFR part 70 or 40 CFR part 71, and if the permitting authority has established dates for submitting semiannual reports pursuant to 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A), you may submit the first and subsequent compliance reports according to the dates the permitting authority has established instead of according to the dates in paragraphs (a)(1) through (4) of this section.

(b) *Quarterly compliance report contents.* Each quarterly report must provide information on compliance with the emission limitations for battery stacks in § 63.7296. The reports must include the information in paragraphs (c)(1) through (3), and as applicable, paragraphs (c)(4) through (8) of this section.

(c) *Semiannual compliance report contents.* Each compliance report must provide information on compliance with the emission limitations, work practice standards, and operation and maintenance requirements for all affected sources except battery stacks. The reports must include the information in paragraphs (c)(1) through (3) of this section, and as applicable, paragraphs (c)(4) through (8) of this section.

(1) Company name and address (including county).

(2) Statement by a responsible official, with the official's name, title, and signature, certifying the truth, accuracy, and completeness of the content of the report. If your report is submitted via the Compliance and Emissions Data Reporting Interface (CEDRI), the certifier's electronic signature during the submission process replaces this requirement.

(3) Date of report and beginning and ending dates of the reporting period. You are no longer required to provide the date of report when the report is submitted via CEDRI.

(4) Beginning on January 2, 2025, if you failed to meet an applicable standard, the compliance report must include, for each instance, the start date, start time, and duration (in hours) of each failure. For each failure, the compliance report must include a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

(5) If there were no deviations from the continuous compliance requirements in § 63.7333(e) for battery stacks, a statement that there were no deviations from the emission limitations during the reporting period. If there were no deviations from the continuous compliance requirements in §§ 63.7333 through 63.7335 that apply to you (for all affected sources other than battery stacks), a statement that there were no deviations from the emission limitations, work practice standards, or operation and maintenance requirements during the reporting period.

(6) If there were no periods during which a continuous monitoring system (including COMS, continuous emission monitoring system (CEMS), or CPMS) was out-of-control as specified in § 63.8(c)(7), a statement that there were no periods during which a continuous monitoring system was out-of-control during the reporting period.

(7) For each deviation from an emission limitation in this subpart (including quench water limits) and for each deviation from the requirements for work practice standards in this subpart that occurs at an affected source where you are not using a continuous monitoring system (including a COMS, CEMS, or CPMS) to comply with the emission limitations in this subpart, the compliance report must contain the information in paragraphs (7)(i) and (ii) of this section. This includes periods of startup, shutdown, and malfunction.

(i) The total operating time of each affected source during the reporting period.

(ii) Information on the duration and cause of deviations (including unknown cause, if applicable) as applicable and the corrective action taken.

(8) For each deviation from an emission limitation occurring at an affected source where you are using a continuous monitoring system (including COMS, CEMS, or CPMS) to comply with the emission limitation in this subpart, you must include the information in paragraphs (c)(4) and (8)(i) through (xii) of this section. This includes periods of startup, shutdown, and malfunction.

(i) The date and time that each malfunction started and stopped.

(ii) The start date, start time, and duration in hours that each continuous monitoring system (including COMS, CEMS, or CPMS) was inoperative, except for zero (low-level) and high-level checks.

(iii) The start date, start time, and duration in hours that each continuous monitoring system (including COMS, CEMS, or CPMS) was out-of-control, including the information in § 63.8(c)(8).

(iv) The date and time that each deviation started and stopped, the duration in hours, and whether each deviation occurred during a period of startup, shutdown, or malfunction or during another period.

(v) A summary of the total duration in hours of the deviation during the reporting period and the total duration as a percent of the total source operating time during that reporting period.

(vi) A breakdown of the total duration in hours of the deviations during the reporting period into those that are due to startup, shutdown, control equipment problems, process problems, other known causes, and other unknown causes.

(vii) A summary of the total duration in hours of continuous monitoring system downtime during the reporting period and the total duration of continuous monitoring system downtime as a percent of the total source operating time during the reporting period.

(viii) An identification of each HAP that was monitored at the affected source.

(ix) A brief description of the process units.

(x) A brief description of the continuous monitoring system.

(xi) The date of the latest continuous monitoring system certification or audit.

(xii) A description of any changes in continuous monitoring systems, processes, or controls since the last reporting period.

(xiii) The total operating time of each affected source during the reporting period.

(d) [Reserved]

(e) *Part 70 monitoring report.* If you have obtained a title V operating permit for an affected source pursuant to 40 CFR part 70 or 40 CFR part 71, you must report all deviations as defined in this subpart in the semiannual monitoring report required by 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A). If you submit a compliance report for an affected source along with, or as part of, the semiannual monitoring report required by 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A), and the compliance report includes all the required information concerning deviations from any emission limitation or work practice standard in this subpart, submission of the compliance report satisfies any obligation to report the same deviations in the semiannual monitoring report. However, submission of a compliance report does not otherwise affect any obligation you may have to report deviations from permit requirements to your permitting authority.

(f) *Electronic reporting of compliance reports.* Beginning on July 7, 2026, or once the report template for this subpart has been available on the CEDRI website for one year, whichever date is later, submit all subsequent reports to the EPA via the CEDRI according to § 63.9(k) except that confidential business information (CBI) should be submitted according to paragraph (h) of this section.

(g) *Electronic Reporting of Performance Tests.* Beginning on September 3, 2024, within 60 days after the date of completing each performance test required by this subpart, you must submit the results of the performance test following the procedure specified in § 63.9(k). CBI should be submitted according to paragraph (h) of this section. Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (*https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert*) at the time of the test must be submitted in a file format generated using the EPA's ERT. Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on the EPA's ERT website. Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test must be included as an attachment in the ERT or alternate electronic file. If a performance test consists only of opacity measurements, reporting using the ERT and CEDRI is not required.

(h) *Confidential business information (CBI).* For notifications and reports required to be submitted to CEDRI:

(1) The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim for some of the information submitted under paragraph (f) or (g) of this section, you must submit a complete file, including information claimed to be CBI, to the EPA.

(2) For performance test reports according to paragraph (g) of this section, the file must be generated using the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website.

(3) Clearly mark the part or all of the information that you claim to be CBI. Information not marked as CBI may be authorized for public release without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

(4) The preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol, or other online file sharing services. Electronic submissions must be transmitted directly to the OAQPS CBI Office at the email address *oaqpscbi@epa.gov,* and as described above, should include clear CBI markings. For performance test reports, CBI should be flagged to the attention of, the Group Leader, Measurement Policy Group; for all other reports and notifications, the Coke Ovens Sector Lead should be flagged. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email *oaqpscbi@epa.gov* to request a file transfer link.

(5) If you cannot transmit the file electronically, you may send CBI information through the postal service to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Group Leader, Measurement Policy Group or Coke Oven Sector Lead as indicated in paragraph (4) of this section. The mailed CBI material should be double wrapped and clearly marked. Any CBI markings should not show through the outer envelope.

(6) All CBI claims must be asserted at the time of submission. Anything submitted using CEDRI cannot later be claimed CBI. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(7) You must submit the same file submitted to the CBI office with the CBI omitted to the EPA via the EPA's CDX as described in paragraph (f) or (g) of this section.

■ 38. Section 63.7342 is revised to read as follows:

§ 63.7342 What records must I keep?

(a) You must keep the records specified in paragraphs (a)(1) through (5) of this section.

(1) A copy of each notification and report that you submitted to comply with this subpart, including all documentation supporting any initial notification or notification of compliance status that you submitted, according to the requirements in § 63.10(b)(2)(xiv).

(2) Beginning on January 2, 2025, records of the occurrence and duration of each startup, shutdown, or malfunction of process, air pollution control, and monitoring equipment.

(3) Beginning on January 2, 2025, for each failure to meet an applicable standard, a list of the affected sources or equipment, whether the failure occurred during startup, shutdown, or malfunction, and records of the start date, start time, and duration (in hours) of each failure to meet an applicable standard. Include an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

(4) Beginning on January 2, 2025, records of the actions taken to minimize emissions in accordance with § 63.7310(a), and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

(5) Records of performance tests, performance evaluations, and opacity observations as required in § 63.10(b)(2)(viii).

(b) For each COMS or CEMS, you must keep the records specified in paragraphs (b)(1) through (4) of this section.

(1) Records described in § 63.10(b)(2)(vi) through (xi).

(2) Monitoring data for COMS during a performance evaluation as required in § 63.6(h)(7)(i) and (ii).

(3) You shall keep these written procedures on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan is revised, you shall keep previous (*i.e.,* superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to the plan. The program of corrective action should be included in the plan required under § 63.8(d)(2).

(4) Records of the date and time that each deviation started and stopped, the cause of the deviation, and whether the deviation occurred during a period of startup, shutdown, or malfunction or during another period.

(c) You must keep the records in § 63.6(h)(6) for visual observations.

(d) You must keep the records required in §§ 63.7333 through 63.7335 to show continuous compliance with each emission limitation, work practice standard, and operation and maintenance requirement that applies to you.

■ 39. Section 63.7351 is amended by:
■ a. Revising paragraph (c)(1); and
■ b. Adding paragraph (c)(7).

The revision and addition read as follows:

§ 63.7351 Who implements and enforces this subpart?

* * * * *

(c) * * *

(1) Approval of alternatives to work practice standards for fugitive pushing emissions in § 63.7291(a) for a by-product coke oven battery with vertical flues, fugitive pushing emissions in § 63.7292(a) for a by-product coke oven battery with horizontal flues, fugitive pushing emissions in § 63.7293 for a nonrecovery coke oven battery, soaking for a by-product coke oven battery in § 63.7294(a), and quenching for a coke oven battery in § 63.7295(b) under § 63.6(g).

* * * * *

(7) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

■ 40. Section 63.7352 is amended by:
■ a. Adding definitions in alphabetical order for ''Battery waste heat flues'' and ''Bypass stack'';
■ b. Revising definitions of ''Coke oven battery'' and ''Coke plant'';
■ c. Adding definitions in alphabetical order for ''Heat and/or nonrecovery coke oven battery'', ''Heat recovery steam generator'', ''Heat recovery steam generator bypass/waste heat stack'', and ''Heat recovery steam generator main stack'';
■ d. Revising the definition for ''Nonrecovery coke oven battery''; and
■ e. Adding definitions in alphabetical order for ''Pushing/charging machine (PCM)'', ''Total acid gases'', ''Total polycyclic aromatic hydrocarbons (total PAH)'', and ''Waste heat stack''.

The additions and revisions read as follows:

§ 63.7352 What definitions apply to this subpart?

* * * * *

Battery waste heat flues means the channels outside the coke oven and between the wall separating adjacent ovens as well as each end wall. At any one time, half of the flues in a given wall will be burning gas while the other half will be conveying waste heat from the combustion flues to a brick heat exchanger and then on to the battery combustion stack.

* * * * *

Bypass stack at a heat recovery facility means a stack through which emissions are discharged from a common tunnel that collects gases from a coke oven battery. and where the emissions are not passed through a heat recovery unit. Common tunnels typically are equipped with afterburners to further reduce organic emissions in the coke oven gas.

* * * * *

Coke oven battery means a group of ovens connected by common walls, where coal undergoes destructive distillation to produce coke. A coke oven battery includes by-product and nonrecovery processes.

Coke plant means a facility that produces coke from coal in either a by-product coke oven battery or a nonrecovery coke oven battery.

* * * * *

Heat and/or nonrecovery coke oven battery means a group of ovens, connected by common side walls, in which coal undergoes destructive distillation under negative pressure to produce coke and coke oven gas and from which by-products are not recovered. The common tunnels typically contain afterburners to further reduce organic emissions in the coke oven gas. For nonrecovery plants (*i.e.,* no chemical recovery) with heat recovery, the oven gases are vented through common tunnels to a heat recovery steam generator that produces steam. Heat recovery coke oven batteries may release oven gases through common tunnels and then into the atmosphere through bypass stacks when the heat recovery steam generators are not available due to maintenance or repair. For nonrecovery coke oven batteries (*i.e.,* no chemical recovery) without heat recovery, oven gases are vented through common tunnels and then released to the atmosphere through waste heat stacks.

Heat recovery steam generator is a process unit that recovers heat from coke oven gas in order to produce steam. Units typically are equipped with desulfurization units and baghouses to remove pollutants from the exhaust gases.

Heat recovery steam generator bypass/waste heat stack means a stack that allows coke oven gas to be vented from the coke oven batteries through common tunnels and into the

atmosphere when there are no heat recovery steam generator units available for heat recovery. Common tunnels typically are equipped with afterburners to further reduce organic emissions in the coke oven gas.

Heat recovery steam generator main stack means the stack that is the point of final discharge to the atmosphere of the gases emanating from a heat recovery steam generator and its control devices, which typically are desulfurization units and baghouses.

* * * * *

Nonrecovery coke oven battery means a group of ovens, connected by common walls, where coal undergoes destructive distillation under negative pressure to produce coke and which is designed for the combustion of the coke oven gas from which by-products are not recovered. Also known as a heat and/or nonrecovery battery. Nonrecovery coke oven battery refers to units from which heat is recovered from the coke oven gas exhaust as well as units where heat is not recovered. Both heat and/or nonrecovery batteries are connected by common tunnels that typically include afterburners to further reduce organic emissions in the coke oven gas.

* * * * *

Pushing/charging machine (PCM) means the combined coke oven pushing and charging machine operated on rail tracks to open an oven door, push the finished coke from the open oven, and close the oven door, and to charge the adjacent oven with coal to start the coking cycle. Typically used with horizontal ovens such as those at nonrecovery coke facilities.

* * * * *

Total acid gases means the sum of hydrogen chloride and hydrogen fluoride.

Total polycyclic aromatic hydrocarbons (total PAH) means the sum of acenaphthene, acenaphthylene, anthracene, benz[a]anthracene, benzo[a]pyrene, benzo[b]fluoranthene, benzo[g,h,i]perylene, benzo[k]fluoranthene, chrysene, dibenz[a,h]anthracene, fluoranthene, fluorene, indeno (1,2,3-cd) pyrene, naphthalene, phenanthrene, perylene, and pyrene.

* * * * *

Waste heat stack at a heat and/or nonrecovery facility means a stack that allows coke oven gas to be vented from the coke oven batteries through common tunnels and into the atmosphere when there are no units available for heat recovery. Common tunnels typically contain afterburners to further reduce organic emissions in coke oven gas.

* * * * *

■ 41. Revise table 1 to subpart CCCCC of part 63 to read as follows:

Table 1 to Subpart CCCCC of Part 63—Applicability of General Provisions to Subpart CCCCC

As required in § 63.7350, you must comply with each applicable requirement of the NESHAP General Provisions (subpart A of this part) as shown in the following table:

Citation	Subject	Applies to subpart CCCCC?	Explanation
§ 63.1	Applicability	Yes.	
§ 63.2	Definitions	Yes.	
§ 63.3	Units and Abbreviations	Yes.	
§ 63.4	Prohibited Activities	Yes.	
§ 63.5	Construction/Reconstruction	Yes.	
§ 63.6(a), (b), (c), (d), (e)(1)(iii), (f)(2)–(3), (g), (h)(2)–(8).	Compliance with Standards and Maintenance Requirements.	Yes.	
§ 63.6(e)(1)(i)	General Duty to Minimize Emissions	No	See § 63.7310(a) for general duty requirement.
§ 63.6(e)(1)(ii)	Requirement to Correct Malfunctions ASAP	No.	
§ 63.6(e)(3)	SSM Plan Requirements	No.	
§ 63.6(f)(1)	SSM Exemption	No.	
§ 63.6(h)(1)	SSM Exemption	No.	
§ 63.6(h)(9)	Adjustment to an Opacity Emission Standard.	Yes.	
§ 63.7(a)(3), (b)–(d), (e)(2)–(4), (f)–(h).	Performance Testing Requirements	Yes.	
§ 63.7(e)(1)	Performance Testing	No	See §§ 63.7322(a), 63.7324(a), and 63.7325(a).
§ 63.7(a)(1)–(2)	Applicability and Performance Test Dates	No	Subpart CCCCC specifies applicability and dates.
§ 63.8(a)(1)–(3), (b), (c)(1)(ii), (c)(2)–(3), (c)(4)(i)–(ii), (c)(5)–(8), (d)(1)–(2), (e), (f)(1)–(5), (g)(1)–(4).	Monitoring Requirements	Yes	CMS requirements in § 63.8(c)(4) (i)–(ii), (c)(5), and (c)(6) apply only to COMS for battery stacks.
§ 63.8(c)(1)(i)	General Duty to Minimize Emissions and CMS Operation.	No.	
§ 63.8(c)(1)(iii)	Requirement to Develop SSM Plan for CMS	No.	
§ 63.8(a)(4)	Additional Monitoring Requirements for Control Devices in § 63.11.	No	Flares are not a control device for subpart CCCCC affected sources.
§ 63.8(c)(4)	Continuous Monitoring System (CMS) Requirements.	No	Subpart CCCCC specifies requirements for operation of CMS.
§ 63.8(d)(3)	Written procedures for CMS	No	See § 63.7342(b)(3).
§ 63.8(e)(4)–(5)	Performance Evaluations	Yes	Except COMS performance evaluation must be conducted before the compliance date.
§ 63.8(f)(6)	RATA Alternative	No	Subpart CCCCC does not require CEMS.
§ 63.8(g)(5)	Data Reduction	No	Subpart CCCCC specifies data that can't be used in computing averages for COMS.
§ 63.9	Notification Requirements	Yes	Additional notifications for CMS in § 63.9(g) apply only to COMS for battery stacks.

Citation	Subject	Applies to subpart CCCCC?	Explanation
§ 63.10(a), (b)(1), (b)(2)(vi)–(x), (b)(2)(xiv), (b)(3), (c)(1)–(6), (c)(9)–(14), (d)(1)–(4), (e)(1)–(2), (e)(4), (f).	Recordkeeping and Reporting Requirements.	Yes	Additional records for CMS in § 63.10(c)(1)–(6), (9)–(14), and reports in § 63.10(d)(1)–(2) apply only to COMS for battery stacks.
§ 63.10(b)(2)(i)	Recordkeeping of Occurrence and Duration of Startups and Shutdowns.	No.	
§ 63.10(b)(2)(ii)	Recordkeeping of Failures to Meet a Standard.	No	See § 63.7342(a)(2)–(4).
§ 63.10(b)(2)(iii)	Maintenance Records	Yes.	
§ 63.10(b)(2)(iv)	Actions Taken to Conform with SSM Plan	No	See § 63.7342(a)(4) for records of actions taken to minimize emissions.
§ 63.10(b)(2)(v)	Actions Taken to Minimize Emissions During SSM.	No	See § 63.7342(a)(4) for records of actions taken to minimize emissions.
§ 63.10(b)(2)(xi)–(xii)	CMS Records for RATA Alternative	No	Subpart CCCCC doesn't require CEMS.
§ 63.10(c)(7)–(8)	Records of Excess Emissions and Parameter Monitoring Exceedances for CMS.	No	Subpart CCCCC specifies record requirements.
§ 63.10(c)(15)	Use of SSM Plan	No.	
§ 63.10(d)(5)(i)	Periodic SSM Reports	No	See § 63.7341(c)(4) for malfunction reporting requirements.
§ 63.10(d)(5)(ii)	Immediate SSM Reports	No.	
§ 63.10(e)(3)	Excess Emission Reports	No	Subpart CCCCC specifies reporting requirements.
§ 63.11	Control Device Requirements	No	Subpart CCCCC does not require flares.
§ 63.12	State Authority and Delegations	Yes.	
§§ 63.13–63.16	Addresses, Incorporations by Reference, Availability of Information and Confidentiality, Performance Track Provisions.	Yes.	

[FR Doc. 2024–13186 Filed 7–3–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL REGISTER

Vol. 89 Friday,

No. 129 July 5, 2024

Part III

Department of Health and Human Services

Centers for Medicare and Medicaid Services

42 CFR Parts 410, 413, 494, et al.

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 413, 494, and 512

[CMS–1805–P]

RIN 0938–AV27

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and revise the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2025. This rule also proposes to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. In addition, this proposed rule would update requirements for the Conditions for Coverage for ESRD Facilities, ESRD Quality Incentive Program, and ESRD Treatment Choices Model.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by August 26, 2024.

ADDRESSES: In commenting, please refer to file code CMS–1805–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1805–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1805–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

ESRDPayment@cms.hhs.gov or Nicolas Brock at (410) 786–5148, for issues related to the ESRD Prospective Payment System (PPS) and coverage and payment for renal dialysis services furnished to individuals with acute kidney injury (AKI).

ESRDApplications@cms.hhs.gov, for issues related to applications for the Transitional Drug Add-on Payment Adjustment (TDAPA) or Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).

ESRDQIP@cms.hhs.gov, for issues related to the ESRD Quality Incentive Program (QIP).

ETC–CMMI@cms.hhs.gov, for issues related to the ESRD Treatment Choices (ETC) Model.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/*.

Current Procedural Terminology (CPT) Copyright Notice: Throughout this proposed rule, we use CPT® codes and descriptions to refer to a variety of services. We note that CPT® codes and descriptions are copyright 2020 American Medical Association (AMA). All Rights Reserved. CPT® is a registered trademark of the AMA. Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents.

I. Executive Summary

A. Purpose

This rule proposes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS),

payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the Conditions for Coverage for ESRD facilities, the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model. Additionally, this rule proposes and discusses policies that reflect our commitment to achieving equity in health care for our beneficiaries by supporting our ability to assess whether, and to what extent, our programs and policies perpetuate or exacerbate systemic barriers to opportunities and benefits for underserved communities. For example, we are proposing to expand access to home dialysis for patients with acute kidney injury, which would assist this vulnerable population with transportation and scheduling issues and allow them to have flexibility in their dialysis treatment modality. Additionally, we discuss the incorporation of oral-only drugs into the ESRD PPS bundled payment beginning January 1, 2025, which will expand access to the 21 percent of the ESRD PPS population who do not have Part D coverage. Our internal data show that a significant portion of ESRD beneficiaries who lack Part D coverage are African American/Black patients with ESRD. Our policy objectives include a commitment to advancing health equity, which stands as the first pillar of the Centers for Medicare & Medicaid Services (CMS) Strategic Plan,[1] and reflect the goals of the Administration, as stated in the President's Executive Order 13985.[2] We define health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [3] In the calendar year (CY) 2023 ESRD PPS final rule, we noted that, when compared with all Medicare fee-for-service (FFS) beneficiaries, Medicare FFS beneficiaries receiving dialysis are disproportionately young, male, African American, have disabilities and low income as measured by eligibility for both Medicare and Medicaid (dual eligible status), and reside in an urban setting (87 FR 67183). In this proposed rule, we continue to address health equity for beneficiaries with ESRD who are members of underserved communities, including but not limited to those living in rural communities, those who have disabilities, and racial, and ethnic minorities and sovereign American Indian and Alaska Native tribes. The term 'underserved communities' refers to populations sharing a particular characteristic, including geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life.[4]

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning CY 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule proposes updates to the ESRD PPS for CY 2025.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This proposed rule would update the AKI payment rate for CY 2025. Additionally, this rule proposes to extend payment for home dialysis and the payment adjustment for home and self-dialysis training to renal dialysis services provided to beneficiaries with AKI.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program establishes incentives for facilities to achieve high quality performance on measures with the goal of improving outcomes for ESRD beneficiaries. This rule proposes to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy measure topic and to remove National Healthcare Safety Network (NHSN) Dialysis Event reporting measure beginning with Payment Year (PY) 2027. This rule also requests public comment on two topics relevant to the ESRD QIP.

4. End-Stage Renal Disease Treatment Choices (ETC) Model

The ETC Model is a mandatory Medicare payment model tested under section 1115A of the Act. The ETC Model is operated by the Center for Medicare and Medicaid Innovation (Innovation Center). The ETC Model tests the use of payment adjustments to encourage greater utilization of home dialysis and kidney transplants, to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures. The ETC Model was finalized as part of a final rule published in the **Federal Register** on September 29, 2020, titled ''Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' (85 FR 61114), referred to herein as the ''Specialty Care Models final rule.'' Subsequently, the ETC Model has been updated three times in the annual ESRD PPS final rules for calendar year (CY) 2022 (86 FR 61874), CY 2023 (87 FR 67136), and CY 2024 (88 FR 76344).

This proposed rule would make certain changes to the methodology CMS uses to identify transplant failure for the purposes of defining an ESRD beneficiary and attributing an ESRD beneficiary to the ETC Model. We are also soliciting input from the public

[1] Centers for Medicare & Medicaid Services (2022). Health Equity. Available at: *https://www.cms.gov/pillar/health-equity.*

[2] 86 FR 7009 (January 25, 2021). *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[3] Centers for Medicare & Medicaid Services (2022). Health Equity. Available at: *https://www.cms.gov/pillar/health-equity.*

[4] 86 FR 7009 (January 25, 2021). *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

through a Request for Information (RFI) on topics pertaining to increasing equitable access to home dialysis and kidney transplantation. Feedback we receive from the public will be used to inform CMS' thinking regarding opportunities and barriers the Innovation Center may address in potential successor models to the ETC Model.

B. Summary of the Major Provisions

1. ESRD PPS

• *Proposed update to the ESRD PPS base rate for CY 2025:* The proposed CY 2025 ESRD PPS base rate is $273.20, an increase from the CY 2024 ESRD PPS base rate of $271.02. This proposed amount reflects the application of the wage index budget-neutrality adjustment factor (0.990228) and a productivity-adjusted market basket percentage increase of 1.8 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $273.20 (($271.02 × 0.990228) × 1.018 = $273.20).

• *Proposed modification to the wage index methodology:* We are proposing a new ESRD-specific wage index that would be used to adjust ESRD PPS payment for geographic differences in area wages on an annual basis. For CY 2025, we are proposing to change our methodology to use mean hourly wage data from the Bureau of Labor Statistics (BLS) Occupation Employment and Wage Statistics (OEWS) program and full time equivalent (FTE) labor and treatment volume data from freestanding ESRD facility Medicare cost reports to produce an ESRD-specific wage index for use, instead of using the hospital wage index values for each geographic area, which are derived from hospital cost report data. Additionally, we are proposing to update the wage index to reflect the latest core-based statistical area (CBSA) delineations determined by the Office of Management and Budget (OMB) to better account for differing wage levels in areas in which ESRD facilities are located.

• *Proposed annual update to the wage index:* For CY 2025, we are proposing to update the wage index using the proposed new methodology previously discussed based on the latest available data. This is consistent with our past approach to updating the ESRD PPS wage index but would use the proposed new wage index methodology based on data from BLS and freestanding ESRD facility Medicare cost reports.

• *Proposed modification to the outlier policy:* We are proposing to revise the outlier policy in several ways. For the outlier payment methodology, we are proposing to use a drug inflation factor based on actual spending on drugs and biological products rather than the growth in the price proxy for drugs used in the ESRD Bundled (ESRDB) market basket. We are also proposing to use the growth in the ESRDB market basket price proxies for laboratory tests and supplies to estimate CY 2025 outlier spending for these items. Additionally, we are proposing to account for the post-TDAPA add-on payment adjustment amount for outlier-eligible drugs and biological products during the post-TDAPA period. Lastly, we are proposing to expand the list of eligible ESRD outlier services to include drugs and biological products that were or would have been included in the composite rate prior to establishment of the ESRD PPS.

• *Proposed annual update to the outlier policy:* We are proposing to update the outlier policy based on the most current data and the proposed methodology changes previously discussed. Accordingly, we are proposing to update the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2025 using the latest available CY 2023 claims data. We are proposing to update the ESRD outlier services fixed dollar loss (FDL) amount for pediatric patients using the latest available CY 2023 claims data and update the FDL amount for adult patients using the latest available claims data from CY 2021, CY 2022, and CY 2023. For pediatric beneficiaries, the proposed FDL amount would increase from $11.32 to $223.44, and the MAP amount would increase from $23.36 to $58.39, as compared to CY 2024 values. For adult beneficiaries, the proposed FDL amount would decrease from $71.76 to $49.46, and the MAP amount would decrease from $36.28 to $33.57. We note that the proposed inclusion of composite rate drugs and biological products would cause a significant increase in the proposed FDL and MAP amounts for pediatric patients due to high-cost composite rate drugs furnished to pediatric beneficiaries; this is discussed in further detail in section II.B.3.e of this proposed rule. The 1.0 percent target for outlier payments was achieved in CY 2023, as outlier payments represented approximately 1.0 percent of total Medicare payments.

• *Proposed update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2025:* The proposed CY 2025 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is $10.18. This proposed offset amount reflects the application of the proposed ESRDB productivity-adjusted market basket update of 1.8 percent ($10.00 × 1.018 = $10.18). There are no capital-related assets set to receive the TPNIES in CY 2025 for which this offset would apply.

• *Proposed update to the Post-TDAPA Add-on Payment Adjustment amounts:* We calculate the post-TDAPA add-on payment adjustment in accordance with § 413.234(g). The proposed post-TDAPA add-on payment amount for Korsuva® is $0.4047 per treatment, which would be included in the calculation of the total post-TDAPA add-on payment adjustment for each quarter in CY 2025. The proposed post-TDAPA add-on payment adjustment amount for Jesduvroq is $0.0019 per treatment, which would be included in the calculation for only the fourth quarter of CY 2025. We are proposing to update these post-TDAPA add-on payment adjustment amounts according to the most recent data for the final rule. We are proposing to publish the final post-TDAPA add-on payment adjustment amount for drugs and biological products that do not have a full year of utilization data at the time of rulemaking after the publication of the final rule through a Change Request (CR). For CY 2025, this would be the case for Jesduvroq.

• *Proposed update to the Low-Volume Payment Adjustment (LVPA):* We are proposing to modify the LVPA policy to create a two-tiered LVPA whereby ESRD facilities that furnished fewer than 3,000 treatments per cost reporting year would receive a 28.3 percent upward adjustment to the ESRD PPS base rate and ESRD facilities that furnished 3,000 to 3,999 treatments would receive an 18.0 percent adjustment. We are also proposing that the tier determination would be based on the median treatment count over the past three cost reporting years.

• *Inclusion of oral-only drugs in the ESRD PPS bundled payment:* Under 42 CFR 413.174(f)(6), payment to an ESRD facility for oral-only renal dialysis service drugs and biological products is included in the ESRD PPS bundled payment effective January 1, 2025. In this proposed rule, we are providing information about how we will operationalize the inclusion of oral-only drugs into the ESRD PPS as well as budgetary estimates of the effects of this inclusion for public awareness.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

- *Proposed update to the payment rate for individuals with AKI:* We are proposing to update the AKI payment rate for CY 2025. The proposed CY 2025 payment rate is $273.20, which is the same as the base rate proposed for the ESRD PPS for CY 2025.
- *Proposed payment for home dialysis for beneficiaries with AKI:* We are proposing to allow Medicare payment for beneficiaries with AKI to dialyze at home. Payment for home dialysis treatments furnished to beneficiaries with AKI would be made at the same payment rate as in-center dialysis treatments. We are proposing to permit ESRD facilities to bill Medicare for the home and self-dialysis training add-on payment adjustment for beneficiaries with AKI, and to implement this adjustment in a budget neutral manner. We are proposing changes to the ESRD facility conditions for coverage (CfCs) to implement this policy change.

3. ESRD QIP

Beginning with PY 2027, we are proposing to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure, on which facility performance is scored on a single measure based on one set of performance standards, with a Kt/V Dialysis Adequacy measure topic, which would be comprised of four individual Kt/V measures and scored based on a separate set of performance standards for each of those measures. We are also proposing to remove the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure from the ESRD QIP measure set beginning with PY 2027. We are requesting public comment on a potential health equity payment adjustment and are also requesting public comment on potential future updates to the data validation policy.

4. ETC Model

We are proposing a modification to the methodology used to attribute ESRD Beneficiaries to the ETC Model, specifically, to the definition of an ESRD Beneficiary at 42 CFR 512.310. Under the ETC Model, CMS attributes ESRD beneficiaries to the ETC Model that meet several criteria including having a kidney transplant failure less than 12 months after the transplant date. We are proposing to refine the methodology we use identify ESRD Beneficiaries with a kidney transplant failure to reduce the likelihood that CMS is overestimating the true number of transplant failures for the purposes of the model. We provide more detail on the proposal and its rationale in section V.B of this proposed rule.

We are also seeking input from the public through a RFI on the future of the ETC Model, potential successor Models and other approaches CMS may consider to support beneficiary access to patient-centered modalities for treatment of ESRD.

C. Summary of Costs and Benefits

In section VIII.D.5 of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Proposed ESRD PPS

The impact table in section VIII.D.5.a of this proposed rule displays the estimated change in Medicare payments to ESRD facilities in CY 2025 compared to estimated Medicare payments in CY 2024. The overall impact of the CY 2025 payment changes is projected to be a 2.2 percent increase in Medicare payments. Hospital-based ESRD facilities have an estimated 3.9 percent increase in Medicare payments compared with freestanding ESRD facilities with an estimated 2.1 percent increase. We estimate that the aggregate ESRD PPS expenditures would increase by approximately $170 million in CY 2025 compared to CY 2024 as a result of the proposed payment policies in this rule. Because of the projected 2.2 percent overall payment increase, we estimate there would be an increase in beneficiary coinsurance payments of 2.2 percent in CY 2025, which translates to approximately $30 million.

Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. Under this authority, CMS implemented § 413.234 to establish the TDAPA, a transitional drug add-on payment adjustment for certain new renal dialysis drugs and biological products and § 413.236 to establish the TPNIES, a transitional add-on payment adjustment for certain new and innovative equipment and supplies. The TDAPA and the TPNIES are not budget neutral.

As discussed in section II.D of this proposed rule, since no new items were approved for the TPNIES for CY 2024 (88 FR 76431) there are no continuing TPNIES payments for CY 2025. In addition, since we did not receive any applications for the TPNIES for CY 2025, there would be no new TPNIES payments for CY 2025. As discussed in section II.E of this proposed rule, the TDAPA payment periods for Jesduvroq and DefenCath®, would continue into CY 2025. As described in section VIII.D.5.b of this proposed rule, we estimate that the TDAPA payment amounts in CY 2025 would be approximately $207,675, of which, $41,535 would be attributed to beneficiary coinsurance amounts.

2. Impacts of the Proposed Payment Rate for Renal Dialysis Services Furnished to Individuals With AKI

The impact table in section VIII.D.5.c of this proposed rule displays the estimated change in Medicare payments to ESRD facilities for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for such services in CY 2024. The overall impact of the CY 2025 changes is projected to be a 1.9 percent increase in Medicare payments for individuals with AKI. Hospital-based ESRD facilities would have an estimated 2.6 percent increase in Medicare payments compared with freestanding ESRD facilities that would have an estimated 1.9 percent increase. The overall impact reflects the effects of the proposed Medicare payment rate update and the proposed CY 2025 ESRD PPS wage index, as well as the proposed policy to extend payment for AKI dialysis at home, which is not expected to have any impact on payment rates. As discussed in section III.C.3, we are proposing to extend the ESRD PPS home and self-dialysis training add-on adjustment to AKI patients; however, that adjustment is required to be implemented in a budget neutral manner for AKI payments, so it would not have any impact on the overall payment amounts for AKI renal dialysis services and therefore is not included in these estimates. We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to individuals with AKI, at the proposed CY 2025 ESRD PPS base rate, would increase by $1 million in CY 2025 compared to CY 2024.

3. Impacts of the PY 2027 ESRD QIP as Proposed

We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are proposing in this proposed rule, the overall economic impact of the PY 2027 ESRD QIP will be approximately $145.1 million. The $145.1 million estimate for PY 2027 includes $130.5 million in costs associated with the collection of information requirements and approximately $14.6 million in payment reductions across all facilities.

4. Impacts of the Proposed Changes to the ETC Model

The proposed change to the definition of an ESRD Beneficiary for the purposes of attribution in the ETC Model is not expected to have a net effect on the model's projected economic impact.

II. Calendar Year (CY) 2025 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, CMS implemented the ESRD PPS, a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148), established that beginning with CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014, to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals [5] (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule, we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. Section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket percentage increase should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis drugs and biological products cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single per-treatment payment is made to an ESRD facility for all the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to an individual for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definition of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome). A different set of case-mix adjusters are applied for the pediatric population. Pediatric patient-level adjusters include two age categories (under age 13, or age 13 to 17) and two dialysis modalities (that is, peritoneal or hemodialysis) (§ 413.235(a) and (b)(1)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second payment adjustment reflects differences in area wage levels developed from core-based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

There are six additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) a training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3) a TDAPA for certain new renal dialysis drugs and biological products (§ 413.234(c)); (4) a TPNIES for certain new and innovative renal dialysis equipment and supplies (§ 413.236(d)); (5) a transitional pediatric ESRD add-on payment adjustment (TPEAPA) of 30 percent of the per-treatment payment amount for renal dialysis services furnished to pediatric ESRD patients (§ 413.235(b)(2)); and (6) a post-TDAPA add-on payment adjustment for certain new renal dialysis drugs and biological products after the end of the TDAPA period (§ 413.234(g)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule appeared in the August 12, 2010, issue of the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

[5] As discussed in the CY 2019 ESRD PPS final rule (83 FR 56922), we began using the term ''biological products'' instead of ''biologicals'' under the ESRD PPS to be consistent with FDA nomenclature. We use the term ''biological products'' in this proposed rule except where referencing specific language in the Act or regulations.

Most recently, we published a final rule, which appeared in the November 6, 2023, issue of the **Federal Register**, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model,'' referred to herein as the ''CY 2024 ESRD PPS final rule.'' In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy for CY 2024. We also finalized a post-TDAPA add-on payment adjustment; a TPEAPA for pediatric ESRD patients for CYs 2024, 2025, and 2026, administrative changes to the LVPA eligibility requirements to allow additional flexibilities for ESRD facilities impacted by a disaster or other emergency, clarifications on our TPNIES eligibility requirements, and, effective January 1, 2025, requirements for ESRD facilities to report time on machine for in-center hemodialysis treatments, and to report discarded amounts of renal dialysis drugs and biological products from single-dose containers or single-use packages. For further detailed information regarding these updates and policy changes, see 88 FR 76344.

B. Proposed Provisions of the CY 2025 ESRD PPS

1. Proposed CY 2025 ESRD Bundled (ESRDB) Market Basket Percentage Increase; Productivity Adjustment; and Labor-Related Share

a. Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. Section 1881(b)(14)(F)(i) of the Act also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRDB input price index using CY 2008 as the base year (75 FR 49151 through 49162). We subsequently revised and rebased the ESRDB input price index to a base year of CY 2012 in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136). In the CY 2019 ESRD PPS final rule (83 FR 56951 through 56964), we finalized a rebased ESRDB input price index to reflect a CY 2016 base year. In the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154), we finalized a revised and rebased ESRDB input price index to reflect a CY 2020 base year.

Although ''market basket'' technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term ''ESRDB market basket,'' as used in this document, refers to the ESRDB input price index.

The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

b. Proposed CY 2025 ESRD Market Basket Update

We propose to use the 2020-based ESRDB market basket as finalized in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154) to compute the proposed CY 2025 ESRDB market basket percentage increase based on the best available data. Consistent with historical practice, we propose to estimate the ESRDB market basket percentage increase based on IHS Global Inc.'s (IGI) forecast using the most recently available data at the time of rulemaking. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets. As discussed in section II.B.1.b.(3) of this proposed rule, we are proposing to calculate the market basket update for CY 2025 based on the proposed market basket percentage increase and the proposed productivity adjustment, following our longstanding methodology.

(1) Proposed CY 2025 Market Basket Percentage Increase

Based on IGI's first quarter 2024 forecast of the 2020-based ESRDB market basket, the proposed CY 2025 market basket percentage increase is 2.3 percent. We are also proposing that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase), we would use such data, if appropriate, to determine the CY 2025 market basket percentage increase in the final rule.

(2) Productivity Adjustment

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRDB market basket percentage increase shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year (FY), year, cost reporting period, or other annual period) (the ''productivity adjustment'').

The Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States economy. As we noted in the CY 2023 ESRD PPS final rule (87 FR 67155), the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act previously was published by BLS as private nonfarm business MFP. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term ''multifactor productivity'' with ''total factor productivity'' (TFP). BLS noted that this is a change in terminology only and would not affect the data or methodology.[6] As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business TFP; however, as mentioned previously, the data and methods are unchanged. We referred readers to *https://www.bls.gov/productivity/* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on CMS's website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.* In addition, in the CY 2022 ESRD PPS final rule (86 FR 61879), we noted that effective for CY 2022 and future years, we would be changing the name of this adjustment to refer to it as the productivity adjustment rather than

[6] Total Factor Productivity in Major Industries—2020. Available at: *https://www.bls.gov/news.release/prod5.nr0.htm.*

the MFP adjustment. We stated this was not a change in policy, as we would continue to use the same methodology for deriving the adjustment and rely on the same underlying data.

Based on IGI's first quarter 2024 forecast, the proposed productivity adjustment for CY 2025 (the 10-year moving average of TFP for the period ending CY 2025) is 0.5 percentage point. Furthermore, we are proposing that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the productivity adjustment), we would use such data, if appropriate, to determine the CY 2025 productivity adjustment in the final rule.

(3) CY 2025 Market Basket Update

In accordance with section 1881(b)(14)(F)(i) of the Act, we propose to base the CY 2025 market basket percentage increase on IGI's first quarter 2024 forecast of the 2020-based ESRDB market basket. We propose to then reduce the market basket percentage increase by the estimated productivity adjustment for CY 2025 based on IGI's first quarter 2024 forecast. Therefore, the proposed productivity-adjusted CY 2025 ESRDB market basket update is equal to 1.8 percent (2.3 percent market basket percentage increase reduced by a 0.5 percentage point productivity adjustment). Furthermore, as noted previously, we are proposing that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase and/or productivity adjustment), we would use such data, if appropriate, to determine the CY 2025 market basket percentage increase and productivity adjustment in the final rule.

(4) Labor-Related Share

We define the labor-related share as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. For the CY 2025 ESRD PPS payment update, we are proposing to continue using a labor-related share of 55.2 percent, which was finalized in the CY 2023 ESRD PPS final rule (87 FR 67153 through 67154).

2. Proposed CY 2025 ESRD PPS Wage Indices

a. Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, we established a policy to adjust the labor-related portion of the ESRD PPS base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. Under current policy, we use the Office of Management and Budget's (OMB's) CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at *https://www.whitehouse.gov/omb/information-for-agencies/bulletins/*.

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there are no hospital data. For a full discussion, see the CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we have computed the average wage index value of all hospitals in urban areas within the State to serve as a reasonable proxy for the wage index of that urban CBSA. For rural areas with no hospital data, we have computed the wage index using the average hospital wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We applied the statewide urban average based on the average of all urban areas within the State to Hinesville Fort Stewart, Georgia (78 FR 72173), and we applied the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172).

Under § 413.231(d), a wage index floor value of 0.6000 is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values, as finalized in the CY 2023 ESRD PPS final rule (87 FR 67161). Currently, all areas with wage index values that fall below the floor are located in Puerto Rico and the US Virgin Islands. However, the wage index floor value is applicable for any area that may fall below the floor. A further description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967) and the CY 2023 ESRD PPS final rule (87 FR 67161).

An ESRD facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2023 ESRD PPS final rule (87 FR 67153), we finalized the use of a labor-related share of 55.2 percent. In the CY 2021 ESRD PPS final rule (85 FR 71436), we updated the OMB delineations as described in the September 14, 2018, OMB Bulletin No. 18–04, beginning with the CY 2021 ESRD PPS wage index. In that same rule, we finalized the application of a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. We finalized that the transition would be phased in over 2 years, such that the reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. In the CY 2023 ESRD PPS final rule (87 FR 67161), we finalized a permanent policy under § 413.231(c) to apply a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. For CY 2025, as discussed in section II.B.1.b.(4) of this proposed rule, the proposed labor-related share to which the wage index would be applied is 55.2 percent.

In the CY 2011 ESRD PPS final rule (75 FR 49116) and the CY 2011 final rule on Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Part B (75 FR 73486) we established an ESRD PPS wage index methodology to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the hospital inpatient prospective payment system (IPPS). The ESRD PPS wage index values have historically been calculated without regard to geographic reclassifications authorized for acute care hospitals under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix.

b. Proposed Methodology Changes for the CY 2025 ESRD PPS Wage Index

CMS has received feedback on our longstanding ESRD PPS wage index methodology from interested parties through comments on routine wage index updates in the annual ESRD PPS proposed rules. Commenters often suggest specific improvements for the

ESRD PPS wage index. In the CY 2024 ESRD PPS final rule (88 FR 76359 through 76361), we discussed the comments on the routine wage index proposals from the CY 2024 ESRD PPS proposed rule (88 FR 42436); commenters, including the Medicare Payment Advisory Commission (MedPAC), suggested that we establish an ESRD PPS wage index for all ESRD facilities using wage data that represents all employers and industry-specific occupational weights, rather than the hospital wage data currently used. MedPAC specifically suggested that CMS implement the recommendations discussed in its June 2023 report to Congress,[7] which recommended moving away from the current IPPS wage index methodology in favor of a methodology based on all employer wage data for all Medicare PPSs with industry specific occupational weights. Additionally, MedPAC suggested that the new methodology reflect local area level differences in wages between and within metropolitan statistical areas and statewide rural areas and smooth wage index differences across adjacent local areas. MedPAC stated that, compared to the current IPPS wage index methodology, a methodology based on all employer wage data with industry-specific occupational weights would improve the accuracy and equity of payments for provider types other than inpatient acute care hospitals, such as ESRD facilities.

In past years some interested parties have contended that the methodology used to construct the current ESRD PPS wage index does not accurately reflect the ESRD facility labor market. These interested parties have noted that the ESRD PPS wage index is based on the IPPS wage index, which uses hospital data, which commenters have stated may not be applicable for ESRD facilities. More specifically, commenters have suggested that the types of labor used in ESRD facilities differ significantly from the types of labor used by hospitals, which may result in the use of relative wage values across the United States that do not accurately match the actual relative wages paid by ESRD facilities. For example, if ESRD facilities have a different proportion of registered nurses (RNs), technicians and administrative staff compared to hospitals, and if wages for each of those labor categories vary differentially across the country, it is possible that relative wages for ESRD facilities, given their occupational mix, would vary differently from relative wages for hospitals across CBSAs. Because of this, some commenters have specifically requested that CMS develop an ESRD PPS wage index based only on data from ESRD facilities. Additionally, some commenters have criticized the time lag associated with using the IPPS wage index, which is generally based on data from four FYs prior to the rulemaking year (see, for example, 88 FR 58961).

(1) December 2019 Technical Expert Panel (TEP)

In response to feedback from interested parties on the ESRD PPS wage index, CMS's data contractor hosted a Technical Expert Panel (TEP) in December of 2019.[8] During this TEP, the contractor presented a potential alternative approach to the wage index, which utilized BLS data to address the concerns of commenters, to initiate a discussion on the ramifications of a potential new ESRD PPS wage index that would combine two sources of existing data to more closely reflect the occupational mix in ESRD facilities. The methodology presented at this TEP utilized publicly available wage data for selected occupations from the BLS OEWS survey and occupational and fulltime equivalency (FTE) data from freestanding ESRD facility cost reports (Form CMS 265–11, OMB No. 0938–0236). Specifically, this approach used the freestanding ESRD facility cost reports to determine the national average occupational mix and relative weights for ESRD facilities. Next, the contractor applied the estimated county-level wages based on BLS OEWS [9] to obtain occupation-specific wages in each county. The BLS OEWS data is updated annually using sample data collected in six semiannual survey panels over the prior 3-year period, which allows for the inclusion of more recent data than the hospital cost-report data that is utilized by the IPPS wage index. Therefore, as noted during the TEP, this new methodology would allow CMS to adjust wage index values to reflect relative changes in wage conditions in a timelier fashion compared to the current ESRD PPS wage index methodology. Additionally, as noted during the TEP, by utilizing FTE data reported on the freestanding ESRD facility cost reports, this methodology is likely more reflective of the occupational mix employed by ESRD facilities than the hospital wage index.

Panelists at this TEP generally indicated their preference for the presented alternative wage index methodology, because it utilized more recent wage data from the BLS OEWS program. Panelists also favored how the alternative methodology was more targeted to ESRD facilities by utilizing FTE data from ESRD facility cost reports in determining the occupational mix. Some panelists voiced concerns about using publicly available BLS geographic area data, as the data do not disaggregate wages by health care sector, and therefore wages from acute care hospitals are not differentiated from outpatient care centers and other non-hospital health care settings. Some panelists noted that this would result in a wage index based on the publicly available BLS OEWS data having some of the same limitations for which the use of the IPPS wage index has been criticized—mainly that it includes wage data from hospitals.

(2) Proposed New Methodology for Using BLS Data To Calculate the ESRD PPS Wage Index

Based on feedback we received in response to past ESRD PPS proposed rules and from the December 2019 TEP, we have developed a new ESRD PPS wage index methodology that we believe better reflects the ESRD facility labor market. Similar to the methodology presented in the December 2019 TEP, this proposed new methodology utilizes two data sources: one for occupational mix and one for geographic wages. First, we determine a national ESRD facility occupational mix (NEFOM) based on cost report data from freestanding ESRD facilities. Second, we extract and use data from the publicly available BLS OEWS survey on the average wages in each CBSA for each labor category present in the NEFOM. We note that because the publicly available BLS data are available at the Metropolitan Statistical Area (MSA), non-MSA and New England City and Town Area (NECTA) levels, and the wage index is designated at the CBSA level (which uses MSAs and other area designations that differ from non-MSAs and NECTAs), we use the area definition dataset [10] that accompanies

[7] *https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf.*

[8] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-may-2020.pdf.*

[9] The OEWS program produces estimates of employment and wages by occupation based on a survey of business establishments. OEWS data are released annually with a May reference date. Each set of OEWS estimates is based on data from six semiannual survey panels collected over a 3-year period. For example, the May 2022 OEWS wage estimates are based on six semiannual survey panels from November 2019 through May 2022.

[10] For more information on MSAs and non-MSAs please see: *https://www.bls.gov/oes/current/msa_def.htm.* For more information on the most recent

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the BLS data to assign wages at the county level, and map counties to CBSAs using a crosswalk. This crosswalk is included in Addendum B, available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices*.

(a) Description of Proposed Data Sources

(i) Data From the BLS OEWS Metropolitan and Nonmetropolitan Area Occupational Employment and Wage Estimates

The BLS OEWS program publishes annual estimates of employment and wages by occupation. Each set of OEWS estimates is based on data from six semiannual survey panels collected over a 3-year period. For example, the May 2022 OEWS wage estimates, published in April 2023, are based on six semiannual survey panels from November 2019 to May 2022. We are proposing to use publicly available mean hourly wage data at the MSA level,[11] which is available online at *https://www.bls.gov/oes/*. OEWS wage data collected in earlier survey panels are ''aged'' or updated to the reference date of the estimates based on adjustment factors derived from the OEWS survey data using a regression model. The BLS OEWS mean hourly wage data that are presented in this proposed rule, and are utilized for the new wage index methodology described in detail later in this section of this proposed rule, reflect this updated data. Table 1 shows the occupation codes based on the Standard Occupational Classification (SOC) and the corresponding SOC occupational title for each SOC, alongside the colloquial name that we use to refer to workers in specific occupations throughout this proposed rule. The ESRD PPS colloquial names match the FTE categories captured on Worksheet S–1, lines 23 through 30 of the freestanding ESRD facility cost report form. The SOC System is a United States government system for classifying occupations. It is used by Federal Government agencies collecting occupational data, enabling comparison of occupations across data sets. When considering the use of BLS data we had to determine which occupation code was appropriate for each occupation in the NEFOM. For many of these occupations, the corresponding BLS code was straightforward. For example, BLS code 29–1141 is for ''Registered Nurses'' which matches the category on the cost reports from which the NEFOM is derived exactly. For the occupations that were not necessarily specific to the healthcare field, for example administrative staff, we used BLS codes that were specific for healthcare, such as code 43–6013 for ''Medical Secretaries and Administrative Assistants.'' We believe that these are the most appropriate codes, as a more general code may not capture the specifics of the healthcare labor market.

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TABLE 1: Crosswalk of BLS Occupation Codes to ESRD Facility Cost Reports Occupation Classifications

ESRD PPS Colloquial Name	BLS Occupation Title	Occupation Code
Registered Nurses (RN)	Registered Nurses	29-1141
Licensed Practical Nurses (LPN)	Licensed Practical and Licensed Vocational Nurses	29-2061
Nurse Aides	Nursing Assistants	31-1131
Technicians	Health Technologists and Technicians, All Other	29-2099
Social Workers	Healthcare Social Workers	21-1022
Dietitians	Dietitians and Nutritionists	29-1031
Administrative Staff	Medical Secretaries and Administrative Assistants	43-6013
Management	Medical and Health Services Managers	11-9111

CBSA delineations (as discussed later in this section) please see: *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*.

[11] We use the territory-level data for Guam and Virgin Islands, since the MSA and non-MSA level data is not available.

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The BLS OEWS data used for this analysis includes mean wages by occupation for all industries combined located in a MSA (or non-MSA area or NECTA), including the hospital industry. While interested parties have criticized the current ESRD PPS wage index methodology's sole reliance on hospital data, we believe that inpatient hospital data is appropriate to include here for several reasons. Principally, as explained later in this section, the wage data is being weighted based on an occupational mix that is specific to ESRD facilities, which makes this proposed methodology more accurate to the wage environment of ESRD facilities regardless of the source of the wage data. Additionally, ESRD facility data is included in the BLS data, while ESRD facilities generally are not included in the hospital cost report data used in the IPPS wage index (with the exception of hospital-based ESRD facilities). Lastly, hospitals are a major contributor to labor markets, and it is reasonable to think that ESRD facilities compete with hospitals (as well as other healthcare facilities) when it comes to hiring labor; as such, the inclusion of hospital data would provide additional insight into the labor markets of these areas.

A limitation of the publicly available BLS OEWS data is that the survey only includes information on the wages that employers paid to their employees. Therefore, the OEWS does not include self-employed contract labor wages or benefits paid to employees, which are reflected in the IPPS wage index. Nevertheless, we believe that this data source would be an improvement over the use of the IPPS wage index for the ESRD PPS, as its purpose is to identify geographic differences in wages. Assuming wages spent on self-employed contract labor wages and employee benefits vary similarly to employee wages; we would not expect any significant difference arising from this limitation of the BLS data. We anticipate that most traveling nurses and technicians would be employed by an agency, and therefore would be included in the OEWS estimates; however as worksite location reporting is optional,[12] we note it is possible that some of the wages for these traveling nurses and technicians could be included in the MSA in which their employing agency is located, rather than the MSA in which they worked. However, we would not anticipate that this would have an appreciable impact on the OEWS estimates used for this methodology. Additionally, we note that the OEWS would only include the wages paid to these contract workers, so the OEWS estimates would likely not include the full cost of the contract labor paid by the ESRD facilities to the contracting agency. We cannot separately estimate the prevalence of self-employed contract labor at ESRD facilities from the rest of contract labor, which we believe would still provide some insight into the potential limitation of the exclusion of self-employed contract labor wages from the BLS OEWS. We note that all contract labor costs represent approximately 5 percent of compensation costs in the 2020-based ESRDB market basket (87 FR 67143). Our analysis of freestanding ESRD facility cost report FTE data indicates that approximately 1.3 percent of RN hours and 1.1 percent of technician hours were contract labor in 2022. Additionally, our data show that the share of contract labor hours has been relatively stable over time but has increased slightly when compared to the prior few years.

One potential concern about use of the BLS OEWS data is that in some cases, the BLS OEWS may not have usable data for a county for an occupation, which is used in the construction of the new ESRD PPS wage index according to the methodology presented later in this section. This occurs when BLS is unable to publish a wage estimate for a specific occupation and area because the estimate does not meet BLS quality or confidentiality standards.[13] For reference, among the 25,808 unique county-occupation combinations, the wage information missing rate is 5.2 percent. To impute the missing data, we perform a regression using the most similar (by mean hourly wage) occupation (of the occupations we are proposing to include in the wage index methodology, presented in table 1) for which there is no missing data. For dietitians we use RNs, for technicians we use LPNs and for nurses' aides we use administrative staff. The regression includes controls for whether the county is rural, the census region in which the county is located, and the natural logarithm of the treatment count of the county. For the CY 2025 ESRD PPS wage index we only had to impute missing county-level data for dietitians, technicians, and nurses' aides; however, for future years, we may have to impute data for other occupations.

We have conducted an analysis on historical BLS OEWS data for the occupations presented in table 1. We have found that mean hourly wages for these categories are increasing over time, consistent with what we would expect given the ESRD PPS market basket increases. Given this analysis, we believe that the BLS OEWS data are reasonably stable and appropriately reflect general wage inflation trends that ESRD facilities face. Therefore, the mean hourly wage estimates for a given year are appropriately reflective of wages which ESRD facilities face.

(ii) Data From Freestanding ESRD Facility Cost Reports

Under § 413.198(b)(1), all ESRD facilities must submit the appropriate CMS-approved cost report in accordance with §§ 413.20 and 413.24, which provide rules on financial data and reports, and adequate cost data and cost finding, respectively. Generally, these cost reports have a time range of January 1 to December 31 of a given year, but they can represent any 12-month period. Included in these cost reports is information on the number of full-time equivalent (FTE) positions employed by the ESRD facility. FTEs are stratified by occupation type, such as RNs, LPNs, technicians, and administrative staff. For the purpose of these cost reports, an FTE represents a 40-hour work week averaged across the year. Specifically, the cost reports define FTEs as the sum of all hours for which employees were paid during the year divided by 2080 hours. The cost reports also state personnel involved in more than one activity must have their time prorated among those activities. For example, an RN who provided professional services and administrative services is counted in both the RN line and the administrative line according to the number of hours spent in each activity.

For the proposed methodology presented in this section, we are proposing to use FTEs to calculate the occupational mix for all freestanding ESRD facilities. For the purposes of this section, we use the term ''freestanding ESRD facilities'' to mean ESRD facilities that complete the independent renal dialysis facility cost report (Form CMS 265–11, OMB No. 0938–0050). We note that these ESRD facilities are a subset of ''independent'' facilities as defined at § 413.174(b), as cost-reporting is only one of 5 criteria used in the determination of whether an ESRD facility is independent or hospital-based as listed at § 413.174(c). For the purposes of this section, we refer to ESRD facilities that complete the hospital cost report (Form CMS 2552–10, OMB No. 0938–0050) as ''ESRD facilities that are financially integrated

[12] *https://www.bls.gov/respondents/oes/instructions.htm#online.*

[13] *https://www.bls.gov/oes/oes_ques.htm.*

with a hospital,'' per the criteria at § 413.174(c)(5). This occupational mix represents the average proportion of hours spent on the duties of that occupation at all freestanding ESRD facilities nationally. This national mix includes FTE data on both staff and contract labor from freestanding ESRD facility cost reports for each occupational category. Table 2 presents the NEFOM calculated from the freestanding ESRD facility cost report data from cost reporting periods beginning on or after January 1, 2022, and before December 31, 2022 (2022 cost report data), with four decimal places of precision. We note that this is the most recent complete year of cost reporting data for both this proposed rule and for the CY 2025 ESRD PPS final rule, as the latest 2022 cost reports could have begun in December 2022 and ended in December 2023, although some 2022 cost reports were not yet available at the time of the analysis for this proposed rule. For the approximately 1.7 percent of freestanding ESRD facilities without 2022 cost report data available at the time of rulemaking for this proposed rule, 2021 cost report data was used. The occupational mix weights used in the proposed new wage index methodology are presented in terms of the number of FTEs per 1000 treatments, although we note that the specific denominator does not impact the calculation, as these are relative weights. Table 2 also includes percentages that represent the percent of FTEs for each occupation in the NEFOM. For example, RNs represent approximately 30 percent of the NEFOM, which means that across the nation, 30 percent of all hours worked by employees at freestanding ESRD facilities are worked by RNs. We note that we did not include FTEs that were reported as ''other'' occupations in the cost reports in this occupational mix, because we could not determine what occupation(s) this represented and, therefore, could not get appropriate wage estimates. ''Other'' occupations would have accounted for 3.8 percent of the NEFOM if included.

TABLE 2: CY 2025 National ESRD Facility Occupational Mix (NEFOM)

Occupation	Freestanding Facilities 2022 Occupational Mix (FTEs/1000 treatments)	Freestanding Facilities 2022 Occupational Mix Percentage
Registered Nurse	0.4208	29.9690%
Licensed Practical Nurse	0.0566	4.0310%
Nurse Aide	0.0339	2.4131%
Technicians	0.5350	38.1040%
Social Worker	0.0661	4.7078%
Administrative staff	0.1505	10.7194%
Dietitian	0.0635	4.5220%
Management	0.0777	5.5337%

We note that the NEFOM is calculated as a part of the proposed wage index methodology described in detail below from freestanding ESRD facilities cost reports, and that the NEFOM is not an input in the wage index calculation. However, we are presenting the NEFOM here to inform the calculation process for any interested parties which wish to replicate the calculation.

For this proposed methodology, we are proposing to only utilize data from freestanding ESRD facilities, which comprise the vast majority of ESRD facilities. ESRD facilities that are financially integrated with a hospital represent approximately 4.5 percent of ESRD facilities. It is necessary to make this distinction, as ESRD facilities that are financially integrated with a hospital complete a different cost report form (Form CMS 2552–10, OMB No. 0938–0050), which does not include all the occupational categories included on the freestanding facility cost report (Form CMS 265–11, OMB No. 0938–0050). Specifically, ESRD facilities that are financially integrated with a hospital do not include administrative and management staff hours in their cost reports. FTE data for administrative and management staff are necessary for this analysis, so we are proposing to exclude hospital-integrated cost reports. We believe that the occupational mix for freestanding ESRD facilities is likely similar to the mix for ESRD facilities that are financially integrated with a hospital (which, as noted earlier, make up a small proportion of all ESRD facilities), such that we would not expect significantly different results if we were able to include ESRD facilities that are financially integrated with a hospital in this analysis.

We conducted additional analyses to ensure that this occupational mix data would be appropriate for the construction of an ESRD facility wage index. First, we reviewed the occupational mix for ESRD facilities on a regional level to determine if the use of a single national occupational mix was appropriate. While we found some variation across regions, the variation was generally relatively small between regions, with the weight values for each occupation being within a few percentage points. The main exceptions to this were in the United States territories, which had higher variation in occupational mix, likely due in large part to the relatively few ESRD facilities in those regions. Additionally, we found that lower volume ESRD facilities tended to have slightly different occupational mixes, requiring relatively more administrative and management staff FTEs, likely due to the lack of economies of scale for these occupations at lower treatment volume levels. Second, we conducted an analysis on the change in the national occupational mix over the past 5 years and found little variation over this time period. Both of these analyses indicate that the use of a single national occupational mix is appropriate for constructing an ESRD facility wage index as the occupational mix is reasonably similar to most region's occupational mixes and relatively stable over time.

Additionally, we are proposing to use treatment volume data from freestanding ESRD facilities as reported on freestanding ESRD facility cost reports. This treatment volume data is used in the wage index calculation as a weight on the county level wages when calculating the wages for a CBSA. The calculation is described in further detail in section II.B.2.b.(2)(b) of this proposed rule.

We emphasize the importance of accurate cost report data for this proposed policy as well as other current and potential policies under the ESRD PPS, such as facility-level or case-mix adjustment refinement. We strongly urge ESRD facilities to carefully review cost report data to ensure continued accuracy so that future refinements to the ESRD PPS are based on the best data possible.

(iii) IPPS Hospital Wage Index

The new proposed wage index methodology uses the established ESRD PPS wage index methodology, which is based on the IPPS hospital wage index, for the purposes of standardizing the new wage index (step 6 in the methodology described in section II.B.2.b.(2).(b)). Consistent with our established ESRD PPS methodology, we use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the IPPS. The ESRD PPS wage index values under the established methodology are calculated without regard to geographic reclassifications authorized for acute care hospitals under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. For CY 2025, the updated wage data are generally for hospital cost reporting periods beginning on or after October 1, 2020, and before October 1, 2021 (FY 2021 cost report data). Under § 413.231(d), a wage index floor value of 0.6000 is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values, as finalized in the CY 2023 ESRD PPS final rule (87 FR 67161). For the purposes of the proposed new wage index methodology, we are referring to this older wage index methodology as the ''ESRD PPS legacy wage index.'' Consistent with our established policy of updating wage indices in the final rule, we intend to use the most recent IPPS wage index for the construction of the CY 2025 ESRD PPS legacy wage index for the final rule. We note that the purpose of calculating the ESRD PPS legacy wage index is solely for standardizing the new ESRD PPS wage index, ensuring that the treatment weighted average of the new ESRD PPS wage index is the same as it would have been under the established methodology. This ensures that the changes associated with the proposed new wage index methodology are contained to the wage index, whereas changes associated with shifts in utilization would be reflected in the wage index budget neutrality factor. For example, if the new methodology resulted in a significant increase in the number of high-wage index facilities, the standardization factor would decrease wage index values across the board to keep the treatment-weighted average of the legacy and new wage index methodologies the same; in contrast, if utilization trends resulted in a significant increase in the number of treatments furnished by ESRD facilities in high-wage index areas, the treatment weighted average of both the legacy and new wage index methodologies would increase which would need to be accounted-for by the wage index budget neutrality adjustment factor. This is described in more detail in step 6 of the proposed new wage index methodology in section II.B.2.b.(2)(b) of this proposed rule.

(iv) Time Lag Associated With Proposed New Data Sources

One concern expressed by interested parties about the current ESRD PPS wage index methodology is that the IPPS wage index, used as its basis, uses data from approximately 4 fiscal years prior. Interested parties have opined that this delay makes the ESRD PPS wage index less responsive to certain changes in wages, such as inflation.[14] We note that the purpose of the wage index is to reflect geographic difference in the area wage levels, and that national trends in wages, including wage inflation, are accounted for by the ESRDB market basket percentage increase. We note that the IPPS wage index is generally responsive to geographic variation in wages, including variation stemming from local or regional inflation. However, as interested parties have raised concerns about the time lag associated with our use of the IPPS wage data, we discuss the difference between the time lag associated with our use of the IPPS wage index for the ESRD PPS and the proposed new ESRD PPS wage index methodology discussed later in this section of the preamble.

As previously discussed in this section, the new ESRD PPS wage index methodology that we are proposing would use data from BLS OEWS and freestanding ESRD facility cost reports. BLS publishes OEWS data annually with a May reference date, with estimates typically released in late March or early April of the following year. Each set of OEWS estimates is based on six semi-annual survey samples spanning the prior 3 years. Wages collected in earlier survey panels are updated to the reference date of the estimates based on wage adjustment factors derived from the OEWS survey data using a regression model. The freestanding ESRD facility cost report data that can be analyzed at the time of rulemaking are generally from 2 CYs prior. Specifically, for the proposed wage index presented in Addendum B of this ESRD PPS proposed rule, the BLS OEWS data is derived from surveys conducted from November 2019 through May 2022, and the cost report data generally covers cost reporting periods

[14] We note that in accordance with section 1886(d)(14)(E)(1) of the Act, the IPPS wage index is required to employ data based on ''a survey conducted by the Secretary (and updated as appropriate) of the wages and wage-related costs of subsection (d) hospitals in the United States.'' The IPPS is based on the most current audited hospital wage data from Worksheet S–3, Parts II, III and IV of the Medicare cost report, CMS Form 2552–10 (OMB Control Number 0938–0050 with an expiration date of September 30, 2025) (see, for example, 88 FR 58961).

beginning on or after January 1, 2022, and before December 31, 2022.[15] The publicly available BLS OEWS data is an average using data collected over a 3-year period which improves stability and predictability of the OEWS estimates over time. We note that, should this methodology be finalized as proposed in the CY 2025 ESRD PPS final rule, the most recent update of BLS OEWS data for a given year would be available early enough to be included in the ESRD PPS final rule, but not in the proposed rule. Under this proposed new methodology, BLS OEWS data collected as recently as May 2023 would be utilized for the final CY 2025 ESRD PPS wage index.

Both the ESRD facility cost report data and the BLS OEWS data are more recent than the data used for the IPPS wage index. Additionally, the purpose of using the freestanding ESRD facility cost report data in this proposed methodology would be to establish a national occupational mix for ESRD facilities, which we are calling the NEFOM. We intend to present the NEFOM annually to reflect the latest complete year of cost report data at the time of rulemaking to inform the public of the relative weights assigned to each occupation. Given that freestanding facility cost reports are submitted on a rolling basis, the most recent data would generally be obtained from cost reports beginning in the CY 3 years prior to the CY for which we are setting rates (that is, for this CY 2025 proposed rule, the latest complete year of cost report data are from cost reports beginning in CY 2022). Based on our analysis of prior years' cost report data, we do not anticipate that the national occupational mix would change much from year-to-year. Additionally, we note that the use of a single national occupational mix for all ESRD facilities would limit the impact of changes in employment patterns on the wage index, as all ESRD facilities would be similarly impacted by a change in the NEFOM. As the wage index is a relative value, the main way that a change in the NEFOM would impact an ESRD facility's wage index would be if the CBSA in which that ESRD facility is located has relatively high or low wages for an occupation that experiences growth or shrinkage in the NEFOM. Thus, the main driver in changes from year-to-year under this proposed new wage index methodology likely would be the BLS OEWS data, which, for the final rule, would include survey data as recent as May of the year prior to the rulemaking year.

We note that, at the time of the analysis conducted for this proposed rule, the May 2023 BLS OEWS update was not yet available. As previously discussed, some ESRD facilities' CY 2022 cost reports were not available. Should the proposed new wage index methodology be finalized, we would update the wage index values based on the most recent BLS OEWS data available. We are also proposing to use most recent cost report data available for cost reporting periods beginning in CY 2022 and update the NEFOM accordingly in the final rule. Using the most recent 2022 data available for the calculation of the new ESRD PPS wage index methodology in the final rule would be consistent with our established ESRD PPS wage index methodology of updating ESRD facility wage indices between the proposed and final rules.

We note that our proposed new wage index methodology does use the IPPS wage index to create the ESRD PPS legacy wage index, which is used to standardize the results of the new ESRD PPS wage index methodology. We recognize the concerns we have heard regarding the data lag associated with our use of the IPPS wage index for the ESRD PPS. However, as the ESRD PPS legacy wage index would only be used to calculate a treatment-weighted average of the legacy wage index to standardize the wage index values derived under the proposed new methodology, the proposed new ESRD PPS wage index would continue to reflect the relative differences in area wages based on the more recent BLS OEWS data. Therefore, any effect of any data lag of the ESRD PPS legacy wage index on the proposed new ESRD PPS wage index would be minimal.

(v) Comparison Between Proposed New Methodology Data Sources and Hospital Data

The other main concern that interested parties have raised about our current ESRD PPS wage index methodology is that the IPPS wage index is based on hospital cost report data. As previously discussed, interested parties have stated that hospital cost report data is not necessarily the most appropriate source for estimating geographic differences in wages paid by ESRD facilities. These interested parties predominantly point to the different occupational mix employed by ESRD facilities as the main differentiator between inpatient hospitals and ESRD facilities; however, there may also be differences in wages paid for the same occupational labor category in the two settings. Differences in wages within the same occupation could arise from any number of factors, including differences in duties, hours, required experience, or desirability of the position.

Table 3 compares the national average occupational mix and corresponding wages for occupations employed by freestanding ESRD facilities to that of hospitals from IPPS data. The source of average wages used here for ESRD facilities is the BLS OEWS and average IPPS wages are derived from the IPPS occupational survey (Form CMS–10079) as presented in the fiscal year (FY) 2024 IPPS Public Use File (PUF),[16] representing data from 2019. The mean hourly wage data from BLS is from the May 2022 OEWS estimates, which are based on six panels of survey data from November 2019 through May 2022.

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[15] In cases where 2022 freestanding cost report data are not available at the time of this proposed rule, 2021 data was used. This was the case for 131 ESRD facilities, approximately 1.7 percent of the ESRD facilities in this analysis. We expect that in calculating the wage indices in the final rule only 2022 cost report data would be used.

[16] Files related to the FY 2024 IPPS final rule are available online at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2024-ipps-final-rule-home-page*.

TABLE 3: Comparison of Occupational Mix and Mean Hourly Wages for Selected Occupations between Freestanding ESRD Facilities and Acute Care Hospitals

Occupation (Column A)	Freestanding Facilities Occupational Mix (Column B)	Mean Hourly Wage – BLS (Column C)		Occupation (Column D)	Acute Care Hospitals Occupational Mix (Column E)	Mean Hourly Wage – IPPS (Column F)
Registered Nurse	30.0%	$42.97		Registered Nurse	28.2%	$44.42
Licensed Practical Nurse	4.0%	$27.30		Licensed Practical Nurse	2.6%	$26.85
Nurse Aide	2.4%	$17.34		Nurse Aide	7.8%	$18.53
Medical Aide	-	-		Medical Aide	1.5%	$19.51
Technicians	38.1%	$24.42		Other	60.0%	$34.92
Social Worker	4.7%	$30.61				
Administrative staff	10.7%	$19.42				
Dietitian	4.5%	$32.63				
Management	5.5%	$60.45				

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We note that the hospital wage data (column F) presented in table 3 presents the wages paid by hospitals to employees, as derived from the IPPS occupational survey data, for the purposes of comparing to the BLS data. This data is used to adjust the hospital average hourly wage, calculated using hospital cost report data, based on the provider-specific occupational mix. This differs from the hospital cost report data used for the IPPS wage index, as that does not break down all wages and related costs by occupation.

Compared to hospitals, ESRD facilities generally use slightly higher proportions of RNs and LPNs and significantly fewer nurse aides and medical aides (column B). Additionally, the freestanding ESRD facility cost reports include additional occupational categories to reflect the labor mix employed by ESRD facilities.

(b) Construction of the Proposed New ESRD PPS Wage Index

Under our proposal, once we have the calculated wages for each relevant labor category by county (using a crosswalk between MSA, non-MSA and NECTA and counties) and the NEFOM, we would construct the new ESRD PPS wage index using the following steps. These are the general steps which we use when constructing the proposed new ESRD PPS wage index; for a more detailed look at the specific computational steps we execute in the code to calculate the proposed wage index, including steps related to data collection and cleaning, see the supplementary document in Addendum C.

1. We calculate the treatment count-weighted mean hourly wage for each occupation for each CBSA by multiplying the mean hourly wage data from the BLS OEWS by the treatment count for each county within that CBSA and dividing by the total treatment count of all counties within the CBSA. We weight mean hourly wage by treatment count to ensure that the mean hourly wage for the CBSA is proportional with the actual wages paid by ESRD facilities in the CBSA. This avoids a situation where a particularly high or low wage county within a CBSA has no ESRD facilities but still has a large impact on the wage index for that

CBSA. This reasoning extends to each instance in which we weight values by treatment counts.

2. We calculate the ESRD facility mean hourly wage in each CBSA by multiplying the treatment count-weighted mean hourly wage (from step 1) for each occupation for a given CBSA with the corresponding weight of the NEFOM for each occupation and then sum each category's amount to get the total.

3. We calculate the treatment count-weighted mean hourly wage for each occupation at the national level by multiplying the mean hourly wage for the occupation in each CBSA by the treatment count of that CBSA and dividing by the aggregated treatment count nationally.

4. We calculate the national ESRD facility mean hourly wage by multiplying the national mean hourly wage (from step 3) for each occupation by the corresponding weight of the NEFOM for each occupation and then sum each category's amount to get the total.

5. We divide the ESRD facility mean hourly wage for each CBSA by the national ESRD facility mean hourly wage to create a raw wage index level (that is, a wage index that has not been normalized as described in step 6).

6. We multiply the raw wage index level for each CBSA by a treatment weighted average of the CY 2025 ESRD PPS legacy wage index constructed using the established ESRD PPS methodology based on IPPS Medicare cost report data and divide the product by the treatment weighted average of raw wage indices, which equals 1 by construction.[17] This is to ensure that the treatment-weighted average of new BLS-based wage indices is the same as the weighted average of the current wage indices. By ensuring the weighted average of the new wage index is the same as the weighted average of the pre-floor pre-reclassification IPPS wage index we have normalized the new wage index such that it is more comparable to the former ESRD PPS wage index methodology. This prevents the possibility that the treatment-weighted average of the new wage index is significantly different than the treatment-weighted average of the established methodology. We include this step because our goal in establishing the proposed new wage index methodology is not to alter the significance of the wage index in determining each ESRD facility's payment, but rather to ensure that the wage index values better reflect relative labor costs that affect ESRD facilities specifically. We note that because we apply a wage index budget neutrality adjuster (discussed in section II.B.4.b), the proposed new wage index methodology would not increase total payments to ESRD facilities even absent this step.

7. We apply the 0.6000 floor to the wage index by replacing any wage index values that fall below 0.6000 with a value of 0.6000, which is the wage index floor for the ESRD PPS as established in the CY 2023 ESRD PPS final rule (87 FR 67166).

After following these steps, we would obtain the wage index values for each CBSA (based on the new OMB delineations as discussed later in this section of the preamble) according to the proposed ESRD PPS wage index methodology described previously. We note that the 5 percent cap in year-over-year decreases in wage index values would be applied for each ESRD facility after the new wage index is calculated based on the proposed methodology for the CBSA in which the ESRD facility is located and, therefore, is not reflected in the wage index value for a CBSA in Addendum A, available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices*. This is necessary as this cap protects ESRD facilities in the rare circumstances when changes in policy related to the wage index methodology or CBSA delineations cause an ESRD facility to be in a significantly lower wage index area in a given year when compared to the previous year (87 FR 67161). As discussed later in this section, for CY 2025 we are proposing to adopt new OMB delineations of CBSAs relative to those used in the CY 2024 ESRD PPS wage index. As this 5 percent cap applies to an ESRD facility, and not to a CBSA, it would protect any ESRD facility that is delineated into a much lower wage-index CBSA for CY 2025.

(c) Methodological Alternatives Considered

While developing this new wage index methodology, we have considered several different alternatives regarding both data sources used for the new wage index methodology and construction of the wage index itself. We considered the feasibility of requesting the use of confidential BLS OEWS data. This was one suggestion from the December 2019 TEP. Confidential data would have some benefits over public data, primarily that it would provide greater disaggregation of wages by employer type, such as wages paid by ESRD facilities. Additionally, confidential BLS data could have a timeframe other than the 3-year pooled sample used in the public data, for example using only the most recent year's data. However, we note that the OEWS survey sample is designed to be statistically representative only when all 3 years of the sample are combined, so the use of an alternative or shorter timeframe may not be appropriate. We have determined that the publicly available BLS data would be the most appropriate for our wage index, as it still provides precise estimates of wages and would allow for far better transparency. Additionally, we believe that the inclusion of data from other employers (meaning employers that are not ESRD facilities) would improve the robustness of the methodology, as ESRD facilities compete for labor against these other employers.

When considering the use of BLS data we had to determine which occupation code was appropriate for each occupation in the NEFOM. As discussed previously, for many of these occupations, the corresponding BLS code was straightforward as many of the occupations present in the freestanding ESRD facility cost reports matched a single BLS code. However, for technicians employed by ESRD facilities we gave further consideration to two different BLS codes. As presented in table 1, we are proposing to use code 29–2099 for ''Health Technologists and Technicians, All Other'' for the construction of the methodology to account for the labor costs of technicians. This is the most appropriate category, as ''technicians'' in the freestanding ESRD facility cost reports generally refers to dialysis technicians, which do not fall into any of the other BLS codes for health technologists and technicians. Additionally, we note that the SOC uses ''dialysis technician'' as an illustrative example for code 29–2099.[18] However, we had some concerns about using this category, as it does not specifically represent dialysis technicians, but rather all health technicians that do not fit in the other categories. Because the category is non-specific, also known as a ''residual'' category, we were concerned with the impact of the inclusion of other, non-dialysis technicians in this category. To avoid any issues arising from the use of a

[17] Treatment weighted average of wage indices are calculated by multiplying the wage index value for each CBSA by the treatment count in the CBSA, and dividing by the aggregate national treatment count.

[18] *https://www.bls.gov/soc/2018/major_groups.htm.*

residual category, we considered using code 29–2010 for ''Clinical Laboratory Technologists and Technicians.'' Although this category does not fit dialysis technicians as well, it has the benefit of not being a residual category, and it had fewer counties with missing data. However, we determined that it was most appropriate to use the most similar category for dialysis technicians, being the category in which data for dialysis technicians would be included, which is code 29–2099 ''Health Technologists and Technicians, All Others.''

As an alternative to using a single national occupational mix for ESRD facilities we considered using regional or state-level occupational mixes. The considered alternative would use a similar methodology to the construction of the NEFOM, but with a different occupational mix for each census region or state and would apply the occupational mix in the same way in the construction of the wage index. This is to say, the BLS data for a CBSA would be weighted by the occupational mix for the region or state in which that CBSA is located. This alternative was considered, in part, because of a suggestion from a panelist at the December 2019 TEP who pointed out that different states have different laws regarding staffing requirements for ESRD facilities, which was not reflected in the methodology presented at the TEP. We conducted an analysis comparing a state-level occupational mix wage index to the national occupational mix wage index methodology presented previously. This analysis found some notable differences, including higher wage index values in the pacific census region, but many regions experienced little change. We decided against the use of state-level or regional occupational mixes for three main reasons. The first is that the use of different occupational mixes for different ESRD facilities made the methodology significantly more complicated and difficult to understand. The second is that this methodology made it so that one ESRD facility could be in an area with higher wages for all occupations compared to another ESRD facility but receive a lower wage index value due to having an occupational mix which favored lower-paying occupations. This could be perceived as being inconsistent with the intent of the wage index to recognize differences in ESRD facility resource use for wages specific to the geographic area in which facilities are located (83 FR 56967). Lastly, we are concerned about the possibility that, should we use anything other than a national occupational mix, the state-level or regional occupational mix could be manipulated. This would be especially relevant for states or regions with few ESRD facilities and, therefore, individual ESRD facilities would have an outsized impact on the occupational mix for that state or region. Accordingly, we believe that the use of a single national occupational mix is the most appropriate for this proposed new ESRD facility wage index methodology.

We considered proposing a ''phase-in'' policy for this proposed wage index methodology change, which could be implemented in addition to the 5 percent cap on wage index decreases. One potential example of a phase-in policy could be a 50/50 blended methodology, where an ESRD facility would receive the average of their wage indices from the proposed new and legacy methodologies for the first year of implementation. However, we decided that such a phase-in policy was unnecessary in light of the 5 percent cap on year-to-year wage index decreases for ESRD facilities. We believe that an additional, or alternative, phase-in policy would further complicate this change. Additionally, a phase-in policy could hurt ESRD facilities that would receive a higher wage-index under the new methodology, which we do not believe would be appropriate, as we believe the new methodology based on BLS data is the best approximation of the labor costs those ESRD facilities face.

We considered setting the NEFOM through rulemaking separately from the routine wage index update. Under this alternative, we would periodically update the NEFOM, for example every 2 years, with potentially more years of freestanding ESRD facility cost report data. This would mean that the NEFOM would be a rounded input in the wage index methodology, rather than a figure precisely calculated as an intermediary step in the methodology. This would slightly simplify the calculation steps and would allow for complete transparency on the NEFOM. However, we have decided to instead derive the FTEs per 1000 treatments for each occupation as the weights as a part of the wage index calculation as that would increase the precision of this calculation. Additionally, given the transparency of the FTE data derived from publicly available cost reports, we can still publish the NEFOM for the coming year in rulemaking alongside the updated wage index; however, we note that the NEFOM we publish would have a lower precision so replications using the published NEFOM as an input may be slightly off. Furthermore, compared to setting the NEFOM through rulemaking less frequently than annually, the proposed methodology to calculate the NEFOM as a part of the wage index methodology annually would be more responsive to national trends in occupational mix for ESRD facilities.

Finally, we considered whether it was most appropriate to use something other than the mean hourly wage for the BLS OEWS data for the construction of the wage index. There are always concerns when using the mean of a data set that the figure could be unduly influenced by outliers. One potential alternative would be to use the median hourly wage data instead. The median hourly wage is available by occupation in publicly available BLS data, and the median is not as influenced by outliers as the mean. We also considered using the geometric mean, instead of arithmetic mean, as that is also less influenced by outliers; however the geometric mean is not provided in publicly available BLS data. Ultimately, we determined that the mean hourly wage is the most appropriate for this new wage index methodology, as any outliers are relevant data points insofar as some ESRD facilities may pay wages significantly higher than the average.

c. Example Calculation Using the Proposed New Wage Index Methodology

Table 4 is an example of a calculation of the wage index for a hypothetical ESRD facility in a hypothetical CBSA under the proposed new methodology. This CBSA contains three counties, each with a different mean hourly wage and treatment count. Table 4 presents the mean hourly wage and treatment count used in the calculation.

TABLE 4: Hypothetical BLS Data for Example

	County 1	County 2	County 3
Treatment count	200 treatments	300 treatments	500 treatments
RN wage	$45	$40	$50
LPN wage	$30	$30	$35
Nurse aide wage	$15	$20	$10
Technicians wage	$30	$35	$25
Social worker wage	$30	$25	$35
Administration wage	$20	$25	$20
Dietitian wage	$35	$30	$30
Management wage	$60	$65	$50

Step 1. Calculate the treatment count-weighted mean hourly wage for each occupation for each CBSA by multiplying the mean hourly wage data from the BLS OEWS by the treatment count for each county within that CBSA and dividing by the total treatment count of all counties within the CBSA.

RN wage = [(200 * $45) + (300 * $40) + (500 * $50)]/1000 = $46.0
LPN wage = [(200 * $30) + (300 * $30) + (500 * $35)]/1000 = $32.5
Nurse aide wage = [(200 * $15) + (300 * $20) + (500 * $10)]/1000 = $14.0
Technicians wage = [(200 * $30) + (300 * $35) + (500 * $25)]/1000 = $29.0
Social worker wage = [(200 * $30) + (300 * $25) + (500 * $35)]/1000 = $31.0
Administration wage = [(200 * $20) + (300 * $25) + (500 * $20)]/1000 = $21.5
Dietitian wage = [(200 * $35) + (300 * $30) + (500 * $30)]/1000 = $31.0
Management wage = [(200 * $60) + (300 * $65) + (500 * $50)]/1000 = $56.5

Step 2. Calculate the ESRD facility mean hourly wage in the CBSA by multiplying the treatment count-weighted mean hourly wage (from step 1) for each occupation for the CBSA with the corresponding weight of the NEFOM for each occupation and sum each category's amount to get the total. The NEFOM for CY 2025 is presented in table 5. For the purposes of ensuring the calculation in this section is as easy to understand as possible we are using the percentage values from the NEFOM rounded to the nearest tenth of a percent. This makes the wage values calculated in this step and step 4 more intuitive as they would represent a weighted average of the wages in the CBSA. We note that in the actual calculation of the wage index, as described in Addendum C, we calculate the number of FTEs per 1000 treatments for each occupation and use those as the weights, so that the weights have a higher level of precision.

TABLE 5: CY 2025 National ESRD Facility Occupational Mix (NEFOM)

Occupation	ESRD Freestanding Facilities FTE Percentage (rounded)
Registered Nurse	30.0%
Licensed Practical Nurse	4.0%
Nurse Aide	2.4%
Technicians	38.1%
Social Worker	4.7%
Administration	10.7%
Dietitian	4.5%
Management	5.5%

ESRD facility mean hourly wage for this CBSA = (0.300 * $46.0) + (0.040 * $32.5) + (0.024 * $14.0) + (0.381* $29.0) + (0.047 * $31.0) + (0.107 * $21.5) + (0.045 * $31.0) + (0.055 * $56.5) = $34.75

Step 3. Calculate the treatment count-weighted mean hourly wage for each occupation at the national level by multiplying the mean hourly wage for the occupation in each CBSA by the treatment count of that CBSA and dividing by the aggregated treatment count nationally.

To simplify this calculation, assume there are 3 CBSAs as follows:

	CBSA 1	CBSA 2	CBSA 3	Calculated National
Treatment count	1000 treatments	800 treatments	1550 treatments	3350 treatments
RN wage	$46	$42	$50	$46.90
LPN wage	$32.5	$28	$35	$32.58
Nurse aide wage	$14	$20	$21	$18.67
Technicians wage	$29	$35	$33	$32.28
Social worker wage	$31	$30	$35	$32.61
Administration wage	$21.5	$20	$18	$19.52
Dietitian wage	$31	$35	$30	$31.49
Management wage	$56.5	$60	$55	$56.64

Step 4. Calculate the national ESRD facility mean hourly wage by multiplying the national mean hourly wage (from step 3) for each occupation by the corresponding weight of the NEFOM for each occupation and sum each category's amount to get the total. Similarly to step 2, we are using the percentages from the NEFOM as weights for the purposes of this example calculation.

National average ESRD facility wage = (0.300 * $46.90) + (0.040 * $32.58) + (0.024 * $18.67) + (0.381 * $32.28) + (0.047 * $32.61) + (0.107 * $19.52) + (0.045 * $31.49) + (0.055 * $56.64) = $36.27

Step 5. Divide the ESRD facility mean hourly wage for each CBSA by the national ESRD facility mean hourly wage to create a raw wage index level.

Raw wage index value = $34.75/$36.27 = 0.95809

Step 6. Multiply the raw wage index for each CBSA by a treatment weighted average of the CY 2025 ESRD PPS legacy wage index constructed using the established ESRD PPS methodology based on IPPS data and divide the product by the treatment weighted average of raw wage indices (which equals 1 by construction). This is to ensure that the treatment-weighted average of new BLS-based wage indices is the same as the weighted average of the current wage indices (for the purpose of this hypothetical calculation we have used a value of 1.00679).

Pre-floor wage index value = 0.95809 * 1.00679/1 = 0.9646

Step 7. Apply the 0.6000 floor to the wage index by replacing any wage index values which fall below 0.6000 with 0.6000.

Final wage index value = 0.9646

d. Estimated Impacts of Proposed Change to Wage Index Methodology

The proposed new wage index methodology described previously would be a substantial change from the current approach used by the ESRD PPS to evaluate variations in wages across geographic areas. Compared to the current methodology based on hospital cost report data, this new methodology would use survey data on wages for occupations relevant to furnishing renal dialysis services, which includes data from ESRD facilities and other similar outpatient settings and is weighted according to the average occupational mix of freestanding ESRD facilities. This proposed methodological change, if finalized, would be associated with significant changes in wage index values, and therefore payment amounts, for ESRD facilities. Full impacts for the proposed CY 2025 ESRD PPS wage index, alongside the updated CBSA delineations and rural transition policy discussed in section II.B.2.f of this proposed rule, are presented in table 18 in section VIII.D.5.a of this proposed rule, including application of the 5 percent cap on year-to-year wage index decreases. The 5 percent cap policy would mitigate the impact of the proposed changes to the wage index methodology for CY 2025. Column 3 of table 6 presents the payment impacts associated with only the proposed new wage index methodology without the 5 percent cap on decreased wage indices (with an appropriate wage index budget neutrality adjustment following the established methodology discussed at section II.B.4.b) for the purpose of demonstrating its potential long-term ramifications. For comparison, column 4 of table 6 presents the same payment impacts with the 5 percent cap applied. The figures in these columns represent the expected payment change associated from the move from the CY 2025 ESRD PPS legacy wage index to the proposed new wage index methodology. As an example, this table shows that rural ESRD facilities would see a payment increase of 1.014 (or an increase of 1.4 percent) without the 5 percent cap but only 1.007 (or 0.7 percent) with the 5 percent cap. One major driver of this discrepancy is the fact that changes to the ESRD PPS wage index are budget neutral, so by limiting the negative impact of the change on some facilities through the 5 percent cap, we reduce payments to ESRD facilities not impacted by the cap. Because the 5 percent cap would impact fewer ESRD facilities in each subsequent year by design, column 4 is not a reasonable proxy for long term payment impacts associated with this policy, but rather it represents the expected change in payment to ESRD facilities for CY 2025 as a result of only the proposed wage index methodology change.

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TABLE 6: Hypothetical Impacts of Proposed New Wage Index Methodology, With and Without Application of the 5 Percent Cap on Wage Index Decreases

ESRD Facility Type (Column 1)	# Facilities (Column 2)	Change in Payment without 5% Cap (Column 3)	Change in Payment with 5% Cap (Column 4)
All Facilities	7,695	1.000	1.000
Type			
Hospital-based	347	1.009	1.011
Freestanding	7,348	1.000	1.000
Ownership Type			
Large dialysis organization	5,942	1.002	1.000
Regional chain	908	0.994	0.999
Independent	461	0.984	0.990
Hospital-based	347	1.009	1.011
Unknown	37	0.981	0.979
Geographic Location			
Rural	1,245	1.014	1.007
Urban	6,450	0.998	0.999
Census Region			
East North Central	1,188	1.009	1.000
East South Central	602	1.013	1.004
Guam, AS, MP	11	0.930	0.964
Middle Atlantic	870	0.992	1.001
Mountain	438	1.006	1.002
New England	199	1.038	1.029
Pacific[1]	970	0.973	0.993
Puerto Rico and Virgin Islands	54	1.041	1.031
South Atlantic	1,793	1.009	1.001
West North Central	475	1.000	0.993
West South Central	1,095	1.010	1.002
Facility Size			
Less than 3,000 treatments	763	1.005	1.001
3,000 to 4,000 treatments	444	1.006	1.002
4,000 to 5,999 treatments	582	1.005	1.000
5,000 to 9,999 treatments	2,879	1.007	1.002
10,000 or more treatments	3,027	0.996	0.999

1Includes AK and HI

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Column 3 of table 6 shows the effect that this proposed new wage index methodology would have on ESRD facilities, stratified by facility type,

location, and size, without application of the 5 percent cap on any decrease in wage index values. These impacts still include the 0.600 wage index floor because, unlike the 5 percent cap on decreased wages, the wage index floor could affect an ESRD facility for every future year. The 5 percent cap, however, would likely only affect an ESRD facility for a limited number of years until its wage index value lines up with the wage index value for the CBSA in which it is located. We note that the ESRD PPS does not have a cap on wage index increases, so ESRD facilities located in CBSAs that receive a substantial increase in wage index value associated with this proposed new methodology would not have the impact of that change mitigated and, therefore, that change is reflected in the full impacts in section VIII.D.5.a of this proposed rule. However, without the 5 percent cap on wage index decreases the budget-neutrality factor applied to the ESRD PPS in the hypothetical model from which column 3 was derived is larger (the application of which would result in a smaller decrease to the ESRD PPS base rate), such that ESRD facilities that had a positive change in wage index would experience an even greater positive change.

For comparison, column 4 represents the impacts for CY 2025 with the 5 percent cap applied. As discussed previously, this is not a reasonable proxy for long term payment impacts because (assuming no other changes) the 5 percent cap on wage index decreases would apply to a lower number of ESRD facilities each year until ESRD facilities receive the wage index for the CBSA in which they are located. However, this column does show the impact of applying the 5 percent cap for CY 2025, both for ESRD facilities for which the cap would apply and other ESRD facilities that would receive lower payments due to budget neutrality.

Based on column 3 (as a proxy for long-term impacts), the use of the proposed new wage index methodology would result in a notable increase in payments to rural ESRD facilities and ESRD facilities located in the East South Central census region. Use of the proposed new wage index methodology would result in a notable decrease in payments to the Pacific census region and the United States Pacific Territories (that is, Guam, American Samoa, and the Northern Marianas Islands, which are the only Unites States Pacific Territories with an ESRD facility). Generally, we include the United States Pacific territories together with the Pacific census region, as that is the census region in which these territories are located according to the United States Census Bureau. However, for this analysis examining the effects of CMS' proposed wage index methodology we have opted to separate the territories from the Pacific census region, because we believe that it is important to evaluate the impact on these territories carefully due to their remote geographic location and resulting unique economic situation. Column 4 of table 6 shows how the application of the 5 percent cap mitigates these changes for CY 2025, as ESRD facilities in the United States Pacific territories would have a decrease in payment by a factor of only 0.964 rather than 0.930.

We note that the 5 percent cap on wage index decreases would apply to ESRD facilities that are located in a CBSA (based on CY 2025 CBSA delineations) with a wage index value 5 percent lower than the CY 2024 wage index value for their CBSA (based on CY 2024 CBSA delineations). The impacts detailed in column 3 are presented for the sole purpose of illustrating the potential long-term ramifications of the proposed new wage index methodology once sufficient time has passed such that the 5 percent cap on year-over-year decreases would no longer constrain the overall effect of this proposed new methodology on wage index values.

We have conducted an analysis comparing the hypothetical results of applying this new wage index methodology in past years to the actual ESRD PPS wage index methodology based on the IPPS wage index for those years. We have found that the application of the new wage index methodology consistently yields mean and median wage index values slightly higher than the actual mean and median wage index values used for those years, implying that the wage index resulting from this new methodology is relatively stable. Additionally, we have found that the payment impacts based on facility type did not change much when using data from claim years 2019 through 2022, with most facility types that are projected to receive a payment increase for CY 2025 associated with the proposed new wage index methodology seeing a payment increase in past years. Similarly, most facility types that are projected to receive a payment decrease in CY 2025 associated with the proposed new wage index methodology were found to have received payment decreases in our hypothetical analysis of past years. Therefore, we have determined that this new wage index methodology is relatively stable when analyzing the differences between the new proposed wage index and the ESRD PPS legacy wage index.

e. Proposed CY 2025 ESRD PPS Wage Index

For CY 2025, we propose to update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using the proposed new methodology described previously, in subpart b of this section, according to the most recent available data. We believe that the use of this proposed new methodology is appropriate and responds to the feedback we have received from interested parties regarding the limitations of the current wage index. Specifically, the use of BLS OEWS data would allow for this new wage index methodology to be more responsive to differences in ESRD facility wage levels across the country. Additionally, by using occupational mix data from the freestanding ESRD facility cost reports, this proposed methodology would better reflect the actual wage costs incurred by ESRD facilities. We believe that this proposed new methodology would be most appropriate to use for the ESRD PPS due to several reasons specific to ESRD facilities. First, freestanding ESRD facility cost reports contain detailed occupational FTE data, which allows CMS to create a wage index that is tailored to the wage costs faced by ESRD facilities based on their unique staffing needs. Dissimilarities between hospital occupation mix and ESRD facility occupational mix make the use of the IPPS data less appropriate for ESRD facilities. In addition, the ESRD PPS has a lower labor-related share than most other Medicare payment systems.[19] This proposed new ESRD PPS wage index methodology addresses these specific circumstances.

We recognize that there are several methodological limitations to using a wage index based on publicly available BLS OEWS data. Specifically, this data source lacks information on employee benefits and the full cost of contract labor and includes information from hospitals and other healthcare providers. However, we believe that the benefits of using this proposed new wage index methodology would outweigh these limitations, as the use of BLS OEWS wage data weighted by an occupational mix derived from freestanding ESRD facility cost report data would allow for a wage index that is more representative of the geographic

[19] For example, under section 1886(d)(3)(E) of the Act, the IPPS applies a labor related share of 62 percent for each hospital unless this would result in lower payments to the hospital than would otherwise be made.

variation in wages faced by ESRD facilities.

For CY 2025, we are also proposing to use OMB's most recent CBSA delineations as published in OMB Bulletin No. 23–01, which is based on the data from the 2020 decennial census, for the purposes of the CY 2025 ESRD PPS wage index and rural facility adjustment. This is consistent with our historical practice of updating the CBSA delineations periodically according to the most recent OMB delineations, most recently in the CY 2021 ESRD PPS final rule (85 FR 71430 through 71434). We discuss this policy in greater detail in section II.B.2.f of this proposed rule. For more information on the OMB delineations we refer readers to the OMB Bulletin No. 23–01: *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.*

To implement the proposed change in wage index methodology, we are proposing to amend the regulations at 42 CFR 413.196(d)(2) and 413.231(a). Effective January 1, 2025, the amended § 413.196(d)(2) would state that CMS updates on an annual basis ''The wage index using the most current wage data for occupations related to the furnishing of renal dialysis services from the Bureau of Labor Statistics and occupational mix data from the most recent complete calendar year of Medicare cost reports submitted in accordance with § 413.198(b).'' The amended § 413.231(a) would state that ''CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index (established by CMS) which reflects the relative level of wages relevant to the furnishing of renal dialysis services in the geographic area in which the ESRD facility is located.''

For CY 2025, we propose to update the ESRD PPS wage index to use the most recent BLS OEWS wage data and the most recent CY 2022 freestanding ESRD facility cost report occupational mix and treatment volume data available. At the time the analysis was conducted for this proposed rule, the most recent BLS OEWS wage data available represented May 2022. We propose that if more recent data become available after the development of this ESRD PPS proposed rule and before the publication of the ESRD PPS final rule (for example, the April 2024 release of May 2023 OEWS data, which was published after the analysis performed for this proposed rule), we would use such data, if appropriate, to determine the CY 2025 ESRD PPS wage index in the ESRD PPS final rule. The proposed CY 2025 ESRD PPS wage index is set forth in Addendum A and is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.* Addendum A provides a crosswalk between the CY 2024 wage index and the proposed CY 2025 wage index. Addendum B provides an ESRD facility level impact analysis. Addendum B is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.*

(1) Alternative CY 2025 ESRD PPS Wage Index Using Established Methodology

We are presenting a version of the current ESRD PPS wage index constructed using our established methodology with the most recent available data, which we are referring to as the ESRD PPS legacy wage index methodology. The purpose of presenting the legacy methodology with modifications is to illustrate an alternative to the proposed new methodology described previously for consideration by interested parties to facilitate comments on this proposed rule. The inclusion of a CY 2025 version of the ESRD PPS legacy wage index methodology allows for interested parties to compare wage index values under the current methodology and proposed new methodology. For the reasons previously discussed, we believe that the proposed new wage index methodology based on BLS data is the most appropriate for ESRD facilities; however, we intend to consider commenters' input on this proposal and the alternative wage index based on the established methodology (updated with the most recent data) when making a determination about the best approach in the final rule.

For this alternative wage index, we would use the ESRD PPS legacy wage index, which is based on the most recent pre-floor, pre-reclassified hospital wage data collected annually under the IPPS. The ESRD PPS legacy wage index values are calculated without regard to geographic reclassifications authorized for acute care hospitals under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. For CY 2025, the updated wage data are generally for hospital cost reporting periods beginning on or after October 1, 2020, and before October 1, 2021 (FY 2021 cost report data). This CY 2025 version of the legacy wage index methodology includes the updates to OMB's CBSA delineations, as the proposal to update those delineations is separate from the proposal to use the new wage index methodology. Under this possible alternative wage index using the legacy ESRD PPS methodology, we would still use the most recent available OMB CBSA delineations.

Under this alternative methodology, we would update the ESRD PPS legacy wage index to use the most recent hospital wage data. We would update those data if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, using a more recent estimate of the IPPS hospital wage data), and we would use such data, if appropriate, to determine the CY 2025 ESRD PPS alternative wage index in the final rule. The alternative CY 2025 ESRD PPS wage index is set forth in Addendum A and is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.* Addendum A provides a crosswalk between the CY 2024 wage index and the alternative CY 2025 wage index. Addendum B provides an ESRD facility level impact analysis. Addendum B is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.*

(2) Request for Comments on This Proposal

We believe that our proposed new ESRD PPS wage index methodology would more accurately estimate the geographic variation in wages paid by ESRD facilities when compared to the current ESRD PPS wage index based on the IPPS wage index. However, we acknowledge that this proposed new methodology, if finalized, would represent a significant change to the established ESRD PPS wage index methodology, both by changing the data sources and the calculations for the wage index. We are requesting comments on all aspects of the proposed new methodology, including the use of BLS OEWS data for CBSA-level wage estimates, the use of mean hourly wage (rather than median hourly wage), the use of freestanding ESRD facility cost reports for deriving occupational mix weights based on FTEs for each occupation per 1000 treatments as presented in the NEFOM, the use of the ESRD PPS legacy wage index for standardization, and the computational

steps used to calculate the wage index. We welcome any insights into potential methodological improvements, particularly related to some of the limitations of the new data sources discussed previously, including the absence of the cost of employee benefits and the full cost of contract labor in the BLS data, and the inability of this proposed methodology to capture differences in ESRD facility occupational mix across different geographic areas. Based on the comments we receive, we may modify the methodological steps used to calculate the wage index in the final rule. Additionally, we are requesting comments on the proposed use of the new wage index methodology compared to the established wage index methodology based on the IPPS wage index which was used to create the alternative ESRD PPS legacy wage index. We are also requesting comments on the distributional implications of this wage index proposal, with specific consideration to rural areas and remote or isolated areas such as the United States territories in the Pacific. Lastly, we are requesting comments on our proposal to begin using our new wage index methodology beginning on January 1, 2025.

f. Proposed Implementation of New OMB Labor Market Delineations

(1) Background

As previously discussed in this proposed rule, the wage index used for the ESRD PPS is historically calculated using the most recent pre-floor, pre-reclassified hospital wage data collected annually under the IPPS and is assigned to an ESRD facility based on the labor market area in which the ESRD facility is geographically located. We are proposing a new wage index methodology that would similarly be based on the labor market in which an ESRD facility is located. ESRD facility labor market areas are delineated based on the CBSAs established by OMB. In accordance with our established methodology, we have historically adopted through rulemaking CBSA changes that are published in the latest OMB bulletin. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses.

In the CY 2015 ESRD PPS final rule (79 FR 66137 through 66142), we finalized changes to the ESRD PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01[20] issued on February 28, 2013. We implemented these changes with a 2-year transition period (79 FR 66142). OMB Bulletin No. 13–01 established revised delineations for United States Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas based on the 2010 Census. OMB Bulletin No. 13–01 also provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252).

On July 15, 2015, OMB issued OMB Bulletin No. 15–01,[21] which updated and superseded OMB Bulletin No. 13–01 issued on February 28, 2013. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the United States Census Bureau population estimates for July 1, 2012, and July 1, 2013.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01,[22] which updated and superseded OMB Bulletin No. 15–01 issued on July 15, 2015. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the United States Census Bureau population estimates for July 1, 2014, and July 1, 2015. In OMB Bulletin No. 17–01, OMB announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300).

On April 10, 2018, OMB issued OMB Bulletin No. 18–03[23] which updated and superseded OMB Bulletin No. 17–01 issued on August 15, 2017. On September 14, 2018, OMB issued OMB Bulletin No. 18–04,[24] which updated and superseded OMB Bulletin No. 18–03 issued on April 10, 2018. OMB Bulletin Numbers 18–03 and 18–04 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the United States Census Bureau population estimates for July 1, 2015, and July 1, 2016. In the CY 2021 ESRD PPS final rule (85 FR 71430 through 71434), we finalized changes to the ESRD PPS wage index based on the most recent OMB delineations from OMB Bulletin No 18–04. This was the most recent time we have updated the labor market delineations used for the ESRD PPS and, as such, reflects the labor market delineations we used for CY 2024 (88 FR 76360).

In the July 16, 2021, **Federal Register** (86 FR 37777), OMB finalized a schedule for future updates based on results of the decennial Census updates to commuting patterns from the American Community Survey, an ongoing survey conducted by the Census Bureau. In accordance with that schedule, on July 21, 2023, OMB released Bulletin No. 23–01. A copy of OMB Bulletin No. 23–01 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.* According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (''the 2020 Standards''), which appeared in the **Federal Register** on July 16, 2021 (86 FR 37770 through 37778), and the application of those standards to Census Bureau population and journey-to-work data (that is, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data).

We believe it is important for the ESRD PPS to use, as soon as reasonably possible, the latest available labor market area delineations to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We believe that using the most current OMB delineations would increase the integrity of the ESRD PPS wage index system by creating a more accurate representation of geographic variations in wage levels, especially given the proposed new wage index methodology discussed previously. We have carefully analyzed the impacts of adopting the new OMB delineations and find no compelling reason to delay implementation. Therefore, we are proposing to adopt the updates to the OMB delineations announced in OMB Bulletin No. 23–01 effective for CY 2025 under the ESRD PPS for use in determining both the wage index and the rural adjustment for ESRD facilities. This would be implemented along with the new ESRD PPS wage index methodology, if finalized, or along with the alternative ESRD PPS legacy wage

[20] *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/bulletins/2013/b13-01.pdf.*

[21] *https://www.bls.gov/bls/omb-bulletin-15-01-revised-delineations-of-metropolitan-statistical-areas.pdf.*

[22] *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/bulletins/2017/b-17-01.pdf.*

[23] *https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf.*

[24] *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.*

index based on IPPS data, should the proposed new wage index methodology not be finalized.

As previously discussed, we finalized a 5 percent permanent cap on any decrease to a provider's wage index from its wage index in the prior year in the CY 2023 ESRD PPS final rule (87 FR 67161). We are not proposing any additional transition policy for the CY 2025 wage index as we believe the 5 percent cap effectively mitigates the negative impact of large wage index decreases for an ESRD facility in a single year. In addition, we are proposing to phase out the rural adjustment for ESRD facilities that are transitioning from rural to urban based on these CBSA revisions, as discussed in section II.B.2.f.(2) of this proposed rule. For a further discussion of changes to OMB's CBSA delineations, including a list of changes to specific CBSAs, see the FY 2025 IPPS proposed rule (89 FR 36139).

(2) Proposal To Phase Out the Rural Facility Adjustment for Facilities Affected by Changes to CBSAs

In the CY 2016 ESRD PPS final rule (80 FR 69001), we established a policy to provide a 0.8 percent payment adjustment to the base rate for ESRD facilities located in a rural area. This adjustment was based on a regression analysis, which indicated that the per diem cost of providing renal dialysis services for rural facilities was 0.8 percent higher than that of urban facilities after accounting for the influence of the other variables included in the regression. This 0.8 percent adjustment has been part of the ESRD PPS each year since it was finalized beginning for CY 2016, and its inclusion in the ESRD PPS is codified at § 413.233.

As previously discussed in this proposed rule, we are proposing a methodological change to the ESRD PPS wage index methodology as well as changes to the CBSA delineations. In the CY 2023 ESRD PPS final rule, we finalized a policy to cap year-to-year decreases in the wage index for any ESRD facility at 5 percent (87 FR 67161). The primary purpose of this change was to mitigate the negative effect associated with an ESRD facility being reclassified into a lower wage index CBSA as a result of changes in OMB's most recent CBSA delineations. We anticipate that the proposed change to the CBSA delineations and the changes to the wage index methodology, if finalized, would lead to numerous ESRD facilities having a significant decrease in wage index value in CY 2025 compared to CY 2024. As previously discussed, the adoption of OMB Bulletin No. 23–01 would determine whether an ESRD facility is classified as urban or rural for purposes of the rural facility adjustment in the ESRD PPS. Although the rural facility adjustment is not directly related to the wage index, the application of both is determined by the CBSA in which an ESRD facility is located and, therefore, is potentially subject to significant changes associated with the new CBSA delineations. It is reasonable to conclude that these proposed shifts in the CBSA delineations, in combination with the wage index methodological changes proposed in this proposed rule, could lead to a year-over-year decrease in payment greater than what a 5 percent decrease to the wage index would cause even if the decrease in the wage index value alone would be less than 5 percent. To mitigate the scope of changes that would impact ESRD facilities in any single year, we are proposing to implement a 3-year phase out of the rural facility adjustment for ESRD facilities that are located in a CBSA that was categorized as rural in CY 2024 and is recategorized as urban in CY 2025, as a result of the updates to the CBSA delineations associated with the proposed adoption of OMB Bulletin No. 23–01.

Overall, we believe implementing updated OMB delineations would result in the rural facility adjustment being applied where it is appropriate to adjust for higher costs incurred by ESRD facilities in rural locations. However, we recognize that implementing these proposed changes, if finalized, would have different effects among ESRD facilities and that the loss of the rural facility adjustment could lead to some hardship for ESRD facilities that had anticipated receiving the rural facility adjustment in CY 2025. Therefore, we believe it would be appropriate to consider whether a transition period should be used to implement these proposed changes.

For ESRD facilities located in a county that transitioned from rural to urban in OMB Bulletin 23–01, we considered whether it would be appropriate to phase out the rural facility adjustment for affected ESRD facilities. Adoption of the updated CBSAs in OMB Bulletin 23–01, if finalized as proposed, would change the status of 44 ESRD facilities currently designated as ''rural'' to ''urban'' for CY 2025 and subsequent CYs. As such, these 44 newly urban ESRD facilities would no longer receive the 0.8 percent rural facility adjustment. Consistent with the rural transition policy proposed for Inpatient Psychiatric Facilities (IPFs) and Inpatient Rehabilitation Facilities (IRFs) for FY 2025 (89 FR 23188, 89 FR 22267 through 22268) we are proposing a 3-year, budget neutral phase-out of the rural facility adjustment for ESRD facilities located in the 54 rural counties that would become urban under the new OMB delineations, given the potentially significant payment impacts for these ESRD facilities. We believe that a phase-out of the rural facility adjustment transition period for these 44 ESRD facilities would be appropriate, because we expect these ESRD facilities would experience a steeper and more abrupt reduction in their payments compared to other ESRD facilities. We are proposing to adopt these new CBSA delineations in a year in which we are also proposing substantial methodological changes to our wage index. While these proposed changes, if finalized, would increase payment accuracy across the ESRD PPS, we also recognize that some ESRD facilities could lose the rural facility adjustment and receive a significantly lower wage index value in the same year. We believe that it is appropriate for this proposed transition policy to be budget-neutral compared to ending the rural adjustment for these facilities in CY 2025 because it is an extension of the rural facility adjustment, which is implemented budget-neutrally, and a result of the change in CBSA delineations, which is proposed to be implemented budget-neutrally alongside the wage index changes. The reasoning behind this proposal is similar to the reasoning behind the 5 percent cap on year-to-year decreases in wage index values which was finalized in the CY 2023 ESRD PPS final rule (87 FR 67161), as it would ameliorate unexpected negative impacts to certain ESRD facilities. This rural phase-out in combination with the 5 percent cap policy would best reduce the negative effects on any single ESRD facility resulting from changes to the CBSA delineations. Therefore, we are proposing to phase out the rural facility adjustment for these facilities to reduce the impact of the loss of the CY 2024 rural facility adjustment of 0.8 percent over CYs 2025, 2026, and 2027, consistent with the similar IPF and IRF proposals previously discussed. This policy would allow ESRD facilities that are classified as rural in CY 2024 and would be classified as urban in CY 2025 to receive two-thirds of the rural facility adjustment for CY 2025, or a 0.53 percent adjustment. For CY 2026, these ESRD facilities would receive one-third of the rural facility adjustment, or a 0.27

percent adjustment. For CY 2027, these ESRD facilities would not receive a rural facility adjustment. We believe a 3-year budget-neutral phase-out of the rural facility adjustment for ESRD facilities that transition from rural to urban status under the new CBSA delineations would best accomplish the goals of mitigating the loss of the rural facility adjustment for existing CY 2024 rural ESRD facilities. The purpose of the gradual phase-out of the rural facility adjustment for these ESRD facilities is to mitigate payment reductions and promote stability and predictability in payments for existing rural ESRD facilities that may need time to adjust to the loss of their CY 2024 rural payment adjustment or that experience a reduction in payments solely because of this re-designation. This policy would be specifically for ESRD facilities that are rural in CY 2024 that become urban in CY 2025. We are not proposing a transition policy for urban ESRD facilities that become rural in CY 2025 because these ESRD facilities would receive the full rural facility adjustment of 0.8 percent beginning January 1, 2025, and they would not experience the same adverse effects as an ESRD facility that unexpectedly loses a payment adjustment. We understand that compared to rural payment adjustments in other Medicare payment systems, the ESRD PPS rural facility adjustment is not large in magnitude (for example, the rural adjustments for IPFs and IRFs are 17 percent and 14.9 percent, respectively), but it is important for ESRD facilities to be able to reasonably predict what their payments from the ESRD PPS would be in the next year. We solicit comments on this proposed policy.

3. Proposed CY 2025 Update to the Outlier Policy

a. Background

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care are frailty and obesity. A patient's specific medical condition, such as secondary hyperparathyroidism, may result in higher per treatment costs. The ESRD PPS recognizes that some patients require high cost care, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237.

Section 413.237(a)(1) enumerates the following items and services that are eligible for outlier payments as ESRD outlier services: (i) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iii) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iv) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and (v) Renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.[25]

In the CY 2011 ESRD PPS final rule (75 FR 49142), CMS stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the ESRD facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as ESRD outlier services were specified in Transmittal 2134, dated January 14, 2011.[26] We use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. For example, we use these issuances to identify renal dialysis oral drugs that were or would have been covered under Part D prior to 2011 to provide unit prices for determining the imputed MAP amounts. In addition, we use these issuances to update the list of ESRD outlier services by adding or removing items and services that we determined, based our monitoring efforts, are either incorrectly included or missing from the list.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its imputed (that is, calculated) MAP amount per treatment for ESRD outlier services exceeds a threshold. In past years, the MAP amount has reflected the average estimated expenditure per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted MAP per treatment plus the fixed dollar loss (FDL) amount. As described in the following paragraphs, the ESRD facility's predicted MAP amount is the national adjusted average ESRD outlier services MAP amount per treatment, further adjusted for case-mix and facility characteristics applicable to the claim. We use the term ''national adjusted average'' in this section of this proposed rule to more clearly distinguish the calculation of the average ESRD outlier services MAP amount per treatment from the calculation of the predicted MAP amount for a claim. The average ESRD outlier services MAP amount per treatment is based on utilization from all ESRD facilities, whereas the calculation of the predicted MAP amount for a claim is based on the individual ESRD facility and patient characteristics of the monthly claim. In accordance with § 413.237(c), ESRD facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and codified in § 413.220(b)(4), using 2007 data, we established the outlier percentage—which is used to reduce the per treatment ESRD PPS base rate to account for the proportion of the estimated total Medicare payments under the ESRD PPS that are outlier payments—at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric

[25] Under § 413.237(a)(1)(vi), as of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

[26] Transmittal 2033 issued August 20, 2010, was rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf.*

patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis used to compute the payment adjustments.

Lastly, in the CY 2023 ESRD PPS final rule, we finalized an update to the outlier methodology to better target 1.0 percent of total Medicare payments (87 FR 67170 through 67177). We explained that for several years, outlier payments had consistently landed below the target of 1.0 percent of total ESRD PPS payments (87 FR 67169). Commenters raised concerns that the methodology we used to calculate the outlier payment adjustment since CY 2011 results in underpayment to ESRD facilities, as the base rate has been reduced by 1.0 percent since the establishment of the ESRD PPS to balance the outlier payment (85 FR 71409, 71438 through 71439; 84 FR 60705 through 60706; 83 FR 56969). In response to these concerns, beginning with CY 2023, we began calculating the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years. We stated in the CY 2023 ESRD PPS final rule that we would continue to calculate the adult and pediatric MAP amounts for CY 2023 and subsequent years following our established methodology. In that same CY 2023 ESRD PPS final rule, we provided a detailed discussion of the methodology we use to calculate the MAP amounts and FDL amounts (87 FR 67167 through 67169).

For CY 2025, we are proposing several methodological and policy changes to the ESRD PPS outlier policy to address a number of concerns that interested parties have raised in recent years. Although we note that the 1.0 percent outlier target was achieved in CY 2023, it was not achieved in the majority of the years since the establishment of the ESRD PPS in 2011. We expect that each of the proposed changes would support the ability of the ESRD PPS to continue targeting outlier payments at 1.0 percent in CY 2025 and subsequent years. We discuss each of these proposed changes in detail in the following sections.

b. Proposed Expansion of ESRD Outlier Services

(1) Background and Current Issues

In the CY 2011 ESRD PPS final rule we finalized a policy that only renal dialysis services that were or would have been separately billable prior to the inception of the ESRD PPS would be eligible for the outlier payment. In the CY 2011 ESRD PPS proposed rule we explained that we believed that any unusual variation in the cost of the renal dialysis services comprising the base rate under the ESRD PPS would likely to be due to variation in the items and services that were, at that time, separately billable under Part B or renal dialysis service drugs and biological products that were then covered under Part D (74 FR 49988). We received some comments at that time that requested CMS consider alternative ways to determine outlier eligibility, including expanding eligibility to all renal dialysis services. However, we noted that we did not have adequate data at that time to include all Composite Rate Services (that is, renal dialysis services included in the composite payment system established under section 1881(b)(7) of the Act and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act, as defined in regulation at § 413.171) in the outlier calculation (74 FR 49989, 75 FR 49135).

In the CY 2019 ESRD PPS proposed rule we issued a comment solicitation on the potential expansion of outlier payments to composite rate supplies, drugs, and biological products (83 FR 34332). In this RFI, we detailed that such a change could promote appropriate payment for composite rate drugs once the TDAPA period has ended. Commenters' responses to this comment solicitation were mixed (83 FR 56969 through 56970). One commenter expressed that such a change would promote and incentivize the development of innovative new therapies and devices to treat the highly vulnerable ESRD adult and pediatric patient populations. Some commenters responded specifically regarding the TDAPA that extending availability of outlier payments would be particularly important when no additional money is being added to the base rate for the drug, as is the case with most drugs and biological products receiving the TDAPA. However, some commenters, including MedPAC, did not agree that such an expansion of the outlier eligible services would improve care, generally indicating that expanding the list of ESRD outlier services would hamper the outlier payment's functionality. One commenter stated that the purpose of the outlier adjustment was to pay for unusually costly patients, not new drugs and biological products, which the commenter felt the outlier payment was unable to do adequately. MedPAC commented that an outlier policy should act as a stop-loss insurance for medically necessary care, and outlier payments are needed when the ESRD PPS' payment adjustments do not capture all of the factors affecting providers' costs of delivering care. To that end, MedPAC stated that to develop an effective outlier policy, CMS must first develop accurate patient-level and facility-level payment adjustments. MedPAC further cautioned that should CMS expand the list of eligible ESRD outlier services, we should be clear as to what would qualify for the outlier payment.

In subsequent years, we took steps to expand the outlier policy to include certain potentially costly renal dialysis services that would have been included in the composite rate prior to the ESRD PPS. In the CY 2020 ESRD PPS final rule we finalized that any new and innovative renal dialysis equipment or supply would be eligible for the outlier adjustment after the end of the TPNIES period, regardless of whether it would have been separately billable prior to 2011 (84 FR 60697). In that rule, we explained that we believed allowing these items to be outlier eligible after the end of the TPNIES period would allow for these new and innovative supplies to be competitive with the other equipment and supplies also accounted for in the ESRD PPS base rate by establishing a level playing field where products could gain market share by offering the best practicable combination of price and quality (84 FR 60693). In the CY 2021 ESRD PPS final rule, we finalized that capital-related assets that are home dialysis machines will not become ESRD outlier services at the end of the TPNIES payment period (85 FR 71399). We explained that as assets, capital-related home dialysis machines are distinct from operating expenses such as the disposable supplies and leased equipment with no conveyed ownership rights. Unlike assets, these latter items are generally accounted for on a per patient basis and therefore, when used in excess of the average, constitute outlier use, which makes them eligible for outlier payments (85 FR 71424).

The definition of ESRD outlier services is codified at § 413.237(1)(a). Currently, drugs and biological products that were or would have been paid under the composite rate are not considered ESRD outlier services, and

costs for these drugs are not included in the calculation for outlier payments on ESRD PPS claims. Current regulations at § 413.171 define Composite Rate Services as: ''Items and services used in the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite payment system established under section 1881(b)(7) and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.'' Under our longstanding policy, drugs and biological products that are substitutes for composite rate drugs and biological products are considered to be included in the composite rate portion of the ESRD PPS. In the CY 2011 ESRD PPS final rule (75 FR 49048), we cited to existing guidance in the Medicare Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1, which explicitly stated, ''drugs used in the dialysis procedure are covered under the facility's composite rate and may not be billed separately. Drugs that are used as a substitute for any of these items, or are used to accomplish the same effect, are also covered under the composite rate.'' This guidance remains in effect and was subsequently re-designated to section 20.3.F of the same chapter.

In the CY 2024 ESRD PPS final rule (88 FR 76391), we finalized a policy to pay, beginning for CY 2024, a post-TDAPA add-on payment adjustment for any new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate that has previously been paid for using the TDAPA under § 413.234(c)(1). This post-TDAPA add-on payment adjustment generally will be applied for a period of 3 years following the end of the TDAPA period for those products. We finalized that the post-TDAPA add-on payment adjustment amount will be calculated based on the most recent available 12 months of claims data and the latest available full calendar quarter of average sales price (ASP) data (88 FR 76396). We explained that we divide the total expenditure of the new renal dialysis drug or biological product by the total number of ESRD PPS treatments furnished during the same 12-month period. In addition, we finalized that we adjust the post-TDAPA add-on payment adjustment amount paid on claims by the patient-level case-mix adjustment factors; accordingly, we apply a reduction factor to the post-TDAPA add-on payment adjustment amount to account for the application of the patient-level case-mix adjustment factors. We codified these policies by revising § 413.234(c)(1)(i) and adding regulations at § 413.234(b)(1)(iii), (c)(1)(ii), (c)(3), and (g) that describe the post-TDAPA add-on payment adjustment and the calculation we use to determine the post-TDAPA add-on payment adjustment amount. In addition, we amended § 413.230 by adding reference to the post-TDAPA add-on payment adjustment in the calculation of the ESRD PPS per treatment payment amount.

In the same CY 2024 ESRD PPS final rule, we summarized comments regarding the outlier policy as it pertains to the post-TDAPA add-on payment adjustment (88 FR 76396). One commenter pointed out that the CY 2024 ESRD PPS proposed rule did not indicate whether the ESRD PPS outlier adjustment would apply to products for which a post-TDAPA add-on payment adjustment is calculated. In response, CMS stated that under current policy, after the end of the TDAPA period, a drug or biological product is considered an eligible outlier service only if it meets the requirements of § 413.237(a)(1). We clarified that any renal dialysis drug or biological product included in the calculation of the post-TDAPA add-on payment adjustment would be considered an eligible ESRD outlier service only if it meets the requirements of § 413.237(a)(1). However, we further clarified that under current policy, Korsuva®, the only renal dialysis drug with a TDAPA period ending in CY 2024, would not be considered an eligible ESRD outlier service after the end of its TDAPA period, because it is a substitute for diphenhydramine hydrochloride, which was included in the composite rate prior to 2011, and therefore does not meet the requirements of § 413.237(a)(1) (that is, it would not have been, prior to January 1, 2011, separately billable under Medicare Part B).

Most recently, we have heard concerns from interested parties that excluding drugs and biological products that are substitutes for—or are used to achieve the same effect as—composite rate drugs and biological products from the definition of ESRD outlier services could limit the ability of the ESRD PPS outlier adjustment to appropriately recognize the drivers of cost for renal dialysis services. We considered these concerns, as well as the comments we received in response to prior rulemaking, to develop proposed changes to the definition of ESRD outlier services.

(2) Proposed Definition of ESRD Outlier Services

We are proposing to change the definition of ESRD outlier services at § 413.237(a)(1) to include drugs and biological products that were or would have been included in the composite rate prior to the establishment of the ESRD PPS. We note that this proposal would expand outlier eligibility to longstanding drugs and biological products that were historically included in the composite rate, as well as newer drugs and biological products that are currently included in the calculation of the post-TDAPA add-on payment adjustment. As discussed in section II.B.3.c of this proposed rule, we are proposing technical changes to the calculation of outlier payments that would appropriately account for the post-TDAPA add-on payment adjustment for ESRD outlier services that are drugs and biological products.

First, we considered the original intent behind the policy to limit outlier payments to drugs that were or would have been separately billable prior to 2011, which was that these drugs were likely the main drivers of the variation in the costs of treatment (74 FR 49988). We continue to believe that an important aspect of the outlier adjustment should be its ability to target ESRD cases that are unusually costly. If the outlier adjustment methodology failed to recognize the main drivers of variation in the costs of ESRD treatment, then it could result in cases that are not unusually costly qualifying for the outlier adjustment, which would mean the impact of the outlier adjustment would be diluted. As we noted earlier in this proposed rule, many of the responses to the comment solicitation in the CY 2019 ESRD PPS proposed rule expressed concerns that expanding the scope of ESRD outlier services would potentially dilute the impact of the outlier adjustment. We considered the potential impact of expanding the definition of ESRD outlier services to include additional drugs and biological products not currently included. We agree with the commenters who noted that the purpose of the outlier payment is not to pay for new drugs and biological products (83 FR 56969). Rather, as we discussed in the CY 2011 ESRD PPS final rule (75 FR 49134), CMS established the current outlier policy, including the 1.0 percent outlier target, because it struck an appropriate balance between our objective of paying an adequate amount for the most costly, resource-intensive patients while providing an appropriate level of payment for those patients who do not qualify for outlier payments. Under our current policy, new renal dialysis drugs and biological products that are paid for using the TDAPA are not considered

ESRD outlier services. As we explained in the CY 2016 ESRD PPS final rule (80 FR 69023), this is because during the TDAPA period we make a payment adjustment for the specific drug in addition to the base rate, whereas outlier services have been incorporated into the base rate. In contrast, the post-TDAPA add-on payment adjustment is paid on all claims, and drugs that are included in the post-TDAPA add-on payment adjustment amount are considered included in the ESRD PPS base rate. As a result, the amount paid under the post-TDAPA add-on payment adjustment does not correspond to the amount of a drug or biological product used on a claim, which would not be accounted for in any existing payment adjustment other than the outlier adjustment. For example, our analysis shows that patients using Korsuva® have costs of approximately $150 per treatment; however, because this drug is not recognized as an ESRD outlier service, these costs are not accounted for in determining the payment amount for the claim. Beginning April 1, 2024, the CY 2024 post-TDAPA add-on payment adjustment for Korsuva® increases the payment amount per treatment by approximately $0.25, which is adjusted by the patient-level case-mix adjusters applicable to the claim. In aggregate, the post-TDAPA add-on payment adjustment accounts for 65 percent of the cost of furnishing Korsuva®; however, this payment is spread across all ESRD PPS treatments.

We are not proposing to expand outlier eligibility to drugs and biological products that are paid for using the TDAPA during the TDAPA payment period, as the TDAPA amount is based on the full price (100 percent of ASP) for the amount of such drugs that is utilized and billed on the claim.

We considered only expanding the definition of ESRD outlier services to include drugs and biological products that were previously paid for using the TDAPA. As commenters have noted, new renal dialysis drugs and biological products are likely to be drivers of cost, because these drugs are typically more expensive. We recognized the importance of supporting access to new renal dialysis drugs and biological products under the ESRD PPS through the establishment of the post-TDAPA add-on payment adjustment beginning in CY 2024 (88 FR 76391). We explained in the CY 2024 ESRD PPS final rule that we agreed with commenters who expressed concerns that the ESRD PPS' current mechanisms may not fully account for the costs of these new drugs (88 FR 76388). We noted that several commenters stated that the outlier adjustment and the ESRDB market basket updates cannot adequately account for these costs, and several organizations noted that if additional renal dialysis drugs and biological products with significant costs were incorporated into the outlier payment calculation, the threshold to qualify for outlier payments would increase dramatically, thus adversely affecting access to products traditionally eligible for the outlier payment adjustment. We described comments which expressed that this increase in the outlier threshold may also raise health equity concerns because, as we noted in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67171), the outlier adjustment protects access for beneficiaries whose care is unusually costly. We recognized that if the outlier threshold were to increase significantly due to significant use of a new renal dialysis drug or biological product after the end of the TDAPA period, then ESRD facilities might be incentivized to avoid treating costlier beneficiaries.

We believe it would be appropriate for the definition of ESRD outlier services to include all drugs and biological products that previously were paid for using the TDAPA. The inclusion of these drugs and biological products would help ensure appropriate payment when a patient's treatment is exceptionally expensive due to an ESRD facility furnishing such drugs or biological products to the patient whose treatment requires them. In the CY 2011 ESRD PPS proposed rule, we explained that significant variations in formerly separately billable items and services could impair access to appropriate care, as an ESRD facility may have a disincentive to provide adequate treatment to those ESRD patients likely to have significantly higher than average costs (74 FR 49988). We believe ESRD facilities may face similar disincentives for furnishing drugs and biological products that previously received payment under the TDAPA. We believe that this change would also align with the statutory authority for the outlier adjustment under section 1881(b)(14)(D)(ii) of the Act by protecting patients' access to medically necessary care through a payment adjustment that more fully recognizes unusual variations in the type or amount of such care. Specifically, we believe this change would encourage ESRD facilities to take on ESRD patients who would potentially require expensive new drugs and biological products, promoting health equity for these patients who require costlier care. Additionally, the technical changes we are proposing in section II.B.3.c of this proposed rule would limit the impact of such drugs and biological products on the outlier threshold calculation, thereby enabling the ESRD PPS outlier adjustment to continue to protect access for beneficiaries whose care is unusually costly.

In light of the past comments described earlier in this section, we further considered whether expanding eligibility to all renal dialysis drugs and biological products that are Composite Rate Services, as defined at § 413.171, would be appropriate. As we have previously stated, the purpose of the outlier adjustment is to protect access for beneficiaries whose care is unusually costly. Although we continue to expect that the main drivers of cost would be drugs and biological products that were previously separately billable under Part B or Part D, or were previously paid for using the TDAPA, we nevertheless recognize that some patients could require higher utilization of composite rate drugs and biological products, which may result in the overall cost of their renal dialysis care being unusually high. For example, as noted in section II.B.3.e of this proposed rule, our analysis has identified that certain composite rate drugs are significant drivers of cost for pediatric patients, and therefore the proposed inclusion of those drugs as ESRD outlier services would improve the ability of the ESRD PPS outlier adjustment to target payment for pediatric patients whose care is exceptionally costly. Including composite rate drugs and biological products in the calculation of the outlier adjustment could appropriately support care for such ESRD patients, because payments under the outlier adjustment would better align with resource use.

We also considered the comments from MedPAC in response to the CY 2019 ESRD PPS proposed rule. Specifically, MedPAC stated that to develop an effective outlier policy, CMS must first develop accurate patient-level and facility-level payment adjustments. As we stated in the CY 2024 ESRD PPS final rule, interested parties have encouraged CMS to develop a patient cost model that is based on a single patient-level cost variable that accounts for all composite rate and formerly separately billable services (88 FR 76399). We finalized the collection of time on machine data, beginning for CY 2025, which we stated would allow for a higher proportion of composite rate costs to be allocated to patients with longer renal dialysis treatment times, and ultimately inform CMS refinements to existing patient-level adjusters,

including age and comorbidities (88 FR 76400). We believe that expanding the definition of ESRD outlier services could further support our understanding of the costs of Composite Rate Services, because it would encourage more comprehensive reporting of renal dialysis drugs and biological products that were formerly included in the composite rate for the purposes of calculating outlier payments. This increased reporting would in turn support future revisions to patient-level adjustment factors that consider more complete information about costs at the patient level.

We do not agree that the proposed inclusion of composite rate drugs and biological products would dilute the impact of the outlier adjustment, as some commenters in response to the CY 2019 ESRD PPS proposed rule suggested. Rather, our analysis indicates that the inclusion of these drugs and biological products would appropriately recognize the situations when the provision of these services is unusually costly, which we estimate would increase the amount of outlier payment per outlier-eligible claim, thereby more effectively protecting access for beneficiaries whose care is exceptionally costly. As discussed in section II.B.3.e. of this proposed rule, if we made no changes to our outlier methodology or the definition of ESRD outlier services for CY 2025, the average outlier payment for outlier-eligible cases among pediatric patients would be $25.02, and the average outlier payment for adult patients would be $53.45. Under the proposed changes to outlier eligibility, the average outlier payment for pediatric and adult patients would increase to $73.24 and $57.16, respectively. Furthermore, as discussed later in section II.B.3.e of this proposed rule, the inclusion of composite rate drugs and biological products would increase the pediatric MAP amount by a large amount, reflecting the utilization of certain high-cost composite rate drugs. Although the proposed CY 2025 adult MAP amount is lower than the final CY 2024 adult MAP amount, we note that the proposed adult MAP amount for CY 2025 is approximately $0.79 higher than it would be absent the proposed policy changes in this rule, which demonstrates that the inclusion of composite rate drugs and biological products would result in a higher MAP amount for adults.

In summary, the inclusion of composite rate drugs and biological products as ESRD outlier services would include more costs in the calculation of the ESRD PPS outlier adjustment for each case. As a result, fewer claims would qualify for outlier payments, but the amount of outlier payment per claim would be higher. Therefore, rather than diluting the impact of the outlier adjustment, these proposed changes would increase the impact of the outlier adjustment.

We are proposing to amend the language at 42 CFR 413.237 by adding a new paragraph (a)(1)(vii), which would add to the list of renal dialysis services defined as ESRD outlier services the following: ''Renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171.''

c. Proposed Changes to Predicted MAP Calculation for Outlier Eligibility

As we discussed in the CY 2023 ESRD PPS final rule (87 FR 67169), a claim is eligible for outlier payment when its imputed MAP amount exceeds the sum of the predicted MAP amount and the fixed dollar loss threshold. The predicted MAP amount for a claim is based on the national average MAP amount, adjusted by the case-mix adjustment factors that apply for that claim's patient-level and facility-level characteristics. As a result, when a claim's adjustment factors increase the payment amount per treatment, the claim's predicted MAP is also increased. This is because we expect that more complex patients would require a higher amount of spending for outlier services. However, this higher expected cost is recognized through a higher per treatment payment amount. In other words, a more complex patient must have even higher costs than are already accounted for in the adjustment factors compared to a less complex patient to be considered unusually costly. By increasing the predicted MAP based on the case-mix adjustment factors, the ESRD PPS outlier policy ensures that only cases that are unusually costly are considered for outlier payment.

As previously discussed in this proposed rule, we finalized a post-TDAPA add-on payment adjustment in the CY 2024 ESRD PPS final rule. The post-TDAPA add-on payment adjustment for certain new renal dialysis drugs and biological products is generally applied for 3 years after the end of the TDAPA period (88 FR 76388 through 76397). The amount of this post-TDAPA add-on payment adjustment that is applied to an ESRD PPS claim is adjusted by any applicable patient-level case-mix adjustments under § 413.235, and this adjusted amount is added to the payment amount for each ESRD PPS treatment billed. We explained in the CY 2024 ESRD PPS final rule that during this 3-year post-TDAPA add-on payment period, a drug or biological product would be eligible for the outlier add-on payment if it met all of the other criteria for the outlier payment (88 FR 76396). The only drug or biological product which was set to end its TDAPA period in CY 2024 (and therefore would receive the post-TDAPA add-on payment adjustment that year) was Korsuva®, which is a substitute for a composite rate drug and, therefore, not outlier eligible under existing § 413.237(a)(1) (88 FR 76396). Therefore, we did not propose any changes to the ESRD PPS outlier methodology to account for the post-TDAPA add-on payment adjustment in the CY 2024 ESRD PPS proposed rule as that would not have affected payments for CY 2024.

As noted previously, we are proposing to expand outlier eligibility to include renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171. This would mean that new drugs and biological products that are included in the calculation of the post-TDAPA add-on payment adjustment amount would become outlier eligible after the end of the TDAPA period, regardless of whether they are substitutes for composite rate drugs or biological products.

We are also proposing changes to the ESRD PPS outlier methodology to account for any future drugs and biological products which are outlier eligible during the post-TDAPA period. We propose to add the case-mix adjusted post-TDAPA add-on payment adjustment amount to the predicted MAP for a patient. This is appropriate because the post-TDAPA add-on payment adjustment amount represents average utilization of a drug or biological product, and is added to the payment amount, adjusted by the case-mix adjusters for the patient. This would prevent duplicate payment for these drugs and biological products by accounting for the portion of the cost for these drugs or biological products which is included in the ESRD PPS bundled payment. We note that this proposed change would not affect the calculation of the imputed MAP for a claim, because a claim's imputed MAP would include the actual utilization of the drug or biological product that is included in the calculation of the post-TDAPA add-on payment adjustment, if that drug or biological product is billed on the claim.

We considered proposing to modify the average MAP amount to account for outlier eligible drugs and biological products that are already included in the calculation of the post-TDAPA add-

on payment adjustment amount, rather than proposing to modify the predicted MAP amount for each claim. However, we note two main limitations with taking such an approach. First, the average MAP is set annually for an entire year and does not change from quarter to quarter; in contrast, the post-TDAPA add-on payment adjustment amount can change from quarter to quarter depending on when a drug or biological product's TDAPA period ends and the number of drugs and biological products included in the calculation. Second, our longstanding methodology for calculating the predicted MAP for outlier payments applies the outlier services multipliers to the average MAP. However, when we calculate the post-TDAPA add-on payment adjustment amount for a claim, we apply the ESRD PPS case-mix adjusters, which are different from the outlier services multipliers. We believe it would be most appropriate to continue to apply the ESRD PPS case-mix adjusters to the post-TDAPA add-on payment adjustment amount for the purposes of outlier calculation, so that the estimate of a claim's expected spending would align with the calculation used for the post-TDAPA add-on payment adjustment. For these reasons, we believe that it is more appropriate and more operationally feasible to apply the case-mix adjusted post-TDAPA add-on payment adjustment amount to the predicted MAP for claims during the quarters in which the drug or biological product is receiving the post-TDAPA add-on payment adjustment, rather than publishing different average MAPs for different quarters of a single year.

For CY 2025, the impact of this technical modification would be a small increase to the pediatric and adult FDL amounts, due to the small post-TDAPA add-on payment adjustment amount calculated for each quarter of CY 2025, as discussed in section II.B.6 of this proposed rule. Without this proposed methodological change, the pediatric FDL amount would increase by $0.68. Likewise, the adult FDL amount would increase by $0.89. This proposed methodological change would avoid those increases, resulting in the proposed CY 2025 adult and pediatric MAP and FDL amounts shown in table 7 of this proposed rule. Although the effect would be small for CY 2025, we note that the proposed increase would be larger in potential future situations when utilization of a drug or biological product during the post-TDAPA payment period could be higher.

d. Proposed Technical Modifications to the Inflation Factors Used for the Outlier Calculations

(1) Background

In the CY 2011 ESRD PPS final rule we finalized our ESRD PPS outlier methodology, which included our methodology for updating data from past years to the CY for which CMS is establishing payment rates (75 FR 49134). In the CY 2023 ESRD PPS final rule, we finalized an update to the outlier methodology to better target 1.0 percent of total Medicare payments (87 FR 67170 through 67177) by prospectively calculating the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years. In that final rule we also clarified our longstanding methodology for updating data from prior years for the purposes of the outlier calculations (87 FR 67167). For drugs and biological products, we use a blended 4-quarter moving average of the ESRDB market basket price proxies for pharmaceuticals to inflate drug prices to the CY for which CMS is establishing payment rates. For laboratory tests, we inflate laboratory test prices to the CY for which CMS is establishing payment rates using a CPI forecast to estimate changes for years in which a new data reporting period will take place for the purpose of setting Clinical Laboratory Fee Schedule (CLFS) rates.[27] For supplies, we apply a 0 percent inflation factor, because these prices are based on predetermined fees or prices established by the Medicare contractor.

In the CY 2023 ESRD PPS final rule (87 FR 67173), we noted that MedPAC supported the proposed revisions to the FDL methodology, but also urged CMS to refine its approach for applying the pricing data that the agency uses to project future spending for outlier services, particularly for drugs. Specifically, MedPAC suggested CMS use a drug price inflation factor based on ASP values and noted that the ASP data that CMS uses to determine facilities' actual outlier payments might be a more accurate data source on drug prices than the ESRDB market basket pharmaceutical price proxies that are currently used.

As discussed in the following sections, we have undertaken analysis of prices for ESRD outlier services and are proposing several technical changes to the inflation factors.

(2) Proposed Changes to the Inflation Factor for Outlier Eligible Drugs and Biological Products

As described earlier, we use a blended 4-quarter moving average of the ESRDB market basket price proxy for Pharmaceuticals to inflate drug prices to the upcoming CY for the purpose of estimating spending for outlier drugs and biological products in that CY. Historically, this 4-quarter moving average is a positive factor, meaning that our longstanding methodology for modeling outlier spending amounts assumes that prices for ESRD outlier drugs and biological product will increase. For example, the current projection of the CY 2025 price growth for ESRD outlier drugs and biological products, based on the ESRDB market basket price proxy for Pharmaceuticals for CY 2025, is 1.9 percent, based on the IGI 1st quarter 2024 forecast with historical data through the 4th quarter of 2023.

To compare the actual changes in prices for ESRD outlier drugs and biological products against the assumed rate of change derived from the ESRDB market basket price proxies, we constructed an index of prices for ESRD outlier drugs and biological products. As previously discussed in section II.B.3.b of this proposed rule, we are proposing to expand the definition of ESRD outlier services to include renal dialysis drugs and biological products that were or would have been included in the composite rate prior to the establishment of the ESRD PPS. Accordingly, our constructed drug price index included these drugs and biological products as well as drugs and biological products that have historically been included in the definition of ESRD outlier services.

Because the list of ESRD outlier drugs and biological products changes over time, we are proposing to derive a chained Laspeyres price index of the drugs and biological products included in the definition of the ESRD outlier services. A chained Laspeyres price index does not require a fixed basket of drugs and biological products during the observation window. We constructed and then trended forward the year-over-year change in price index levels for this outlier drug index to calculate a projected inflation factor for ESRD outlier drugs and biological products for CY 2025, using the following steps:

Step 1: We obtained the annual list of ESRD outlier service drugs and biological products that appear in ESRD

[27] Since 2018, there has been no updated reporting for most clinical diagnostic laboratory tests; therefore, the forecast estimate used since CY 2018 for the ESRD PPS outlier methodology has been 0.

PPS claims during the CYs 2017 through 2023. These include both composite rate and formerly separately billable drugs and biological products.

Step 2: We obtained quarterly ASP for each drug and biological product during the same period 2017 through 2023, substituting annual ASP when quarterly information was not available.

Step 3: We obtained quarterly utilization data for each drug and biological product for the period 2017 through 2023.

Step 4: For each quarter, we established the base period as the prior quarter and held utilization fixed at the base period. We then constructed a Laspeyres price index based on all drugs and biological products that had price information in that quarter and the prior quarter.

Step 5: We chained together the quarterly indices starting from the 1st quarter 2017 through the 4th quarter 2023 to express price changes in the 4th quarter 2017 relative to the 1st quarter 2017. This step was repeated for all prior quarters, keeping the starting period fixed at the 1st quarter 2017.

Step 6: We calculated the percentage change between the current and prior 4th quarter chained price index for each year for CY 2021, 2022, and 2023, which we used as the annual drug price inflation factor for each year.

Step 7: Using the chained price indexes for the three most recent CYs (2021, 2022, and 2023), we used a linear regression to project forward these three historical inflation factors to determine the CY 2025 inflation factor.

Using this methodology, we calculated a projected inflation factor of −0.7 percent, meaning that prices for ESRD outlier drugs and biological products are projected to be 0.7 percent lower in CY 2025 relative to the prices of the ESRD outlier drugs and biological products in than in CY 2024. We note that our analysis of year-over year changes in prices for ESRD outlier drugs and biological products shows a consistent, downward trend in prices, which stands in contrast to the positive inflation factors we have historically used to model outlier payments. As a result, our modeling of outlier spending in prior years has assumed that outlier prices would increase, when the ASP data shows that overall the prices have decreased.

Based on the results of our analysis, we believe that applying an inflation factor based on the actual change in prices for ESRD outlier drugs and biological products would enable the ESRD PPS outlier adjustment to better target 1.0 percent of outlier payments in CY 2025, because such an inflation factor would better reflect the observed historical trend in spending and utilization for such drugs and biological products. Although we have historically used the ESRDB market basket price proxy for Pharmaceuticals as the basis of our inflation assumptions for outlier modeling, and we believe that market basket price proxies would continue to be a reasonable and technically appropriate source for such assumptions, we note that the market basket price proxies serve a distinctly different purpose than the inflation factors. As we explained in the CY 2023 ESRD PPS final rule (87 FR 67147), we select the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. In contrast, the purpose of the inflation factors used in our outlier modeling is to represent the expected rate of change in price and utilization, so that we can prospectively set accurate FDL and MAP amounts that will result in outlier payments that equal 1.0 percent of total ESRD PPS payments. Decreasing our estimates of future outlier spending, as we are proposing to do, would result in lower FDL and MAP amounts, thereby increasing the number of claims that could be eligible for the outlier payment adjustment and the amount of outlier payments that would be paid on each claim. Revising our assumptions about future spending for ESRD outlier drugs and biological products would improve the ability of the ESRD outlier adjustment to pay for the costliest ESRD PPS claims. Therefore, we are proposing to use the projected inflation factor for ESRD outlier services that are drugs and biological products derived from the historical trend in prices and utilization for ESRD outlier drugs, as described in the previous paragraph. In section II.B.3.e of this proposed rule, we present the proposed CY 2025 MAP and FDL amounts calculated using this proposed methodology.

(3) Proposed Changes to the Inflation Factors for Outlier Eligible Laboratory Tests and Supplies

As previously discussed, CMS uses different methodologies for the inflation factors for laboratory tests and supplies. We inflate laboratory test prices to the upcoming CY using a CPI forecast to estimate changes for years in which a new data reporting period will take place for the purpose of setting CLFS rates; however, the forecast estimate used since CY 2018 for the ESRD PPS outlier methodology has been 0, because there has been no updated reporting for most clinical diagnostic laboratory tests since the CY 2018 CLFS. For supplies, we apply a 0 percent inflation factor, because these prices are based on predetermined fees or prices established by the Medicare contractor. In the CY 2011 ESRD PPS proposed rule, we explained that we chose to use these factors so that the MAP would be based on pricing mechanisms currently in place for these services (74 FR49991).

The ESRDB market basket uses price proxies for goods and services included in furnishing renal dialysis services to determine the ESRDB market basket update. For example, the market basket price proxy for laboratory services is the PPI Industry for Medical and Diagnostic Laboratories (BLS series code #PCU621511621511) representing the change in the price of laboratory services conducted by medical and diagnostic laboratories reported on the ESRD facility cost reports. Similarly, the market basket price proxy for supplies is the PPI Commodity for Surgical and Medical Instruments (BLS series code #WPU1562) representing the change in the price of medical supplies reported on the ESRD facility cost reports.

We have considered whether these longstanding assumptions about price changes for laboratory tests and supplies would be appropriate for modeling changes in spending for outlier-eligible laboratory tests and supplies. Unlike with drugs and biological products, we do not have detailed historical pricing data for ESRD outlier laboratory tests and supplies to permit us to perform a similar analysis for these services as we did for drugs and biological products. However, we can compare the historical inflation factors we have used to the growth in the market basket price proxies for these categories of renal dialysis services. For supplies, we would typically assume a 0 percent update; however, the average 10-year historical growth in the PPI Commodity for Surgical and Medical Instruments is 0.9 percent. Likewise, in years when there is a CLFS data reporting period, we would typically use an inflation factor for laboratory tests based on a CPI projection, reduced by the productivity adjustment, through June of the year prior to the update year; however, the average 10-year historical annual growth for the PPI Industry for Medical and Diagnostic Laboratories is −0.4 percent.

Beginning for CY 2025, we are proposing to use the ESRDB market basket price proxies for laboratory tests and supplies for the purpose of calculating the growth in estimated spending for these outlier services in the upcoming CY. These would replace the current inflation factors which are used for laboratory tests and supplies. Compared to the current inflation

factors we use, we anticipate that the market basket price proxies for laboratory tests and supplies would more appropriately reflect the change in prices of the laboratory tests and supply costs that are used by ESRD facilities. We believe that using the market basket price proxies would better allow the ESRD PPS to estimate the changes in the prices of laboratory tests and supplies, which would improve the ability for CMS to target outlier payments at 1.0 percent of total ESRD PPS payments. We note that decreasing our estimates of future outlier spending would result in lower FDL and MAP amounts, thereby increasing the number of claims that could be eligible for the outlier payment adjustment and the amount of outlier payment that would be paid on each claim. Revising our assumptions about future spending for ESRD outlier drugs and biological products would improve the ability of the ESRD PPS outlier adjustment to pay for the costliest ESRD PPS claims. In section II.B.3.e of this proposed rule, we present the proposed CY 2025 MAP and FDL amounts calculated using these inflation factors.

e. CY 2025 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2025, we are proposing to update the MAP amounts for adult and pediatric patients using the latest available CY 2023 claims data. We are proposing to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2023 claims data, and to update the ESRD outlier services FDL amount for adult patients using the latest available claims data from CY 2021, CY 2022, and CY 2023, in accordance with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174). The latest available CY 2023 claims data showed outlier payments represented approximately 1.0 percent of total Medicare payments.

The impact of this proposed update is shown in table 7, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2024 with the updated proposed estimates for this proposed rule for CY 2025. The estimates for the proposed CY 2025 MAP amounts, which are included in column II of table 7, were inflation adjusted to reflect projected 2025 prices for ESRD outlier services, in accordance with the proposed changes to the inflation factors discussed in section II.B.3.d of this proposed rule.

TABLE 7: Outlier Policy: Impact of Proposal to Use Updated Data for the Outlier Policy

	Column I Final outlier policy for CY 2024 (based on 2022 data, price inflated to 2024)*		Column II Proposed outlier policy for CY 2025 (based on 2023 data, price inflated to 2025)**	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	$22.30	$37.92	$56.60	$35.05
Adjustments				
Standardization for outlier services	1.0691	0.9763	1.0528	0.9772
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$23.36	$36.28	$58.39	$33.57
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$11.32	$71.76	$223.44	$49.46
Patient-month-facilities qualifying for outlier payment	20.86%	4.87%	6.00%	7.18%

*Column I was obtained from column II of table 1 from the CY 2024 ESRD PPS final rule (88 FR 76363).
**The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2021, 2022, and 2023.

As demonstrated in table 7, the estimated FDL per treatment that determines the CY 2025 outlier threshold amount for adults (column II; $49.46) is lower than that used for the CY 2024 outlier policy (column I; $71.76). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $36.28 to $33.57. For pediatric patients, there is an increase in the FDL amount from $11.32 to $223.44. There is a corresponding increase in the adjusted average MAP for outlier services among pediatric patients, from $23.36 to $58.39. We note that this substantial increase in the outlier threshold for pediatric patients reflects the proposed inclusion of certain composite rate drugs for outlier consideration, notably Healthcare Common Procedure Coding System (HCPCS) code J2997 (Injection, alteplase recombinant, 1 mg). As a result, a smaller proportion of pediatric patients would receive outlier payments, but the average outlier payment amounts would be significantly higher.

We estimate that the percentage of patient months qualifying for outlier

payments in CY 2025 would be 7.18 percent for adult patients and 6.00 percent for pediatric patients, based on the 2023 claims data and methodology changes proposed in sections II.B.3.c and II.B.3.d of this proposed rule.

f. Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1.0 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. In the 2023 ESRD PPS final rule, we finalized a change to the outlier methodology to better achieve this 1.0 percent target (87 FR 67170 through 67174). Based on the CY 2023 claims, outlier payments represented approximately 1.0 percent of total payments, which has been our policy goal since the establishment of the ESRD PPS outlier adjustment. We believe the proposed methodological changes to the outlier calculation and the proposed change to the definition of ESRD outlier services would continue to effectively set the outlier MAP and FDL amounts for CY 2025 and future years, enabling the ESRD PPS to continue targeting outlier payments at 1.0 percent of total payments. We also note that the proposed recalibration of the FDL amounts would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments.

4. Proposed Impacts to the CY 2025 ESRD PPS Base Rate

a. ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), CMS established the methodology for calculating the ESRD PPS per-treatment base rate, that is, the ESRD PPS base rate, and calculating the per-treatment payment amount, which are codified at §§ 413.220 and 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, the TDAPA, the TPNIES, the post-TDAPA add-on payment adjustment, and the TPEAPA for CYs 2024, 2025 and 2026.

b. Proposed Annual Payment Rate Update for CY 2025

We are proposing an ESRD PPS base rate for CY 2025 of $273.20. This would be a 0.8 percent increase from the CY 2024 ESRD PPS base rate of $271.02. This proposed update reflects several factors, described in more detail as follows:

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2025, we are not proposing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the proposed CY 2025 wage index budget-neutrality adjustment factor using treatment counts from the 2023 claims and facility-specific CY 2024 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2024. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2025. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the proposed CY 2025 ESRD PPS wage index and proposed labor-related share for CY 2025. As discussed in section II.B.2 of this proposed rule, the ESRD PPS wage index for CY 2025 includes the proposed new wage index methodology based on BLS data and the proposed use of the most recent OMB delineations based on 2020-census data.[28] The total of these payments becomes the new CY 2025 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budget-neutrality factor is calculated as the target amount divided by the new CY 2025 amount. When we multiplied the wage index budget-neutrality factor by the applicable CY 2025 estimated payments, aggregate Medicare payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget-neutrality adjustment factor ensures that the wage index updates and revisions do not increase or decrease aggregate Medicare payments. The proposed CY 2025 wage index budget-neutrality adjustment factor is 0.990228. This proposed CY 2025 wage index budget-neutrality adjustment factor reflects the impact of all proposed wage index policy changes, including the proposed CY 2025 ESRD PPS wage index using the new ESRD PPS wage index methodology based on BLS data, the 5 percent cap on year-to-year decreases in wage index values, the updated CBSA delineations, the 3 year rural phase-out for ESRD facilities in currently-rural CBSAs that would become urban under the new delineations, and the labor-related share. We note that the application of the 5 percent cap on wage index decreases has a sizable impact on the budget-neutrality factor this year due to the proposed new wage index methodology. That is, because a substantial number of ESRD facilities would have experienced a greater than 5 percent decrease in wage index value as a result of the proposed new wage index methodology, the budget-neutrality adjustment factor needed to offset the effect of limiting those decreases to 5 percent is larger than we expect it would be in a typical year. We note that the proposed CY 2025 wage index budget-neutrality factor does not include any impacts associated with the TPEAPA, as was the case with last year's combined wage index-TPEAPA budget-neutrality factor. This is consistent with how we have historically applied budget neutrality for case-mix adjusters, including pediatric case-mix adjusters. We do not routinely apply a budget-neutrality factor to account for changes in overall payment associated with changes in patient case-mix in years in which we do not propose any changes to the case-mix adjustment amount. Although the TPEAPA was established under the authority in section 1881(b)(14)(D)(iv) of the Act, which does not require budget neutrality, we stated in the CY 2024 ESRD PPS final rule that we were implementing the TPEAPA in a budget neutral manner because it was similar to the pediatric case-mix adjusters, and it accounts for costs which would have been included in the cost reports used in the analysis conducted when we created the ESRD PPS bundled payment in the CY 2011 ESRD PPS final rule (88 FR 76378). Therefore, it would not be

[28] *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.*

appropriate to apply a budget-neutrality factor for the TPEAPA for CY 2025.

Market Basket Update: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase. As discussed in section II.B.1.b.(1) of this proposed rule, the latest CY 2025 projection of the ESRDB market basket percentage increase is 2.3 percent. In CY 2025, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As previously discussed in section II.B.1.b.(2) of this proposed rule, the latest CY 2025 projection of the productivity adjustment is 0.5 percentage point, thus yielding a proposed CY 2025 productivity-adjusted ESRDB market basket update of 1.8 percent for CY 2025. Therefore, the proposed CY 2025 ESRD PPS base rate is $273.20 (($271.02 × 0.990228) × 1.018 = $273.20). We are also proposing that if more recent data become available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2025 ESRDB market basket update in the final rule.

5. Proposed Update to the Average per Treatment Offset Amount for Home Dialysis Machines

In the CY 2021 ESRD PPS final rule (85 FR 71427), we expanded eligibility for the TPNIES under § 413.236 to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. To establish the TPNIES basis of payment for these items, we finalized the additional steps that the Medicare Administrative Contractors (MACs) must follow to calculate a pre-adjusted per treatment amount, using the prices they establish under § 413.236(e) for a capital-related asset that is a home dialysis machine, as well as the methodology that CMS uses to calculate the average per treatment offset amount for home dialysis machines that is used in the MACs' calculation, to account for the cost of the home dialysis machine that is already in the ESRD PPS base rate. For purposes of this proposed rule, we refer to this as the ''TPNIES offset amount.''

The methodology for calculating the TPNIES offset amount is set forth in § 413.236(f)(3). Section 413.236(f)(3)(v) states that effective January 1, 2022, CMS annually updates the amount determined in § 413.236(f)(3)(iv) by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor. The TPNIES for capital-related assets that are home dialysis machines is based on 65 percent of the MAC-determined pre-adjusted per treatment amount, reduced by the TPNIES offset amount, and is paid for 2 CYs.

There are currently no capital-related assets that are home dialysis machines set to receive TPNIES for CY 2025, as the TPNIES payment period for the Tablo® System ended on December 31, 2023, and there are no TPNIES applications for CY 2025. However, as required by § 413.236(f)(3)(v), we propose to update the TPNIES offset amount annually according to the methodology described previously.

We propose a CY 2025 TPNIES offset amount for capital-related assets that are home dialysis machines of $10.18, based on the proposed CY 2025 ESRDB productivity-adjusted market basket update of 1.8 percent (proposed 2.3 percent market basket percentage increase reduced by the proposed 0.5 percentage point productivity adjustment). Applying the proposed update factor of 1.018 to the CY 2024 offset amount resulted in the proposed CY 2025 offset amount of $10.18 ($10.00× 1.018 = $10.18). We propose to update this calculation to use the most recent data available in the CY 2025 ESRD PPS final rule.

6. Proposed Updates to the Post-TDAPA Add-On Payment Adjustment Amounts

In the CY 2024 ESRD PPS final rule we finalized an add-on payment adjustment for certain new renal dialysis drugs and biological products, which would be applied for 3 years after the end of the TDAPA period (88 FR 76388 through 76397). This adjustment, known as the post-TDAPA add-on payment adjustment, is adjusted by the patient-level case-mix adjuster and is applied to every ESRD PPS claim. In that final rule we also clarified that for each year of the post-TDAPA period we would update the post-TDAPA add-on payment adjustment amounts based on utilization and ASP of the drug or biological product. For CY 2024 there is one drug, Korsuva® (difelikefalin), included in the calculation of the post-TDAPA add-on payment adjustment. In the CY 2024 ESRD PPS final rule (88 FR 76397), we finalized that the post-TDAPA add-on payment adjustment amount for Korsuva® would be $0.2493 and would begin on April 1, 2024.

For CY 2025, we will have two drugs included in the calculation of the post-TDAPA add-on payment adjustment. The post-TDAPA add-on payment adjustment period for one of these drugs, Korsuva®, began on April 1, 2024, so, conditional upon the continued receipt of the latest full calendar quarter of ASP data as described in § 413.234(c)(3), Korsuva® will be included in the calculation for the post-TDAPA add-on payment adjustment for the entirety of CY 2025. The other drug, Jesduvroq (daprodustat), began its 2-year TDAPA period on October 1, 2023, so its post-TDAPA add-on payment adjustment period will begin on October 1, 2025, conditional upon the continued receipt of the latest full calendar quarter of ASP data.

Based on the most recent utilization data, and following the calculation explained in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76389) and § 413.234(g), the proposed post-TDAPA add-on payment adjustment amount for Korsuva® is $0.4047 for all 4 quarters of CY 2025. Under that same methodology, the proposed post-TDAPA add-on payment adjustment amount for Jesduvroq is $0.0019 for only the last quarter of CY 2025. We note that utilization data available at the time of this proposed rulemaking for Jesduvroq included only data from October 2023 through February 2024. As discussed in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76389), we intend to update these calculations with the most recent available data in the final rule. Table 8 shows the proposed post-TDAPA add-on payment adjustment amounts for each quarter of CY 2025.

TABLE 8: Proposed Post-TDAPA Add-on Payment Adjustment Amounts for CY 2025 by Quarter

Quarter	Add-on amount for Korsuva®	Add-on amount for Jesduvroq	Total post-TDAPA add-on payment adjustment amount
Q1 (January – March)	$0.4047	0	$0.4047
Q2 (April – June)	$0.4047	0	$0.4047
Q3 (July – September)	$0.4047	0	$0.4047
Q4 (October – December)	$0.4047	$0.0019	$0.4066

a. Proposal To Publish Post-TDAPA Add-On Payment Adjustment Amounts After the Final Rule in Certain Circumstances

As discussed in the CY 2024 ESRD PPS final rule (88 FR 76393) and codified at 42 CFR 413.234(g), we have finalized a post-TDAPA add-on payment adjustment, which is based on the most recent year of utilization data and is calculated annually in each rulemaking cycle. Under § 413.234(g)(1), CMS bases the post-TDAPA add-on payment adjustment calculation on the most recent 12-month period of utilization for the new renal dialysis drug or biological product and the most recent available full calendar quarter of ASP data. However, when a drug or biological product begins its TDAPA period in the fourth quarter of a CY, and, therefore, would be included in the post-TDAPA add-on payment adjustment calculation beginning in the fourth quarter 2 CYs later, there would likely not be a full year's worth of utilization data available at the time of proposed or final rulemaking for that CY due to the time-lag associated with collecting and processing utilization data for the final rule. For example, at the time of rulemaking for last year's ESRD PPS final rule, we had data available through June 2023 when calculating the post-TDAPA add-on payment adjustment amount for Korsuva® (88 FR 73697). However, for a drug or biological product that began its TDAPA payment period in October of the prior year, data from October through June would only represent 9 months of data. We believe it is important to have a full year's utilization data when determining the post-TDAPA add-on payment adjustment amount so that the post-TDAPA add-on payment adjustment appropriately captures the utilization of the drug or biological product as required by § 413.234(g)(1).

We are proposing that when there is insufficient data at the time of rulemaking, we would publish the post-TDAPA add-on payment adjustment amount via Change Request (CR) once we have a full 12 months of data. Specifically, we would publish the post-TDAPA add-on payment adjustment amount in a CR under the following circumstances: (1) a drug or biological product is ending its TDAPA period during the CY, and therefore under § 413.234(c)(1) will begin being included in the post-TDAPA add-on payment adjustment amount calculation during that CY; and (2) that drug or biological product does not have at least 12 full months of utilization data at the time the final rule is developed. We would still include an estimated post-TDAPA add-on payment adjustment amount in the proposed rule and update that estimated amount in the final rule, but we would note that the estimated amount presented in the final rule is subject to change. We note that the final post-TDAPA add-on payment adjustment amount published after the final rule could be higher or lower than the estimated amount presented in the final rule. We do not anticipate having less than a full year's utilization data at the time of rulemaking for drugs and biological products that begin receiving TDAPA payments in quarters other than the fourth quarter of the year; however, should such an instance arise, we would similarly publish the post-TDAPA add-on payment adjustment amount in a CR once 12 months of utilization data is available. We would indicate the quarterly release CR in which we intend to publish the final post-TDAPA add-on payment adjustment amount.

For CY 2025, there is one TDAPA drug, Jesduvroq, which is ending its TDAPA period in CY 2025 and for which we do not anticipate having a full 12 months' worth of utilization data at the time of final rulemaking. As such, we would indicate in the final rule that we intend to publish the post-TDAPA add-on payment adjustment amount for CY 2025 for Jesduvroq once we have a full year of utilization data. We generally intend to publish this updated post-TDAPA add-on payment adjustment amount two calendar quarters prior to the end of the TDAPA period, as this would allow for sufficient time to gather and analyze a year's worth of utilization data. For this drug, and for any drug or biological product that begins its TDAPA period in the fourth quarter of a CY, we would generally publish the post-TDAPA add-on payment adjustment amount at the beginning of the second quarter of the last CY of that drug or biological product's TDAPA period (that is, two calendar quarters before the drug is included in the post-TDAPA add-on payment adjustment amount). However, should circumstances arise that prevent us from calculating a post-TDAPA add-on payment adjustment amount at that time, we would publish the final post-TDAPA add-on payment adjustment amount at a later time.

This approach to publishing the post-TDAPA add-on payment adjustment amount calculation would not impact any drug or biological product that has at least one full year's worth of utilization data at the time when the analysis for the final rule is developed, nor would it impact any drug or biological product that is already

included in the post-TDAPA add-on payment adjustment calculation for a given CY. We do not intend to routinely update post-TDAPA add-on payment adjustment amounts quarterly, as we believe this would make it more difficult for ESRD facilities to estimate payments. However, for drugs or biological products that lack a full year's worth of utilization data at the time when the analysis for the final rule is developed, we believe it is appropriate to take this additional step to ensure that their post-TDAPA add-on payment adjustment is based on 12 months of utilization data as required by § 413.234(g)(1).

7. Inclusion of Oral-Only Drugs Into the ESRD PPS Bundled Payment

a. Background

Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. Section 1881(b)(14)(B) of the Act defines renal dialysis services, and subclause (iii) of that section states that these services include other drugs and biologicals [29] that are furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, and any oral equivalent form of such drug or biological.

When we implemented the ESRD PPS in 2011 (75 FR 49030), we interpreted this provision as including not only injectable drugs and biological products used for the treatment of ESRD (other than ESAs and any oral form of ESAs, which are included under clause (ii) of section 1881(b)(14)(B) of the Act), but also all oral drugs and biological products used for the treatment of ESRD and furnished under title XVIII of the Act. We also concluded that, to the extent oral-only drugs or biological products used for the treatment of ESRD do not fall within clause (iii) of section 1881(b)(14)(B) of the Act, such drugs or biological products would fall under clause (iv) of that section, and constitute other items and services used for the treatment of ESRD that are not described in clause (i) of section 1881(b)(14)(B) of the Act.

We finalized and promulgated payment policies for oral-only renal dialysis service drugs or biological products in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053). In that rule, we defined renal dialysis services at § 413.171 as including drugs and biological products with only an oral form. We also finalized a policy to delay payment for oral-only drugs under the ESRD PPS until January 1, 2014. Accordingly, we codified the delay in payment for oral-only renal dialysis service drugs and biological products at § 413.174(f)(6), and provided that payment to an ESRD facility for renal dialysis service drugs and biological products with only an oral form would be incorporated into the ESRD PPS payment rates effective January 1, 2014, once we had collected and analyzed adequate pricing and utilization data. Since oral-only drugs are generally not a covered service under Medicare Part B, this delay of payment under the ESRD PPS also allowed coverage to continue under Medicare Part D for those beneficiaries with such coverage.

In the CY 2011 ESRD PPS proposed rule (74 FR 49929), we noted that the only oral-only drugs that we identified were phosphate binders and calcimimetics, specifically, cinacalcet hydrochloride, lanthanum carbonate, calcium acetate, sevelamer hydrochloride, and sevelamer carbonate. All of these drugs fall into the ESRD PPS functional category for bone and mineral metabolism.

Since then, the Congress has acted three times to further delay the inclusion of oral-only renal dialysis service drugs and biological products in the ESRD PPS. Specifically, as discussed in section II.A.1 of this proposed rule, ATRA in 2013, as amended by PAMA in 2014, and amended by ABLE in 2014, ultimately delayed the inclusion of oral-only drugs into the ESRD PPS until January 1, 2025.

Section 217(c)(1) of PAMA also required us to adopt a process for determining when oral-only drugs are no longer oral-only and to incorporate them into the ESRD PPS bundled payment. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that, in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. In the CY 2016 ESRD PPS proposed rule (80 FR 37839), we noted that when the existing oral-only drugs (which were, at that time, only phosphate binders and calcimimetics) were determined no longer to be oral-only drugs, we would pay for them using the TDAPA. We stated that this would allow us to collect data reflecting current utilization of both the oral and injectable or intravenous forms of the drugs, as well as payment patterns and beneficiary co-pays, before we add these drugs to the ESRD PPS bundled payment.

In 2017, when an injectable calcimimetic became available, CMS issued a Change Request [30] to add all calcimimetics, including oral and injectable forms, to the ESRD PPS bundled payment beginning in CY 2018. CMS paid the TDAPA for calcimimetics for a period of 3 years (CY 2018 through CY 2020). When the TDAPA period ended, we went through rulemaking (85 FR 71410) to increase the ESRD PPS base rate beginning in CY 2021 to incorporate the cost of calcimimetics.

Most recently, in the CY 2023 ESRD PPS final rule (87 FR 67185 through 67186), we finalized a revision to the regulatory definition of an oral-only drug, effective January 1, 2025, to clarify our longstanding policy by specifying that an oral-only drug has no injectable functional equivalent. The effective date of this revised definition will coincide with the January 1, 2025, incorporation of oral-only drugs into the ESRD PPS under § 413.174(f)(6). The revised definition of oral-only drugs reflects that drugs with similar end-action effects are treated as equivalent under the ESRD PPS, consistent with our approach to designating drugs into ESRD PPS functional categories.

b. Current Policy for Oral-Only Drugs in CY 2025

Existing regulations at § 413.174(f)(6) state that effective January 1, 2025, oral-only drugs will be paid for under the ESRD PPS. Although oral-only drugs are excluded from the ESRD PPS bundled payment until January 1, 2025, they are currently recognized as renal dialysis services as defined in regulation at § 413.171. Accordingly, CMS is planning to incorporate oral-only drugs into the ESRD PPS bundled payment beginning January 1, 2025, using the TDAPA, as described in the CY 2016 ESRD PPS final rule (80 FR 69027) and subsequent rules.

As we stated in the CY 2023 ESRD PPS final rule (87 FR 67180), if an injectable equivalent or other form of administration of phosphate binders were to be approved by FDA prior to January 1, 2025, the phosphate binders would no longer be considered oral-only drugs and would no longer be paid for outside the ESRD PPS. We stated that

[29] As discussed in the CY 2019 ESRD PPS final rule (83 FR 56922), we began using the term ''biological products'' instead of ''biologicals'' under the ESRD PPS to be consistent with FDA nomenclature. We use the term ''biological products'' in this proposed rule except where referencing specific language in the Act or regulations.

[30] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm10065.pdf* and *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2018downloads/r1999otn.pdf.*

we would pay for the oral and any non-oral version of the drug using the TDAPA under the ESRD PPS for at least 2 years, during which time we would collect and analyze utilization data. We stated that if no other injectable equivalent (or other form of administration) of phosphate binders is approved by the FDA prior to January 1, 2025, we would pay for these drugs using the TDAPA under the ESRD PPS for at least 2 years beginning January 1, 2025. CMS will use the same process that it used for calcimimetics to incorporate phosphate binders into the ESRD PPS beginning January 1, 2025. CMS discussed its process for incorporating calcimimetics in CMS Transmittal 1999, dated January 10, 2018, and in MLN Matters Number: MM10065.[31] [32] Pricing for phosphate binders under the TDAPA will be based on pricing methodologies available under section 1847A of the Act. A new renal dialysis drug or biological product is paid for using the TDAPA, which is based on 100 percent of ASP. If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. In such cases, CMS will undertake rulemaking to modify the ESRD PPS base rate, if appropriate, to account for the cost and utilization of phosphate binders in the ESRD PPS bundled payment.

We note that on October 17, 2023, a new oral phosphate lowering agent received FDA marketing approval. According to the FDA label information for this drug, XPHOZAH™ (tenapanor) is indicated to reduce serum phosphorus in adults with chronic kidney disease who are on dialysis. CMS has identified XPHOZAH™ to be a renal dialysis service because it is used to treat or manage a condition associated with ESRD. Specifically, it is used as an add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. XPHOZAH™ tablets are taken orally, usually twice a day with meals. CMS has also determined that XPHOZAH™ meets the current regulatory definition of an oral-only drug as defined at § 413.234(a), and therefore, in accordance with § 413.174(f)(6), is not paid for under the ESRD PPS until January 1, 2025. Consistent with policies adopted in the CY 2016 and CY 2023 ESRD PPS final rules (see 80 FR 69025 and 87 FR 67183), XPHOZAH™ will be included in the ESRD PPS effective January 1, 2025, using the drug designation process under § 413.234.

As set forth in § 413.174(f)(6), effective January 1, 2025, payment to an ESRD facility for renal dialysis service drugs and biological products with only an oral form furnished to ESRD patients will be incorporated within the prospective payment system rates established by CMS in § 413.230 and separate payment will no longer be provided. As noted earlier in this section, we have recently published operational guidance, including information about TDAPA payment, HCPCS codes, and ASP reporting requirements and timelines for phosphate binders at *https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf*. We note that we will use the same process that it used for calcimimetics to incorporate phosphate binders into the ESRD PPS beginning January 1, 2025, and that we will not be following this process for any other oral drugs or biological products. Manufacturers would need to apply for a HCPCS code and the TDAPA for any other oral drugs or biological products.

We note that for any other oral-only drugs, such as XPHOZAH™, we will apply our drug designation process as we do for all new renal dialysis drugs and biological products, consistent with § 413.234 and the policy finalized in CY 2016 ESRD PPS final rule (80 FR 69027) and reiterated in the CY 2023 ESRD PPS final rule (87 FR 67180).

c. Operational Considerations Related to the Incorporation of Oral-Only Drugs

In the CY 2011 ESRD PPS final rule (75 FR 49043), we explained that there were certain advantages to delaying the implementation of payment for oral-only drugs and biological products under the ESRD PPS. These advantages included allowing ESRD facilities additional time to make operational changes and logistical arrangements to furnish oral-only renal dialysis service drugs and biological products to their patients.

In November 2023, in accordance with section 632(d) of ATRA, the Government Accountability Office (GAO) published a Report to Congressional Committees titled, ''End-Stage Renal Disease: CMS Plans for including Phosphate Binders in the Bundled Payment.'' (GAO–24–106288).[33] The report summarized the current status of payment for the phosphate binders as well as identifying areas of operational concerns. These include challenges related to hiring the staff needed for ESRD facilities to provide phosphate binders to patients, complexities relating to system updates needed to accommodate the volume and broad array of phosphate binders, and costs related to dispensing, storage, and transportation. The considerations identified in the GAO report generally align with the comments we have received on past ESRD PPS proposed rules. The GAO also interviewed dialysis organization representatives who stated that they are preparing to make the anticipated adjustments needed to dispense the phosphate binders.

With respect to considerations related to staffing, we note that the ESRD PPS includes payment for staffing related to the provision of renal dialysis services. We believe there are several strategies that ESRD facilities could employ to efficiently use available staff time to provide phosphate binders. There are parallels between the administration of phosphate binders and the administration of oral calcimimetics, which are also typically taken daily. First, we expect that patients with ESRD generally receive treatment for at least 3 hours per session, typically three times per week. We believe that during this treatment window there is generally staff availability to provide the patient with pre-packaged medication, which we note could include medication for multiple days. Second, ESRD facilities could maximize the efficiency of staff time by mailing the prescriptions, to the extent that doing so is consistent with state pharmacy laws. For example, the GAO report identified that one large dialysis organization only mails oral prescriptions to patients' homes, while others mail the medication to either the ESRD facility or the patient's home. Third, the GAO report identified that some ESRD facilities contract with outside pharmacies rather than operating their own pharmacy. By contracting with outside pharmacies, ESRD facilities could reduce or avoid the need to hire additional pharmacists and pharmacy staff to manage the volume of prescriptions.

Another challenge identified by the dialysis organizations was the complexity of dispensing phosphate binders because of the broad array of phosphate binders and the high volume of pills.[34] We acknowledge there are six

[31] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R1999OTN.pdf.*

[32] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10065.pdf.*

[33] *https://www.gao.gov/assets/d24106288.pdf.*

[34] Ibid.

common types of phosphate binders as compared to only one type of calcimimetics. The GAO report also noted that unlike calcimimetics, phosphate binders are typically taken with every meal and snack. We note that although Medicare will begin paying for phosphate binders under the ESRD PPS beginning January 1, 2025, we are not establishing any requirements regarding how or where patients take these medications. These decisions are made and will continue to be made by the patient, nephrologist, and care team.

We recognize that updates may be required to ESRD facilities' systems, including electronic medical records, billing systems, and inventory management systems to accommodate new procedures for dispensing phosphate binders. As we previously noted, we initially delayed the incorporation of oral-only drugs into the ESRD PPS in 2011, in part to allow ESRD facilities to make such operational changes and logistical arrangements. In addition, we have provided operational guidance at *https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf* that addresses HCPCS coding, billing, and price information. We expect that ESRD facilities will be able to make these system changes in advance of January 1, 2025.

Dialysis organizations have expressed concerns surrounding CMS using ASP to determine the TDAPA amount added to the ESRD PPS base rate for phosphate binders, which they believe does not adequately provide for dispensing cost.[35] Under current TDAPA policy, CMS plans to pay the TDAPA based on 100 percent of ASP for phosphate binders for at least 2 years. However, recognizing the high percentage of ESRD beneficiaries that have at least one phosphate binder prescription and the large volume of phosphate binder prescriptions, we are considering whether it may be appropriate to make additional payment to account for operational costs in excess of 100 percent of ASP, such as dispensing fees, when paying the TDAPA for phosphate binders. Unlike drugs and biological products for which payment is already included in the ESRD PPS base rate, including all other drugs and biological products in existing functional categories, dispensing fees and other costs are not currently included in the ESRD PPS base rate for phosphate binders. Therefore, we are considering whether a potential change in TDAPA payment policy for phosphate binders to account for such costs would be consistent with the TDAPA policy as finalized in the CY 2019 and CY 2020 ESRD PPS final rules (83 FR 56948 and 84 FR 60673 through 60676). For example, we may consider paying ASP + 6 percent for 2 years as we did for calcimimetics. As discussed in the CY 2011 ESRD PPS final rule, the amounts added to the ESRD PPS base rate for oral drugs at that time were based on data from Part D, which included dispensing fees (75 FR 49043). We are soliciting comment on the extent to which 100 percent of ASP is appropriate for TDAPA payment amount for phosphate binders and whether there are any costs associated with the inclusion of phosphate binders into the ESRD PPS bundled payment that may not be accounted for by 100 percent of ASP. CMS may finalize a change in the TDAPA payment amount for phosphate binders after considering comments on this topic.

As noted earlier, we have issued guidance [36] about the process we will use for paying the TDAPA for the phosphate binders and for their incorporation into the ESRD PPS bundled payment. This guidance addresses several key topics including billing information, information about the discarded drug policy, and information for manufacturers about reporting timelines for ASP data.

d. Expected Impact of Incorporation of Oral-Only Drugs

We anticipate that the incorporation of oral-only drugs into the ESRD PPS will increase access to these drugs for beneficiaries. We estimate that there will be an increase in Medicare spending as a result of this increase in access. Specifically, CMS has been monitoring and analyzing data regarding beneficiary access to Medicare Part D drugs; increases in expenditures for renal dialysis drugs paid under Medicare Part D; health equity implications of varying access to Medicare Part D drugs among patients with ESRD; and ESRD facility behavior regarding drug utilization. We have seen that incorporating Medicare Part D drugs into the ESRD PPS has had a significant positive effect of expanding access to such drugs for beneficiaries who do not have Medicare Part D coverage, with significant positive health equity impacts. For example, based on the results of our ESRD PPS monitoring analyses, in December 2017, prior to incorporation of calcimimetics into the ESRD PPS bundle, utilization was at 28.97 percent for African American/Black beneficiaries but went up to 35.31 percent in January 2018 and eventually to 39.04 percent in at the end of the TDAPA period for calcimimetics in December 2021. This 10.07 percentage point increase in utilization reflects the significant access improvement for African American/Black beneficiaries of incorporating formerly oral-only drugs into the ESRD PPS.

Lastly, as part of the preparation for the inclusion of phosphate binders into the ESRD PPS, CMS has monitored Part D utilization of, and spending for, phosphate binders. We have developed budgetary estimates of the changes in Medicare Part B and Part D spending, which are discussed in section VIII.C.1 of this proposed rule.

8. Proposed Changes to the Low-Volume Payment Adjustment (LVPA)

a. Background on the LVPA

Section 1881(b)(14)(D)(iii) of the Act provides that the ESRD PPS shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent. Therefore, the ESRD PPS provides a facility-level payment adjustment to ESRD facilities that meet the definition of a low-volume facility.

Under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation: (1) furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month costs reports, whichever is most recent, except as specified in paragraphs (g)(4) and (5)) preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type or as specified in paragraph (g)(6)) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

In addition, under § 413.232(c), for purposes of determining eligibility for the LVPA, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD

[35] Ibid.

[36] *https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd* and *https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf.*

facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question. To receive the LVPA, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) confirming that it meets the requirements as specified in § 413.232 and qualifies as a low-volume ESRD facility. For purposes of determining eligibility for the LVPA, ''treatments'' mean total hemodialysis equivalent treatments (Medicare and non-Medicare). For peritoneal dialysis patients, one week of peritoneal dialysis is considered equivalent to three hemodialysis treatments (80 FR 68994). Section 413.232(e) generally imposes a yearly November 1 deadline for attestation submissions unless extraordinary circumstances justify an exception and specifies exceptions for certain years where the deadline is in December or January. The November 1 attestation timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236). The ESRD facility would then receive the LVPA for all the Medicare-eligible treatments in the payment year. Once an ESRD facility is determined to be eligible for the LVPA, a 23.9 percent increase is applied to the ESRD PPS base rate for all treatments furnished by the ESRD facility (80 FR 69001).

In the CY 2011 ESRD PPS final rule (75 FR 49118 through 49125), we finalized the methodology used to target the appropriate population of ESRD facilities that were low-volume facilities based on a treatment threshold. After consideration of public comments, we originally established an 18.9 percent adjustment for ESRD facilities that furnish less than 4,000 treatments annually and indicated that this increase to the base rate would encourage small ESRD facilities to continue providing access to care.

In the CY 2016 ESRD PPS proposed rule (80 FR 37819), we analyzed ESRD facilities that met the definition of a low-volume facility under § 413.232(b) as part of the updated regression analysis and found that these ESRD facilities still had higher costs compared to other ESRD facilities. A regression analysis of low-volume facility claims from CYs 2012 and 2013 and cost report data indicated a multiplier of 1.239; therefore, we proposed an updated LVPA adjustment factor of 23.9 percent in the CY 2016 ESRD PPS proposed rule (80 FR 37819) and finalized this policy in the CY 2016 ESRD PPS final rule (80 FR 69001). This update was implemented budget neutrally alongside numerous other changes to the case-mix and facility-level adjusters. In CY 2022, 352 ESRD facilities received the LVPA. Using the most recent available data for CY 2023, the number of ESRD facilities receiving the LVPA was 330.

In the CY 2021 ESRD PPS final rule (85 FR 71443), we finalized a policy to allow ESRD facilities flexibility for LVPA eligibility due to the COVID–19 Public Health Emergency (PHE). Under § 413.232(g)(4), for purposes of determining ESRD facilities' eligibility for payment years 2021, 2022, and 2023, we only considered total dialysis treatments for any 6 months of their cost-reporting period ending in 2020. In the CY 2024 ESRD PPS final rule (88 FR 76344), we finalized changes to the LVPA regulation at § 413.232 that allow ESRD facilities affected by disasters and other emergencies to qualify for exceptions to certain eligibility requirements for the LVPA. Facilities may close and reopen if they experience an emergency, or they may temporarily exceed the 4,000-treatment threshold if they take on additional patients displaced by an emergency and still qualify for the LVPA.

(1) Current Issues and Concerns

Interested parties, including MedPAC and the GAO,[37] have recommended that we make refinements to the LVPA to better target ESRD facilities that are critical to beneficiary access to dialysis care in remote or isolated areas.[38] These groups and other interested parties have also expressed concern that the strict treatment count used to determine eligibility introduces a ''cliff-effect'' that may incentivize ESRD facilities to restrict their patient caseload to remain below the 4,000 treatments per year for the LVPA threshold.[39]

We considered several changes to the LVPA eligibility criteria to address the concerns that interested parties, including the GAO and MedPAC, raised about targeting LVPA payments to ESRD facilities that are necessary to protect access to care and are not located near other ESRD facilities. Specifically, these interested parties have requested that we take into consideration the geographic isolation of an ESRD facility within the LVPA methodology. Section 1881(b)(14)(D)(iii) of the Act requires that the LVPA must reflect the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services. Our analysis has found that isolated low-volume facilities do not face higher costs than other low-volume facilities. Therefore, we do not believe that this requested change reconciles with the central statutory requirements and limitations for the LVPA, and we are considering alternative approaches, including potentially addressing this issue through a new payment adjustment separate from the LVPA based on section 1881(b)(14)(D)(iv) of the Act. Currently, we are analyzing claims and cost data regarding dialysis treatment levels and cost to inform options for potentially tailoring our methodology to meet the requirements of the statute, while simultaneously collecting additional data on geographic isolation of ESRD facilities. The ESRD PPS has separate facility-level payment adjustments for low-volume facilities, as set forth in 42 CFR 413.232, and facilities in rural areas, as set forth in § 413.233. To avoid overlap with these existing facility-level adjustments, we are analyzing the impact of potentially creating a new payment adjustment and considering innovative methodological options, such as the local dialysis need methodology on which we requested information in the CY 2024 ESRD PPS proposed rule (88 FR 42441 through 42445).

In addition, we have heard from interested parties that the eligibility criteria for the LVPA are very explicit and leave little room for flexibility in certain circumstances (85 FR 71442). Some also view the attestation process as burdensome to ESRD facilities and believe it may discourage participation by small ESRD facilities with limited resources that would otherwise qualify for the LVPA.[40] Given these concerns, we have considered alternative approaches to the LVPA that would reduce burden, remove negative incentives that may result in gaming, and better target ESRD facilities that are critical for beneficiary access.

CMS's contractor has held three Technical Expert Panels (TEPs) to discuss potential refinements to the ESRD PPS.[41] During the 2018, 2019, and

[37] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf.*

[38] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

[39] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

[40] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

[41] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources.*

2020 TEPs, panelists, including representatives from ESRD facilities, independent researchers, patient advocates, and representatives from professional associations and industry groups (86 FR 36397), discussed limitations of the current LVPA methodology and potential alternatives. In the CY 2022 ESRD PPS proposed rule, we included a RFI to inform LVPA payment reform (86 FR 36398 through 36399). All fourteen responses to the CY 2022 ESRD PPS RFI for LVPA wrote in support of either eliminating or revising the current LVPA or rural facility adjustment.[42] One small dialysis organization within a large non-profit health system responded that it is reliant upon the LVPA and the rural facility adjustment and supports both adjustments, albeit with modifications. MedPAC renewed its support for a new Low-Volume and Isolated (LVI) adjustment with a recommendation for a three-tiered approach for treatment thresholds, which would incorporate geographic isolation into its methodology and may disincentivize gaming. MedPAC called upon CMS to provide clear and timely criteria for ESRD facility eligibility and ensure the LVPA methodology is transparent. In concurrence with MedPAC, a coalition of dialysis organizations, three large dialysis organizations (LDOs), a non-profit kidney organization, and a provider advocacy coalition commented that the rural facility adjustment should be eliminated and a LVI methodology should be adopted, as they considered a methodology based upon census tracts to be both complicated and lacking transparency. Numerous commenters wrote in support of a tiered adjustment to mitigate the cliff effect and gaming. Commenters raised concerns regarding the reliance of the census tract methodology used by the rural facility adjustment upon 'driving time' as a data measure, noting this presents legitimate equity issues. ESRD facilities that have relied upon both the LVPA and rural payment adjustments to remain operational expressed opposition to elimination of either adjustment.[43]

In the CY 2022 ESRD PPS proposed rule LVPA RFI, we sought input on alternative approaches to the LVPA methodology (86 FR 36398 through 36399).[44] Specifically, we requested input on—(1) whether a distinction other than census tract information should be considered; and (2) what criteria should be used to determine the threshold(s) of adjusted latent demand (in treatment counts) which determine LVPA eligibility. Additionally, we explored the LVI adjustment that MedPAC recommended in its June 2020 report to Congress. Under the LVI methodology, a determination that a facility is low volume and isolated would be based on that facility's distance from the nearest facility and its total treatment volume. Regarding the LVI methodology, we requested input on the concerns for facilities that would lose the LVPA under the LVI methodology and the potential for gaming within the LVI methodology. In addition, we requested input regarding the extent that the LVI methodology captures more isolated (and most often rural) facilities, and whether a separate rural facility adjustment should be maintained. As previously discussed, our most recent analysis of cost report data does not support the claim that isolated low-volume ESRD facilities face higher costs than non-isolated ESRD facilities; therefore, the LVI methodology would not adhere to the statutory requirement for the LVPA set forth at section 1881(b)(14)(D)(iii) of the Act.

(2) CY 2024 RFI on Potential Changes to the LVPA

In the CY 2024 ESRD PPS proposed rule (88 FR 42430 through 42544), we issued a RFI regarding several possible modifications to the current LVPA methodology.[45] We provided commenters the option of maintaining a single LVPA threshold, establishing LVPA tiers, or utilizing a continuous function. We received 23 comments in response to the RFI, all of which had differing opinions. A coalition of dialysis organizations recommended a two-tiered approach, while MedPAC reiterated their support for a LVI adjustment. A common theme among a handful of comments was concern about administrative burden and transparency regarding the methodology that is chosen. Most commenters believed that the issue of payment cliffs is substantial, but many did not believe any of the options presented in the RFI could successfully eliminate gaming completely.

(3) CY 2024 RFI on the Rural Facility Adjustment

We have considered several changes to the LVPA eligibility criteria to address the concerns that the GAO and MedPAC raised about targeting LVPA payments to ESRD facilities that are necessary to protect access to care and are not located near other ESRD facilities. As previously discussed, we do not believe the suggestion to consider facilities' geographic isolation reconciles with the central statutory requirements and limitations for the LVPA, and we are considering alternative approaches, including potentially addressing this issue through a new payment adjustment separate from the LVPA based on section 1881(b)(14)(D)(iv) of the Act.

The LVPA and rural adjusters currently result in increased payments to some geographically isolated ESRD facilities, but these adjusters do not specifically target geographically isolated ESRD facilities. Interested parties, including MedPAC and the GAO, have recommended that CMS make refinements to the LVPA and rural adjusters to better target ESRD facilities that are critical to beneficiary access to dialysis care in remote or isolated areas. The GAO and MedPAC, among others, have also raised concerns about targeting LVPA payments to ESRD facilities that are not located near other ESRD facilities to protect access to care.

In the CY 2024 ESRD PPS proposed rule's LVPA RFI (88 FR 42441 through 42445), we solicited comments on a potential new payment adjustment that accounts for isolation, rurality, and other geographical factors, including local dialysis need (LDN). The LDN methodology, as described in the CY 2024 ESRD PPS proposed rule (88 FR 42430 through 42544), would consider LDN instead of basing payment strictly upon a rural designation, as provided for by §§ 413.233 and 413.231(b)(2). In the CY 2024 ESRD PPS proposed rule's LVPA RFI, we suggested the utilization of census tracts to identify geographic areas with low demand, then calculating latent demand by multiplying the number of beneficiaries near (''near'' was defined by driving time to ESRD facilities) an ESRD facility by the average number of treatments for ESRD beneficiaries. The threshold to qualify for the LVPA could then be applied by determining the amount of adjusted latent demand. The ESRD facilities that fall below the threshold would be eligible. The statutory requirements for the LVPA under section 1881(b)(14)(D)(iii) of the Act generally would not allow for CMS to account for geographic isolation outside of the extent to which low-volume facilities face higher costs in furnishing renal dialysis services than other facilities, and preliminary analysis found that, in general, low-volume facilities that are rural, isolated, or located in low-demand areas did not have higher costs than low-volume ESRD facilities overall. Because of this, the LDN methodology

[42] *https://www.cms.gov/files/document/cy-2022-esrd-pps-rfi-summary-comments.pdf.*

[43] The materials from the TEPs and summary reports can be found at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources.*

would be implemented under the authority in section 1881(b)(14)(D)(iv) of the Act, which states that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate.

We received 23 comments in response to the LVPA RFI, all of which had differing opinions.[46] Some commenters supported eliminating the rural adjuster and reallocating its funds to either the LVPA or to a new adjustment that considers LDN. Others stated the rural facility adjustment should be removed, and those dollars be incorporated into one of the tiered LVPA methodologies. Many commenters noted that a LVPA, a rural facility adjustment, and a possible LDN-based adjustment would be redundant. A coalition of dialysis organizations stated that CMS's reliance on zip codes to identify rural facilities is no longer an adequate proxy for facilities in need, and cited data that many rural facilities enjoy a large patient count and positive profit margins. Other commenters supported the rural facility adjustment, explaining that it was especially appropriate in conjunction with a modified LVPA methodology, since under the options presented by CMS in the RFI, many facilities would experience significant decreases in payment. They claimed that the additional funds provided by the rural facility adjustment would protect against the closure of rural facilities. Several commenters expressed concern about administrative burden and transparency in a general sense, no matter the methodology chosen.

Generally, commenters were opposed to a payment adjustment based on the LDN methodology, reiterating many of the concerns raised during the 2020 TEP. A coalition of dialysis organizations voiced the concern that the LDN methodology would take away providers' ability to make financial decisions about their operations, since they would not be able to predict their eligibility for the LDN payment adjustment nor the amount they would receive. They maintained that the LDN may not target the appropriate facilities and could provide opportunities for gaming. The coalition also claimed that the central issue faced by these facilities is low patient count, which they stated that the LDN methodology would not recognize, and thus the adjustment could be provided to facilities that are isolated, but have high patient counts, and are not in need of an additional payment adjustment. A coalition of dialysis organizations and a non-profit dialysis association both stated that the current LVPA provision to aggregate the treatments of facilities under common ownership that are not at least 5 miles apart is an important feature that discourages gaming, one that is not included in the LDN methodology. Furthermore, the coalition noted that the LDN methodology would lack stability, given that patient location varies over time. MedPAC suggested that if the LDN were adopted, CMS should ensure that the methodology is transparent; for example, making the specifications and results for the regression equation available on CMS's website and in the **Federal Register**. In addition, MedPAC stated that CMS should note how often the model would be updated, discuss how census tract populations changing over time would affect the stability of the adjustment, and how the approach would address MedPAC's anticipated increase in home dialysis use.

In addition to the questions outlined in the CY 2024 ESRD PPS proposed rule LVPA RFI, CMS has also considered incorporating isolation criteria into the rural facility adjustment, where payment of the adjustment could be limited to ESRD facilities that are isolated from other ESRD facilities, or a higher adjustment could be applied for isolated rural facilities than for non-isolated rural facilities. Alternatively, the current rural facility adjustment could be replaced by an adjustment based solely on isolation. We note that recent analysis has confirmed that, in general, low-volume facilities that are rural, isolated, or located in low-demand areas did not have higher costs than low-volume ESRD facilities overall. This analysis aligns with suggestions from various commenters, including MedPAC, to refine or remove the rural facility adjustment to better target ESRD facilities that are critical to beneficiary access and are likely not being adequately targeted under the current methodology. However, we note that many ESRD facilities which receive the rural facility adjustment are critical to patient access and that these ESRD facilities may be relying on the additional payment from the rural facility adjustment for the coming years. As discussed in section II.B.2.f.(2) of this proposed rule, we are proposing to implement a phase-out policy for ESRD facilities that lose the rural facility adjustment as a result of being redesignated from a rural area to an urban area in the most recent CBSA delineations. We are not proposing any other changes to the rural facility adjustment in this proposed rule.

b. Proposed Tiered LVPA Methodology

The goals of the ESRD PPS (including the LVPA) are to align resource use with payment, advance health equity and protect access to renal dialysis services for vulnerable beneficiaries in underserved communities, including rural and isolated communities, by increasing payments to certain ESRD facilities in these areas to align with their higher costs. As noted in the CY 2016 ESRD PPS final rule (80 FR 68967 through 69077), we aim to target the benefit of the LVPA to facilities that serve the access needs of patients in remote locations. In the CY 2022 ESRD PPS final rule (86 FR 61874 through 62026), we detailed our commitment to achieving equity in health care outcomes for our beneficiaries using the definition of equity set forth in Executive Order 13985,[47] which places emphasis on individuals who belong to underserved communities. In the CY 2023 ESRD PPS proposed rule RFI (87 FR 38464 through 38586), we reiterated our commitment to achieving equity in health care and noted that we aim to align ESRD facility resource use with payment. Recent feedback from interested parties indicates that the current LVPA payment structure may lead some ESRD facilities to treat fewer patients to avoid a payment cliff. Proposing a revised methodology that would reduce the incentive for gaming, as the GAO described, would help advance health equity by removing the incentive for some ESRD facilities to limit access to renal dialysis services. We would expand access through payments that incrementally align resource use with payment to ESRD facilities that furnish different volumes of treatment.

In this proposed rule, we are proposing to refine the LVPA methodology to include two tiers based on treatment volume with different payment adjustments for each tier. This proposed methodology would be similar to the methodology described in the CY 2024 ESRD PPS proposed rule RFI (88 FR 42430 through 42544), but with methodological changes to improve consistency in an ESRD facility's tier assignment from year to year.

We analyzed cost report data from ESRD facilities to develop the tiered thresholds and adjustment amounts for the proposed LVPA. This analysis used a logarithmic regression model that controls for various geographical and

[46] *https://www.cms.gov/files/document/cy-2024-esrd-pps-lvpa-rfi-summary-comments.pdf.*

[47] 86 FR 7009 (January 25, 2021). *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

facility level characteristics, including facility type and region, to estimate cost differences based on treatment volume. We also simulated attestation patterns by excluding a stratified random sample of ESRD facilities who are eligible for LVPA payment but do not submit LVPA attestations. This step allowed us to account for the fact that a portion of ESRD facilities that were within the treatment volume threshold routinely did not attest to meeting the LVPA requirements for other reasons. We analyzed numerous different potential tiered payment structures based on this analysis, where the estimated cost for the tier uses the upper bound of the treatment count for that tier. Based on the results of this analysis, we are proposing a two-tiered approach; we believe the two-tiered approach is appropriate because it strikes a balance between simplicity for ESRD facilities, sufficiently large tiers to allow for treatment volume variation from one year to the next, and payment adequacy for current low-volume facilities, particularly those with the lowest volume.

Table 9 presents our proposed two-tiered LVPA methodology, which is based on data from ESRD facility cost reports such that the reporting periods include some part of the period between January 1, 2020, to December 31, 2022 (that is, beginning or ending during these 3 CYs). We note that we have required budget neutrality for any change to the LVPA methodology, so any proposed changes to the LVPA cannot increase or decrease total estimated ESRD PPS payments; therefore, the two sets of potential adjustment factors in table 9 would be implemented budget-neutrally. The second column presents the unscaled adjusters, which if implemented, would cause the ESRD PPS base rate to be reduced by a factor of 0.999262, approximately $0.20, to achieve budget neutrality. The third column presents the adjusters scaled down by a factor of 0.815 to maintain the LVPA payment amount under the existing methodology of $26.7 million based on the expected CY 2025 LVPA payments. Using the scaled adjusters would maintain budget neutrality without lowering the ESRD PPS base rate.

TABLE 9: Proposed LVPA Methodology with Two Tiers

Tier	LVPA Adjusters without Scaling	LVPA Adjusters with Scaling	Number of Eligible CMS Certification Numbers (CCNs)
Tier 1 (less than 3,000)	34.9%	28.4%	202
Tier 2 (3,000 – 3,999)	22.2%	18.1%	128

The adjustment factors in the second column are derived from the regression explained previously. These results indicate that facilities which furnish less than 3,000 treatments have costs that are 34.9 percent higher than non-low-volume facilities, and facilities that furnish between 3,000 and 3,999 treatments have costs that are 22.2 percent higher. The adjustment factors in the third column, which are scaled down, reflect the same relationship between the two tiers of low-volume facilities and non-low-volume facilities.

We believe that a two-tier scaled approach is appropriate because it would increase payments to facilities with the lowest volume while keeping payment changes contained within the LVPA. In CY 2016 ESRD PPS final rule (80 FR 68972 through 69004) when we last updated the LVPA adjustment factor, we also updated most of the facility-level and case-mix adjusters. At that time, it was appropriate to apply a budget-neutrality factor that represented all of the changes to the facility-level and case-mix adjusters. However, we are only proposing changes to the LVPA at this time, and it is most appropriate to contain the changes within the current LVPA by applying a scaling factor to the LVPA adjusters.

We also analyzed a three-tiered option that would include a tier for ESRD facilities furnishing between 4,000 and 5,000 treatments, which is presented in table 10. As noted previously, we considered both scaled and unscaled adjustment factors, with both maintaining budget neutrality. Our analysis showed that the scaled, three-tiered option would reduce payments for facilities furnishing less than 3,000 treatments as compared to both the current LVPA methodology and the proposed two-tiered scaled methodology. Because payments for facilities furnishing between 4,000 and 5,000 treatments would increase, payments for the lowest-volume facilities would need to decrease to maintain budget neutrality, which we do not believe would align with the goals of the LVPA outlined previously. We believe that if we were to propose a three-tiered option, budget neutralizing the base rate rather than scaling the adjustment factors would better align with these goals. Our analysis shows that an unscaled three-tiered adjustment would result in a $0.99 reduction to the base rate. We are seeking comment on our proposed scaled, two-tier proposal and on the alternative three-tier LVPA structure. We note that, should this alternative be finalized, we would make changes to § 413.232(b)(1) to reflect the increased LVPA threshold of 5,000. As discussed further in the next subsection, we are proposing to determine an ESRD facility's LVPA tier based on the median treatment count volume of the last three cost-reporting years, rather than using a single year treatment count. Therefore, expanding LVPA eligibility to ESRD facilities that furnished fewer than 5,000 treatments in each of the past three cost-reporting years would also increase the number of ESRD facilities that would qualify for tier 1 and tier 2, since ESRD facilities which furnished between 4,000 and 4,999 treatments in one of the

past 3 years and fewer than 4,000 (or 3,000 for tier 1) in the other 2 years could qualify in these tiers.

TABLE 10: Alternative LVPA Methodology with Three Tiers

Tier	LVPA Adjusters without Scaling	LVPA Adjusters with Scaling	Number of Eligible CCNs
Tier 1 (less than 3,000)	34.9%	16.2%	257
Tier 2 (3,000 – 3,999)	22.2%	10.3%	224
Tier 3 (4,000 – 4,999)	14.2%	6.6%	166

c. Proposed Changes to the LVPA for CY 2025

We are proposing a two-tiered LVPA using the scaled adjusters presented in the second column of table 9. ESRD facilities that fall into the first tier (those that furnish fewer than 3,000 treatments) would receive a payment adjustment of 28.4 percent. Those that fall in the second tier (those that furnish 3,000 or more treatments but fewer than 4,000 treatments) would receive a payment adjustment of 18.1 percent. Outside of the change to the LVPA amount, this proposed change would not impact how the LVPA is applied to ESRD PPS payments.

One potential complication with a tiered approach to the LVPA is that there are still payment cliffs present between the tiers. This may discourage ESRD facilities from increasing their treatment volume in a given year, especially if it is uncertain whether the ESRD facility's treatment volume in future years will stay at the increased level. To address this, we are proposing to determine an ESRD facility's LVPA tier based on the median treatment count volume of the last three cost-reporting years, rather than using a single year treatment count. This proposed methodology would smooth payments over years, increasing stability and predictability in payments to low-volume facilities. We are also proposing that, should a facility receive an exception under § 413.232(g)(5) in one or more of the past three cost-reporting years, the median treatment count of the unaffected cost-reporting years would be used to make the facility's tier determination. We note that the median of two numbers is the average of those numbers, and the median of one number is that number. In the case that a facility does not have cost-reporting data from the last 3 years that are unaffected by a disaster or other emergency, we would assign the facility to a tier based on their last full year of unaffected treatment volume, assuming all LVPA eligibility criteria are met.

We believe that the proposed median treatment approach would promote stability, especially for facilities whose treatment counts are on the margins of a tier. We also believe that the proposed smoothing methodology for determining the treatment volume tier for which an ESRD facility qualifies is better than the alternative of using the highest tier (in terms of treatment volume) for which an ESRD facility has qualified in each of the past years. For example, if we used the highest tier of the last 3 years and a facility furnishes 3,500 treatments in one of the past 3 years, it would be categorized as tier 2 even if it furnished fewer than 3,000 treatments in the other 2 years. We believe that the proposed smoothing would mitigate the introduction of a cliff-effect within the tiers.

By contrast, under the proposed smoothing methodology, if the cost-reporting data indicated that the facility furnished 2,500, 2,999, and 3,500 treatments in the 3 years preceding the payment year, the median tier would be identified (tier 1 in this case), and the facility would (in the proposed two-tier system with scaling) receive a 28.4 percent payment adjustment for all of the treatments furnished during the payment year. We expect that any higher or lower payments from year to year under this policy would balance out over time without putting additional burden on the MACs. The structure of the proposed scaled, two-tier LVPA methodology is presented in table 10, and the structure of the alternative three-tier unscaled LVPA methodology is presented in table 11. For the purposes of comparison, we have included the scaled and unscaled version of both of the potential LVPA structures.

We note that we are not proposing any changes to the methodology for determining eligibility for the LVPA under § 413.232(b)(1), as the purpose of this proposed change is to better allocate payments within the LVPA, not to expand the LVPA to facilities that have furnished more than 4,000 treatments in one of the past three cost-reporting years. We would continue to determine eligibility for the LVPA based on a facility's treatment count in each of the three cost-reporting years preceding the payment year as set forth in § 413.232(b)(1) and would not consider the median treatment count over that period for purposes of determining eligibility. Likewise, we are not proposing any changes to § 413.232(g)(5), which allows for an exception to the requirement at § 413.232(b)(1) in the case of a disaster or other emergency. In the CY 2011 ESRD PPS final rule (75 FR 49030 through 49214), we stated that we believe a 3-year waiting period serves as a safeguard against facilities that have the opportunity to take a financial loss in establishing facilities that are purposefully small. In response to the CY 2024 ESRD PPS proposed rule RFI (88 FR 42430 through 42544), several interested parties commented that they believe CMS should maintain the 3-year attestation to determine eligibility for the LVPA, as it is an important

safeguard against gaming. In addition, if we were to use the median tier methodology to determine LVPA eligibility, we estimate that the adjustment factors would decrease, because the scaling factor used to maintain budget neutrality within the LVPA would be smaller to account for a larger amount of ESRD facilities qualifying for the LVPA.

If finalized, the proposed median treatment count methodology for determining an eligible ESRD facility's LVPA tier would improve the stability and predictability of the LVPA by basing tier determination on the median treatment count of the last 3 years as opposed to the treatment count for each of the last 3 years, where facilities could be disqualified from a higher adjustment based on marginal changes. The proposed tiered smoothing methodology would also better align payment with resource use by minimizing the impact of the payment cliff between the LVPA tiers in a transparent and reproducible fashion. We are soliciting comments on each aspect of our proposal: (1) the tiered structure of the LVPA; (2) using the median treatment count volume to determine the LVPA payment tier for ESRD facilities that are eligible for the adjustment; and (3) the scaling of the adjusters to maintain LVPA payments at the same level. As previously discussed, we are also considering an alternative three-tiered structure, which would have the effect of reducing the base rate by $0.99. We are soliciting comments on whether this alternative methodology could be more appropriate than the proposed methodology. We recommend readers to provide as much detail as possible in their response to the comment solicitation.

d. RFI on Improving the LVPA for New ESRD Facilities

As previously discussed, we recognize the importance of revising the ESRD PPS LVPA methodology to ensure that payments are accurately aligned with resource use, adequately target low-volume facilities, and strive for healthcare equity for ESRD beneficiaries. We are seeking information from the public about potential approaches to further refine the ESRD PPS methodology, which we would take into consideration for any potential future changes to the LVPA.

This section describes a RFI regarding the LVPA. Upon reviewing this RFI, respondents are encouraged to provide complete, but concise responses. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), application, proposal abstract, or quotation. This RFI does not commit the United States Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the United States Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Failing to respond to this RFI will not preclude participation in any future procurement, if conducted.

We note that we will not respond to questions about the policy issues raised in this RFI. We may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this RFI are not offers and cannot be accepted by the United States Government to form a binding contract or issue a grant. Information obtained because of this RFI may be used by the United States Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. All submissions become United States Government property and will not be returned. We may publicly post the comments received, or a summary thereof.

As previously discussed, under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation: (1) furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month costs reports, whichever is most recent, except as specified in paragraphs (g)(4) and (5)) preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type or as specified in paragraph (g)(6)) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

We are soliciting comment on potential changes to the LVPA eligibility for new ESRD facilities that could be included as part of either the proposed tiered structure or a different methodology in the future. As previously discussed, the current single-threshold LVPA methodology and the proposed tiered LVPA methodology (discussed in the previous section) rely upon 3 years of cost-reporting data to determine eligibility for the adjustment. We are considering whether it could be appropriate to modify this requirement to support access to renal dialysis in underserved areas by allowing LVPA payments for new ESRD facilities that have not yet accrued 3 years of cost-reporting data. We are also evaluating the most appropriate way for a new low-volume ESRD facility to demonstrate or attest that it expects to be low-volume. Alongside this potential change, we are considering whether it would be appropriate to implement a reconciliation process for ESRD facilities that fail to furnish a low enough treatment volume to qualify for the LVPA or their predicted tier. For example, should the proposal to implement a tiered LVPA be finalized, the determination of a facility's tier assignment for the first year would be based on their anticipated treatment count, for which they would receive the corresponding LVPA amount. Then, if the ESRD facility furnished a treatment volume count that would otherwise have qualified them for a different tier, we would also undergo a reconciliation process. For future years the ESRD facility would receive the LVPA amount of the tier following the same smoothing methodology (should it be finalized) based on the median of their treatment counts for the available years. After we receive the cost-reporting data for the year in question, the facility could be placed in the appropriate LVPA tier, and could either re-pay CMS for an overestimation, or receive additional payment from CMS for an underestimation, if applicable. The anticipated treatment count for the following year could then be based upon the actual treatment count of the prior year. This process would be followed until a new ESRD facility gathers 3 years of cost-reporting data, after which the median treatment count over those 3 years would determine the facility's tier assignment if the proposed LVPA methodology is finalized. We are issuing this RFI to seek feedback on the potential future changes to the LVPA, as described previously, and to solicit further input from interested parties to inform potential future modifications to the methodology used to determine the LVPA.

In particular, we seek input and responses to the following considerations, requests, and questions:

++ Whether the LVPA or another adjustment, such as the LDN methodology discussed earlier, would be the most appropriate payment pathway to support access to renal dialysis services in areas that do not

currently have sufficient capacity to furnish these services to all Medicare beneficiaries.

++ What would be the most appropriate way or ways for a new ESRD facility to demonstrate or attest that it expects to be low-volume?

++ The potential for future reconciliation process as an appropriate accommodation for new ESRD facilities.

++ Whether a reconciliation process would be an effective tool for making appropriate payments to existing ESRD facilities that have three or more years of cost reporting data.

++ Would a reconciliation process be operationally straightforward and understandable for an ESRD facility that has opened in the past 3 years?

++ Would a reconciliation process make it more difficult for ESRD facilities to plan and budget for future payment years? Is this outweighed by the potential benefit of earlier access to the LVPA for these new facilities?

++ Would it be useful or feasible to implement a reconciliation process for ESRD facilities that have not opened in the past 3 years but, for whatever reason, may have furnished a low enough treatment volume to qualify for the LVPA?

++ Could the LVPA be changed in any way to better support ESRD facilities opening in underserved areas? Are there any costs specific to low-volume facilities for which the current LVPA does not account?

++ How are the costs for providers of low-volume home dialysis different from the costs for providers of low-volume in-center dialysis? Could the LVPA be an appropriate pathway to support the provision of home dialysis through increased payment?

C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Applications and Proposed Technical Change for CY 2025

1. Background

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we established the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS, under the authority of section 1881(b)(14)(D)(iv) of the Act, to support ESRD facility use and beneficiary access to these new technologies. For additional background of the TPNIES we refer readers to the CY 2024 ESRD PPS final rule (88 FR 76410 through 76412).

Our practice is to include the summary of each TPNIES application and our analysis of the eligibility criteria for each application in the annual ESRD PPS proposed rule. Because we did not receive any applications for the TPNIES for CY 2025, no TPNIES application summary or CMS analysis has been included in this proposed rule.

2. Proposed Technical Change to § 413.236(b)(4)

As part of the TPNIES eligibility requirements in § 413.236(b)(4), a covered equipment or supply must have a complete HCPCS Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular CY. We have identified a minor error in § 413.236(b)(4). Specifically, we inadvertently transposed the words orthotics and prosthetics within the DMEPOS acronym. The acronym was intended to read durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) instead of durable medical equipment, orthotics, prosthetics and supplies (DMEPOS).

As described in the HCPCS Level II Coding Procedures, HCPCS Level II is a standardized coding system that is used primarily to identify drugs, biologicals and non-drug and non-biological items, supplies, and services not included in the CPT® code set jurisdiction, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office.

While the HCPCS level II Coding Procedures include DMEPOS as an example of items for which HCPCS Level II codes are established, we believe that the phrase non-drug and non-biological items more broadly reflects all items, supplies, and services for which HCPCS Level II codes are established and aligns with the HCPCS Level II coding procedures on the CMS website. Therefore, we are proposing a technical change at § 413.236(b)(4) to remove the reference to the phrase durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) and replace it with the phrase non-drug and non-biological items. We are also adding the word supplies. These technical changes would better reflect the broader category of non-drug and non-biological item coding in the HCPCS Level II Coding Procedures available on the CMS website.[48]

D. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2025

In this section of the final rule, we identify any items previously approved for the TPNIES and for which payment is continuing for CY 2025. As described in the CY 2024 ESRD PPS final rule, no new items were approved for the TPNIES for CY 2024 (88 FR 76431). As such there are no items previously approved for the TPNIES for which payment is continuing in CY 2025.

E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for CY 2025

Under § 413.234(c)(1), a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the TDAPA for 2 years. In July 2023, CMS approved Jesduvroq (daprodustat) for the TDAPA under the ESRD PPS, effective October 1, 2023. Implementation instructions are specified in CMS Transmittal 12157, dated July 27, 2023, and available at: *https://www.cms.gov/files/document/r12157cp.pdf*.

In April 2024, CMS approved DefenCath® (taurolidine and heparin sodium) for the TDAPA under the ESRD PPS, effective July 1, 2024. Implementation instructions are specified in CMS Transmittal 12628, dated May 9, 2024, and available at: *https://www.cms.gov/files/document/r12628CP.pdf*.

Table 11 identifies the two new renal dialysis drugs for which the TDAPA payment period as specified in § 413.234(c)(1) would continue in CY 2025: Jesduvroq (daprodustat) that was approved for the TDAPA effective in CY 2023 and DefenCath® (taurolidine and heparin sodium) that was approved for the TDAPA effective in CY 2024. Table 11 also identifies the products' HCPCS coding information as well as the payment adjustment effective dates and end dates.

[48] Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures. Available at: *https://www.cms.gov/medicare/coding/medhcpcsgeninfo/downloads/2018-11-30-hcpcs-level2-coding-procedure.pdf*. Accessed on January 16, 2024.

TABLE 11: Continuation of Approved Transitional Drug Add-On Payment Adjustments

HCPCS Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment End Date
J0889	Daprodustat, oral, 1 mg, (for ESRD on dialysis)	10/1/2023	9/30/2025
J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)	7/1/2024	6/30/2026

III. Proposed CY 2025 Payment for Renal Dialysis Services Furnished to Individuals With AKI

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies to implement subsection (r) of section 1834 of the Act and the amendments to section 1861(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872 and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Proposal To Allow Medicare Payment for Home Dialysis for Beneficiaries With AKI

1. Background

In the CY 2017 ESRD PPS final rule, we indicated that we did not expect beneficiaries with AKI to dialyze at home; therefore, the home dialysis benefit was not extended to beneficiaries with AKI (81 FR 77870). There were commenters who advocated for beneficiaries to have the option to dialyze in a home setting, particularly those beneficiaries who started peritoneal dialysis (PD) in the hospital and desired to continue PD after discharge. However, other commenters indicated that beneficiaries with AKI needed close supervision during dialysis. Additionally, some commenters indicated that dialysis for AKI is a short-term treatment, and beneficiaries would not have time to learn to administer a home therapy. Therefore, we finalized the AKI payment policy in the CY 2017 ESRD PPS final rule as proposed without extending the AKI benefit to home dialysis beneficiaries. We indicated that we would gather data on the AKI population and the extent of home training necessary to safely self-administer dialysis in the home, and that we would consider the use of home dialysis for beneficiaries with AKI in the future as we find that it may be beneficial for subsets of beneficiaries.

In past years we have received comments regarding the site of renal dialysis services for Medicare beneficiaries with AKI, with the most recent comments received in response to the CY 2024 ESRD PPS proposed rule to update to the AKI dialysis payment rate (88 FR 76433). We have monitored data for beneficiaries with AKI and researched data in journal articles discussing the potential to expand dialysis for beneficiaries with AKI to a home setting, as noted in the CY 2017 ESRD PPS final rule (81 FR 77871).

In the CY 2017 ESRD PPS final rule, we clarified that the ESRD Facility Conditions for Coverage (CfCs) apply to ESRD facilities, not to ESRD beneficiaries, and noted that the ESRD facility CfCs would be the appropriate regulatory location for standards addressing care provided to beneficiaries with AKI in ESRD facilities. We finalized a policy that our CfCs would not need to be revised to address the provision of dialysis treatment to beneficiaries with AKI (81 FR 77871 through 77872).

In December 2020, CMS's data contractor held a TEP that considered data related to utilization review and cost of AKI treatments since 2017. The TEP solicited input regarding how reported costs align with realized costs of treatment for beneficiaries with AKI. During the TEP, participants suggested that we extend Medicare payment for beneficiaries with AKI to allow them to dialyze in a home setting. Additionally, the TEP indicated that beneficiaries with AKI could benefit from different treatment regimens. The TEP noted that more frequent, gentler dialysis with a lower ultrafiltration rate would be a viable option for some beneficiaries. Members of the panel commented on the similar treatment frequencies observed for beneficiaries with AKI and ESRD, stating that the payment system is currently constructed to facilitate the standard treatment plan for beneficiaries with AKI. Panelists recommended that the ESRD PPS should be flexible in terms of number of treatments for beneficiaries with AKI, so that those who need more frequent treatments are not impeded from receiving them.

Panelists related instances of hospitals starting a patient on PD, which can be done frequently in the home setting, only to convert the patient to a more standard treatment regimen such as three in-center hemodialysis treatments per week before discharging the patient to a dialysis facility. Panelists also advocated that we provide Medicare payment for beneficiaries with AKI to be treated at home.

We solicited comments regarding potentially modifying the site of renal dialysis services for beneficiaries with AKI and payment for AKI in the home setting as a RFI in the CY 2022 ESRD PPS proposed rule (86 FR 36322, 36408). We received 16 comments from LDOs, patient advocacy groups, professional organizations, small dialysis organization within a large non-profit health system, and non-profit organizations. Most of the comments favored providing a payment option for beneficiaries with AKI to dialyze in a home setting; however, some commenters expressed concerns about doing so. A small dialysis organization within a large non-profit health system indicated that beneficiaries with AKI may have chronic kidney disease at a lesser stage, such as, Stage 3 or Stage 4 chronic kidney disease (CKD) rather than ESRD; however, the AKI makes dialysis necessary. This commenter noted that if the AKI were to cause the beneficiary's underlying Stage 3 or Stage 4 CKD to progress to ESRD in the future, training them to use a home modality during the AKI episode could prepare the patient for a home modality if they are diagnosed as having ESRD. One LDO indicated there is evidence that PD, which is typically used in the home setting, is associated with better preservation of residual kidney function compared to hemodialysis. A national organization of beneficiaries and kidney health care professionals advocated that PD may be learned quickly, reduces rapid hemodynamic changes that may potentiate kidney injury and impede recovery, and does not require a high-risk central venous catheter to provide treatment. We note that these comments are specific to PD as a treatment modality; however, when considering such a policy we would include payment for both PD and hemodialysis (HD) in the home setting for beneficiaries with AKI, consistent with our payment policy for home dialysis for patients with ESRD.

Most recently, as noted in the CY 2024 ESRD PPS final rule (88 FR 76433), we received 10 public comments on our proposal to update the payment rate for renal dialysis services furnished to individuals with AKI. Commenters included a coalition of dialysis organizations, a non-profit dialysis organization, a trade association, a renal product development company, and multiple large dialysis organizations. Most of the commenters requested that we allow payment for beneficiaries with AKI to select home dialysis modalities by changing the current policy, even though it was not proposed in the CY 2024 ESRD PPS proposed rule.

We acknowledge there have been concerns in the past regarding the safety of beneficiaries with AKI dialyzing at home. However, we have carefully reviewed the totality of the information and evidence presented to the agency and now recognize that current information regarding beneficiaries with AKI dialyzing in a home setting supports more frequent dialysis at a lower ultrafiltration rate. The ability to dialyze at a lower ultrafiltration rate supports a decrease in hemodynamic fluctuation and the complications associated with it, which in turn support recovery of kidney function.

2. Technical Analysis

Although there is only limited research regarding the use of home dialysis for the treatment of AKI, we note that several studies support the use of home dialysis to generally improve access to dialysis and provide care that better meets patient needs. We note that many of the studies related to home dialysis in the AKI patient population use PD as the treatment modality, which is consistent with comments received during the December 2020 TEP and comments received during rulemaking as noted previously. Additionally, data from the United States Renal Data System (USRDS) Annual Data Report (ADR), indicates the percentage of incident dialysis patients performing home HD was only 0.4 percent in 2021, and a significant majority of dialysis patients performing home dialysis chose PD.[49] We believe that the choice of a home modality would be comparable in the beneficiary population for those with AKI as those initiating chronic maintenance dialysis for ESRD. However, we affirm payment would be provided for either modality of home dialysis. For example, PD was used frequently for patients during the COVID–19 PHE due to challenging situations such as supply shortages, staffing shortages, and limited surgical availability for the placement of a venous access. A multicenter, retrospective, observational study of 94 patients who received acute PD in New York City in the spring of 2020 indicated that rapid deployment of acute PD was feasible. The rates of death and renal recovery were like those of patients with AKI requiring kidney replacement therapy (KRT) in other cohorts. Of those who were discharged on dialysis, four were discharged on PD, and one was discharged on HD.[50]

The International Society for Peritoneal Dialysis (ISPD) reiterated in the 2020 guidelines, updated from the 2014 guidelines for PD in AKI, that PD should be considered a suitable modality for treatment of AKI in all settings. This was a strong recommendation from the ISPD based on evidence rated at the second highest level used by ISPD.[51] Researchers found little to no difference between PD and hemodialysis in all-cause mortality, recovery of kidney function, or infection as a complication.[52] This finding is augmented by an article that reviewed the resurgence of PD for the treatment of AKI since the COVID–19 PHE. The article lists cost effectiveness, low infrastructure requirements, ease of staff training, and more rapid recovery of renal function as benefits to the use of PD to treat AKI. A survey of nephrologists from three international conferences reported that 50.8 percent and 36.4 percent of respondents felt that PD was suitable for treating AKI in the wards and ICU, respectively. PD is the predominant therapy used to treat pediatric patients with AKI, and until the mid to late 1990s was the predominant therapy to treat adults with AKI, but the use of this therapy has waned since the advent of pump driven continuous kidney replacement therapy.[53]

Admittedly, most studies regarding recovery of kidney function in patients with AKI are based around hospitalized patients. There are very limited studies suggesting that self-care dialysis can yield faster recovery of kidney function; however, the results are not conclusive.[54] One study of hospitalized patients with AKI indicated that a median of 10 patients recovered kidney function more quickly utilizing PD.[55] Another study of hospitalized patients with AKI indicated that while the

[49] Annual Data Report √ USRDS (*nih.gov*), *https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/2-home-dialysis.*

[50] *https://www.sciencedirect.com/science/article/pii/S0085253821004567.*

[51] *https://journals.sagepub.com/doi/10.1177/0896860820970834.*

[52] *https://pubmed.ncbi.nlm.nih.gov/29199769/.*

[53] *https://academic.oup.com/ckj/article/16/2/210/6696026.*

[54] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4594060/.*

[55] *https://onlinelibrary.wiley.com/doi/pdfdirect/10.1111/1744-9987.12660.*

recovery of kidney function was similar in PD and HD (28 and 26 percent) there was a significantly shorter time to the recovery of kidney function for patients with AKI that utilized PD.[56]

Further support for this proposal comes from CMS AKI monitoring data, in which we found that current provision of AKI dialysis is very similar to the provision of ESRD dialysis. Data from the 2021 Quarter 4 public use file (PUF) [57] for AKI showed that hemoglobin for beneficiaries with ESRD averaged 10.6 gm/dL while the average hemoglobin for beneficiaries with AKI averaged 9 gm/dL. Beneficiaries with AKI were less likely to be prescribed an ESA than patients with ESRD. However, research indicates that patients using PD have a lower rate of anemia that those using HD. Patients receiving PD require lower doses of ESAs and iron than patients receiving HD.[58] This may indicate that dialyzing in a home environment could be effective to manage anemia in beneficiaries with AKI more appropriately, as the USRDS ADR indicates incident patients with ESRD typically choose PD as a home modality over home HD.[59] We believe that beneficiaries with AKI would make similar choices. Approximately 8 percent of beneficiaries with ESRD experience incidences of fluid overload, while beneficiaries with AKI experience episodes for which congestive heart failure was reported within 30, 60, and 90 days (which can be related to fluid overload) at rates of around 42 percent, 50 percent, and 53 percent, respectively.[60] This data is of concern because fluid overload in beneficiaries with AKI can be detrimental to recovering kidney function. Additionally, this data supports conclusions drawn from an article involving the review of 1754 patients with AKI requiring dialysis. The article indicates that treatment protocols for patients with AKI were like those of incident ESRD patients despite the underlying differences in treatment goals. The article further indicates that most patients with AKI who recovered had discontinued dialysis without ever having been weaned from their initial dialysis prescription, suggesting there may be substantial opportunity to wean dialysis sooner.[61] There is significant need to individualize the treatment of every kidney patient, but particularly beneficiaries with AKI, as this omission could result in a missed opportunity to recover kidney function.

We believe the proposal to provide payment for beneficiaries with AKI to dialyze in a home setting aligns closely with the CMS Strategic Pillars [62] of expanding access, engaging the ESRD community by being responsive to TEPs and RFIs, and driving innovation to promote patient centered care. While there is not utilization data for beneficiaries with AKI using a home modality, the USRDS ADR, indicates that disparities currently exist for self-care dialysis in the home setting for the ESRD beneficiary population, with fewer Black and Hispanic beneficiaries choosing a home dialysis modality. Additionally, fewer Medicare and Medicaid dual eligible beneficiaries choose a home dialysis modality.[63] Providing the ability for beneficiaries with AKI to choose self-care dialysis in a home setting would offer a pathway to reduce these current disparities (insofar as the AKI population mirrors the ESRD beneficiary population) by promoting access to treatment, as well as removing a disparity in care between AKI beneficiaries and ESRD beneficiaries. It is crucial that the policy revisions to payment for AKI renal dialysis consider health equity and the effects on underserved populations. The rate of AKI was about 81 percent higher among Black beneficiaries than among White beneficiaries.[64] We have reviewed comments and concerns from interested parties and agree that home dialysis could benefit beneficiaries with AKI. We note that issues with fluid management could be managed with more frequent, gentler modalities, such as PD. We trust that providing an avenue to expand treatment modalities would encourage individualized and patient-centered treatment plans for beneficiaries with AKI, for example, addressing anemia and ESA management. We would continue to monitor outcomes for beneficiaries with AKI with the expectation that AKI PUF are being reviewed in quality improvement efforts by ESRD facilities that provide services to beneficiaries with AKI.

3. Proposal To Extend Home Dialysis Benefit to Beneficiaries With AKI

As previously discussed, we did not extend the home dialysis benefit to beneficiaries with AKI when initially implementing the benefit (81 FR 77870). However, as discussed in the prior section, we reviewed AKI monitoring data showing that outcomes for anemia, ESA use, and fluid management are not necessarily reflective of the specific, individualized care, and close supervision by qualified staff currently required during the in-center dialysis process. We note research demonstrates the use of PD is correlated with positive outcomes for fluid management and a lower rate of anemia with less utilization of ESAs and iron, as previously discussed. As we stated in the previous section, research related to home dialysis in the AKI patient population has primarily discussed results using PD as the modality; however, we would provide payment for either PD or HD as a home modality. CMS's goal is for beneficiaries with AKI to receive the necessary care to improve their condition, recover kidney function, and be weaned from dialysis treatment. We also note that the literature exhibits a high correlation between the use of PD treatment for beneficiaries with AKI and positive outcomes for fluid management, infection rates, mortality, and recovery of kidney function.[65] Additionally, we reviewed analysis demonstrating that the use of PD to manage the care of beneficiaries with AKI as a result of COVID–19 was successful and that beneficiaries who have successfully begun a treatment regime that could transition from the hospital to a home modality should not have to change treatment to an in-center treatment modality.

After careful review of current research and the outcomes noted during the COVID–19 PHE, we propose to extend the home dialysis benefit as defined at 42 CFR 410.52 to beneficiaries with AKI for either PD or HD. As discussed in section III.C.1 of this proposed rule, we are proposing that the payment amount for home dialysis for AKI beneficiaries would be the same as the payment amount for in-center dialysis for AKI beneficiaries, consistent with payment parity within the ESRD PPS. This payment amount

[56] *https://www.sciencedirect.com/science/article/pii/S0085253815528664.*

[57] *https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-prospective-payment-system-esrd-pps-overview-claims-based-monitoring-program.*

[58] *https://academic.oup.com/ckj/article/16/12/2493/7210548.*

[59] Annual Data Report √ USRDS (*nih.gov*), *https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/2-home-dialysis.*

[60] *https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-prospective-payment-system-esrd-pps-overview-claims-based-monitoring-program.*

[61] *https://journals.lww.com/jasn/abstract/2023/12000/initial_management_and_potential_opportunities_to.9.aspx.*

[62] *https://www.cms.gov/about-cms/what-we-do/cms-strategic-plan.*

[63] *https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/2-home-dialysis.*

[64] Annual Data Report √ USRDS (*nih.gov*), *https://usrds-adr.niddk.nih.gov/2023/chronic-kidney-disease/4-acute-kidney-injury.*

[65] *https://pubmed.ncbi.nlm.nih.gov/29199769/.*

would be the ESRD PPS base rate, adjusted for geographic area, as described in section II.C.2 of this proposed rule. Additionally, as discussed in section III.C.3 of this proposed rule, we are proposing to extend the add-on payment adjustment for home and self-dialysis training in the same amount as for patients with ESRD, on a budget neutral basis. We propose to revise § 413.373, which currently states ''The payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act,'' by adding paragraph (a) before ''The payment rate'' that reads ''CMS applies the wage-adjusted add-on per treatment adjustment for home and self-dialysis training as set forth at § 413.235(c) to payments for AKI dialysis claims that include such training.'' We propose to move the current language to paragraph (b) with a technical revision to add ''of the Act'' after ''section 1834(r)''. Furthermore, as discussed in section III.D of this proposed rule, we are proposing changes to the ESRD facility CfCs that would accommodate the provision of home dialysis for beneficiaries with AKI and help ensure safe and high-quality care for Medicare beneficiaries in this setting.

We are proposing to amend § 410.52 to provide Medicare payment for the treatment of patients with AKI in the home setting. We are proposing to revise § 410.52 to read ''Medicare Part B pays for the following services, supplies, and equipment furnished to a patient with ESRD or an individual with Acute Kidney Injury (AKI) as defined in § 413.371 of this chapter in his or her home:'' by striking the words ''an ESRD patient'' after ''to'' and adding the words ''a patient with ESRD or an individual with Acute Kidney Injury (AKI) as defined in § 413.371 of this chapter'' after ''to''. We are also proposing to revise § 413.374(a) to read: ''The AKI dialysis payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act, including home services, supplies, and equipment, and self-dialysis.''

C. Proposed Annual Payment Rate Update for CY 2025

1. CY 2025 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual market basket update, geographic wage adjustments, and any other discretionary adjustments, for such year. We note that ESRD facilities could bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis. As discussed in section II.B.4 of this proposed rule, the proposed ESRD PPS base rate is $273.20, which reflects the application of the proposed CY 2025 wage index budget-neutrality adjustment factor of 0.990228 and the proposed CY 2025 ESRDB market basket percentage increase of 2.3 percent reduced by the proposed productivity adjustment of 0.5 percentage point, that is, 1.8 percent. Accordingly, we are proposing a CY 2025 per treatment payment rate of $273.20 (($271.02 × 0.990228) × 1.018 = $273.20) for renal dialysis services furnished by ESRD facilities to individuals with AKI. This proposed payment rate is further adjusted by the wage index, as discussed in the next section of this proposed rule.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and regulations at § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRDB market basket percentage increase and reduced by the productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS. As discussed in section II.B.2.b of this proposed rule, we are proposing a new ESRD PPS wage index methodology, which utilizes BLS OEWS data and freestanding ESRD facility cost report data. We are proposing to use this same methodology when adjusting AKI dialysis payments to ESRD facilities, consistent with our historical practice of using the ESRD PPS wage index for AKI dialysis payments. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that ESRD facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. We also apply the wage index policies regarding the 0.600 wage index floor (87 FR 67161 through 67166) and the 5 percent cap on wage index decreases (87 FR 67159 through 67161) to AKI dialysis payments to ESRD facilities. ESRD facilities would utilize the same staff to provide renal dialysis services to and educate beneficiaries with AKI as those beneficiaries with ESRD. Therefore utilizing the same wage index methodology would be appropriate in accordance with § 413.372, which addresses the payment rate for AKI dialysis and refers to § 413.231 for the wage adjustment. As stated previously, we are proposing a CY 2025 AKI dialysis payment rate of $273.20, adjusted by the ESRD facility's wage index.

3. Other Adjustments to the AKI Payment Rate

Section 1834(r)(1) also provides that the payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act. As discussed in the previous section, we are proposing to extend AKI dialysis payment to home dialysis.

In implementing payment for home dialysis in the AKI patient population, we considered our existing payment policies for home dialysis for beneficiaries with ESRD. In the CY 2011 ESRD PPS final rule, we explained that although we included payments for providing training to beneficiaries in computing the ESRD PPS base rate, we agreed with commenters that we should pay for home dialysis training as an add-on payment adjustment under the ESRD PPS to account for the cost of providing training to beneficiaries on the use of home dialysis modalities. Thus, we finalized the home dialysis training add-on payment adjustment of $33.44 per treatment as an additional payment made under the ESRD PPS when one-on-one home dialysis training is furnished by a nurse for either hemodialysis or peritoneal dialysis training and retraining (75 FR 49063). We clarified our policy on payment for home dialysis training again in the CY 2013 ESRD PPS final rule, in which we stated that training costs are included in the ESRD PPS base rate; however, we also provide an add-on payment adjustment for each home and self-dialysis training treatment furnished by a Medicare-certified home dialysis training facility (77 FR 67468). We explained in the CY 2017 ESRD PPS final rule that it is not the intent of the add-on treatment to reimburse a facility

for all of the training costs furnished during training treatments. Rather, the single ESRD PPS base rate, all applicable case-mix and facility-level adjustments, as well as the add-on payment should be considered the Medicare payment for each training treatment and not the training add-on payment alone (81 FR 77854).

We considered making payment for home dialysis for beneficiaries with AKI under the ESRD PPS base rate without an add-on payment adjustment for home modality training. As we noted in the background section, the ESRD PPS base rate upon which the AKI dialysis payment rate is established contains monies for training related costs. However, we are concerned that not providing a home and self-dialysis training add-on payment adjustment for AKI dialysis may limit access to home dialysis care for the AKI beneficiary population. As previously noted, incorporation of an adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act into AKI dialysis payments must be done on a budget neutral basis for payments under section 1834(r) of the Act. Therefore, establishing an add-on adjustment for training for home and self-care dialysis could have an impact on the AKI base rate.

We have reviewed options for applying budget neutrality to a home and self-dialysis training add-on payment adjustment for beneficiaries with AKI. We are considering applying a budget neutrality adjustment factor by reducing the AKI dialysis payment rate amount (which is based on the ESRD PPS base rate and is then adjusted for wages according to § 413.372) for renal dialysis services provided to patients with AKI to account for the add-on training adjustment. For example, we might estimate utilization of home dialysis in the AKI patient population using ESRD PPS data and on that basis derive a budget neutrality adjustment factor to apply to the AKI payment rate that would ensure that total payments to ESRD facilities for renal dialysis services provided to patients with AKI do not increase as a result of implementing the home and self-dialysis add-on training adjustment. To develop an estimate for consideration we used publicly available data to build an example. Using the fourth quarter data from the 2022 ESRD PUF,[66] the average monthly percentage of renal dialysis treatment furnished via home dialysis for 2022 was 15.4 percent. Using data from table 19 in section VIII.D.5.c, which indicates there were 279,000 AKI dialysis treatments in 2023, we could estimate that the same percentage of beneficiaries with AKI would choose a home modality as did beneficiaries with ESRD; therefore, we could estimate that 42,966 AKI dialysis treatments would be performed in a home setting. Using the USRDS ADR data, we could estimate the average beneficiary with AKI using a home PD modality would receive 15 PD training treatments. From the fourth quarter 2022 AKI PUF,[67] we calculate 10,802 first time beneficiaries with AKI. Using this data, we could estimate a cost of training to be $2,370,498.90 ($10,802 \times 0.154 \times 15 \times \$95.57$) or $8.50 ($2,370,498.90/279,000) per AKI treatment. Therefore, in this example, we would reduce the AKI dialysis payment rate by this per treatment amount to budget neutralize the home dialysis training add-on payment adjustment for beneficiaries with AKI. This means the AKI CY 2025 base rate would be $264.70 ($273.20 − $8.50) using this estimate. Although we do not include it in this example, we note the training add-on payment adjustment is affected by the wage index; therefore, the wage index would be reflected in a final estimated reduction.

However, this option would entail that the ESRD PPS base rate would not be equal to the AKI dialysis payment rate once the budget neutrality adjustment factor is applied, which could disincentivize ESRD facilities from treating patients who have AKI. Additionally, we do not have utilization data for home and self-dialysis in the AKI beneficiary population. Therefore, any initial budget neutrality adjustment to the AKI dialysis payment rate would require an estimation as in the potential equation described previously. We are further considering whether, if we apply a budget neutrality adjustment factor to the AKI payment rate based on an estimation, we should reconcile payments to ESRD facilities for renal dialysis services provided to patients with AKI later to modify the budget neutrality adjustment factor based on actual utilization data.

Due to these constraints, we are seeking comments regarding the need for a home and self-dialysis training add-on payment adjustment for AKI beneficiaries along with suggestions on how to budget neutralize the add-on payment adjustment for home and self-dialysis training for AKI beneficiaries considering the statutory requirement. Additionally, we are soliciting comments on other venues in which beneficiaries with AKI might receive training for home and self-dialysis, such as inpatient or outpatient hospital departments or nephrologist offices.

We propose, in accordance with section 1834(r)(1) of the Act and § 413.373, to extend the home and self-dialysis training add-on payment adjustment under § 413.235(c) to payments for renal dialysis services provided to beneficiaries with AKI using a home modality. We propose to make payment for a home and self-dialysis add-on training adjustment at the same amount currently applicable under the ESRD PPS of $95.57 with a limit of 15 training treatments for PD and a limit of 25 training treatments for HD per patient excluding retraining sessions (75 FR 49063). Additional information regarding the maximum number of training treatments for which CMS provides payment under the ESRD PPS is located in the Medicare Claims Processing Manual.[68] To further inform our decisions on the AKI home and self-dialysis training payment policies we would need to have data regarding the utilization of AKI home renal dialysis service. We are interested in receiving data that could provide additional insight for calculating a budget neutrality adjustment factor for the AKI home and self-dialysis training add-on adjustment as described previously, such as, the actual or estimated number of training sessions furnished and the number of beneficiaries with AKI using a home modality. The analysis of this data would inform our estimates for a budget neutrality adjustment factor for training for home dialysis for beneficiaries with AKI or future decisions about how we compute the AKI home and self-dialysis training add-on adjustment. We intend to use this information to make a determination on an add-on training adjustment in the CY 2025 ESRD PPS final rule or in future rulemaking for subsequent years. If the proposal to extend the home and self-dialysis training add-on payment adjustment to payment for renal dialysis services provided to patients with AKI is finalized, we would also adopt an approach to ensure that the adjustment is implemented budget neutrally in the final rule, considering the comments received on this proposed rule.

[66] *https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-prospective-payment-system-esrd-pps-overview-claims-based-monitoring-program.*

[67] *https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-prospective-payment-system-esrd-pps-overview-claims-based-monitoring-program.*

[68] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c08.pdf.*

D. AKI and the ESRD Facility Conditions for Coverage

1. Statutory and Regulatory Background

ESRD is a kidney impairment that is irreversible and permanent. Dialysis is a process for cleaning the blood and removing excess fluid artificially with special equipment when the kidneys have failed. People with ESRD require either a regular course of dialysis or kidney transplantation to live. Given the high costs and absolute necessity of transplantation or dialysis for people with failed kidneys, Medicare provides health care coverage to qualifying individuals diagnosed with ESRD, regardless of age, including coverage for kidney transplantation, maintenance dialysis, and other health care needs. AKI is an acute decrease in kidney function due to kidney damage or kidney failure that may require dialysis. Unlike people with ESRD, individuals with AKI who require dialysis are expected to regain kidney function within three months. People with either ESRD or AKI can receive outpatient dialysis services from Medicare-certified ESRD facilities, also called dialysis facilities.

The Medicare ESRD program became effective July 1, 1973, and initially operated under interim regulations published in the **Federal Register** on June 29, 1973 (38 FR 17210). In the July 1, 1975, **Federal Register** (40 FR 27782), we published a proposed rule that revised sections of the ESRD requirements. On June 3, 1976, the final rule was published in the **Federal Register** (41 FR 22501). Subsequently, the ESRD Amendments of 1978 (Pub. L. 95–292), amended title XVIII of the Social Security Act (the Act) by adding section 1881. Sections 1881(b)(1) and 1881(f)(7) of the Act further authorize the Secretary to prescribe health and safety requirements (known as conditions for coverage or CfCs) that a facility providing dialysis and transplantation services to dialysis patients must meet to qualify for Medicare payment. In addition, section 1881(c) of the Act establishes ESRD Network areas and Network organizations to assure that dialysis patients are provided appropriate care. The ESRD CfCs were first adopted in 1976 and comprehensively revised in 2008 (73 FR 20369). The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

Medicare pays for routine maintenance dialysis provided by Medicare-certified ESRD facilities, also known as dialysis facilities. To gain certification, the State survey agency performs an on-site survey of the facility to determine if it meets the ESRD CfCs at 42 CFR part 494. If a survey indicates that a facility is in compliance with the conditions, and all other Federal requirements are met, CMS then certifies the facility as qualifying for Medicare payment. Medicare payment for outpatient maintenance dialysis is limited to facilities meeting these conditions. As of March 2024, there are approximately 7,700 Medicare-certified dialysis facilities in the United States,[69] providing dialysis services and specialized care to people with ESRD; 3,700 of which provide home dialysis services, including training and support.[70]

The ESRD CfCs found at 42 CFR part 494, consist of the health and safety standards that all Medicare participating dialysis facilities must meet. These standards set baseline requirements for patient safety, infection control, care planning, staff qualifications, record keeping, and other matters to ensure that all patients with kidney failure receive safe and appropriate care. In addition, the CfCs require patients to be informed about all treatment modalities (hemodialysis or peritoneal dialysis) and settings (home dialysis modalities or in-facility hemodialysis) (§ 494.70(a)(7)). A dialysis facility that is certified to provide services to home patients must ensure that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of § 494.100. The patient's interdisciplinary team must oversee training of the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in § 494.10). Dialysis facilities monitor home dialysis by documenting adequate comprehension of the training; retrieving and reviewing complete self-monitoring data and other information at least every two months; and maintaining this information in the patient's medical record.

In the CY 2017 ESRD PPS final rule (81 FR 77834), we clarified that ESRD facility CfCs apply to ESRD facilities, not to people with ESRD, and noted that the ESRD CfCs would be the appropriate regulatory location for standards addressing care provided to beneficiaries with AKI in ESRD facilities. While the language of the ESRD CfCs does not directly address treatment of beneficiaries with AKI, we believe that the current ESRD facility requirements are sufficient to ensure that such patients are dialyzed safely. For example, infection control protocols are the same for any individual receiving hemodialysis, regardless of the cause or likely trajectory of their kidney disfunction. For the areas in which care and care planning may differ, such as frequency of certain patient assessments, we note that the CfCs set baseline standards and do not limit additional or more frequent services that may be necessary for beneficiaries with AKI receiving temporary dialysis as they recover kidney function.

During the development of the CY 2017 ESRD PPS final rule, we did not anticipate that beneficiaries with AKI would be candidates for home dialysis due to the likely short-term duration of treatment and the unique needs of AKI. Specifically, it was our understanding that beneficiaries with AKI require supervision by qualified staff during their dialysis and close monitoring through laboratory tests, often conducted more frequently than for people with ESRD, to ensure that they are receiving appropriate care as their kidney function improves. Therefore, we did not propose to extend the home dialysis benefit to beneficiaries with AKI at that time (81 FR 77870). However, for the reasons discussed in section III of this proposed rule, we are proposing to extend coverage of home dialysis services to beneficiaries with AKI, allowing them flexibility in choosing their preferred treatment modality. The choice between home and in-center dialysis reflects a combination

[69] *https://qcor.cms.gov/active_nh.jsp?which=7&report=active_nh.jsp.*

[70] *https://qcor.cms.gov/active_nh.jsp?which=7&report=active_nh.jsp.*

of clinical, social, and financial considerations. Since the ESRD CfCs apply to ESRD facilities as a whole, not to solely to their patients with ESRD, we are proposing clarifying revisions to the CfCs to align with the proposed coverage changes.

2. AKI and Home Dialysis

The United States Renal Data System 2023 Annual Data Report (ADR) contains updated information about the chronic kidney disease and ESRD populations in the U.S. through the end of 2021; the statistics in this section were published in this report.[71] The number of Medicare fee-for-service beneficiaries over the age of 18 years who received outpatient dialysis for the treatment of AKI increased steadily until 2019, when it reached 11,180 and then plateaued.[72] The adjusted percentage of hospitalizations in which AKI was diagnosed increased steadily between 2011 (15.5 percent) and 2021 (26.8 percent), with a particularly large increase in 2020 during the first year of the COVID–19 pandemic.[73]

Under current Medicare regulations, ESRD facility beneficiaries with AKI are restricted to receiving in-center hemodialysis, regardless of their individual prognosis or course of treatment prior to hospital discharge.[74] Since Congress expanded treatment options for those living with AKI to include dialysis facilities in 2017 (81 FR 77834, 77866), clinical understanding of AKI has advanced. However, these patients are often subject to the standardized treatment durations and schedules intended to treat patients with ESRD; unlike these patients, individuals with dialysis-dependent AKI could potentially avoid long-term dialysis through recovery of kidney function. As a result, we believe it is necessary to provide for more flexibility in the modality options available to beneficiaries with AKI. In this proposed rule, we propose to expand coverage of home dialysis for beneficiaries with AKI, increasing patient options for dialysis treatment beyond in-center hemodialysis and empowering these patients to make decisions about their care. In addition, this proposed change reflects efforts to increase home dialysis access and uptake. We are proposing to revise the ESRD facility CfCs to align with the proposed payment changes.

Hemodialysis (HD) is the modality most often initiated by hospital staff for urgent start patients, but often the patient is discharged to an in-center clinic. Given a choice, most patients with ESRD prefer home dialysis over in-center hemodialysis. Peritoneal dialysis (PD) is a home dialysis method and offers benefits such as absence of central venous access and therefore preservation of veins, low cost, and decreased time per dialysis session, as well as convenience.[75] While home hemodialysis (HHD) is a safe and effective modality for beneficiaries with AKI, the dominant modality is PD. From 2011 to 2021, the percentage of all adults with dialysis performing home dialysis increased from 7.5 percent to 13.4 percent.[76] Individuals living in more rural areas were more likely to be using PD (9.9 percent) and HHD (2.0 percent) than their more urban counterparts (8.2 percent PD and 1.5 percent HHD).[77]

The current policies restricting access to home dialysis modalities for beneficiaries with AKI perpetuate current inequities in dialysis experiences. The percentage of all-cause hospitalizations of beneficiaries with AKI is consistently higher among older populations, men, and Black beneficiaries.[78] The ADR reported Black beneficiaries experienced a slightly larger increase in the percentage of hospitalizations with AKI in 2020 than White beneficiaries (14.8 percent vs. 11.6 percent).[79] In 2021, the rate of AKI was about 81 percent higher among Black Medicare beneficiaries, at 108.8 per 1000 person-years, than among White beneficiaries (60.1 per 1000 person-years).[80] White beneficiaries were less likely to develop dialysis-requiring AKI than Black or Hispanic beneficiaries.[81] Those with a higher neighborhood Social Deprivation Index score (more deprivation) were more likely to experience AKI requiring dialysis than those living in neighborhoods with less deprivation; this was especially true among Hispanic beneficiaries.[82] Older Medicare beneficiaries living in a neighborhood with more deprivation were more likely to experience an AKI hospitalization with dialysis than those living in neighborhoods with less deprivation.[83]

There is a disproportionate lack of home dialysis for low-income communities and communities of color. This data includes all dialysis beneficiaries, not just those with AKI. Patients in all race/ethnicity groups living in neighborhoods with more deprivation are less likely to initiate dialysis at home. The ADR shows White and Asian patients were substantially more likely to dialyze at home than Black and Hispanic patients.[84] Across all levels of neighborhood deprivation Black and Hispanic patients were much less likely to start dialysis at home than White patients.[85] Overall, the ADR highlights large racial/ethnic and socioeconomic disparities in access to home dialysis. We anticipate that providing the option of home dialysis to beneficiaries with AKI, will increase access and equitable care.

By providing multiple choices of dialysis modality (in-center dialysis, PD, or HHD), patients can choose which one best suits their needs. Solutions that encourage and facilitate initiation of home education and training in the hospital by nephrologists, dialysis nurses and hospital social workers, could significantly increase the adoption of home dialysis for beneficiaries with AKI. Initially, in the CY 2017 ESRD PPS final rule, we expressed concern about beneficiaries with AKI receiving dialysis at home, particularly PD, due to the unique medical needs of the patients; we finalized the rule as proposed without extending the AKI benefit to home dialysis patients (81 FR 77870). As discussed in section III.C.1 of this proposed rule, we have received comments regarding the site of renal dialysis services for Medicare beneficiaries with AKI. Over the years, we have monitored data for beneficiaries with AKI and research discussing the potential to expand dialysis for beneficiaries with AKI to a home setting. In addition, during the COVID–19 PHE, many patients who developed AKI received home dialysis successfully.[86] [87] Both professional

[71] United States Renal Data System. 2023 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 2023. *https://usrds-adr.niddk.nih.gov/2023/chronic-kidney-disease/4-acute-kidney-injury.*

[72] Ibid.

[73] Ibid.

[74] 42 CFR part 494.

[75] Bassuner J, Kowalczyk B, Abdel-Aal AK. Why Peritoneal Dialysis is Underutilized in the United States: A Review of Inequities. Semin Intervent Radiol. 2022 Feb 18;39(1):47–50. doi: 10.1055/s–0041–1741080.

[76] USRDS Annual Data Report 2023.

[77] Ibid.

[78] USRDS Annual Data Report 2023.

[79] Ibid.

[80] Ibid.

[81] Ibid.

[82] Ibid.

[83] Ibid.

[84] Ibid.

[85] Ibid.

[86] Cozzolino M, Conte F, Zappulo F, Ciceri P, Galassi A, Capelli I, Magnoni G, La Manna G. COVID–19 pandemic era: is it time to promote home dialysis and peritoneal dialysis? Clin Kidney J. 2021 Feb 2;14(Suppl 1):i6–i13. doi: 10.1093/ckj/sfab023.

[87] Geetha D, Kronbichler A, Rutter M, Bajpai D, Menez S, Weissenbacher A, Anand S, Lin E,

Continued

nephrologist societies, the Renal Physicians Association and the American Society of Nephrology, agree beneficiaries with AKI can safely receive dialysis at home via PD or HHD.[88] The Renal Physicians Association has long supported access to all dialysis modalities for beneficiaries with AKI as it aligns with the goals to expand access to home dialysis and increase the number of programs utilizing emergent or urgent PD, as opposed to HD, as rescue therapy for patients presenting in urgent need.[89] By revising the CfCs to allow beneficiaries with AKI to utilize home dialysis, we would increase patient options for renal replacement treatment beyond in-center hemodialysis and empower these patients to make decisions about their care.

3. Proposed Changes

To support treatment location choices for individuals with AKI requiring dialysis and to align with the proposed coverage changes, we propose conforming changes throughout the ESRD CfCs at 42 CFR part 494 to clarify that the option for home dialysis services is available to all patients. Specifically, we note that the phrase ''ESRD patients'' is exclusive of beneficiaries with AKI. The phrase ''kidney failure'' is inclusive of people whose kidney function is inadequate such that dialysis is necessary to maintain or prolong life. This can be a temporary (AKI) or permanent (ESRD) condition. Accordingly, we are proposing to amend the definitions of home dialysis and self-dialysis at §§ 494.10, 494.70(c)(1)(i), and 494.130 introductory text by removing the descriptor ''ESRD.'' In addition, we are proposing to amend §§ 494.70(a)(1) and (10) and 494.80 introductory text by revising the phrase ''ESRD'' to say ''kidney failure;'' § 494.90(b)(4) by revising the phrase ''ESRD care'' to say ''dialysis care;'' § 494.100(a)(3)(i) by revising the phrase ''management of ESRD'' to say ''management of their kidney failure;'' § 494.120 introductory text by revising the phrase ''serve ESRD patients'' to say ''serve patients with kidney failure;'' and lastly § 494.170 introductory text by revising the phrase ''provider of ESRD services'' to say ''provider of dialysis services.'' We welcome comments on these proposed changes. Specifically, are these proposed revisions adequate to ensure access to home dialysis services for individuals with AKI?

4. Expected Impact

Beneficiaries with AKI requiring dialysis represent a small subset of individuals treated in outpatient dialysis facilities. Specifically, around 12,000 patients would be eligible for this optional service.[90] Expanding coverage to include beneficiaries with AKI would not present any changes in burden on ESRD facilities or establish new information collections subject to the Paperwork Reduction Act.

IV. Proposed Updates to the End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the ESRD QIP's background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the citations provided at IV.A of the CY 2024 ESRD PPS final rule (88 FR 76433). We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Proposed Updates to Requirements Beginning With the PY 2027 ESRD QIP

1. PY 2027 ESRD QIP Measure Set

In this proposed rule, we are proposing to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure, a comprehensive measure on which facilities are scored for each payment year using one set of performance standards, with a Kt/V measure topic comprised of four individual Kt/V measures, beginning with PY 2027. We are also proposing to remove the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure from the ESRD QIP measure set beginning with PY 2027. Table 12 summarizes the previously finalized and proposed updated measures that we would include in the PY 2027 ESRD QIP measure set. The technical specifications for current measures that would remain in the measure set for PY 2027 can be found in the CMS ESRD Measures Manual for the 2024 Performance Period.[91] The proposed technical specifications for the measures in the proposed Kt/V measure topic can be viewed at *https://www.cms.gov/medicare/quality/end-stage-renal-disease-esrd-quality-incentive-program/technical-specifications-esrd-qip-measures.* If the Kt/V measure topic is finalized, these specifications will be included in the CMS ESRD Measures Manual for the 2025 Performance Period.

BILLING CODE 4120–01–P

Carlson N, Sozio S, Fowler K, Bignall R, Ducharlet K, Tannor EK, Wijewickrama E, Hafidz MIA, Tesar V, Hoover R, Crews D, Varnell C, Danziger-Isakov L, Jha V, Mohan S, Parikh C, Luyckx V. Impact of the COVID–19 pandemic on the kidney community: lessons learned and future directions. Nat Rev Nephrol. 2022 Nov;18(11):724–737. doi: 10.1038/s41581–022–00618–4.

[88] AdvaMed to CMS (January 24, 2023).

[89] Renal Physicians Association. ''RPA Comments on the 2017 ESRD PPS Proposed Rule Including AKI Policy'' *http://ww.renalmed.org/page/ESRDPPSRuleComments*? (2016).

[90] USRDS Annual Data Report 2023.

[91] *https://www.cms.gov/files/document/esrd-measures-manual-v91.pdf.*

[92] In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

TABLE 12: Previously Finalized and Proposed Updated Measures for the PY 2027 ESRD QIP Measure Set

Consensus-Based Entity[92] (CBE) #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple survey questions.
2496	Standardized Readmission Ratio (SRR), a clinical measure
Consensus-Based Entity[92] (CBE) #	**Measure Title and Description**
	Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on CBE #2979	Standardized Transfusion Ratio (STrR), a clinical measure Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
Based on CBE #0323, #0321, #2706, and #1423*	(Kt/V) Dialysis Adequacy Measure Topic, a clinical measure topic Four measures of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. The individual Kt/V measures would be adult hemodialysis (HD) Kt/V, adult peritoneal dialysis (PD) Kt/V, pediatric HD Kt/V, and pediatric PD Kt/V.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a reporting measure Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on CBE #0418	Clinical Depression Screening and Follow-Up, a clinical measure Facility reports in ESRD Quality Reporting System (EQRS) one of four conditions for each qualifying patient treated during performance period.
Based on CBE #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.
3636	COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP), a reporting measure Percentage of HCP who are up to date on their COVID-19 vaccination.
N/A	Facility Commitment to Health Equity, a reporting measure Facilities will receive two points each for attesting to five different domains of commitment to advancing health equity for a total of ten points.
N/A	Screening for Social Drivers of Health, a reporting measure Percentage of patients at a dialysis facility who are 18 years or older screened for all five health-related social needs (HRSNs) (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety).
N/A	Screen Positive Rate for Social Drivers of Health, a reporting measure Percentage of patients at a dialysis facility who are 18 years or older screened for all five HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety), and who screened positive for one or more of the HRSNs.

*We are proposing to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with the Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027, as discussed in section IV.B.2 of this proposed rule. We note that, although the proposed Kt/V Dialysis Adequacy Measure Topic is not endorsed by the CBE, the four individual Kt/V measures that are included in the measure topic are CBE-endorsed.

**We are proposing to remove the NHSN Dialysis Event reporting measure beginning with PY 2027, as discussed in section IV.B.3 of this proposed rule.

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2. Proposal To Replace the Kt/V Dialysis Adequacy Comprehensive Clinical Measure With a Kt/V Dialysis Adequacy Measure Topic Beginning With the PY 2027 ESRD QIP

Section 1881(h)(2)(A)(i) states that the ESRD QIP must evaluate facilities based on measures of dialysis adequacy. Beginning with the PY 2027 ESRD QIP, we are proposing to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure, a single comprehensive measure on which facility performance is calculated using one set of performance standards for each payment year, with a Kt/V Dialysis Adequacy Measure Topic, a measure topic comprised of four individual Kt/V measures on which facility performance is calculated using performance standards for each individual Kt/V measure.[93] We are proposing to remove the Kt/V Dialysis Adequacy Comprehensive clinical measure under § 413.178(c)(5)(i)(E), Measure Removal Factor 5 (a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available), and proposing to replace it with the proposed Kt/V Dialysis Adequacy Measure Topic, which consists of four individual Kt/V measures. Under this proposed update, the individual Kt/V measures would be adult hemodialysis (HD) Kt/V, adult peritoneal dialysis (PD) Kt/V, pediatric HD Kt/V, and pediatric PD Kt/V.

By replacing the current Kt/V Dialysis Adequacy Comprehensive clinical measure with four separate measures, we would be able to assess Kt/V performance more accurately based on whether the patient is an adult or child and what type of dialysis the patient is receiving. We are also proposing to score the four measures as a Kt/V Dialysis Adequacy Measure Topic and to limit the total weight of that topic to 11 percent of the TPS, which is the weight of the current Kt/V Dialysis Adequacy Comprehensive clinical measure. These proposals would continue to maintain Kt/V measurement as an important part of the quality of care assessed by the ESRD QIP. Facilities are eligible to receive an individual Kt/V measure score if they treat at least 11 eligible patients using the modality addressed by that particular measure. For example, a facility treating at least 11 eligible pediatric HD patients during the applicable performance period would be scored on the Kt/V Pediatric HD measure. We would calculate a facility's measure topic score by first calculating the facility's performance on each of the Adult HD Kt/V, Adult PD Kt/V, Pediatric HD Kt/V, and Pediatric PD Kt/V measures, as applicable, using the applicable achievement threshold, benchmark, and improvement threshold for the payment year. Second, we would calculate the total number of eligible patients for weighting each of these measure scores to calculate a single measure topic score. We would calculate this total number by summing all eligible patients included in the denominator for each individual measure. Third, we would calculate the weighted score for each measure within the measure topic by dividing the number of patients included in the denominator for each individual measure by the total number of eligible patients for all of the measures within the measure topic and multiplying by the respective measure score. Finally, we would add the weighted measure scores together and round them to the nearest integer. An example of how we would calculate the measure topic score for a facility that treats the minimum number of patients to be eligible for scoring on all four of the measures is provided below.

Measure	Measure Score	# Patients in denominator	Weighted Score
Kt/V Adult HD	8	60	8 * (60/125) = 3.84
Kt/V Adult PD	6	30	6 * (30/125) = 1.44
Kt/V Pediatric HD	9	15	9 * (15/125) = 1.08
Kt/V Pediatric PD	5	20	5 * (20/125) = 0.80

Kt/V Topic Score= 3.84+1.44+1.08+0.80 = 7.16, which rounds to **7**.

Under our proposal, a facility would not need to be eligible for scoring on all four individual measures to receive a measure topic score. For example, a facility that exclusively treats adult HD patients and, for that reason, is eligible to be scored on only the Kt/V Adult HD measure would receive a topic score that is the same score as its individual Kt/V measure score. The proposed measure topic scoring considers both a facility's individual ESRD patient population and the treatment modalities it offers, and then weights its performance on the topic proportionately to its overall ESRD patient population. As a result, we believe that a facility's measure topic score will be more reflective of its actual performance among its patient population and offered modalities than its current Kt/V Dialysis Adequacy Comprehensive clinical measure score, which is a composite assessment that blends the Kt/V measure data of all patients treated at that facility.

We previously adopted a Kt/V Dialysis Adequacy Measure Topic that included three of the four measures that we are now proposing to include in the topic (adult HD Kt/V, adult PD Kt/V, and pediatric HD Kt/V) in the CY 2013 ESRD PPS final rule (77 FR 67487 through 67490). In the CY 2015 ESRD PPS final rule (79 FR 66197 through 66198), we updated the Kt/V Dialysis Adequacy Measure Topic to include the pediatric PD Kt/V measure as well. In the CY 2016 ESRD PPS final rule (80 FR 69053 through 69057), we replaced the Kt/V Dialysis Measure Topic with the current Kt/V Dialysis Adequacy Comprehensive clinical measure, which assesses the percentage of all patient-months for both adult and pediatric patients whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the performance period. This change allowed more facilities to be eligible for measure

[93] For further information related to the Kt/V Dialysis Adequacy Comprehensive clinical measure, we refer readers to 77 FR 67487 through 67490, 79 FR 66197 through 66198, and 80 FR 69053 through 69057.

scoring, which in turn allowed us to evaluate the care provided to a greater proportion of ESRD patients.

At the time we finalized the Kt/V Dialysis Adequacy Comprehensive clinical measure, three facilities were eligible for scoring on the pediatric HD Kt/V measure, six facilities were eligible for scoring on the pediatric PD Kt/V measure, 1,402 facilities were eligible for scoring on the adult PD Kt/V measure, and 6,117 facilities were eligible for scoring on the adult HD Kt/V measure. Given the relatively low numbers of facilities eligible for scoring on the pediatric HD Kt/V, pediatric PD KT/V, and adult PD Kt/V measures at that time, we adopted the Kt/V Dialysis Adequacy Comprehensive clinical measure to help ensure that data reflecting those patient populations contributed to facilities' total performance scores. Since the CY 2016 ESRD PPS final rule, however, Kt/V measure data (using the PY 2024/CY 2022 ESRD QIP eligible facility list, CY 2022 EQRS data, and CY 2022 claims data) indicates that more facilities are treating greater numbers of pediatric HD patients and pediatric PD patients, as well as greater numbers of adult PD patients, and therefore would be eligible to be scored on the individual measures based on an 11-patient case minimum. For example, there are now 21 pediatric HD facilities and 28 pediatric PD facilities with at least 11 qualifying patients. This shows a 600 percent increase in facilities eligible to be scored on the pediatric HD Kt/V measure, and a 366 percent increase in facilities eligible to be scored on the pediatric PD Kt/V measure, since the CY 2016 ESRD PPS final rule. Additionally, there are now 2,538 facilities eligible for scoring on the adult PD Kt/V measure, an 81 percent increase since the CY 2016 ESRD PPS final rule. By contrast, the number of facilities eligible for scoring on the adult HD Kt/V measure has increased by 14 percent during that same period of time.

In light of the increase in the proportions of pediatric HD patients, pediatric PD patients, and adult PD patients being treated at ESRD facilities since the time we adopted the Kt/V Dialysis Adequacy Comprehensive clinical measure, we have determined that it is appropriate and more reflective of facility performance to reintroduce the Kt/V Dialysis Adequacy Measure Topic in the ESRD QIP. In addition, the proposed measure topic scoring methodology will more accurately capture facility performance with respect to dialysis adequacy because it assesses those facilities based on performance standards tailored according to Kt/V measurements that reflect ESRD patient age and treatment modality.

The proposed replacement of the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic would also not affect a facility's measure data reporting requirements. A facility would continue to report the same Kt/V measure data into EQRS and Medicare claims as it would for the current Kt/V Dialysis Adequacy Comprehensive clinical measure. However, under the proposed Kt/V Dialysis Adequacy Measure Topic, the measure data would be used to score the facility on four individual Kt/V measures, as applicable based on their ESRD patient population and treatment modalities.

The proposed replacement of the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic would also advance the CMS National Quality Strategy Goals by scoring facilities on measure data that more accurately reflects the quality of care provided to different kinds of ESRD patients on different treatment modalities. The proposed Kt/V Dialysis Adequacy Measure Topic would allow us to evaluate dialysis adequacy in adult HD patients, adult PD patients, pediatric HD patients, and pediatric PD patients by scoring facilities in a way that accounts for differences in patient populations and treatment modalities. Therefore, this proposed update would ensure that a facility's performance on the measure topic more accurately reflects the quality of care provided by the facility.

We welcome public comment on this proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic consisting of an adult HD Kt/V measure, an adult PD Kt/V measure, a pediatric HD Kt/V measure, and a pediatric PD Kt/V measure, for the PY 2027 ESRD QIP and subsequent years.

3. Proposal To Remove the NHSN Dialysis Event Reporting Measure From the ESRD QIP Measure Set Beginning With PY 2027

To ensure continued impact and effectiveness of our measure set on facility performance, we are proposing to remove the NHSN Dialysis Event reporting measure beginning with PY 2027. When we first adopted the NHSN Dialysis Event reporting measure in the CY 2012 ESRD PPS final rule (76 FR 70268 through 70269), we stated that reporting dialysis events to the NHSN by all facilities supports national goals for patient safety, including the reduction of Hospital Acquired Infections (HAIs). In the CY 2014 ESRD PPS final rule, we replaced the NHSN Dialysis Event reporting measure with the NHSN Bloodstream Infection (BSI) clinical measure (78 FR 72204 through 72207). We introduced the clinical version of the measure to hold facilities accountable for monitoring and preventing infections in the ESRD population, and to hold facilities accountable for their actual clinical performance on the measure. In the CY 2017 ESRD PPS final rule (81 FR 77879 through 77882), we reintroduced the NHSN Dialysis Event reporting measure to complement the NHSN BSI clinical measure as a way to incentivize facilities to report complete and accurate monthly dialysis event data in compliance with the NHSN Dialysis Event protocol.[94] In reintroducing the measure, we noted our concerns that facilities were not consistently reporting monthly dialysis event data, given the incentive to achieve high clinical performance scores on the NHSN BSI clinical measure. We stated that this may have been an unintended consequence of replacing the previous NHSN Dialysis Event reporting measure with the NHSN BSI clinical measure (81 FR 77879). Therefore, in the CY 2017 ESRD PPS final rule, we reintroduced the NHSN Dialysis Event reporting measure to be included in the ESRD QIP measure set along with the NHSN BSI Clinical Measure.

Based on our analyses, facilities are consistently reporting monthly dialysis event data, and have been doing so for several years. In an assessment of ESRD QIP measure rate performance trends during PY 2020 through PY 2022, performance in the 5th percentile through the 100th percentile was 100 percent on the NHSN Dialysis Event reporting measure for all three performance years, meaning that most eligible facilities reported data on the measure for each of those years.[95] If most eligible facilities are reporting NHSN Dialysis Event measure data each year and measure performance levels at the 5th percentile and the 100th percentile are the same each year, then NHSN dialysis event data are now reported consistently and the measure is

[94] For further information related to the NHSN Dialysis Event reporting measure, we refer readers to 76 FR 70268 through 70269 and 78 FR 72204 through 72207.

[95] Partnership for Quality Measurement. 2023 Measure Set Review (MSR): End Stage Renal Disease Quality Incentive Program (ESRD–QIP). September 2023. Available at: *https://p4qm.org/sites/default/files/2023-09/MSR-Report-ESRD-QIP-20230911.pdf.*

not likely to drive improvements in care.

Our proposal to remove the NHSN Dialysis Event reporting measure is consistent with evolving the program to focus on a measure set of high-value, impactful measures that have been developed to drive care improvements for a broader set of ESRD patients. As such, we are proposing to remove this measure from the ESRD QIP measure set under § 413.178(c)(5)(i)(A), Measure Removal Factor 1 (measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made). Although we believe that removing this measure would enable facilities to focus on the remaining measures in the ESRD QIP measure set, we note that facilities would still be required to fully comply with the NHSN Dialysis Event protocol and report all dialysis event data, including BSI, for the NHSN BSI Clinical Measure.

We welcome public comment on our proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set, beginning with PY 2027.

4. Proposed Revisions to the Clinical Care and Reporting Measure Domains Beginning With the PY 2027 ESRD QIP

In the CY 2024 ESRD PPS final rule (88 FR 76481 through 76482), we finalized revisions to the ESRD QIP measure domains beginning with PY 2027. The measure domains and weights we finalized in the CY 2024 ESRD PPS final rule are depicted in table 13a.

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TABLE 13a: Current PY 2027 ESRD QIP Measure Domains and Weights

Measures by Domain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	**15.00**
ICH CAHPS measure	15.00
Care Coordination Measure Domain	**30.00**
SHR clinical measure	7.50
SRR clinical measure	7.50
PPPW measure	7.50
Clinical Depression Screening and Follow-Up measure	7.50
Clinical Care Measure Domain	**35.00**
Kt/V Dialysis Adequacy Comprehensive measure	11.00
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	**10.00**
NHSN BSI clinical measure	10.00
Reporting Measure Domain	**10.00**
Screening for Social Drivers of Health measure	1.43
Screen Positive Rate for Social Drivers of Health reporting measure	1.43
Facility Commitment to Health Equity reporting measure	1.43
Hypercalcemia reporting measure	1.43
MedRec reporting measure	1.43
NHSN Dialysis Event reporting measure	1.43
COVID-19 HCP Vaccination reporting measure	1.43

In this proposed rule, we are proposing to revise the Clinical Care Domain beginning with PY 2027 to reflect our proposal to replace the Kt/V Comprehensive Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic, and to revise the measure weights in the Reporting Measure Domain to reflect our proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set. Under our proposal, the weight of the Kt/V Dialysis Adequacy Topic would continue to be the same as the current weight of the Kt/V Dialysis Adequacy Comprehensive Measure, but that weight would be applied to a facility's measure topic score, instead of being applied, as it is now, to a facility's score on the single Kt/V Comprehensive Dialysis Adequacy Comprehensive clinical measure.

Given our proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP beginning with PY 2027, we are also proposing to update the individual measure weights in the Reporting Domain to accommodate the proposed new number of measures. Consistent with our approach in the CY 2023 ESRD PPS final rule, we are proposing to assign individual measure weights to reflect the proposed updated number of measures in the Reporting Measure Domain so that each measure is weighted equally (87 FR 67251

through 67253). Although we are proposing to change the number of measures and the weights of the individual measures in the Reporting Measure Domain, we are not proposing to change the weight of any of the five domains. The measures that would be included in each domain, along with the proposed new measure weights, for PY 2027 are depicted in table 13b.

TABLE 13b: Previously Finalized and Newly Proposed ESRD QIP Measure Domains and Weights for PY 2027

Measures by Domain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	**15.00**
ICH CAHPS measure	15.00
Care Coordination Measure Domain	**30.00**
SHR clinical measure	7.50
SRR clinical measure	7.50
PPPW measure	7.50
Clinical Depression Screening and Follow-Up measure	7.50
Clinical Care Measure Domain	**35.00**
Kt/V Dialysis Adequacy Measure Topic*	11.00
Adult Hemodialysis (HD) Kt/V	
Pediatric Hemodialysis (HD) Kt/V	
Adult Peritoneal Dialysis (PD) Kt/V	
Pediatric Peritoneal Dialysis (PD) Kt/V	
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	**10.00**
NHSN BSI clinical measure	10.00
Reporting Measure Domain**	**10.00**
Screening for Social Drivers of Health measure	1.67
Screen Positive Rate for Social Drivers of Health reporting measure	1.67
Facility Commitment to Health Equity reporting measure	1.67
Hypercalcemia reporting measure	1.67
MedRec reporting measure	1.67
COVID-19 HCP Vaccination reporting measure	1.67

*We are proposing to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027, as discussed in section IV.B.2 of this proposed rule.
** We are proposing to remove the NHSN Dialysis Event reporting measure beginning with PY 2027, as discussed in section IV.B.3 of this proposed rule.

We welcome public comment on these proposals to update the Clinical Care Measure Domain and Reporting Measure Domain.

5. Performance Standards for the PY 2027 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as determined appropriate by the Secretary, and must be established prior to the beginning of the performance period for the year involved, as required by sections 1881(h)(4)(B) and (C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277), as well as § 413.178(a)(1), (3), (7), and (12), for further information related to performance standards.

In the CY 2024 ESRD PPS final rule (88 FR 76480 through 76481), we set the performance period for the PY 2027 ESRD QIP as CY 2025 and the baseline period as CY 2023. In this proposed rule, we are estimating the performance standards for the PY 2027 clinical measures in table 14 using data from CY 2022, which are the most recent data available. We intend to update these performance standards for all measures, using CY 2023 data, in the CY 2025 ESRD PPS final rule.

TABLE 14: Performance Standards for the Previously Finalized and Proposed Updated ESRD QIP Clinical Measures for PY 2027

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Vascular Access Type (VAT)			
Long-Term Catheter Rate	18.35%	11.04%	4.69%
Kt/V Dialysis Adequacy Measure Topic*			
Adult Hemodialysis (HD) Kt/V	94.41%	97.81%	99.54%
Pediatric Hemodialysis (HD) Kt/V	80.77%	94.39%	100.00%
Adult Peritoneal Dialysis (PD) Kt/V	85.90%	94.56%	98.86%
Pediatric Peritoneal Dialysis (PD) Kt/V	63.48%	82.45%	96.30%
Standardized Readmission Ratio[a]	34.27	26.50	16.19
NHSN BSI	0.734	0.248	0
Standardized Hospitalization Ratio[b]	166.60	129.14	87.98
Standardized Transfusion Ratio[b]	48.29	26.19	8.86
PPPW	8.12%	16.73%	33.90%
Clinical Depression	87.10%	94.29%	100.00%
ICH CAHPS: Nephrologists' Communication and Caring	58.20%	67.90%	79.15%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.87%	63.22%	72.83%
ICH CAHPS: Providing Information to Patients	74.49%	81.09%	87.80%
ICH CAHPS: Overall Rating of Nephrologists	49.33%	62.22%	76.57%
ICH CAHPS: Overall Rating of Dialysis Center Staff	51.01%	64.86%	78.86%
ICH CAHPS: Overall Rating of the Dialysis Facility	54.58%	69.42%	84.09%
*We are proposing to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with the Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027, as discussed in section IV.B.2 of this proposed rule.			

[a]Rate calculated as a percentage of hospital discharges.

[b]Rate per 100 patient-years.

Data sources: VAT measure: 2022 EQRS; SRR, SHR: 2022 Medicare claims; STrR: 2022 Medicare claims; Kt/V: 2022 EQRS; Hypercalcemia: 2022 EQRS; NHSN: 2022 Centers for Disease Control and Prevention (CDC); ICH CAHPS: CMS 2022; PPPW: 2022 EQRS and 2022 Organ Procurement and Transplantation Network (OPTN); Clinical Depression: 2022 EQRS.

In addition, we summarize in table 15 our requirements for successful reporting on our previously finalized reporting measures for the PY 2027 ESRD QIP.

TABLE 15: Requirements for Successful Reporting of ESRD QIP Reporting Measures for PY 2027

Measure	Reporting Frequency	Data Elements
MedRec	Monthly	• Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: o physician, o nurse, o advanced registered nurse practitioner (ARNP), o physician assistant (PA), o pharmacist, or o pharmacy technician personnel • Name of eligible professional
Hypercalcemia	Monthly	Total uncorrected serum or plasma calcium lab values
COVID-19 Vaccination Coverage Among HCP	At least one week of data each month, submitted quarterly	Cumulative number of HCP eligible to work in the facility for at least one day during the reporting period and who are up to date on their COVID-19 vaccination.
Facility Commitment to Health Equity	Annually	Domains to which facility must attest affirmatively: • Equity is a Strategic Priority • Data Collection • Data Analysis • Quality Improvement • Leadership Engagement
Screening for Social Drivers of Health	Annually	Number of eligible patients who were screened for all five HRSNs: • Food insecurity, • Housing instability, • Transportation needs, • Utility difficulties, or • Interpersonal safety.
Screen Positive Rate for Social Drivers of Health	Annually	Number of eligible patients with 'Yes' or 'No' (non-missing) screening responses for each of the five HRSNs.

6. Eligibility Requirements for the PY 2027 ESRD QIP

In this proposed rule, we are proposing to update eligibility requirements as part of our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027. Our previously finalized and proposed new minimum eligibility requirements are described in table 16.

TABLE 16: Previously Finalized and Proposed New Eligibility Requirements for Scoring on ESRD QIP Measures Beginning with PY 2027

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Dialysis Adequacy Measure Topic: Adult HD Kt/V (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Pediatric HD Kt/V (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Adult PD Kt/V (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Pediatric PD Kt/V (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Clinical)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
COVID-19 Vaccination Coverage Among HCP (Reporting)	N/A	Before September 1 of the performance period that applies to the program year.	N/A
Facility Commitment to Health Equity (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
Screening for Social Drivers of Health (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A

Screen Positive Rate for Social Drivers of Health (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A

* We are proposing to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027, as discussed in section IV.B.2 of this proposed rule.
** We are proposing to remove the NHSN Dialysis Event reporting measure beginning with PY 2027, as discussed in section IV.B.3 of this proposed rule.

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We welcome public comment on these proposals to update the minimum eligibility requirements to reflect the proposed Kt/V Dialysis Adequacy Measure Topic.

7. Payment Reduction Scale for the PY 2027 ESRD QIP

Under our current policy, a facility does not receive a payment reduction for a payment year in connection with its performance under the ESRD QIP if it achieves a TPS that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined the mTPS in our regulations at § 413.178(a)(8).

Under § 413.177(a), we implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the mTPS, up to a maximum reduction of 2 percent. For PY 2027, we estimate using available data that a facility must meet or exceed an mTPS of 51 to avoid a payment reduction. We note that the mTPS estimated in this proposed rule is based on data from CY 2022 instead of the PY 2027 baseline period (CY 2023) because CY 2023 data are not yet available. We will update and finalize the mTPS and associated payment reduction ranges for PY 2027, using CY 2023 data, in the CY 2025 ESRD PPS final rule.

TABLE 17: Estimated Payment Reduction Scale for PY 2027 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-51	0%
50-41	0.5%
40-31	1.0%
30-21	1.5%
20-0	2.0%

C. Requests for Information (RFIs) on Topics Relevant to ESRD QIP

As discussed in the following sections, we are requesting information on two topics to inform future revisions to the ESRD QIP. First, we are requesting information regarding potential future modifications to the existing ESRD QIP scoring methodology to reward facilities based on their performance and the proportion of their patients who are dually eligible for Medicare and Medicaid. Second, we are requesting information regarding potential updates to the data validation policy to encourage accurate, comprehensive reporting of ESRD QIP data.

Please note that each of these sections in this proposed rule is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), these general solicitations are exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Respondents are encouraged to provide complete but concise responses. These RFIs are issued solely for information and planning purposes; they do not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. These RFIs do not commit the United States Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the United States Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party's expense. Not responding to these RFIs does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor these RFI announcements for additional information pertaining to this request. Please note that we will not respond to questions about the policy issues raised in these RFIs. CMS may or may not

choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the United States Government to form a binding contract or issue a grant. Information obtained as a result of these RFIs may be used by the United States Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. These RFIs should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become United States Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

1. Request for Public Comment on Future Change to the Scoring Methodology To Add a New Adjustment That Rewards Facilities Based on Their Performance and the Proportion of Their Patients Who Are Dually Eligible for Medicare and Medicaid

Achieving health equity, addressing health disparities, and closing the performance gap in the quality of care provided to disadvantaged, marginalized, or underserved populations continue to be priorities for CMS as outlined in the CMS National Quality Strategy.[96] CMS defines ''health equity'' as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.[97] We are working to advance health equity by designing, implementing, and operationalizing policies and programs that reduce avoidable differences in health outcomes.

The ESRD QIP adopted three new health-equity focused quality measures in the CY 2024 ESRD PPS final rule (88 FR 76437 through 76446; 76466 through 76480). Although commenters were generally supportive of the new measures, a few commenters recommended that the ESRD QIP take additional action to support facilities that treat patient populations with higher proportions of health-related social needs (HRSNs) (88 FR 76473). We are considering updating our scoring methodology in future rulemaking to add Health Equity Adjustment bonus points to a facility's TPS that would be calculated using a methodology that incorporates a facility's performance across all five domains for the payment year and its proportion of patients with dual eligibility status (DES), meaning those who are eligible for both Medicare and Medicaid coverage.

In the 2016 Report to Congress on Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) reported that beneficiaries with social risk factors had worse outcomes and were more likely to receive a lower quality of care.[98] Patients with DES experience significant disparities are also likely to be more medically complex and remain one of the most vulnerable populations.[99] [100] [101] DES remains the strongest predictor of negative health outcomes.[102]

We recently finalized a Health Equity Adjustment scoring policy for the Hospital Value-Based Purchasing (VBP) Program (88 FR 59092 through 59106) and the Skilled Nursing Facility (SNF) VBP Program (88 FR 53304 through 53316). These policies provide Health Equity Adjustment bonus points to top tier performing hospitals and SNFs with a high proportion of patients with DES, and each program's policy is tailored to meet the needs of the specific program. For example, in the Hospital VBP Program, the Health Equity Adjustment bonus is calculated based on a hospital's performance on each of the four measure domains and its proportion of patients with DES (88 FR 59095 through 59096). In the SNF VBP Program, the Health Equity Adjustment bonus is calculated based on a facility's performance on each measure and its proportion of patients with DES (88 FR 53309 through 53311).

Our policy for scoring performance on the ESRD QIP is codified at § 413.178(e). In this proposed rule, we are requesting public comment on potential future modifications to the existing scoring methodology to reward excellent care to underserved populations. We also note that any Health Equity Adjustment bonus for the ESRD QIP would need to align with the Program's statutory requirements under section 1881(h) of the Act. We welcome public comment on the following:

- Would a Health Equity Adjustment be valuable to the ESRD QIP?

++ If a Health Equity Adjustment would be valuable to the ESRD QIP, how should it be structured?

++ If a Health Equity Adjustment would not be valuable to the ESRD QIP, why not?

- Are there other approaches that the ESRD QIP could propose to adopt to effectively address healthcare disparities and advance health equity?

2. Request for Public Comment on Updating the Data Validation Policy for the ESRD QIP

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. The ESRD QIP includes two types of data validation for this purpose: The EQRS data validation (OMB Control Number 0938–1289) and the NHSN validation (OMB Control Number 0938–1340). In the CY 2019 ESRD PPS final rule, we adopted the CROWNWeb (now EQRS) data validation as a permanent feature of the Program (83 FR 57003). In the CY 2020 ESRD PPS final rule, we adopted the NHSN data validation as a permanent feature of the Program (84 FR 60727). Under both data validation policies, we validate EQRS and NHSN data from a sample of facilities randomly selected for validation. If a facility is randomly selected for validation but does not submit the requested records, 10 points are deducted from the facility's TPS.

[96] Centers for Medicare & Medicaid Services. (2022) CMS National Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[97] Health Equity Strategic Pillar. Centers for Medicare & Medicaid Services. *https://www.cms.gov/pillar/health-equity*.

[98] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. First Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2016. Available at: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf*.

[99] Johnston, K.J., & Joynt Maddox, K.E. (2019). The Role of Social, Cognitive, And Functional Risk Factors In Medicare Spending For Dual And Nondual Enrollees. *Health Affairs (Project Hope), 38*(4), 569–576. *https://doi.org/10.1377/hlthaff.2018.05032*.

[100] Johnston, K.J., & Joynt Maddox, K.E. (2019). The Role of Social, Cognitive, and Functional Risk Factors in Medicare Spending for Dual and Nondual Enrollees. *Health Affairs (Project Hope), 38*(4), 569–576. *https://doi.org/10.1377/hlthaff.2018.05032*.

[101] Wadhera, R.K., Wang, Y., Figueroa, J.F., Dominici, F., Yeh, R.W., & Joynt Maddox, K.E. (2020). Mortality and Hospitalizations for Dually Enrolled and Nondually Enrolled Medicare Beneficiaries Aged 65 Years or Older, 2004 to 2017. *JAMA, 323*(10), 961–969. *https://doi.org/10.1001/jama.2020.1021*.

[102] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. Available at: *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs*.

In this proposed rule, we are requesting public comment on ways to update the data validation policy to encourage accurate, comprehensive reporting of ESRD QIP data. We have reviewed data validation policies in other quality reporting programs such as the Hospital Inpatient Quality Reporting (IQR) Program (81 FR 57180) and the Hospital Outpatient Quality Reporting (OQR) Program (76 FR 74486). These programs have adopted data validation policies that require a hospital selected for data validation to achieve a 75 percent reliability or accuracy threshold to receive full credit for data validation reporting.

We welcome comments on potential future policy proposals that would encourage accurate, comprehensive reporting for data validation purposes, such as introducing a penalty for facilities that do not meet an established reporting or data accuracy threshold, introducing a bonus for facilities that perform above an established reporting or data accuracy threshold, developing targeted education on data validation reporting, or requiring that a facility selected for validation that does not meet an established reporting or data accuracy threshold be selected again the next year.

V. End-Stage Renal Disease Treatment Choices (ETC) Model

A. Background

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of these programs. The purpose of the ETC Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home dialysis and kidney transplantation, support ESRD Beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. As described in the Specialty Care Models final rule (85 FR 61114), beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD Beneficiaries require dialysis or kidney transplantation to survive, and the majority of ESRD Beneficiaries receiving dialysis receive hemodialysis in an ESRD facility. However, as described in the Specialty Care Models final rule, alternative renal replacement modalities to in-center hemodialysis, including home dialysis and kidney transplantation, are associated with improved clinical outcomes, better quality of life, and lower costs than in-center hemodialysis (85 FR 61264).

The ETC Model is a mandatory payment model. ESRD facilities and Managing Clinicians are selected as ETC Participants based on their location in Selected Geographic Areas—a set of 30 percent of Hospital Referral Regions (HRRs) that have been randomly selected to be included in the ETC Model, as well as HRRs with at least 20 percent of ZIP codes™ located in Maryland.[103] CMS excludes all United States Territories from the Selected Geographic Areas.

Under the ETC Model, ETC Participants are subject to two payment adjustments. The first is the Home Dialysis Payment Adjustment (HDPA), which is an upward adjustment on certain payments made to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on home dialysis claims, and an upward adjustment to the Monthly Capitation Payment (MCP) paid to participating Managing Clinicians on home dialysis-related claims. The HDPA applies to claims with claim service dates beginning January 1, 2021, and ending December 31, 2023.

The second payment adjustment under the ETC Model is the Performance Payment Adjustment (PPA). For the PPA, we assess ETC Participants' home dialysis rates and transplant rates during a Measurement Year (MY), which includes 12 months of performance data. Each MY has a corresponding PPA Period—a 6-month period that begins 6 months after the conclusion of the MY. We adjust certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY.

Based on an ETC Participant's achievement in relation to benchmarks based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year, and the ETC Participant's improvement in relation to their own home dialysis rate and transplant rate during the Benchmark Year, we would make an upward or downward adjustment to certain payments to the ETC Participant. The magnitude of the positive and negative PPAs for ETC Participants increases over the course of the Model. These PPAs apply to claims with claim service dates beginning July 1, 2022 and ending June 30, 2027.

CMS has modified the ETC Model several times. In the CY 2022 ESRD PPS final rule, we finalized a number of changes to the ETC Model. We adjusted the calculation of the home dialysis rate (86 FR 61951 through 61955) and the transplant rate (86 FR 61955 through 61959) and updated the methodology for attributing Pre-emptive LDT Beneficiaries (86 FR 61950 through 61951). We changed the achievement benchmarking and scoring methodology (86 FR 61959 through 61968), as well as the improvement benchmarking and scoring methodology (86 FR 61968 through 61971). We specified the method and requirements for sharing performance data with ETC Participants (86 FR 61971 through 61984). We also made a number of updates and clarifications to the kidney disease patient education services waivers and made certain related flexibilities available to ETC Participants (86 FR 61984 through 61994). In the CY 2023 ESRD PPS final rule (87 FR 67136) we finalized further changes to the ETC Model. We updated the PPA achievement scoring methodology beginning in the fifth MY of the ETC Model, which began on January 1, 2023 (87 FR 67277 through 67278). We also clarified requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model's Medicare program waivers (87 FR 67278 through 67280) and finalized our intent to publish participant-level model performance information to the public (87 FR 67280). In the CY 2024 ESRD PPS final rule (88 FR 76344) we finalized a policy whereby an ETC Participant may seek administrative review of a targeted review determination provided by CMS.

B. Provisions of the Proposed Rule

We are proposing a modification to the definition of ESRD Beneficiary at 42 CFR 512.310 as that definition is used for the purposes of attributing beneficiaries to the ETC Model. As finalized in the Specialty Care Models final rule and codified at § 512.360, CMS retrospectively, that is, following a MY, attributes ESRD Beneficiaries and Pre-emptive Living Donor Transplant (LDT) Beneficiaries to an ETC Participant for each month during a MY. An ESRD Beneficiary may be attributed to an ETC Participant if the beneficiary has already had a kidney transplant and has a non-AKI dialysis or MCP claim less than 12 months after the beneficiary's transplant date and has a kidney transplant failure ICD–10

[103] ZIP code™ is a trademark of the United States Postal Service.

diagnosis code documented on any Medicare claim. Based on feedback from model participants, we became aware that the use of the ICD–10 code T86.12 to identify transplant failures may be incorrectly identifying beneficiaries for attribution to the ETC Model because a claim that is only coded with T86.12 may signify delayed graft function rather than a true transplant failure. To ensure that we are correctly identifying ESRD beneficiaries for the purposes of ETC Model ESRD Beneficiary attribution, we are proposing to modify our definition of an ESRD Beneficiary at § 512.310. Our regulations currently define an ESRD Beneficiary as a beneficiary that meets either of the following criteria: (1) is receiving dialysis or other services for end-stage renal disease, up to and including the month in which the beneficiary receives a kidney transplant up to and including the month in which the beneficiary receives a kidney transplant, or (2) has already received a kidney transplant and has a non-AKI dialysis or MCP claim at least 12-months after the beneficiary's latest transplant date; or less than 12-months after the beneficiary's latest transplant date and has a kidney transplant failure diagnosis code documented on any Medicare claim. We are proposing to modify the second criterion to specify that the beneficiary's latest transplant date must be identified by at least one of the following: (1) two or more MCP claims in the 180 days following the date on which the kidney transplant was received; (2) 24 or more maintenance dialysis treatments at any time after 180 days following the transplant date; or (3) indication of a transplant failure after the beneficiary's date of transplant based on data from the Scientific Registry of Transplant Recipients (SRTR). We are proposing that if a beneficiary meets more than one of these criteria, that CMS will consider that beneficiary an ESRD Beneficiary for the purposes of ETC model attribution starting with the earliest month in which the transplant failure was recorded. In our analysis of the proposed methodology for identifying transplant failures, we found that the use of all three criterion correctly identified more true transplant failures than did the use of T86.12 alone.

We considered a proposal to modify the language at 42 CFR 512.310 that an ESRD Beneficiary is a beneficiary that has already received a kidney transplant and has a non-AKI or MCP dialysis claim less than 12 months after the beneficiary's latest transplant date with kidney transplant failure diagnosis code documented on any Medicare claim. We considered removing the last clause; in other words, removing the specification that that the beneficiary must have a kidney transplant failure diagnosis code documented on any Medicare claim. We are not proposing this modification to the definition of an ESRD Beneficiary because doing so would preclude the possibility for a beneficiary to be attributed to the ETC Model for 12-months after a transplant, regardless of if the transplant failed. We are concerned that this scenario would reduce the number of attributed beneficiary-months that would be available for us to use to calculate the home dialysis and transplant rate for ETC Participants. We are soliciting comment on our proposal to modify the definition of an ESRD Beneficiary to more accurately identify beneficiaries that may be attributed to the ETC Model due to receiving a kidney transplant that fails within 12-months of its receipt.

C. Request for Information

1. Request for Information

In the Specialty Care Models final rule, we referenced a report from the Public Policy/Advocacy Committee of the North American Chapter of the International Society for Peritoneal Dialysis that describes barriers to increased adoption of home dialysis including educational barriers, the need for home care partner support, the monthly visit requirement for the Monthly Capitation Payment (MCP) under the Physician Fee Schedule, variations in dialysis business practices in staffing allocation, lack of home clinic independence, and other restrictions resulting in the inefficient distribution of home dialysis supplies (85 FR 61265).[104] The National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) controversies conference report, ''Overcoming Barriers for Uptake and Continued Use of Home Dialysis: An NKF–KDOQI Conference Report,'' describes clinical, operational, policy, and societal barriers to increased prescribing of and retention on home modalities. For example, lack of clinical confidence in prescribing home dialysis, lack of infrastructure, financial costs to patients associated with home modifications, the need for space to store home dialysis supplies, lack of housing, lack of appropriate education, care partner burnout, and patient fear of self-cannulation.[105]

Since the Specialty Care Models final rule was published, interested parties have spoken to us about challenges associated with increasing access to home dialysis, particularly among beneficiaries with lower socioeconomic status, who have lower rates of home dialysis and kidney transplantation than people with higher socioeconomic status. The ETC Model was designed to address these barriers; for example, CMS applied the Home Dialysis Payment Adjustment (HDPA) to assist dialysis organizations with overcoming market realities that impose substantial barriers to opening and sustaining home dialysis programs. The upside and downside risk associated with the Performance Payment Adjustment (PPA) are designed to be strong incentives for behavioral change towards increasing beneficiary access to home dialysis. In the CY 2022 ESRD PPS final rule, we finalized a policy whereby we stratify achievement benchmarks based on the proportion of attributed beneficiaries who are dual eligible for both Medicare and Medicaid or who receive the Low-Income Subsidy (LIS) (86 FR 61968). We also finalized the Health Equity Incentive (HEI), which rewards ETC Participant aggregation groups that demonstrate greater than 2.5 percentage points improvement on the home dialysis and transplant rate among dual eligible and LIS recipient beneficiaries from the Benchmark Year (BY) to the MY with a .5 increase in their improvement score (86 FR 61971).

Performance accountability in the ETC Model is scheduled to end on June 30, 2026. We are concerned that the end of performance accountability may reduce incentives for dialysis organizations to invest in access to home dialysis and address the challenges of the type we describe previously in this section. We are interested in hearing from interested parties regarding policies that the Innovation Center may consider specifically incorporating into any successor model to the ETC Model or that CMS may consider generally. Given the growth in ESRD beneficiaries choosing Medicare Advantage plans,[106]

[104] Golper TA, Saxena AB, Piraino B, Teitelbaum, I, Burkart, J, Finkelstein FO, Abu-Alfa A. Systematic Barriers to the Effective Delivery of Home Dialysis in the United States: A Report from the Public Policy/Advocacy Committee of the North American Chapter of the International Society for Peritoneal Dialysis. American Journal of Kidney Diseases. 2011; 58(6): 879–885.doi:10.1053/j.ajkd.2011.06.028.

[105] Chan, C.T., Collins, K., Ditschman, E.P., Koester-Wiedemann, L., Saffer, T.L., Wallace, E., & Rocco, M.V. (2020). Overcoming barriers for uptake and continued use of home dialysis: An NKF-Kdoqi Conference Report. American Journal of Kidney Diseases, 75(6), 926–934. *https://doi.org/10.1053/j.ajkd.2019.11.007*.

[106] Nguyen, K.H., Oh, E.G., Meyers, D.J., Kim, D., Mehrotra, R., & Trivedi, A.N. (2023). Medicare

we are particularly interested in policies that may encourage Medicare Advantage Organizations (MAOs) to improve beneficiary access to home dialysis modalities.

We are soliciting input on the following topics that may improve our understanding of other policy interventions that may increase access to high quality home dialysis within the context of Innovation Center models and across CMS.

1. How should any future Innovation Center model that incorporates home dialysis incorporate what the community has learned from the ETC Model?

2. What barriers to home dialysis could be addressed through the ESRD Prospective Payment System (PPS)? We request that commenters be as specific as possible.

3. What approaches could CMS consider to increase beneficiary access to home dialysis modalities in Medicare Advantage?

4. How should nephrologist payment from traditional, fee-for-service Medicare and from MAOs account for clinician-level barriers to prescribing and retaining patients on home modalities?

2. Exemption of the RFI From the Paperwork Reduction Act Implementing Regulations

Please note, this is a RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Respondents are encouraged to provide complete but concise responses. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the United States Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the United States Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. Please note that we will not respond to questions about the policy issues raised in this RFI. We may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the United States Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the United States Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become United States Government property and will not be returned. We may publicly post the comments received, or a summary thereof.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ESRD QIP—Wage Estimates (OMB Control Numbers 0938–1289 and 0938–1340)

We refer readers to the CY 2024 ESRD PPS final rule for information regarding wage estimates and resulting information collection burden calculations used in this proposed rule (88 FR 76484 through 76485). To derive wage estimates, we used data from the United States Bureau of Labor Statistics' May 2022 National Occupational Employment and Wage Estimates for Medical Records Specialists, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to the ESRD Quality Reporting System (EQRS) (formerly, CROWNWeb) and the Centers for Disease Control and Prevention's (CDC's) NHSN, as well as compiling and submitting patient records for the purpose of data validation. When this analysis was conducted, the most recently available median hourly wage of a Medical Records Specialist was $22.69 per hour.[107] We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. Using these assumptions, we estimated an hourly labor cost of $45.38 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP.

We used this wage estimate, along with updated facility and patient counts, to estimate the total information collection burden in the ESRD QIP for PY 2027 in the CY 2024 ESRD PPS final rule (88 FR 76485 through 76486). We will update the information collection burden to reflect updated wage estimates, along with updated facility and patient counts, in the CY 2025 ESRD PPS final rule.

B. Estimated Burden Associated With the Data Validation Requirements for PY 2027 (OMB Control Numbers 0938–1289 and 0938–1340)

We refer readers to the CY 2024 ESRD PPS final rule for information regarding the estimated burden associated with

advantage enrollment among beneficiaries with end-stage renal disease in the first year of the 21st Century Cures Act. *JAMA, 329*(10), 810. *https://doi.org/10.1001/jama.2023.1426.*

[107] *https://www.bls.gov/oes/2022/may/oes292072.htm.*

data validation requirements for PY 2027 (88 FR 76485 through 76486). In the CY 2024 ESRD PPS final rule, we estimated that the aggregate cost of the EQRS data validation for PY 2027 would be approximately $34,035 (750 hours × $45.38), or an annual total of approximately $113.45 ($34,035/300 facilities) per facility in the sample. We will update the aggregate cost of EQRS data validation to reflect updated wage estimates in the CY 2025 ESRD PPS final rule. The burden cost increase associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938–1289; Expiration date: November 30, 2025). We estimated that the aggregate cost of the NHSN data validation for PY 2027 would be approximately $68,070 (1,500 hours × $45.38), or a total of approximately $226.90 ($68,070/300 facilities) per facility in the sample. We will update the aggregate cost of NHSN data validation to reflect updated wage estimates in the CY 2025 ESRD PPS final rule. While the burden hours estimate would not change, the burden cost updates associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938–1340; Expiration date: November 30, 2025).

C. Estimated EQRS Reporting Requirements for PY 2027 (OMB Control Number 0938–1289)

To estimate the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to EQRS for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into EQRS, and the number of facilities submitting data to EQRS. In the CY 2024 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2027 ESRD QIP was approximately $130.5 million for approximately 2,877,743 total burden hours (88 FR 76486).

We are proposing changes to the ESRD QIP measure set in this proposed rule, but do not anticipate that any of these proposals would affect the burden we have previously estimated for EQRS reporting requirements for PY 2027. Beginning with PY 2027, we are proposing to replace the Kt/V Dialysis Adequacy Comprehensive measure with a Kt/V Dialysis Adequacy Measure Topic. However, we are not proposing to update facility reporting requirements as part of that proposal. Additionally, although we are proposing to remove one measure from the ESRD QIP measure set beginning with PY 2027, the proposed measure removal would not impact EQRS reporting requirements on facilities. We provided the burden estimate for PY 2027 in the CY 2024 ESRD PPS final rule (88 FR 76486), and will update the information collection burden to reflect updated wage estimates, along with updated facility and patient counts, in the CY 2025 ESRD PPS final rule. In the CY 2024 ESRD PPS final rule, we estimated that the amount of time required to submit measure data to EQRS would be 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. There are 136 data elements for 507,837 patients across 7,833 facilities, for a total of 69,065,832 elements (136 data elements × 507,837 patients). At 2.5 minutes per element, this would yield approximately 367.3 hours per facility. Therefore, the PY 2027 burden would be 2,877,743 hours (367.3 hours × 7,833 facilities). Using the Medical Records Specialist wage estimate available at that time, we estimated that the PY 2027 total burden cost would be approximately $130.5 million (2,877,743 hours × $45.38). We intend to re-calculate the burden estimate for PY 2027, using updated estimates of the total number of ESRD facilities, the total number of patients nationally, and wages for Medical Records Specialists or similar staff, as well as a refined estimate of the number of hours needed to complete data entry for EQRS reporting in the CY 2025 ESRD PPS final rule. The information collection request under the OMB Control Number: 0938–1289 will be revised and sent to OMB.

D. ESRD Treatment Choices Model

Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the ETC Model, from the provisions of the PRA. Specifically, this section provides that the provisions of the PRA do not apply to the testing and evaluation of Innovation Center models or to the expansion of such models.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by August 26, 2024.

VII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VIII. Regulatory Impact Analysis

A. Statement of Need

1. ESRD PPS

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Affordable Care Act (Pub. L. 111–148), established that beginning CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This proposed rule includes proposed updates and policy changes to the ESRD PPS for CY 2025. These changes include a proposed new wage index methodology which utilizes BLS data, a proposed wage index budget-neutrality adjustment factor, a proposed expansion to the ESRD PPS outlier list, proposed methodological changes to the outlier calculation, proposed updates to the TPNIES offset amount, proposed updates to the post-TDAPA add-on payment adjustment amounts for Korsuva® and Jesduvroq, and proposed changes to the LVPA payment structure. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2025 for renal dialysis services furnished to ESRD beneficiaries.

This proposed rule also has several proposed policy changes to improve payment stability and adequacy under the ESRD PPS. These include updates to the LVPA and payments for ESRD outlier services. We believe that each of these proposed changes would improve payment stability and adequacy under the ESRD PPS.

2. AKI

This rule proposes updates to the payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI. Additionally, we are proposing to extend Medicare payment for home dialysis to beneficiaries with AKI. As discussed in section III.C of this proposed rule, we are also proposing to apply the updates to the ESRD PPS base rate and wage index to the AKI dialysis payment rate. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2025 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

3. ESRD QIP

Section 1881(h)(1) of the Act requires CMS to reduce the payments otherwise made to a facility under the ESRD PPS by up to two percent if the facility does not satisfy the requirements of the ESRD QIP for that year. This rule proposes updates for the ESRD QIP, which would remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set beginning with PY 2027 and replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027.

4. ETC Model

The ETC Model is a mandatory Medicare payment model tested under the authority of section 1115A of the Act, which authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs.

This proposed rule proposes a change to the ETC Model, specifically to the methodology CMS uses to identify transplant failures for the purposes of defining an ESRD beneficiary and attributing an ESRD beneficiary to the ETC Model. As described in detail in section V.B of this proposed rule, we believe it is necessary, for the purposes of accuracy, to adopt this change to the ETC Model.

B. Overall Impact

We have examined the impacts of this proposed rule as required by 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, entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the 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). Executive Order 14094 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: (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 OMB's Office of Information and Regulatory Affairs (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) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1). Based on our estimates of the combined impact of the ESRD PPS, ESRD QIP, and ETC provisions in this proposed rule, OIRA has determined this rulemaking is significant per section 3(f)(1). Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has also determined that this proposed rule meets the criteria set forth in 5 U.S.C. 804(2). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed these proposed regulations, and the Department has provided the following assessment of their impact.

C. Impact Analysis

1. ESRD PPS

We estimate that the proposed revisions to the ESRD PPS would result in an increase of approximately $170 million in Medicare payments to ESRD facilities in CY 2025, which includes the amount associated with updates to the outlier list, updates to the outlier methodology and thresholds, payment rate update, updates to the wage index methodology, updates to the OMB CBSA delineations, proposed changes to the LVPA, the updated post-TDAPA add-on payment adjustment amounts, and continuation of the approved TDAPA as identified in table 18. Although the incorporation of oral-only renal dialysis drugs and biological products into the ESRD PPS in CY 2025 is provided for by existing regulations and is not impacted by this proposed rule, we estimate for reference that total ESRD PPS spending for phosphate binders will be approximately $870 million in CY 2025 ($220 million in beneficiary coinsurance payments and $650 million in Medicare Part B spending); however we note that these drugs are currently being paid for under Medicare Part D, which we estimate will lead to a decrease in spending of approximately $690 million ($90 million in beneficiary premium offset and $600 million in Medicare Part D spending), for a net payment increase of $180 million.

2. AKI

We estimate that the proposed updates to the AKI payment rate would result in an increase of approximately $1 million in Medicare payments to ESRD facilities in CY 2025.

3. ESRD QIP

We estimate that, as a result of our previously finalized policies and the policies we are proposing in this proposed rule, the updated ESRD QIP will result in $14.6 million in estimated payment reductions across all facilities for PY 2027.

4. ETC Model

The change we are proposing to the definition of an ESRD Beneficiary for the purposes of attribution in the ETC Model is not expected to change the model's projected economic impact.

5. Summary of Impacts

We estimate that the combined impact of the policies proposed in this rule on payments for CY 2025 is $170 million based on the estimates of the updated ESRD PPS and the AKI payment rates. We estimate the impacts of the ESRD

QIP for PY 2027 to be $130.5 million in information collection burden and $14.6 million in estimated payment reductions across all facilities. Finally, we estimate that the proposed methodology change to the ETC Model would not affect the model's projected economic impact described in the Specialty Care Models final rule (85 FR 61114) and in the CY2022 ESRD PPS final rule (86 FR 61874).

D. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes in this proposed rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this proposed rule.

1. Benefits

Under the CY 2025 ESRD PPS and AKI payment, ESRD facilities would continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective Medicare payments to ESRD facilities would enhance the efficiency of the Medicare program. Additionally, we expect that updating the Medicare ESRD PPS base rate and rate for AKI treatments furnished by ESRD facilities by 1.8 percent based on the proposed CY 2025 ESRDB market basket percentage increase of 2.3 percent reduced by the proposed CY 2025 productivity adjustment of 0.5 percentage point would improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services. We estimate that overall payments under the ESRD PPS would increase by 2.2 percent as a result of the proposed policies in this rule.

2. Costs

a. ESRD PPS and AKI

We do not anticipate the provisions of this proposed rule regarding ESRD PPS and AKI rates-setting would create additional cost or burden to ESRD facilities.

b. ESRD QIP

We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for EQRS data validation (previously known as the CROWNWeb validation study) or NHSN data validation. Although we do not anticipate that the proposals in this proposed rule regarding ESRD QIP will create additional cost or burden to ESRD facilities for PY 2027, in the CY 2025 ESRD PPS final rule, we intend to update the estimated costs associated with the information collection requirements under the ESRD QIP, with updated estimates of the total number of ESRD facilities, the total number of patients nationally, wages for Medical Records Specialists or similar staff, and a refined estimate of the number of hours needed to complete data entry for EQRS reporting.

3. Transfers

We estimate that the updates to the ESRD PPS and AKI payment rates would result in a total increase of approximately $170 million in Medicare payments to ESRD facilities in CY 2025, which includes the amount associated with proposed updates to the outlier thresholds, and proposed updates to the wage index. This estimate includes an increase of approximately $1 million in Medicare payments to ESRD facilities in CY 2025 due to the updates to the AKI payment rate, of which approximately 20 percent is increased beneficiary coinsurance payments. We estimate approximately $140 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately $30 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary coinsurance payments because of this proposed rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this ESRD PPS proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the ESRD PPS proposed rule, we assume that the total number of unique commenters on last year's ESRD PPS proposed rule, which was 256 for the CY 2024 ESRD PPS proposed rule, is equal to the number of individual reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the CY 2024 ESRD PPS proposed rule. For these reasons we determined that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of this proposal. We seek comments on this assumption.

Using the May 2023 wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $129.28 per hour, including overhead and fringe benefits [108] (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 160 minutes (2.67 hours) for the staff to review half of this proposed rule, which has a total of approximately 80,000 words. For each entity that reviews the rule, the estimated cost is $345.18 (2.67 hours × $129.28). Therefore, we estimate that the total cost of reviewing this regulation is $88,366.08 ($345.18 × 256).

5. Impact Statement and Table

a. CY 2025 End-Stage Renal Disease Prospective Payment System

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting Medicare payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2024 to estimated payments in CY 2025. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of Medicare payments in CY 2024 and CY 2025 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this proposed rule, we used CY 2023 data from the Medicare Part A and Part B Common Working Files as of February 16, 2024, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2023 claims to 2024 and 2025 using various updates. The proposed updates to the ESRD PPS base rate are described in section II.B.4 of this proposed rule. Table 18 shows the impact of the estimated CY 2025 ESRD

[108] Calculated by multiplying the mean wage for medical and health service managers by 2 to account for overhead and fringe benefits.

PPS payments compared to estimated Medicare payments to ESRD facilities in CY 2024.

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TABLE 18: Impacts of the Proposed Changes in Medicare Payments to ESRD Facilities for CY 2025

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Routine Changes to Outlier Policy (C)	Proposed LVPA Changes (D)	Proposed Changes to TDAPA and Post-TDAPA Payments[1] (E)	Proposed Addition of Composite Rate Drugs to Outlier Services (F)	Proposed Wage Index Methodology Changes and updates to the CBSA delineations (G)	Total Percent Change[2] (H)
All Facilities	7,695	27.0	0.4%	0.0%	0.1%	-0.1%	0.0%	2.2%
Type								
Freestanding	7,348	26.0	0.3%	0.0%	0.1%	-0.1%	0.0%	2.1%
Hospital-based	347	1.0	1.1%	0.0%	0.0%	0.4%	0.5%	3.9%
Ownership Type								
Large dialysis organization	5,942	21.1	0.3%	0.0%	0.1%	-0.1%	0.2%	2.3%
Regional chain	908	3.3	0.4%	0.0%	0.2%	-0.1%	-0.3%	1.9%
Independent	461	1.6	0.5%	0.0%	0.1%	-0.1%	-1.6%	0.5%
Hospital-based	347	1.0	1.1%	0.0%	0.0%	0.4%	0.5%	3.9%
Unknown	37	0.0	0.3%	0.0%	0.1%	-0.1%	-3.1%	-1.1%
Geographic Location								
Rural	1,245	3.8	0.3%	0.0%	0.1%	0.0%	1.5%	3.7%
Urban	6,450	23.2	0.4%	0.0%	0.1%	-0.1%	-0.2%	2.0%
Census Region								
East North Central	1,188	3.6	0.3%	0.0%	0.1%	-0.1%	0.1%	2.3%
East South Central	602	1.7	0.3%	0.0%	0.1%	-0.1%	2.1%	4.2%
Middle Atlantic	870	3.4	0.5%	0.0%	0.1%	-0.1%	-1.0%	1.2%
Mountain	438	1.5	0.3%	0.0%	0.1%	-0.1%	1.7%	3.9%
New England	199	1.0	0.3%	0.1%	0.1%	0.0%	1.9%	4.2%

Pacific[3]	981	4.9	0.4%	0.0%	0.1%	-0.1%	-2.1%	0.0%
Puerto Rico and Virgin Islands	54	0.1	0.3%	0.0%	0.1%	-0.1%	3.1%	5.2%
South Atlantic	1,793	5.9	0.4%	0.0%	0.1%	-0.1%	0.8%	3.0%
West North Central	475	1.5	0.4%	0.0%	0.1%	0.0%	-0.2%	2.1%
West South Central	1,095	3.5	0.4%	0.0%	0.1%	-0.1%	1.0%	3.2%
Facility Size								
Less than 3,000 treatments	763	0.8	0.4%	0.7%	0.1%	0.2%	0.3%	3.4%
3,000 to 3,999 treatments	444	0.7	0.3%	-0.8%	0.1%	0.0%	0.5%	1.9%
4,000 to 4,999 treatments	582	1.1	0.4%	0.0%	0.1%	-0.1%	0.5%	2.7%
5,000 to 9,999 treatments	2,879	8.1	0.4%	0.0%	0.1%	-0.1%	0.7%	2.9%
10,000 or more treatments	3,027	16.3	0.4%	0.0%	0.1%	-0.1%	-0.4%	1.8%
Unknown	0	0.0	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Percentage of Pediatric Patients								
Less than 2%	7,601	26.9	0.4%	0.0%	0.1%	-0.1%	0.0%	2.2%
Between 2% and 19%	31	0.1	0.4%	0.0%	0.1%	0.0%	1.4%	3.7%
Between 20% and 49%	8	0.0	0.0%	0.2%	0.1%	1.3%	-0.3%	3.1%
More than 50%	55	0.0	-0.3%	0.0%	0.1%	0.5%	0.1%	2.3%

[1]This column includes the impact of the end of TDAPA payment for Jesduvroq and the proposed post-TDAPA add-on payment adjustment amounts for both Korsuva® and Jesduvroq (beginning October 1, 2025). This column does not include the TDAPA for phosphate binders.

[2] This column includes the impact of the final updates in columns (C) through (F) in table 18, and of the ESRDB proposed market basket percentage increase for CY 2025 of 2.3 percent, reduced by 0.5 percentage point for the proposed productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the proposed routine updates to the outlier payment policy, including proposed changes to the inflation factors used for calculating MAP and FDL amounts described in section II.B.3 of this proposed rule, is shown in column C. For CY 2025, the impact on all ESRD facilities because of the proposed changes to the outlier payment policy would be an increase in estimated Medicare payments of approximately 0.4 percent.

Column D shows the effect of the proposed 2-tiered LVPA as described in section II.B.8 of this proposed rule. This adjustment is implemented in a budget neutral manner, so the total impact of this proposed change would be 0.0 percent. However, there would be distributional impacts of this change, if finalized, primarily increasing payments to facilities that furnish fewer than 3000 treatments by 0.8 percent and lowering payments to ESRD facilities that furnish between 3000 and 4000 treatments by 0.7 percent. Because we are proposing to use the scaled adjustment factors, the only impact of this proposed policy is among ESRD facilities that are eligible for the LVPA.

Column E shows the effect of year-over-year payment changes related to the proposed post-TDAPA add-on payment adjustment amounts as described in section II.B.6 of this proposed rule and current TDAPA payments. The post-TDAPA add-on payment adjustment will not be budget neutral, but the total impact on payment is 0.1 percent due to relatively low utilization of drugs for which we will pay this adjustment in CY 2025.

Column F reflects the impact of the proposed expansion of outlier eligibility to formerly composite rate drugs. Overall the proposed changes to the outlier policy, including those reflected in column C of this table, are budget neutral insofar as we estimate that we would better hit the 1 percent target for outlier payments. These proposed changes would increase payments for facilities that treat a higher proportion of exceptionally costly cases.

Column G reflects the effect of the proposed changes to the ESRD PPS wage index methodology, the proposed adoption of the new OMB CBSA delineations, the continued application of the 5 percent cap on wage index decreases, and the proposed rural transition policy as described in section II.B.2 of this proposed rule. This proposed update would be budget neutral, so the total impact of this proposed policy change is 0.0 percent. However, there would be distributional impacts of this proposed change, if finalized. The largest increase would be to ESRD facilities in Puerto Rico and the Virgin Islands, which would receive 3.1 percent higher payments because of the

proposed updated ESRD PPS wage index. The largest decrease would be for pacific ESRD facilities, which would receive 2.1 percent lower payments because of the updated ESRD PPS wage index and methodological changes.

Column H reflects the overall impact, that is, the effects of the proposed outlier policy changes, proposed LVPA changes, the proposed post-TDAPA add-on payment adjustment amounts, the proposed new wage index methodology, the proposed new CBSA delineations, the proposed rural transition policy, and the proposed payment rate update as described in section II.B.4 of this proposed rule. The proposed ESRD PPS payment rate update for CY 2025 is 1.8 percent, which reflects the proposed ESRDB market basket percentage increase for CY 2025 of 2.3 percent and the proposed productivity adjustment of 0.5 percent. We expect that overall ESRD facilities would experience a 2.2 percent increase in estimated Medicare payments in CY 2025. The categories of types of ESRD facilities in the impact table show impacts ranging from a 0.0 percent increase to a 5.2 percent increase in their CY 2025 estimated Medicare payments.

This table does not include the impact of the inclusion of oral-only drugs to the ESRD PPS as we are unable to calculate facility level estimates at this time. Furthermore, we note that the incorporation of oral-only renal dialysis drugs and biological products into the ESRD PPS in CY 2025 is provided for by existing regulations and is not impacted by this proposed rule. For public awareness, we estimate an increase in Medicare Part B spending of approximately $870 million in CY 2025, and a corresponding decrease in Medicare Part D spending of approximately $690 million in CY 2025, associated with payment for phosphate binders under the ESRD PPS.

(2) Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2025, we estimate that the ESRD PPS would have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2025 would be approximately $7.2 billion. This estimate considers a projected decrease in fee-for-service Medicare ESRD beneficiary enrollment of 2.1 percent in CY 2025.

(4) Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 2.2 percent overall increase in the CY 2025 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary coinsurance payments of 2.2 percent in CY 2025, which translates to approximately $30 million.

As we have previously noted, the incorporation of oral-only renal dialysis drugs and biological products into the ESRD PPS in CY 2025 is provided for by existing regulations and is not impacted by this proposed rule. For public awareness, we estimate an increase in beneficiary coinsurance payments of $220 million. As noted in section II.B.7 of this proposed rule, we anticipate that the inclusion of oral-only drugs in the ESRD PPS will increase access to these drugs for beneficiaries, particularly disadvantaged populations who currently do not have Part D coverage.

(5) Alternatives Considered

(a) Proposed Wage Index Changes

We considered several alternatives for the proposed new wage index methodology discussed in section II.B.2 of this proposed rule. We considered both alternatives for the data sources we propose to use for the new wage index methodology and construction of the wage index itself. These alternatives include using confidential BLS data instead of the publicly available data, using different occupation codes for the occupations included in the analysis than those chosen, the use of state-level or regional occupational mixes instead of a single national occupational mix, an alternative or additional phase-in policy for the wage index methodology change, setting the NEFOM annually through rulemaking instead of as a part of the wage index methodology, and the use of a summary statistic other than mean hourly wage for the BLS OEWS data (such as the median). These alternatives and the reasons we did not propose them are discussed in further detail in section II.B.2.b.(c) of this proposed rule.

(b) Expansion of Outlier Eligibility

We considered only expanding outlier eligibility to drugs and biological products previously paid for under the TDAPA after the end of the TDAPA period. As discussed in section II.B.3.b of this proposed rule, we have instead decided to propose to expand outlier eligibility to all drugs and biological products that were or would have been composite rate services prior to the inception of the ESRD PPS.

(c) TDAPA for Phosphate Binders

We considered, but did not propose, paying the TDAPA for phosphate binders based on an amount greater than 100 percent of ASP, to account for additional costs such as dispensing fees. For example, we considered paying the TDAPA for phosphate binders at 106 percent of ASP for at least 2 years to mirror our TDAPA payment approach for the first 2 years for calcimimetics. However, as discussed in section II.B.7.c of this proposed rule, we believe that it is most appropriate to use the current standard TDAPA payment amount of 100 percent of ASP for phosphate binders. We are soliciting comments on this policy and may consider finalizing changes in the final rule.

(d) Proposed Changes to the LVPA

We considered, but did not propose, expanding LVPA eligibility to ESRD facilities which furnished more than 4000 treatments in one of the past 3 years whose median treatment volume over the past 3 years was less than 4000. However, we felt that this would be inappropriate as the purpose of this proposed change is to better allocate payments within the LVPA, not to expand the LVPA. Additionally, using the median tier methodology for LVPA eligibility would reduce the LVPA payments for ESRD facilities that would qualify under the current methodology by a notable amount due to the lower scaling factor. As discussed in section II.B.8.c of this proposed rule, we are not proposing any changes to the LVPA eligibility requirements at 42 CFR 413.232(b).

b. Continuation of Approved Transitional Drug Add-On Payment Adjustments (TDAPA) for New Renal Dialysis Drugs or Biological Products for CY 2025

Two renal dialysis drugs for which the TDAPA was paid in CY 2024 would continue to be eligible for the TDAPA in CY 2025.

(1) Jesduvroq (Daprodustat)

On July 27, 2023, CMS Transmittal 12157 [109] implemented the 2-year TDAPA period specified in § 413.234(c)(1) for Jesduvroq (daprodustat). The TDAPA payment period began on October 1, 2023, and will continue through September 30,

[109] CMS Transmittal 12157, dated July 27, 2023, is available at: *https://www.cms.gov/files/document/r12157cp.pdf.*

2025. As stated previously, TDAPA payment is based on 100 percent of ASP. If ASP is not available, then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

We based our impact analysis on the most current 72x claims data from November 2023, when utilization first appeared on the claims, through February 2024. During that timeframe, the average monthly TDAPA payment amount for Jesduvroq (daprodustat) was $23,075. In applying that average to each of the 9 remaining months of the TDAPA payment period in CY 2025, we estimate $207,675 in spending ($23,075 * 9 = $207,675) of which, approximately $41,535 ($207,675 * 0.20 = $41,535) would be attributed to beneficiary coinsurance amounts.

(2) DefenCath® (Taurolidine and Heparin Sodium)

On May 9, 2024, CMS Transmittal 12628 [110] implemented the 2-year TDAPA period specified in § 413.234(c)(1) for DefenCath® (taurolidine and heparin sodium). The TDAPA payment period will begin on July 1, 2024, and will continue through June 30, 2026.

We have not included Medicare impact estimates in this proposed rule but intend to update the impact estimates to include DefenCath in the CY 2025 ESRD PPS final rule.

c. Payment for Renal Dialysis Services Furnished to Individuals With AKI

(1) Effects on ESRD Facilities

To understand the impact of the proposed changes affecting Medicare payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated Medicare payments in CY 2024 to estimated Medicare payments in CY 2025. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the Medicare payment estimates in CY 2024 and CY 2025 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this proposed rule, we used CY 2023 data from the Medicare Part A and Part B Common Working Files as of February 16, 2024, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2023 claims to 2024 and 2025 using various updates. The updates to the AKI payment amount are described in section III.C of this proposed rule. Table 19 shows the impact of the estimated CY 2025 Medicare payments for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for renal dialysis services furnished to individuals with AKI in CY 2024.

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[110] CMS Transmittal 12628, dated May 9, 2024, is available at: *https://www.cms.gov/files/document/r12628CP.pdf.*

TABLE 19: Impacts of the Proposed Changes in Medicare Payments for Renal Dialysis Services Furnished to Individuals with AKI for CY 2025

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Proposed Wage Index Changes (C)	Total Percent Change[1] (D)
All Facilities	5,036	279.0	0.1%	1.9%
Type				
Freestanding	4,937	274.6	0.1%	1.9%
Hospital-based	99	4.3	0.8%	2.6%
Ownership Type				
Large dialysis organization	4,186	231.4	0.2%	2.0%
Regional chain	561	30.2	-0.1%	1.7%
Independent	179	12.8	-1.2%	0.6%
Hospital-based[2]	99	4.3	0.8%	2.6%
Unknown	11	0.3	-2.9%	-1.1%
Geographic Location				
Rural	819	44.3	1.5%	3.3%
Urban	4,217	234.7	-0.1%	1.7%
Census Region				
East North Central	829	43.9	0.3%	2.1%
East South Central	375	17.1	1.9%	3.7%
Middle Atlantic	566	31.4	-0.6%	1.1%
Mountain	310	20.7	0.4%	2.2%
New England	139	7.0	1.7%	3.5%
Pacific[3]	641	47.8	-1.7%	0.0%
Puerto Rico and Virgin Islands	4	0.1	-1.0%	0.8%
South Atlantic	1,184	66.7	1.1%	2.9%
West North Central	322	13.1	-0.3%	1.5%
West South Central	666	31.2	1.0%	2.9%
Facility Size				
Less than 3,000 treatments	280	10.9	0.1%	1.9%
3,000 to 3,999 treatments	250	9.9	0.6%	2.4%
4,000 to 4,999 treatments	336	14.2	0.5%	2.3%

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Proposed Wage Index Changes (C)	Total Percent Change[1] (D)
5,000 to 9,999 treatments	1,968	99.3	0.6%	2.4%
10,000 or more treatments	2,202	144.6	-0.3%	1.5%
Unknown	0	0.0	0.0%	0.0%
Percentage of Pediatric Patients				
Less than 2%	5,023	278.5	0.1%	1.9%
Between 2% and 19%	10	0.4	1.8%	3.6%
Between 20% and 49%	2	0.1	-0.2%	1.6%
More than 50%	1	0.0	0.6%	2.4%

[1] This column includes the impact of the proposed updates in columns (C) as well as the impact of the wage index budget-neutrality adjustment factor in table 19, and of the proposed ESRDB market basket percentage increase for CY 2025 of 2.3 percent, reduced by 0.5 percentage point for the proposed productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

[2] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category, and column B indicates the number of AKI dialysis treatments (in thousands). Column C shows the effect of the proposed CY 2025 wage index changes, including the proposed changes to the ESRD PPS wage index methodology, the proposed adoption of the new OMB CBSA delineations, the continued application of the 5 percent cap on wage index decreases, and the proposed rural transition policy as described in section II.B.2.f.(2) of this proposed rule.

Column D shows the overall impact, that is, the effects of the proposed wage index budget-neutrality adjustment factor, wage index updates, and the payment rate update of 1.8 percent, which reflects the proposed ESRDB market basket percentage increase for CY 2025 of 2.3 percent and the proposed productivity adjustment of 0.5 percentage point. We expect that overall ESRD facilities will experience a 1.9 percent increase in estimated Medicare payments in CY 2025 for treatment of AKI patients. This table does not include any distributional impacts of payments to ESRD facilities associated with the extension of payment for AKI home dialysis or extension of the add-on payment adjustment for training for home and self-dialysis, as we are unable to estimate potential uptake at a facility level at this time. However, we note that because the implementation of that adjustment would be required by section 1834(r)(1) of the Act to be budget neutral, we are considering whether it would be appropriate to apply a reduction to the AKI dialysis payment rate for budget neutrality, which could result in distributional payment changes in the future. The categories of types of ESRD facilities in the impact table show impacts ranging from an increase of 0.0 percent to an increase of 3.7 percent in their CY 2025 estimated Medicare payments for renal dialysis services provided by ESRD facilities to individuals with AKI.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are proposing to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this change would have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately $70 million would be paid to ESRD facilities in CY 2025 because of patients with AKI receiving renal dialysis services in an ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

(4) Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent coinsurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients will continue to be responsible for a 20 percent coinsurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment

amount, we expect beneficiaries to pay less coinsurance when AKI dialysis is furnished by ESRD facilities.

(5) Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD, and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients, and as such, including those policies and adjustments is inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring will assist us in developing knowledgeable, data-driven proposals.

As discussed in section III.B of this proposed rule, we are proposing to allow for payment for AKI dialysis in the home setting, and as discussed in section III.C.3 of this proposed rule we are proposing to apply the home and self-dialysis training add-on payment adjustment for such services provided to AKI patients. We considered proposing to pay for AKI home dialysis without the training add-on adjustment; however, we are concerned that access to home dialysis for AKI beneficiaries could be negatively impacted in the absence of an add-on payment adjustment to support home dialysis training.

d. ESRD QIP

(1) Effects of the PY 2027 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to promote improvements in the quality of ESRD dialysis facility services provided to beneficiaries. The general methodology that we use to calculate a facility's TPS is described in our regulations at § 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2027 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2027, consistent with our regulations at § 413.177.

For the PY 2027 ESRD QIP, we estimate that, of the 7,833 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 28.3 percent or 2,214 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2027. Among an estimated 2,214 facilities that would receive a payment reduction, approximately 65 percent or 1,443 facilities would receive the smallest payment reduction of 0.5 percent. We are updating the estimated impact of the PY 2027 ESRD QIP that we provided in the CY 2024 ESRD PPS final rule (88 FR 76495 through 76497). Based on our proposals, the total estimated payment reductions for all the 2,214 facilities expected to receive a payment reduction in PY 2027 would be approximately $14,647,335. Facilities that do not receive a TPS do not receive a payment reduction.

Table 20 shows the updated overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP.

TABLE 20: Estimated Distribution of PY 2027 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5346	70.7%
0.5%	1443	19.1%
1.0%	552	7.3%
1.5%	168	2.2%
2.0%	51	0.7%

*273 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2027, we scored each facility on achievement and improvement on several clinical measures for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in table 21) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in table 21.

TABLE 21: Data Used to Estimate PY 2027 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2019-Dec 2019	Jan 2022-Dec 2022
SRR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
SHR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
PPPW	Jan 2019-Dec 2019	Jan 2022-Dec 2022
Kt/V Dialysis Adequacy Measure Topic		
Adult HD Kt/V	Jan 2019-Dec 2019	Jan 2022-Dec 2022
Pediatric HD Kt/V	Jan 2019-Dec 2019	Jan 2022-Dec 2022
Adult PD Kt/V	Jan 2019-Dec 2019	Jan 2022-Dec 2022
Pediatric PD Kt/V	Jan 2019-Dec 2019	Jan 2022-Dec 2022
VAT		
% Catheter	Jan 2019-Dec 2019	Jan 2022-Dec 2022
STrR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
NHSN BSI	Jan 2019-Dec 2019	Jan 2022-Dec 2022
Clinical Depression	Jan 2021-Dec 2021	Jan 2022-Dec 2022

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility's TPS. For the STrR clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table consistent with the proposed policies outlined in section IV.B of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2022. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2027 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2022 and December 2022 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 22 shows the estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2027. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2027 ESRD QIP, the actual impact of the PY 2027 ESRD QIP may vary significantly from the values provided here.

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TABLE 22: Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2027

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,833	29.8	7,560	2,214	-0.21%
Facility Type:					
Freestanding	7,481	28.6	7,231	2,077	-0.20%
Hospital-based	352	1.1	329	137	-0.35%
Ownership Type:					
Large Dialysis	6,068	23.2	5,881	1,454	-0.15%
Regional Chain	901	3.6	877	335	-0.30%
Independent	451	1.7	434	272	-0.67%
Hospital-based (non-chain)	352	1.1	329	137	-0.35%
Unknown	61	0.0	39	16	-0.32%
Facility Size:					
Large Entities	6,969	26.9	6,758	1,789	-0.17%
Small Entities[1]	803	2.9	763	409	-0.53%
Unknown	61	0.0	39	16	-0.32%
Rural Status:					
1) Yes	1,264	4.2	1,211	264	-0.15%
2) No	6,569	25.6	6,349	1,950	-0.22%
Census Region:					
Northeast	1,093	4.7	1,049	307	-0.22%
Midwest	1,718	5.7	1,649	475	-0.21%
South	3,555	12.5	3,439	1,102	-0.23%
West	1,404	6.6	1,362	303	-0.15%
US Territories[2]	63	0.2	61	27	-0.26%
Census Division:					
Unknown	11	0.1	10	5	-0.40%
East North Central	1,223	4.0	1,176	362	-0.22%
East South Central	616	2.0	593	171	-0.19%
Middle Atlantic	893	3.7	853	269	-0.24%
Mountain	438	1.6	429	98	-0.16%
New England	200	1.0	196	38	-0.14%
Pacific	966	5.0	933	205	-0.14%
South Atlantic	1,820	6.5	1,758	619	-0.27%
West North Central	495	1.7	473	113	-0.17%
West South Central	1,119	4.0	1,088	312	-0.21%
US Territories[2]	52	0.1	51	22	-0.23%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,267	1.5	1,099	332	-0.27%
4,000-9,999 treatments	3,294	9.2	3,203	815	-0.18%
Over 10,000 treatments	3,272	19.0	3,258	1,067	-0.22%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on EQRS.
[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

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(2) Effects on the Medicare Program

For PY 2027, we estimate that the ESRD QIP would contribute approximately $14,647,335 in Medicare savings. For comparison, table 23 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2027.

TABLE 23: Estimated ESRD QIP Aggregate Payment Reductions for Payment Years 2018 through 2027

Payment Year	Estimated Payment Reductions
PY 2027	$14,647,335
PY 2026	$15,990,524 (88 FR 76500)
PY 2025	$32,457,693 (87 FR 67297)
PY 2024	$17,104,031 (86 FR 62011)
PY 2023	$5,548,653 (87 FR 67297)
PY 2022	$0[111] (86 FR 62011)
PY 2021	$32,196,724 (83 FR 57062)
PY 2020	$31,581,441 (81 FR 77960)
PY 2019	$15,470,309 (80 FR 69074)
PY 2018	$11,576,214 (79 FR 66257)

(3) Effects on Medicare Beneficiaries

The ESRD QIP is applicable to ESRD facilities. Since the Program's inception, there is evidence of improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We continue to monitor and evaluate trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more by examining these impacts through the analysis of available data from our existing measures.

(4) Alternatives Considered

In section IV.B.2 of this proposed rule, we are proposing to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027. We considered not proposing this change. However, we concluded that replacing this measure was appropriate to ensure that facilities are scored on Kt/V measure data according to the individual facility's ESRD patient population and treatment modalities.

e. ETC Model

(1) Overview

The ETC Model is a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in the Specialty Care Models final rule (85 FR 61114), the CY 2022 ESRD PPS final rule (86 FR 61874), the CY 2023 ESRD PPS final rule (87 FR 67136), and the CY 2024 ESRD PPS final rule (88 FR 76344) for ESRD facilities and for Managing Clinicians for claims with dates of service from January 1, 2021, to June 30, 2027. The requirements for the ETC Model are set forth in 42 CFR part 512, subpart C. For the results of the detailed economic analysis of the ETC Model and a description of the methodology used to perform the analysis, see the Specialty Care Models final rule (85 FR 61114).

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the ETC Model relative to baseline expenditures, where baseline expenditures were defined as data from CYs 2018 and 2019 without the changes applied. The simulation relied upon statistical assumptions derived from retrospectively constructed ESRD facilities' and Managing Clinicians' Medicare dialysis claims, transplant claims, and transplant waitlist data reported during 2018 and 2019, the most recent years of complete data available before the start of the ETC Model. Both datasets and the risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary (OACT).

Table 24 summarizes the estimated impact of the ETC Model when the achievement benchmarks for each year are set using the average of the home dialysis rates for year *t*-1 and year *t*-2 for the HRRs randomly selected for participation in the ETC Model. We estimate that the Medicare program would save a net total of $43 million from the PPA and HDPA between January 1, 2021, and June 30, 2027, less $15 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be $28 million in savings. This is consistent with the net impact to Medicare spending estimated for the CY 2022 ESRD PPS final rule, in which the net impact to Medicare spending was also estimated to be $28 million in savings (86 FR 62014 through 62016). The minor methodological change to the definition of an ESRD Beneficiary is not expected to change this estimate.

(3) Medicare Estimate—Primary Specification, Assume Rolling Benchmark

[111] In the CY 2022 ESRD PPS final rule, we adopted a special scoring methodology and payment policy for PY 2022 due to significant impacts related to the COVID–19 public health emergency (86 FR 61918 through 61919). Under this policy, we did not apply any payment reductions to ESRD facilities for PY 2022.

TABLE 24: Estimates of Medicare Program Savings (Rounded $M) for ESRD Treatment Choices (ETC) Model

	Year of Model							
	2021	2022	2023	2024	2025	2026	2027	6.5 Year Total*
Net Impact to Medicare Spending	15	9	-1	-9	-12	-19	-9	-28
Overall PPA Net & HDPA	14	7	-3	-11	-15	-22	-12	-43
Clinician PPA Downward Adjustment		-1	-2	-2	-3	-3	-2	-13
Clinician PPA Upward Adjustment		0	1	1	1	1	1	6
Clinician PPA Net		0	-1	-1	-2	-2	-1	-7
Clinician HDPA	0	0	0					0
Facility Downward Adjustment		-9	-20	-25	-31	-39	-21	-145
Facility Upward Adjustment		5	12	15	18	19	10	79
Facility PPA Net		-3	-8	-10	-14	-20	-11	-66
Facility HDPA	14	10	6					29
Total PPA Downward Adjustment		-9	-22	-27	-34	-43	-23	-158
Total PPA Upward Adjustment		6	13	16	19	21	11	84
Total PPA Net		-4	-9	-11	-15	-22	-12	-73
Total HDPA	14	10	6					30
Kidney Disease Patient Education Services Costs	0	1	1	1	1	1	1	5
HD Training Costs	1	1	1	1	2	2	2	10

In table 24, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. The results for this table were generated from an average of 400 simulations under the assumption that benchmarks are rolled forward with a 1.5-year lag. For a detailed description of the key assumptions underlying the impact estimate, see the Specialty Care Models final rule (85 FR 61353) and the CY 2022 ESRD PPS final rule (86 FR 60214 through 60216).

(4) Effects on the Home Dialysis Rate, the Transplant Rate, and Kidney Transplantation

The change proposed in this rule is not expected to impact the findings reported for the effects of the ETC Model on the home dialysis rate or the transplant rate described in the Specialty Care Models final rule (85 FR 61355) and the CY 2022 ESRD PPS final rule (86 FR 62017).

(5) Effects on Kidney Disease Patient Education Services and HD Training Add-Ons

The change proposed in this rule is not expected to impact the findings reported for the effects of the ETC Model on kidney disease patient education services and HD training add-ons described in the Specialty Care Models final rule (85 FR 61355) and the CY 2022 ESRD PPS final rule (86 FR 62017).

(6) Effects on Medicare Beneficiaries

Our proposal to revise the definition of an ESRD Beneficiary for the purposes of attribution is not expected to impact the findings reported for the effects of ETC Model on Medicare beneficiaries. Further details on the impact of the ETC Model on ESRD Beneficiaries may be found in the Specialty Care Models final rule (85 FR 61357) and the CY 2022 ESRD PPS final rule (86 FR 61874).

(7) Alternatives Considered

Throughout this proposed rule, we have identified our policy proposal and alternatives considered, and provided information as to the likely effects of these alternatives and rationale for our proposal.

The Specialty Care Models final rule (85 FR 61114), the CY 2022 ESRD PPS final rule (86 FR 61874), the CY 2023 ESRD PPS final rule (87 FR 67136), the CY 2024 ESRD PPS final rule (88 FR 76344), and the proposals herein address a model specific to ESRD. These rules provide descriptions of the requirements that we waive, identify the performance metrics and payment adjustments to be tested, and presents rationales for our changes, and where relevant, alternatives considered. For context related to alternatives previously considered when establishing and modifying the ETC Model we refer readers to section V.B. and to the above citations.

E. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in table 25 showing the classification of the impact associated with the provisions of this proposed rule.

TABLE 25: Accounting Statement: Classification of Estimated Transfers and Costs/Savings

ESRD PPS and AKI (CY 2025)	
Category	**Transfers**
Annualized Monetized Transfers	$140 million
From Whom to Whom	Federal Government to ESRD facilities
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$30 million
From Whom to Whom	Beneficiaries to ESRD facilities
ESRD QIP for PY 2027	
Category	Transfers
Annualized Monetized Transfers	-14.6 million
From Whom to Whom	Federal Government to ESRD facilities

F. Regulatory Flexibility Act Analysis (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity. Therefore, the number of small entities estimated in this RFA analysis includes the number of ESRD facilities that are either considered small businesses or nonprofit organizations.

According to the Small Business Administration's (SBA) size standards, an ESRD facility is classified as a small business if it has total revenues of less than $47 million in any 1 year.[112] For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by LDOs and regional chains, which would have total revenues of more than $6.5 billion in any year when the total revenues for all locations are combined for each business (LDO or regional chain), and are not, therefore, considered small businesses. Because we lack data on individual ESRD facilities' receipts, we cannot determine the number of small proprietary ESRD facilities or the proportion of ESRD facilities' revenue derived from Medicare FFS payments. Therefore, we assume that all ESRD facilities that are not owned by LDOs or regional chains are considered small businesses. Accordingly, we consider the 461 ESRD facilities that are independent and 347 ESRD facilities that are hospital-based, as shown in the ownership category in table 18, to be small businesses. These ESRD facilities represent approximately 11 percent of all ESRD facilities in our data set.

Additionally, we identified in our analytic file that there are 779 ESRD facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in our data set. In total, accounting for the 360 nonprofit ESRD facilities that are also considered small businesses, there are 1,227 ESRD facilities that are either small businesses or nonprofit organizations, which is approximately 16 percent of all ESRD facilities in our data set.

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. As shown in table 18, we estimate that the overall revenue impact of this proposed rule on all ESRD facilities is a positive increase to Medicare FFS payments by approximately 2.2 percent. For the ESRD PPS updates in this proposed rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 3.9 percent increase in Medicare FFS payments for CY 2025. An independent facility (as defined by ownership type) is likewise estimated to receive a 0.5 percent increase in Medicare FFS payments for CY 2025. Among hospital-based and independent ESRD facilities, those furnishing fewer than 3,000 treatments per year are estimated to receive a 4.5 percent increase in Medicare FFS payments, and those furnishing 3,000 or more treatments per year are estimated to receive a 1.6 percent increase in Medicare FFS payments. Among nonprofit ESRD facilities, those furnishing fewer than 3,000 treatments per year are estimated to receive a 5.8 percent increase in Medicare FFS payments, and those furnishing 3,000 or more treatments per year are estimated to receive a 2.3 percent increase in Medicare FFS payments.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for $70 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

Based on the estimated Medicare payment impacts described previously, we do not believe that the change in revenue threshold will be reached by the policies in this proposed rule. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

For the ESRD QIP, we estimate that of the 2,214 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2027 ESRD QIP, 409 are ESRD small entity facilities. We present these findings in table 20 (''Estimated Distribution of PY 2027 ESRD QIP Payment Reductions'') and table 22 (''Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2027'').

For the ETC Model, we do not anticipate any impact from our proposal to modify the definition of an ESRD Beneficiary for the purposes of beneficiary attribution in the model.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis 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 603 of the RFA. For purposes of section 1102(b) of

[112] *http://www.sba.gov/content/small-business-size-standards.*

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 do not believe this proposed rule would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 108 rural hospital-based ESRD facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 108 rural hospital-based ESRD facilities would experience an estimated 5.5 percent increase in payments. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act Analysis (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. We do not interpret Medicare payment rules as being unfunded mandates but simply as conditions for the receipt of payments from the Federal Government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, state, local, or Tribal. Therefore, this proposed rule does not mandate any requirements for State, local, or Tribal governments, or for the private sector.

H. 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. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of state, local, or Tribal government.

IX. Files Available to the Public

The Addenda for the annual ESRD PPS proposed and final rule will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet and will be posted on CMS's website under the regulation number, CMS–1805–P, at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices*. In addition to the Addenda, limited data set files (LDS) are available for purchase at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile*. Readers who experience any problems accessing the Addenda or LDS files, should contact CMS by sending an email to CMS at the following mailbox: *ESRDPayment@cms.hhs.gov*.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 21, 2024.

List of Subjects

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 494

Diseases, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Intergovernmental relations, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 2. Section 410.52 is amended by revising paragraph (a) introductory text to read as follows:

§ 410.52 Home dialysis services, supplies, and equipment: Scope and conditions.

(a) Medicare Part B pays for the following services, supplies, and equipment furnished to a patient with ESRD or an individual with Acute Kidney Injury (AKI) as defined in § 413.371 of this chapter in his or her home:

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 3. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 4. Section 413.196 is amended by revising paragraph (d)(2) to read as follows:

§ 413.196 Notification of changes in rate-setting methodologies and payment rates.

* * * * *

(d) * * *

(2) The wage index using the most current wage data for occupations related to the furnishing of renal dialysis services from the Bureau of Labor Statistics and occupational mix data from the most recent complete calendar year of Medicare cost reports submitted in accordance with § 413.198(b).

* * * * *

■ 5. Section 413.231 is amended by revising paragraph (a) to read as follows:

§ 413.231 Adjustment for wages.

(a) CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index (established by CMS) which reflects the relative level of wages relevant to the furnishing of renal dialysis services in the geographic area in which the ESRD facility is located.

* * * * *

■ 6. Section 413.236 is amended by revising paragraph (b)(4) to read as follows:

§ 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

* * * * *

(b) * * *

(4) Has a complete Healthcare Common Procedure Coding System (HCPCS) Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for

biannual Coding Cycle 2 for non-drug and non-biological items, supplies, and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year;

* * * * *

■ 7. Section 413.237 is amended by adding paragraph (a)(1)(vii) to read as follows:

§ 413.237 Outliers.

(a) * * *

(1) * * *

(vii) Renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171.

* * * * *

■ 8. Section 413.373 is revised to read as follows:

§ 413.373 Other adjustments to the AKI dialysis payment rate.

(a) CMS applies the wage-adjusted add-on per treatment adjustment for home and self-dialysis training as set forth at § 413.235(c) to payments for AKI dialysis claims that include such training.

(b) The payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act.

■ 9. Section 413.374 is amended by revising paragraph (a) to read as follows:

§ 413.374 Renal dialysis services included in the AKI dialysis payment rate.

(a) The AKI dialysis payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act, including home services, supplies, and equipment, and self-dialysis.

* * * * *

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

■ 10. The authority citation for part 494 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 11. Section 494.10 is amended by revising the definitions of ''Home dialysis'' and ''Self-dialysis'' to read as follows:

§ 494.10 Definitions.

* * * * *

Home dialysis means dialysis performed at home by a patient or caregiver who has completed an appropriate course of training as described in § 494.100(a).

Self-dialysis means dialysis performed with little or no professional assistance by a patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a).

* * * * *

■ 12. Section 494.70 is amended by revising paragraphs (a)(1) and (10) and (c)(1)(i) to read as follows:

§ 494.70 Condition: Patients' rights.

* * * * *

(a) * * *

(1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with kidney failure;

* * * * *

(10) Be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for kidney failure of his or her own medical status as documented in the patient's medical record, unless the medical record contains a documented contraindication;

* * * * *

(c) * * *

(1) * * *

(i) How plans in the individual market will affect the patient's access to, and costs for the providers and suppliers, services, and prescription drugs that are currently within the individual's plan of care as well as those likely to result from other documented health care needs. This must include an overview of the health-related and financial risks and benefits of the individual market plans available to the patient (including plans offered through and outside the Exchange).

* * * * *

■ 13. Section 494.80 is amended by revising the introductory text to read as follows:

§ 494.80 Condition: Patient assessment.

The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for kidney failure, a social worker, and a dietitian. The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.

* * * * *

■ 14. Section 494.90 is amended by revising paragraph (b)(4) to read as follows:

§ 494.90 Condition: Patient plan of care.

* * * * *

(b) * * *

(4) The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing dialysis care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis.

* * * * *

■ 15. Section 494.100 is amended by revising paragraph (a)(3)(i) to read as follows:

§ 494.100 Condition: Care at home.

* * * * *

(a) * * *

(3) * * *

(i) The nature and management of their kidney failure.

* * * * *

■ 16. Section 494.120 is amended by revising the introductory text to read as follows:

§ 494.120 Condition: Special purpose renal dialysis facilities.

A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve patients with kidney failure while the patients are in a temporary residence) and facilities established to serve patients with kidney failure under emergency circumstances.

* * * * *

■ 17. Section 494.130 is revised to read as follows:

§ 494.130 Condition: Laboratory services.

The dialysis facility must provide, or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the patient. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.

■ 18. Section 494.170 is amended by revising the introductory text to read as follows:

§ 494.170 Condition: Medical records.

The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of dialysis services and all other home dialysis patients

whose care is under the supervision of the facility.

* * * * *

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 19. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 20. Section 512.310 is amended by revising the definition of ''ESRD Beneficiary'' to read as follows:

§ 512.310 Definitions.

* * * * *

ESRD Beneficiary means a beneficiary who meets any of the following:

(1) Is receiving dialysis or other services for end-stage renal disease, up to and including the month in which the beneficiary receives a kidney transplant up to and including the month in which the beneficiary receives a kidney transplant.

(2) Has already received a kidney transplant and has a non-AKI dialysis or MCP claim at least 12 months after the beneficiary's latest transplant date.

(3) Has a kidney transplant failure less than 12 months after the beneficiary's latest transplant date as identified by at least one of the following:

(i) Two or more MCP claims in the180 days following the date on which the kidney transplant was received;

(ii) 24 or more maintenance dialysis treatments at any time after 180 days following the transplant date; or,

(iii) Indication of a transplant failure after the beneficiary's date of transplant based on data from the Scientific Registry of Transplant Recipients (SRTR) database.

(4) If a beneficiary meets more than one of criteria described in paragraphs (3)(i) through (iii) of this definition, the beneficiary will be considered an ESRD beneficiary starting with the earliest month in which transplant failure was recorded.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–14359 Filed 6–27–24; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 89 Friday,
No. 129 July 5, 2024

Part IV

Department of the Treasury

Office of Investment Security

31 CFR Part 850

Provisions Pertaining to U.S. Investments in Certain National Security Technologies and Products in Countries of Concern; Proposed Rule

DEPARTMENT OF THE TREASURY

Office of Investment Security

31 CFR Part 850

RIN 1505–AC82

Provisions Pertaining to U.S. Investments in Certain National Security Technologies and Products in Countries of Concern

AGENCY: Office of Investment Security, Department of the Treasury.

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth regulations that would implement Executive Order 14105 of August 9, 2023, ''Addressing United States Investments in Certain National Security Technologies and Products in Countries of Concern,'' which declares a national emergency to address the threat to the United States posed by countries of concern, which seek to develop and exploit sensitive technologies or products critical for military, intelligence, surveillance, or cyber-enabled capabilities. The proposed rule would require United States persons to provide notification to the U.S. Department of the Treasury regarding certain transactions involving persons of a country of concern who are engaged in activities involving certain national security technologies and products that may contribute to the threat to the national security of the United States; and prohibit United States persons from engaging in certain other transactions involving persons of a country of concern who are engaged in activities involving certain other national security technologies and products that pose a particularly acute national security threat to the United States. This notice of proposed rulemaking (NPRM) seeks public comment on various topics related to the implementation of Executive Order 14105. In accordance with 5 U.S.C. 553(b)(4), a summary of this rule may be found at *https://www.regulations.gov.*

DATES: Written comments must be received by August 4, 2024.

ADDRESSES: Written comments on this proposed rule may be submitted through one of two methods:

- *Electronic Submission:* Comments may be submitted electronically through the Federal Government eRulemaking portal at *https://www.regulations.gov.* Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt, and enables the Department of the Treasury to make the comments available to the public.
- *Mail:* Send to U.S. Department of the Treasury, Attention: Meena R. Sharma, Director, Office of Investment Security Policy and International Relations, 1500 Pennsylvania Avenue NW, Washington, DC 20220.

The Department of the Treasury encourages comments to be submitted via *https://www.regulations.gov.* Please submit comments only and include your name and organization name (if any) and cite ''Provisions Pertaining to U.S. Investments in Certain National Security Technologies and Products in Countries of Concern'' in all correspondence. All comments submitted in response to this NPRM, including attachments and other supporting material, will be made public, including any personally identifiable or confidential business information that is included in a comment. Therefore, commenters should submit only information that they wish to make publicly available. Commenters who wish to remain anonymous should not include identifying information in their comments.

FOR FURTHER INFORMATION CONTACT: Meena R. Sharma, Director, Office of Investment Security Policy and International Relations, at U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220; telephone: (202) 622–3425; email: *OIS.Outbound.Regulations@treasury.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On August 9, 2023, the President issued Executive Order 14105, ''Addressing United States Investments in Certain National Security Technologies and Products in Countries of Concern'' (the Outbound Order), pursuant to his authority under the Constitution and the laws of the United States, including the International Emergency Economic Powers Act (IEEPA), the National Emergencies Act, and section 301 of title 3, United States Code (U.S.C.). In the Outbound Order, the President found that the advancement by countries of concern in sensitive technologies and products critical for the military, intelligence, surveillance, or cyber-enabled capabilities of such countries constitutes a threat to the national security of the United States, which has its source in whole or substantial part outside the United States, and that certain U.S. investments risk exacerbating this threat. In response, the President declared a national emergency to deal with this threat.

The Outbound Order identifies three sectors of national security technologies and products to be covered by the program: semiconductors and microelectronics, quantum information technologies, and artificial intelligence. As described in the Outbound Order, countries of concern are exploiting or have the ability to exploit certain U.S. outbound investments, including certain intangible benefits that often accompany U.S. investments and that help companies succeed. In an Annex to the Outbound Order, the President identified one country, the People's Republic of China (PRC), along with the Special Administrative Region of Hong Kong and the Special Administrative Region of Macau, as a country of concern. The President may modify the Annex to the Outbound Order and update the list of countries of concern.

Advanced technologies and products that are increasingly developed and financed by the private sector form the basis of next-generation military, intelligence, surveillance, or cyber-enabled capabilities. As stated in the Outbound Order, advancements in sensitive technologies and products in the areas of semiconductors and microelectronics, quantum information technologies, and artificial intelligence will accelerate the development of advanced computational capabilities that will enable new applications that pose significant national security risks, such as the development of more sophisticated weapons systems, breaking of cryptographic codes, and other applications that could provide a country of concern with military advantages. The potential military, intelligence, surveillance, or cyber-enabled applications of these technologies and products pose risks to U.S. national security, particularly when developed in or by a country of concern in which the government seeks to (1) direct entities to obtain technologies to achieve national security objectives; and (2) compel entities to share or transfer these technologies to the government's military, intelligence, surveillance, or security apparatuses.

U.S. investments are often more valuable than the capital alone because they can also include the transfer of intangible benefits. Intangible benefits that often accompany U.S. investments and help companies succeed include: enhanced standing and prominence, managerial assistance, access to investment and talent networks, market access, and enhanced access to additional financing. Certain investments by United States persons into a country of concern can be

exploited to accelerate the development of sensitive technologies or products—including military, intelligence, surveillance, or cyber-enabled capabilities—in ways that negatively impact the national security of the United States. Such investments, therefore, risk exacerbating this threat to U.S. national security.

The Outbound Order has two primary components that serve distinct but related objectives with respect to the relevant technologies and products. The first component requires notification to the Secretary of the Treasury (the Secretary) regarding certain types of investments by a United States person in a covered foreign person engaged in covered activities pertaining to specified categories of technologies and products. The second component requires the Secretary to prohibit certain types of investment by a United States person in a covered foreign person engaged in covered activities pertaining to other specified categories of advanced technologies and products. Both components focus on investments that could enhance a country of concern's military, intelligence, surveillance, or cyber-enabled capabilities through the advancement of technologies and products in particularly sensitive areas.

The Outbound Order directs the Secretary, in consultation with the Secretary of Commerce and, as appropriate, the heads of other relevant agencies, to issue, subject to public notice and comment, regulations that, among other things, require *U.S. persons* to submit information to the Department of the Treasury regarding *notifiable transactions* and prohibit U.S. persons from engaging in *prohibited transactions.* Under section 10(a) of the Outbound Order, the President authorizes the Secretary to promulgate rules and regulations, including elaborating upon the definitions contained in the Outbound Order. The Secretary's promulgation of regulations under the Outbound Order is consistent with the President's authority to ''issue such regulations, including regulations prescribing definitions, as may be necessary for the exercise'' of authorities granted under IEEPA (50 U.S.C. 1704) and the President's authority to designate and empower the head of any department or agency in the executive branch to perform any function which is vested in the President by law (3 U.S.C. 301).

The Outbound Order instructs the Secretary to identify in such regulations categories of notifiable transactions that involve covered national security technologies and products that the Secretary, in consultation with the Secretary of Commerce and, as appropriate, the heads of other relevant agencies, determines may contribute to the threat to the national security of the United States identified in the Outbound Order. The Outbound Order also instructs the Secretary to identify categories of prohibited transactions that involve technologies and products that the Secretary, in consultation with the Secretary of Commerce and, as appropriate, the heads of other relevant agencies, determines pose a particularly acute national security threat to the United States. Consistent with the Outbound Order, the Secretary may exempt from the notification requirement or prohibition any transaction determined by the Secretary, in consultation with the heads of relevant agencies, as appropriate, to be in the national interest of the United States. Additionally, the Outbound Order requires the Secretary to investigate, in consultation with the heads of relevant agencies, as appropriate, violations of the Outbound Order or the regulations and pursue civil penalties for such violations.

II. Advance Notice of Proposed Rulemaking

Concurrent with the issuance of the Outbound Order, on August 9, 2023, the Department of the Treasury issued an Advance Notice of Proposed Rulemaking, 88 FR 54961 (August 14, 2023) (ANPRM), to provide transparency and clarity about the intended scope of the program and solicit early stakeholder participation in the rulemaking process. The ANPRM outlined key concepts under consideration and sought public comment on a range of topics related to the implementation of the Outbound Order.

The Department of the Treasury received 60 public comment letters in response to the ANRPM, many from business associations that represent a wide variety of stakeholders across industries as well as from individuals and companies in the financial services, legal, and technology sectors. These comments are available on the public rulemaking docket at *https://www.regulations.gov* (Docket TREAS–DO–2023–0009). The Department of the Treasury considered each comment in developing this proposed rule. In general, comments focused on enhancing the clarity of the scope of the program and the definitions under consideration, aligning the program where possible with other relevant U.S. Government programs, and supporting program development in a targeted manner to reduce unintended consequences for U.S. competitiveness. The key issues raised in the comments are discussed in the next section within the discussion of the proposed rule.

III. The Proposed Rule

A. Scope and Structure of the Proposed Rule

The United States has long maintained an open investment policy and supports cross-border investment where consistent with the protection of United States national security interests. As discussed in the Outbound Order, certain United States investments may accelerate the development of sensitive technologies and products in countries that develop them to counter United States and allied capabilities. The Department of the Treasury has scoped the proposed rule to focus on the types of U.S. investments that present a likelihood of conveying both capital and intangible benefits that can be exploited to accelerate the development of sensitive technologies or products critical for military, intelligence, surveillance, or cyber-enabled capabilities of such countries in ways that negatively impact the national security of the United States. With an interest in minimizing unintended consequences and addressing the national security risks posed by countries of concern developing technologies that are critical to the next generation of military, intelligence, surveillance, or cyber-enabled capabilities, the proposed rule includes detailed definitions and descriptions of terms and elements to appropriately scope coverage and facilitate compliance by United States persons. At the same time, the proposed rule seeks to avoid loopholes that could undermine the national security objectives of the Outbound Order. The Department of the Treasury seeks public input on how the proposed rule can best meet these important objectives.

Consistent with the Outbound Order, the proposed rule would place certain obligations upon any *U.S. person* in connection with a *covered transaction* involving or resulting in the establishment of a *covered foreign person.* The proposed definition of *covered foreign person* focuses on the person's relationship to a *country of concern* and involvement in one or more *covered activity* related to certain national security technologies and products. A *covered transaction* may be a *prohibited transaction,* meaning it could not legally be undertaken, or it may be a *notifiable transaction,* meaning that it would be permitted under the proposed rule, but a *U.S.*

person would need to submit specified information about the transaction to the Department of the Treasury. A *U.S. person* would also have certain obligations under the proposed rule in connection with certain transactions undertaken by any non-*U.S. person* entity that it controls, referred to as a *controlled foreign entity.* Additionally, under the proposed rule, a *U.S. person* would be prohibited from *knowingly directing* a transaction that would be prohibited if undertaken by a *U.S. person.* These and other terms are defined in Subpart B of the proposed rule.

The Outbound Order and the proposed rule seek to complement existing authorities and tools of the U.S. Government, including export controls and inbound investment reviews. However, the proposed rule would not entail a case-by-case review by the Department of the Treasury of *covered transactions* or any other transactions, nor would it establish a licensing process where a *U.S. person* would seek prior authorization for a *covered transaction.* The proposed rule would not establish comprehensive sanctions with respect to a particular jurisdiction or an entire sector. Nor would the proposed rule treat transactions as within its scope solely because they are denominated in U.S. dollars. Rather, as proposed, the relevant *U.S. person* undertaking a transaction would have the obligation to determine whether the given transaction is prohibited, permissible but subject to notification, or not covered by the rule because either it is an *excepted transaction* or it is not within the jurisdiction set forth under the proposed rule. A *U.S. person* could seek a national interest exemption from the notification requirement or prohibition set out in this rule by following the process described in § 850.502 and further discussed below.

As noted in the ANPRM, it is not proposed that the program provide for retroactive application of the provisions related to the prohibition of certain transactions and the notification of others. However, the Department of the Treasury may, after the effective date of the regulations, request information about transactions by *U.S. persons* that were completed or agreed to after the date of the issuance of the Outbound Order to better inform the development and implementation of the program.

In section IV, the Department of the Treasury seeks comment from stakeholders with respect to the proposed rule, accompanied by empirical data or other specific information wherever possible. The Department of the Treasury invites comments on the range of proposals in the proposed rule, and particularly as related to the specific provisions discussed in this section III.

B. Discussion of the Proposed Rule

Subpart A—General

This subpart includes a general discussion of the proposed rule's scope, how the proposed rule relates to other laws and regulations, proposed guidance on how to interpret and apply certain terms and provisions, the application of the knowledge standard in certain circumstances, and, consistent with the Outbound Order, the role of the heads of other relevant agencies in the implementation and administration of the proposed rule.

With respect to the knowledge standard specifically, because a *U.S. person* must determine whether a transaction is a *prohibited transaction,* a *notifiable transaction,* or not covered under the proposed rule, the standard by which a *U.S. person's* knowledge of the relevant facts and circumstances is assessed is an important aspect of the rule. The ANPRM discussed that the Department of the Treasury was considering adopting a knowledge standard across this program, which would have meant that for a transaction potentially to be covered by the regulations, a *U.S. person* would need to know, or reasonably should know, based on information publicly available or available through reasonable and appropriate due diligence, that it is undertaking a transaction involving a covered foreign person and that the transaction is a *covered transaction.* Some commenters to the ANPRM stated that it would be difficult to ascertain when a *U.S. person* should know that a transaction is a *covered transaction.* At the same time, to reduce the risk of circumvention or evasion, the Department of the Treasury seeks to preserve flexibility to inquire into the facts and circumstances of a *U.S. person's* transaction, for example if a *U.S. person* failed to undertake due diligence or deliberately avoided learning certain facts.

In light of these considerations, the proposed rule specifies that certain provisions, including in the definition of *covered transaction,* would apply only if a *U.S. person* has *knowledge* of the relevant facts or circumstances at the time of a transaction. The proposed definition of *knowledge* would include any the following: actual knowledge that a fact or circumstance exists or is substantially certain to occur, an awareness of a high probability of a fact or circumstance's existence or future occurrence, or reason to know of a fact or circumstance's existence. The proposed definition of *covered transaction* would generally require the *U.S. person* to *know* (or in some circumstances, to intend) at the time of a transaction that the transaction involves a *covered foreign person,* will result in the establishment of a *covered foreign person* (in the case of a greenfield, brownfield, or a joint venture investment), or will result in a *person of a country of concern's* engagement in a new *covered activity* (in the case of a business pivot). The Department of the Treasury is not proposing to hold a *U.S. person* liable for a transaction that has all of the other attributes of a *covered transaction* but that the *U.S. person* did not *know* at the time (which includes not having reason to know at the time) was involved with or would result in a *covered foreign person.* If a *U.S. person* failed to conduct a reasonable and diligent inquiry at the time of a transaction and undertook the transaction where a particular fact or circumstance indicative of a *covered transaction* was present, the Department of the Treasury may find in the course of determining compliance with the proposed rule that the *U.S. person* had reason to know of such fact or circumstance (and therefore, for purposes of the proposed rule, *knew*). To provide clarity, the proposed rule includes some of the factors that the Department of the Treasury will consider in assessing whether a *U.S. person* undertook such an inquiry, as applicable. These include efforts to obtain information and contractual assurances that should be obtainable through a reasonable transactional due diligence process with respect to the determination of a transaction's status as a *covered transaction* or relevant entity's status as a *covered foreign person.*

The Department of the Treasury has considered the practical application of this approach. More specifically, if a *U.S. person* has undertaken a reasonable and diligent inquiry and still does not have knowledge of a fact or circumstance relevant to whether a transaction involves or would result in a *covered foreign person* in a way that would render the transaction a *covered transaction,* the Department of the Treasury ordinarily (absent other circumstances) would not attribute *knowledge* of that fact or circumstance to such *U.S. person* even if the transaction has all of the other attributes of a *covered transaction.* Additionally, if a *U.S. person* failed to undertake a reasonable and diligent inquiry but the

transaction in question does not involve a *covered foreign person,* the Department of the Treasury would not hold the *U.S. person* liable for the lack of a reasonable and diligent inquiry.

Commenters to the ANPRM requested a range of additional items from the Department of the Treasury that would assist a *U.S. person* in complying with the program such as including examples, making available answers to frequently asked questions, and publishing a list of entities designated as a *covered foreign person.* To illustrate the application of certain terms and facilitate understanding of this proposed rule, the Department of the Treasury has included a number of examples in the discussion section at Subpart B below, which are numbered sequentially to facilitate public comment. These examples are provided for informational purposes and should not be construed to alter the meaning of the text of the proposed regulations. Additionally, the Department of the Treasury anticipates making available answers to certain frequently asked questions as the program is implemented.

Subpart B—Definitions

§ 850.202—AI System

One of the categories of covered national security technologies and products in the Outbound Order is sensitive technologies and products in the artificial intelligence (AI) sector. As discussed in the ANPRM, the U.S. Government is concerned with the development of *AI systems* that enable the military modernization of countries of concern—including weapons, intelligence, and surveillance capabilities—including those that have applications in areas such as cybersecurity and robotics. The policy objective is to cover U.S. investment into entities that develop *AI systems* that have applications that pose, or have the potential to pose, significant national security risks without broadly capturing investments into entities that develop *AI systems* intended only for consumer applications or other civilian end uses that do not have potential national security consequences. To address these concerns, the proposed rule would have a notification requirement (see the definition of *notifiable transaction*) and a prohibition (see the definition of *prohibited transaction*) with respect to investments in entities engaged in certain *covered activities* involving *AI systems.*

The ANPRM provided an initial definition for ''AI system'' as ''an engineered or machine-based system that can, for a given set of objectives, generate outputs such as predictions, recommendations, or decisions influencing real or virtual environments. AI systems are designed to operate with varying levels of autonomy.''

Commenters to the ANPRM requested that the Department of the Treasury align terms with other U.S. Government programs where possible. After the Outbound Order and ANPRM were published, the President issued Executive Order 14110, ''Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence'' on October 30, 2023 (the AI Order), which, among other things, establishes new standards for AI safety and security. The AI Order provides definitions for the terms ''artificial intelligence'' and ''AI system'' which this proposed rule incorporates in the definition of *AI system.* The Department of the Treasury invites comments on the proposed definition of *AI system.*

§ 850.206—Controlled Foreign Entity

The proposed rule would define *controlled foreign entity* as an entity of which a *U.S. person* is a *parent,* meaning a *U.S. person* directly or indirectly holds more than 50 percent of the outstanding voting interest or voting power of the board of the entity; is a general partner, managing member, or equivalent of the entity; or, if the entity is a pooled investment fund, is an investment adviser to any such fund. The proposed rule would place obligations on a *U.S. person* to take all reasonable steps to prohibit and prevent its *controlled foreign entity* from undertaking a transaction that would be a *prohibited transaction* if undertaken by a *U.S. person,* and to notify the Department of the Treasury if the *controlled foreign entity* undertakes a transaction that would be a *notifiable transaction* if undertaken by a *U.S. person.* This approach is intended to address a potential loophole whereby a *U.S. person* that is a *parent* of a non-*U.S. person* entity could use such an entity to undertake an investment that would otherwise be a *covered transaction* if undertaken by the *U.S. person* directly. Additionally, this approach is aimed at increasing U.S. Government visibility into these transactions or in some cases, limiting the flow of capital and intangible benefits through an entity closely tied to and often influenced by a *U.S. person* that is a *parent,* which would be contrary to the objectives of the Outbound Order. In assessing whether the *parent* has taken all reasonable steps, the Department of the Treasury would consider certain factors with respect to a *U.S. person* and its *controlled foreign entity,* including the existence and implementation of periodic training and reporting requirements with respect to compliance with the proposed regulations and the implementation of internal controls. The Department of the Treasury would assess compliance based on a consideration of the totality of relevant facts and circumstances, including whether such steps were reasonable given the size and sophistication of the *parent.* Generally, if the *U.S. person* has taken steps, including those described in § 850.302(b), that were reasonable given, for example, the size and sophistication of the *U.S. person,* the *U.S. person* would be found in compliance with the proposed rule.

The definition of *controlled foreign entity* is intended to draw a bright line so that a *U.S. person* could easily ascertain whether an entity is its *controlled foreign entity.* In determining whether a *U.S. person* indirectly holds voting interest or voting power of the board via a tiered ownership structure for purposes of this provision, where the relationship between an entity and another entity is that of a *parent* and subsidiary, the voting interest or voting power of the board of a subsidiary would be fully attributed to the *parent.* By contrast, if an entity holds 50 percent or less of another entity's voting interest or voting power of the board—that is, if the relationship is not a *parent*-subsidiary relationship—then the indirect downstream holdings of voting interest or voting power of the board, as applicable, attributed to the first entity would be determined proportionately.

If a *U.S. person* holds both direct and indirect holdings in the same entity, the direct and indirect holdings of the *U.S. person's* voting interest or voting power of the board, as applicable, would be aggregated. For the avoidance of doubt, each of these metrics (voting interest or voting power of the board) would be evaluated independently from the other. For example, if an entity has 20 percent of its voting interest and 15 percent of its voting power of the board each held by a *U.S. person,* these percentages would not be combined to equal 35 percent.

The following examples illustrate the application of the proposed definition of *controlled foreign entity:*

(1) *Example 1.* A *U.S. person* holds more than 50 percent of the voting interest of the non-*U.S. person* Company A, and Company A holds more than 50 percent of the voting interest of the non-*U.S. person* Company B. Each of Company A and

Company B would be a *controlled foreign entity* of the *U.S. person,* because the *U.S. person* directly holds more than 50 percent of Company A's voting interest, so Company A's holding of more than 50 percent of Company B is fully attributed to the *U.S. person.*

(2) *Example 2.* A *U.S. person* holds a 25 percent voting interest of the non-*U.S. person* Company C, and Company C holds 60 percent of the voting interest of the non-*U.S. person* Company D. The *U.S. person* indirectly holds 15 percent of the voting interest of Company D. Company D would not be a *controlled foreign entity* of the *U.S. person* because the *U.S. person* only indirectly holds 15 percent of the voting interest of Company D.

(3) *Example 3.* A *U.S. person* holds more than 50 percent of the voting interest of non-*U.S. person* Company E and 10 percent of the voting interest of the non-*U.S. person* Company F. Company E also holds 41 percent of the voting interest of Company F. Companies E and F would each be a *controlled foreign entity* of the *U.S. person* because the *U.S. person* directly holds more than 50 percent of Company E and has an aggregated voting interest (direct and indirect) of more than 50 percent of Company F (10 percent directly and 41 percent indirectly).

(4) *Example 4.* A *U.S. person* holds 49 percent of the voting interest of Company G; Company G holds 52 percent of the voting interest in Company H; and Company H holds 30 percent of the voting interest of non-*U.S. person* Company I. Since Company G holds more than 50 percent of the voting interest in Company H, Company G is a *parent* of Company H and Company H's 30 percent interest in Company I is fully attributed to Company G. The *U.S. person's* indirect interest in Company I is therefore 14.7 percent, which is calculated by multiplying the *U.S. person's* 49 percent interest in Company G and Company G's 30 percent interest in Company I. Company I is not a *controlled foreign entity* of the *U.S. person.*

The Department of the Treasury invites comments regarding this definition, including considerations with respect to coverage of entities established outside of the United States.

§ 850.208—Covered Activity

The proposed rule identifies activities that would provide the relevant nexus between the *covered foreign person* and the covered national security technologies and products described in the Outbound Order. The Outbound Order defines the term ''covered national security technologies and products'' to mean sensitive technologies and products in the semiconductors and microelectronics, quantum information technologies, and AI sectors that are critical for the military, intelligence, surveillance, or cyber-enabled capabilities of a country of concern, as determined by the Secretary of the Treasury in consultation with the Secretary of Commerce and, as appropriate, the heads of other relevant agencies. The Outbound Order further states that, where applicable, ''covered national security technologies and products'' may be limited by reference to certain end uses of those technologies or products.

The three primary definitions in the proposed rule implementing the term ''covered national security technologies and products'' are *covered activity, notifiable transaction,* and *prohibited transaction.* The term *covered activity* would mean, in the context of a particular transaction, any of the activities referred to in the definition of *notifiable transaction* in § 850.217 or *prohibited transaction* in § 850.224. The Department of the Treasury invites comments on the approach in the proposed rule to incorporating specific covered national security technologies and products in the definitions of *notifiable transaction* and *prohibited transaction* based on a description of the technology or product and the relevant activities, capabilities, or end uses of such technology or product, as applicable, and any alternative approaches that should be considered.

The proposed definitions of *notifiable transaction* and *prohibited transaction* would identify specific *covered activities* relevant to the technology or product within each category. Some such *covered activities* would relate to semiconductors and microelectronics technology, equipment, and capabilities that enable the production and certain uses of integrated circuits that underpin current and future military innovations that improve the speed and accuracy of military decision-making, planning, and logistics, among other things; as well as that enable mass surveillance or other cyber-enabled capabilities. The proposed rule would also address *covered activities* related to quantum information technologies and products that enable capabilities that could compromise encryption and other cybersecurity controls and jeopardize military communications, among other things. In the case of a quantum sensing platform or quantum network, the end-use provision avoids covering use cases in strictly civilian fields. Finally, the proposed rule would address *covered activities* related to certain *AI systems* that have applications that pose or have the potential to pose significant national security risk. The proposed rule would not seek to broadly capture *AI systems* intended only for commercial applications or other civilian end uses and that do not have potential national security consequences, as discussed further below.

Those *covered activities* with respect to technologies and products that pose a particularly acute national security threat are incorporated into the definition of *prohibited transaction.* Those *covered activities* with respect to technologies and products that may contribute to the threat to the national security of the United States are incorporated into the definition of *notifiable transaction.* The scope of *prohibited transaction* and the scope of *notifiable transaction* are intended to be distinct and not overlap. The Department of the Treasury intends that the notification requirement will increase the U.S. Government's visibility into *U.S. person* transactions involving the relevant technologies and products and that these notifications will be helpful in highlighting aggregate sector trends and related capital flows as well as informing future policy development. The proposed prohibitions would be tailored restrictions on specific, identified areas to prevent *U.S. persons* from investing in the development of technologies and products that pose a particularly acute national security threat. Both the specific *covered activities* as well as the technical descriptions in the proposed rule were crafted with these objectives in mind. A more detailed discussion of specific *covered activities* and proposed technical descriptions is below under the sections on *notifiable transaction* and *prohibited transaction.* The Department of the Treasury invites comments on alternative approaches that would meet the stated objectives.

§ 850.209—Covered Foreign Person

The Outbound Order requires the Department of the Treasury to prohibit or require notification of certain transactions involving a *covered foreign person* and defines the term as ''a person of a country of concern who or that is engaged in activities, as identified in the regulations issued under [the Outbound Order], involving one or more covered national security technologies and products.'' The definition of *covered foreign person* in the proposed rule describes three sets of circumstances that would cause a person to be a *covered foreign person.*

§ 850.209(a)(1)

First, a person would be a *covered foreign person* if it is a *person of a country of concern* that is engaged in a *covered activity.*

§ 850.209(a)(2)

Second, a person would be a *covered foreign person* even if it is not itself a *person of a country of concern* or engaged in a *covered activity* but has a particular relationship with a *person of a country of concern* that is engaged in a *covered activity.* The relationship would have to meet two conditions. First, the relevant person would have to hold a specified interest in the *person of a country of concern.* That interest could take the form of a voting interest, board seat (voting or observer), equity interest, or the power to direct or cause the direction of the management or policies of the *person of a country of concern* through contractual arrangement(s) (including, for the avoidance of doubt, any contractual arrangement with respect to a variable interest entity). The exact size of this interest—such as the percentage of voting interest or the number of board seats (voting or observer)—is not determinative as long as there is some interest of the nature described. The policy objective is to cover situations where a vested interest between the two persons exists. Second, if there is such an interest, then more than 50 percent of the first person's revenue, net income, capital expenditure, or operating expenses would need to be attributable to the *person of a country of concern* and that person must be engaged in a *covered activity.* The first person also would meet this condition if that person holds an interest in more than one *person of a country of concern* engaged in a *covered activity,* and more than 50 percent of the first person's revenue, net income, capital expenditure, or operating expenses is attributable to such *persons of a country of concern,* in aggregate. The Department of the Treasury intends the threshold of more than 50 percent of any of the financial metrics to be evaluated independently, not in combination. For example, assuming no other relevant circumstances, if a person's interest in a *person of a country of concern* represents 20 percent of the first person's revenue and 31 percent of its capital expenditures, these metrics would be evaluated independently and not combined to equal 51 percent.

Under this second set of circumstances, the Department of the Treasury intends to capture those entities that, while not directly engaged in a *covered activity* themselves, are significantly financially connected to entities that are engaged in a *covered activity.* The Department of the Treasury considers that if more than 50 percent of an investment target's revenue, net income, capital expenditure, or operating expense is attributable to one or more *persons of a country of concern* that are engaged in a *covered activity,* the intangible benefits associated with a *U.S. person's* investment in the target are likely to be conveyed to such *persons of a country of concern.* Accordingly, the Department of the Treasury considers that the investment target itself should be treated as a *covered foreign person.* Consistent with the policy objectives of the Outbound Order, this approach seeks to focus on transactions where there is a likelihood of the transfer of intangible benefits to a *person of a country of concern* engaged in a *covered activity.* Moreover, in setting the relevant threshold for financial metrics between the investment target and *persons of a country of concern* engaged in a *covered activity* at more than 50 percent, the Department of the Treasury expects that through reasonable and diligent inquiry a *U.S. person* would be able to determine whether a potential investment target meets the applicable conditions. In capturing certain *U.S. person* transactions with entities that have a vested interest in, as well as a significant financial relationship with, a *covered foreign person,* this approach is intended to, among other things, address a common transaction structure whereby investments are made into parent companies or holding companies. Under these circumstances, a U.S. entity or an entity in a third country could be considered a *covered foreign person.*

§ 850.209(a)(3)

Lastly, a *person of a country of concern* would be a *covered foreign person* by virtue of its participation in a joint venture with a *U.S. person* if such joint venture is engaged in a *covered activity.* That is, even though the *person of a country of concern* may not be engaged in a *covered activity* itself, the fact of its participation in a joint venture that is engaged in a *covered activity* would cause the person to be a *covered foreign person.* Consistent with the policy objectives of the Outbound Order, this approach seeks to focus on transactions where there is a likelihood of the transfer of intangible benefits from a *U.S. person* to a *person of a country of concern* in connection with a *covered activity.*

The following examples illustrate the application of the proposed definition of *covered foreign person:*

(5) *Example 5.* Company J holds a 10 percent equity interest in Company K, which is a *person of a country of concern* engaged in a *covered activity,* and income from Company K comprises 30 percent of Company J's net income for the most recent year for which audited financial statements are available. In addition, Company J holds a 10 percent equity interest in Company L, which is a *person of a country of concern* engaged in a *covered activity,* and income from Company L comprises 21 percent of Company J's net income for the most recent year for which audited financial statements are available. Therefore, Company J would be a *covered foreign person* under § 850.209(a)(2), because income from Company K and income from Company L, which are both *persons of a country of concern* that are engaged in *covered activities* in which Company J holds an equity interest, together comprise 51 percent of the net income of Company J for the most recent year for which audited financial statements are available.

(6) *Example 6.* Assume the same facts as Example 5, except that none of Company J's net income is attributable to Company K, and instead, 30 percent of Company J's capital expenditures for the most recent year for which audited financial statements are available at the time of a given transaction is attributable to Company K. Company J would not be a *covered foreign person* under § 850.209(a)(2), because the percentage of capital expenditures attributable to Company K and the percentage of net income attributable to Company L would not be aggregated, and neither the percentage of capital expenditures attributable to Company K nor the percentage of net income attributable to Company L is more than 50 percent for Company J.

The Department of the Treasury invites comments regarding this definition, including its application to a U.S. entity or a third-country entity.

In response to the ANPRM, some commenters requested that the definition of *covered foreign person* include a de minimis threshold below which a *person of a country of concern's* activity involving a covered technology or product would not trigger the definition of *covered activity,* meaning the person would not be a *covered foreign person.* The Department of the Treasury declines to propose a de minimis threshold for this definition. A de minimis threshold based on the financial significance of a covered

activity in relation to any particular entity does not necessarily correspond to the national security significance of such activity. Setting a de minimis threshold based on the level of activity involving a covered technology or product would be challenging and would not effectively respond to the national security objectives of the Outbound Order.

In response to the ANPRM, some commenters requested that the Department of the Treasury maintain a publicly available list of *covered foreign persons.* The Department of the Treasury declines to adopt that suggestion in the proposed rule. Compiling a list of *covered foreign persons* would be challenging given that any such list would likely be subject to frequent change and likely underinclusive, which would undermine the national security goals of the Outbound Order. Limiting the definition of *covered foreign person* to persons included on such a list would risk excluding certain persons that should be covered in order to accomplish the objectives of the Outbound Order, including early-stage companies that may not have come to the attention of the Department of the Treasury. Providing a list of *covered foreign persons* could also result in attempts to evade the rule through corporate restructuring and would be overly burdensome to maintain for the reasons listed above. Rather, under the proposed rule, the Department of the Treasury would expect a *U.S. person* to conduct a reasonable and diligent inquiry to determine whether a transaction is covered under the proposed rule, including whether any *covered foreign person* is involved.

§ 850.210—Covered Transaction

As discussed in greater detail below, the definition of *covered transaction* would include a *U.S. person's* direct or indirect:

- Acquisition of an equity interest or contingent equity interest in a *covered foreign person;*
- Provision of debt financing convertible to an equity interest in a *covered foreign person* or provision of debt financing that affords the lender certain management or governance rights in a *covered foreign person;*
- Conversion of a contingent equity interest or convertible debt in a *covered foreign person;*
- Greenfield investment or certain other corporate expansions that either will establish a *covered foreign person,* or will cause an existing *person of a country of concern* to pivot into a new *covered activity;*
- Entrance into a joint venture, wherever located, with a *person of a country of concern* where the joint venture will undertake a *covered activity;* and
- Investment as a limited partner or equivalent (LP) into a non-*U.S. person* pooled investment fund that invests in a *covered foreign person.*

Each of the above transaction types includes a specific requirement for what a *U.S. person* would need to *know* or intend for a transaction to be a *covered transaction.* Further detail on each of these transaction types is provided below.

The definition of *covered transaction* notes that it does not include an *excepted transaction* or, consistent with the Outbound Order, a transaction for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof.

Acquisition of Equity Interest or Contingent Equity Interest

The definition of *covered transaction* would include the acquisition of an equity interest (or equivalent) in a *covered foreign person* and the acquisition of a financial instrument that does not constitute an equity interest at the time of the covered transaction but is convertible into, or provides the right to acquire, an equity interest in a *covered foreign person* upon the occurrence of a contingency or defined event. While the issuance of debt secured by equity in a *covered foreign person* would not, absent other circumstances, be a *covered transaction,* foreclosure on collateral that constitutes an equity interest in a *covered foreign person* would constitute the acquisition of an equity interest under the proposed rule and would be a *covered transaction.*

Convertible Debt; Debt With Special Rights

The definition of *covered transaction* would include the provision of debt financing that is convertible by the *U.S. person* into equity of a *covered foreign person.* Additionally, the provision of debt financing that affords or will afford the *U.S. person* the right to make management decisions on behalf of a *covered foreign person* or to appoint members of the board of a *covered foreign person* would also be a *covered transaction.* The intent is to capture lending by a *U.S. person* lender only where such lending involves the acquisition of equity or equity-like rights by the *U.S. person* lender with respect to a *covered foreign person.*

Conversion of Contingent Interest or Convertible Debt

The definition of *covered transaction* includes as a separate basis of coverage the conversion of a contingent equity interest or convertible debt in a *covered foreign person.* As stated above, in addition to the conversion, the original acquisition of either such interest is a *covered transaction.* With respect to a *notifiable transaction,* the policy objective of including the conversion of a contingent equity or convertible debt in the definition of *covered transaction* is to gain visibility into the circumstances in which contingent interests in a *covered foreign person* convert. Including the conversion of a contingent equity interest or convertible debt in the scope of *covered transaction* would also address circumstances where the investment target or borrower is not a *covered foreign person* at the time of acquisition of the relevant interest but is a *covered foreign person* at the time of conversion of such interest (*e.g.,* as a result of newly engaging in a *covered activity* or the target's relationship with a *person of a country of concern* engaged in a *covered activity*). The Department of the Treasury anticipates that if the original acquisition was a *notifiable transaction* and was timely notified, the second notification submitted with respect to the conversion would likely be similar to the first notification and thus less time-consuming to prepare. The Department of the Treasury considered alternative approaches such as covering only the acquisition and not the conversion of contingent interests or covering only the conversion. However, each alternative could be either over- or under-inclusive in situations where an investment target has pivoted away from, or into, a *covered activity* in the interim between acquisition and conversion.

Greenfield or Brownfield Investment

The definition of *covered transaction* would include a *U.S. person's* acquisition, leasing, or development of operations, land, property, or other assets in a *country of concern* when the *U.S. person knows* that such acquisition, leasing, or development will, or the *U.S. person* intends it to, either (1) establish a *covered foreign person,* such as the acquisition of land in a *country of concern* with the intent to convert it into a facility that designs an integrated circuit or (2) pivot an existing entity's operations into a new *covered activity,* such as the acquisition of a factory with the intent to retrofit it to produce equipment for performing

volume advanced packaging. A *U.S. person's* intent (as distinct from *knowledge*) would be sufficient in these cases for the transaction to be a *covered transaction.* This is because in the greenfield and brownfield context, a *U.S. person* may not *know* at the time of the transaction that the investment will result in a *covered activity,* yet the Department of the Treasury nevertheless seeks to cover activities intended to bring about the establishment of a *covered foreign person* or a *person of a country of concern's* engagement in a new covered activity, since such a situation is likely to convey intangible benefits from the *U.S. person* to a *covered foreign person.* That a *covered foreign person* ultimately results from a greenfield or brownfield investment would not be necessary for coverage under the proposed rule, as long as the intent to establish a *covered foreign person* is present at the time of the transaction. The Department of the Treasury has assessed that requiring a greenfield or brownfield investment to result in the establishment of a *covered foreign person* or a *person of a country of concern's* engagement in a new covered activity before triggering obligations associated with *covered transaction* status risks undermining the national security goals of the program. For the avoidance of doubt, the Department of the Treasury does not intend to scope in a real estate transaction where the *U.S. person* does not have the requisite *knowledge* or intent.

Joint Venture Investment

The definition of *covered transaction* would include a *U.S. person's* entrance into a joint venture, wherever located, with a *person of a country of concern* where the *U.S. person* either *knows* or intends that the joint venture will engage in a *covered activity.* Like the greenfield or brownfield investment prong above, this is intended to cover situations in which a *covered foreign person* does not exist at the time of a transaction, but the transaction structure presents the opportunity and incentive for the transfer of intangible benefits from a *U.S. person* to a *person of a country of concern* through the joint venture. Similar to a greenfield or brownfield transaction, a *U.S. person's* intent (as distinct from *knowledge*) would be sufficient for coverage in the joint venture context because a *U.S. person* may not *know* at the time of the transaction that the joint venture will engage in a *covered activity,* yet the Department of the Treasury seeks to capture transactions likely to convey intangible benefits to a *covered foreign person.* Also similar to a greenfield or brownfield transaction, the joint venture would need not engage in a *covered activity* for the establishment of the joint venture to be a *covered transaction* under the proposed rule, as long as the *U.S. person* intends for it to do so.

Investment Made as an LP

The definition of *covered transaction* would include *U.S. person* investments made as an LP into certain pooled funds. This approach would differ from other prongs of the definition of *covered transaction* in the ways described below.

First, it would cover only an investment into a non-*U.S. person* pooled investment fund because the activities of such a fund that is a *U.S. person* would be directly addressed by other prongs of this definition.

Second, it would cover an investment only when the *U.S. person knows* at the time of the investment that the pooled fund likely will invest in a *person of a country of concern* engaged in one or more of the three sectors of covered national security technologies and products identified in the Outbound Order. The Department of the Treasury has assessed that when a pooled fund is soliciting investments, it may not yet have identified specific targets in which it seeks to make investments. Therefore, it may not be practicable for an LP to *know* where its investment is going, via the pooled fund, in terms of a specific target entity even following a reasonable and diligent inquiry at the time of its LP investment. However, it is possible for an LP to *know,* through a reasonable and diligent inquiry, where a pooled fund is likely to invest at a higher level in terms of geography and sector. For example, a *U.S. person* could *know* that a pooled fund is likely to invest in PRC AI companies based on researching past investments made by a pooled fund's manager, engaging with the pooled investment fund's general partner, or reviewing such fund's prospectus or other documentation.

Third, this approach would cover an LP investment only when the pooled investment fund undertakes an investment that would be a *covered transaction* if made by the *U.S. person* directly, to avoid regulating transactions by *U.S. person* LPs that do not ultimately result in investments into a *covered foreign person.* In other words, in order to meet the criteria of a *covered transaction,* (1) the *U.S. person* LP would need to invest in a pooled fund that the *U.S. person knows* is likely to invest in a *person of a country of concern* that is in any of the three specified sectors in the Outbound Order; and (2) such pooled fund would need to actually undertake a transaction that would be a *covered transaction* if undertaken by a *U.S. person.* If the transaction is a *notifiable transaction,* this would mean that the *U.S. person* would be required to file the relevant notification no later than 30 calendar days following the earliest date of the pooled fund's investment in a *covered foreign person.* If the investment ultimately made by the pooled fund would have been a *prohibited transaction* if made by a *U.S. person* and the *U.S. person knew* at the time of its LP investment in the pooled fund that the pooled fund likely would invest in a *person of a country of concern* engaged in any of the three specified sectors in the Outbound Order, then such investment made by the pooled fund in a *covered foreign person* would result in the *U.S. person* having made a *prohibited transactio*n, which would be a violation of the proposed rule. On the other hand, a *U.S. person's* investment as an LP into a pooled fund would not be a *covered transaction* if the *U.S. person* does not *know* at the time of its investment that the pooled investment fund likely will invest in a *person of a country of concern* that is in any of the three relevant sectors, even when such fund subsequently undertakes an investment that would be a *covered transaction* if made by a *U.S. person.*

Indirect Covered Transaction

To address a potential loophole, a *U.S. person's* transaction that is indirect, as well as direct, would be a *covered transaction* regardless of the number of intermediary entities involved in such transaction if it meets the elements of the definition. For example, if a *U.S. person* purchased shares in a special purpose vehicle, wherever located, that in turn acquired an equity interest in a *covered foreign person,* and the *U.S. person knew* at the time of its transaction that the special purpose vehicle would be acquiring an equity interest in a *covered foreign person,* that transaction would be a *covered transaction.*

Knowledge Requirement for a Covered Transaction

As set forth in the proposed rule, a transaction that otherwise has the attributes of a *covered transaction* ordinarily would be treated as a *covered transaction* only if the relevant *U.S. person knows* at the time of the transaction that the transaction involves, or will result in the establishment of, a *covered foreign person* (or will result in a *person of a country of concern's* engagement in a

new *covered activity*). As discussed with respect to Subpart A, *knowledge* for this purpose includes both actual knowledge and reason to know of the relevant facts or circumstances—that is, *a U.S. person* that had reason to know of the relevant facts or circumstances would not be excused from obligations or liability associated with entering into a *covered transaction* due to its alleged lack of actual knowledge of those facts or circumstances. Please see the discussion in Subpart A above for further information on how *knowledge,* which includes reason to know, would be assessed.

The following examples illustrate the application of the proposed definition of *covered transaction:*

(7) *Example 7.* A *U.S. person* acquires an existing manufacturing facility in a *country of concern* that does not, at the time of the acquisition, engage in a *covered activity.* Prior to the transaction, the *U.S. person* extensively researches the feasibility of retrofitting the facility to undertake a *covered activity* and secures financing on the basis of future cash flows from the facility's undertaking of such *covered activity.* The acquisition would therefore be a *covered transaction* under § 850.210(a)(4)(i) because it is the acquisition of assets in a *country of concern* that the *U.S. person* intends at the time of the transaction to result in the establishment of a *covered foreign person.*

(8) *Example 8.* A *U.S. person* invests as an LP in Company M, a pooled fund which is not a *U.S. person.* At the time of the *U.S. person's* investment, Company M has not undertaken any investments. However, Company M's manager has an extensive track record of investing predominantly in the artificial intelligence sector in a *country of concern.* Company M's prospectus states that Company M will invest in entities that are leading AI technology advancements including those with a principal place of business in a *country of concern.* One year following the conclusion of fundraising, Company M undertakes a transaction that would be a *covered transaction* if undertaken by a *U.S. person.* The *U.S. person's* investment as an LP would therefore be a *covered transaction* under § 850.210(a)(6), because the *U.S. person* had reason to know (and therefore is deemed to have *known*) that Company M was likely to invest in a *person of a country of concern* engaged in one of the sectors enumerated in § 850.210(a)(6), and Company M subsequently undertook a transaction that would be a *covered transaction* if undertaken by a *U.S. person.* More specifically, if Company M's transaction would be a *prohibited transaction* if undertaken by a *U.S. person,* then the *U.S. person's* investment as an LP into Company M would be a *prohibited transaction;* if Company M's transaction would be a *notifiable transaction* if undertaken by a *U.S. person,* then the *U.S. person's* investment as an LP into Company M would be a *notifiable transaction.* The *completion date* of the transaction for the purpose of the deadline for a submission of the required notification would be the earliest date upon which any interest, asset, property, or right in the relevant *covered foreign person* was conveyed, assigned, delivered, or otherwise transferred to Company M. It would not be the date of the *U.S. person's* original investment in Company M.

(9) *Example 9.* Assume the same facts as Example 8, except that Company M never undertakes a transaction that would be a *covered transaction* if undertaken by a *U.S. person.* As a result, the *U.S. person's* LP investment in Company M would not be a *covered transaction,* as Company M's undertaking of a transaction that would be a *covered transaction* if undertaken by a *U.S. person* is a necessary element of § 850.210(a)(6) of the proposed rule.

Some commenters to the ANPRM requested that certain other activities be either included in the definition of *excepted transaction* or explicitly excluded from the definition of *covered transaction.* These include university-to-university research collaborations; the sale of goods and services; the purchase, sale, and licensing of intellectual property; and a variety of financial and non-financial services ancillary to a transaction such as the processing, clearing, or sending of payments by a bank. The proposed definition of *covered transaction* has been crafted to refer to a narrow set of specific transaction types, and the proposed rule does not explicitly exclude a list of other activities from this definition as it is not necessary (for any transaction to be covered, the elements in the definition of *covered transaction* need to be met).

Under § 850.210(b)(ii), consistent with the Outbound Order, a transaction undertaken for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof would not be a *covered transaction.*

§ 850.214—Excepted Transaction

The proposed rule includes a definition of *excepted transaction* that refers to a transaction that is not a *covered transaction* because it meets specified conditions. See the discussion of Subpart E below for more information.

§ 850.216—Knowledge

The proposed rule defines *knowledge* (which includes variants such as ''know'') as actual knowledge that a fact or circumstance exists or is substantially certain to occur, an awareness at the time of a transaction of a high probability of a fact or circumstance's future occurrence, or reason to know of a fact or circumstance's existence. Consistent with commenter requests in response to the ANPRM that the terms align with other U.S. Government programs where possible, this language is similar to the definition of knowledge found in the Export Administration Regulations at 15 CFR 772.1. See the above discussion of Subpart A for more information on how this term would be applied in the proposed rule.

§ 850.217—Notifiable Transaction

A *notifiable transaction* would be a *covered transaction* in which the relevant *covered foreign person* undertakes (or in the case of certain greenfield, brownfield, or joint venture investments, the *U.S. person knows* will or intends to undertake) any of several specified *covered activities* listed in the proposed definition of *notifiable transaction.* At this time, the Department of the Treasury has determined that the listed activities may contribute to the threat to the national security of the United States identified in the Outbound Order. Each of the technical descriptions and, where applicable, references to end uses in the proposed definition, is designed to achieve the national security policy objectives of the Outbound Order, and the Department of the Treasury may consider further technical refinements consistent with these objectives. Each *covered activity* for purposes of a *notifiable transaction* is discussed below.

The submission of information to the Department of the Treasury regarding a *notifiable transaction* would increase the U.S. Government's visibility into a transaction involving technologies and products relevant to the threat to the national security of the United States identified in the Outbound Order. This information would be instructive in identifying sectoral trends and related capital flows in the covered activities. Additionally, it would inform future policy development with respect to both implementation of the Outbound Order, as well as the establishment or expansion of other U.S. Government programs relevant to the covered

national security technologies and products. It is expected that this information would help policymakers determine whether any existing legal authorities should be used, or new action should be taken to address the threat to the national security of the United States identified in the Outbound Order. The Department of the Treasury invites comments on whether the proposed definition of *notifiable transaction* meets these goals.

Integrated Circuit Design and Production

The *covered activities* set forth in the definition of *notifiable transaction* would include the design, fabrication, or packaging of any integrated circuit that is not covered by the *prohibited transaction* definition (*i.e.,* that does not meet the performance parameters and criteria identified in § 850.224(c), (d) and (e), as applicable). The proposed rule separately defines the terms *fabricate* and *package,* adding further technical detail as to both the notification and prohibition provisions. The Department of the Treasury assesses that the scope of this notification requirement would increase the U.S. Government's visibility into the volume and nature of investments of *U.S. person* transactions involving the defined technologies and products that may contribute to the threat to the national security of the United States.

AI Systems

The *covered activities* set forth in the definition of *notifiable transaction* would include the development of an *AI system* that is not covered by the *prohibited transaction* definition (*i.e.,* that does not meet the criteria identified in § 850.224(j) or (k)) and that is:

(1) Designed to be used for any government intelligence or mass-surveillance end use (*e.g.,* through mining text, audio, or video; image recognition; location tracking; or surreptitious listening devices) or military end use (*e.g.,* for weapons targeting, target identification, combat simulation, military vehicle or weapons control, military decision-making, weapons design, or combat system logistics and maintenance);

(2) Intended by the relevant *covered foreign person* to be used for cybersecurity applications, digital forensics tools, and penetration testing tools, or the control of robotic systems; or

(3) Trained using a quantity of computing power greater than a certain level of computational operations (*e.g.,* integer or floating-point operations). The Department of the Treasury is considering three potential alternates for the level of computational operations: $10\wedge23$, $10\wedge24$, or $10\wedge25$.

This approach to covering the development of an *AI system* for purposes of a *notifiable transaction* reflects further consideration since the end-use qualification discussed in the ANPRM and focuses on the *AI system's* design in some cases and its intended use by the relevant *covered foreign person* in other cases. Additionally, the proposed rule would include a technical parameter based on the amount of compute used to train an *AI system.* Commenters to the ANPRM recommended, in the context of *prohibited transactions,* adding coverage of transactions involving frontier AI models, defined based on a set of technical parameters. Given the approach related to the development of an *AI system* for purposes of a *prohibited transaction* (discussed below), the proposed rule offers for comment specific technical parameters in the definition of *notifiable transaction* as well. The Department of the Treasury intends to select one of the compute power alternates for purposes of the *prohibited transaction* definition and would potentially set the relevant amount of compute power for the corresponding provision in the definition of *notifiable transaction* below the amount of compute power in the definition of *prohibited transaction* (at § 850.224(k)(1)). For the definition of *notifiable transaction* as well as the definition of *prohibited transaction,* the Department of the Treasury is interested in considering alternatives, including whether the definition should account for (1) specialized AI models trained on high-quality data that could require a lower amount of compute power; (2) AI models that can be fine-tuned or retrained to remove safety features; (3) other techniques (such as model scaling, Monte Carlo Tree Search, pruning, chain of thought, that could be used to increase performance); or (4) other relevant considerations, including alternative language with respect to the definition of *covered activities* relating to *AI systems* for purposes of *notifiable transactions* to add clarity or more precisely capture activities giving rise to the national security concerns related to the development of *AI systems.*

§ 850.221—Person of a Country of Concern

This defined term is a component of the definitions of *covered foreign person* and *covered transaction.* It would include an individual who is a citizen or permanent resident of a *country of concern* and exclude U.S. citizens and U.S. permanent residents. It would also include an entity with a principal place of business in, headquartered in, incorporated in, or organized under the laws of a *country of concern.* The Department of the Treasury invites comments on the impact of this definition as proposed, particularly whether other categories of persons in addition to U.S. citizens and permanent residents should be excluded from the definition of *person of a country of concern.*

The definition would also include the government of a *country of concern,* persons acting on behalf of such a government, and persons controlled by or directed by such a government. The Department of the Treasury expects that, through a reasonable and diligent inquiry, a *U.S. person* should be able to determine whether a potential investment target involves *a person of a country of concern* as defined in the proposed rule.

Finally, the definition would include any entity, wherever located, in which one or more *persons of a country of concern,* individually or in the aggregate, hold at least 50 percent of any outstanding voting interest, voting power of the board, or equity interest, regardless of whether the interest is held directly or indirectly. This is intended to capture entities located outside of a *country of concern* that are majority-owned by *persons of a country of concern,* because a *U.S. person* investment into such an entity could result in the transfer of intangible benefits to or for the benefit of one or more *persons of a country of concern.* When evaluating a tiered ownership structure for any given entity, a *U.S. person* would need to determine whether *persons of a country of concern,* individually or in the aggregate, hold at least 50 percent of the entity's voting interest, voting power of the board, or equity interest, in which case, the entity would be considered a *person of a country of concern.* If the entity meets this criteria, another entity in which it holds at least 50 percent of the entity's voting interest, voting power of the board, or equity interest would also be a *person of a country of concern,* and so on. The definition is intended to draw a bright line so that it is straightforward for a *U.S. person* to ascertain whether an entity is a *person of a country of concern.*

The following examples illustrate the application of the proposed definition of *person of a country of concern:*

(10) *Example 10.* Company N has its principal place of business in a country outside of a *country of concern* and is headquartered and incorporated outside

of a *country of concern.* Six citizens of a *country of concern,* each of whom is not a U.S. citizen or U.S. permanent resident, each hold 10 percent of Company N's equity interest. Company N would therefore be a *person of a country of concern* under § 850.221(d), because an aggregate of 60 percent of the entity's equity interest is held by *persons of a country of concern.*

(11) *Example 11.* Assume the same facts as Example 10. In addition, Company N holds 60 percent of the voting power of the board of Company O, which also has its principal place of business in a country outside of a *country of concern* and is headquartered and incorporated outside of a *country of concern.* Company O would therefore be a *person of a country of concern* under § 850.221(e), because 60 percent of Company O's board voting power is held by Company N, which is a *person of a country of concern* under § 850.221(d).

§ 850.224—Prohibited Transaction

A *prohibited transaction* would be a *covered transaction* in which the relevant *covered foreign person* undertakes (or in the case of certain greenfield, brownfield, or joint venture investments, the *U.S. person knows* will or intends to undertake) any of several specified *covered activities* listed in the proposed definition of *prohibited transaction.* At this time, the Department of the Treasury has determined that the listed activities pose a particularly acute national security threat to the United States identified in the Outbound Order. Each of the technical descriptions and, where applicable, references to end uses in the proposed definition, is designed to achieve the focused national security policy objectives of the Outbound Order, and the Department of the Treasury may consider further technical refinements consistent with these objectives. Each *covered activity* for purposes of a *prohibited transaction* is discussed below.

Advanced Integrated Circuit Design and Equipment

The *covered activities* set forth in the definition of *prohibited transaction* would include developing or producing any electronic design automation software for the design of integrated circuits or *advanced packaging.* The proposed rule separately defines the terms *advanced packaging, develop,* and *produce,* adding further technical detail to the prohibition provision. Additional *covered activities* included in the definition of *prohibited transaction* would include developing or producing any of the following: certain front-end semiconductor fabrication equipment designed for performing the volume fabrication of integrated circuits, equipment for performing volume advanced packaging, or other items designed exclusively for use in or with extreme ultraviolet lithography fabrication equipment.

Advanced Integrated Circuit Design and Production

The *covered activities* set forth in the definition of *prohibited transaction* would include designing any integrated circuit that meets or exceeds certain advanced technical thresholds identified by the Bureau of Industry and Security of the Department of Commerce, or integrated circuits designed for operation at or below 4.5 Kelvin. The term would also include the fabrication of advanced integrated circuits that meet the technical criteria specified in the proposed rule. Additionally, the term would include the packaging of any integrated circuit using *advanced packaging* techniques.

Supercomputers

The *covered activities* set forth in the definition of *prohibited transaction* would include developing, installing, selling, or producing any supercomputer enabled by advanced integrated circuits that can provide a theoretical compute capacity of 100 or more double-precision (64-bit) petaflops or 200 or more single-precision (32-bit) petaflops of processing power within a 41,600 cubic foot or smaller envelope. The Department of the Treasury invites comments on the scope of *covered activities* involving supercomputers in the definition of *prohibited transaction* including whether any adjustments or clarification should be made.

Quantum Computers and Components

The *covered activities* set forth in the definition of *prohibited transaction* would include developing a *quantum computer* or producing any of the critical components required to produce a *quantum computer* such as a dilution refrigerator or two-stage pulse tube cryocooler. The proposed rule separately defines the term *quantum computer,* adding further technical detail to the prohibition provision. The Department of the Treasury invites comments regarding this prong of the definition including input on how further clarity might be provided with respect to what is meant by critical components, and the extent to which dilution refrigerator or two-stage pulse tube cryocooler can be further defined in terms of critical performance or otherwise.

Quantum Sensors

The *covered activities* set forth in the definition of *prohibited transaction* would include developing or producing any quantum sensing platform designed for, or which the relevant *covered foreign person* intends to be used for, military, government intelligence, or mass-surveillance end uses. The proposed rule includes an end-use limitation to appropriately scope this activity to circumstances that could give rise to a particularly acute national security threat, recognizing that similar technologies could have important civilian purposes.

Quantum Networking and Quantum Communication Systems

The *covered activities* set forth in the definition of *prohibited transaction* would include developing or producing any quantum network or quantum communication system designed for, or which the relevant *covered foreign person* intends to be used for: (1) networking to scale up the capabilities of *quantum computers;* (2) secure communications, such as quantum key distribution; or (3) any other application that has military, government intelligence, or mass-surveillance end use. The proposed rule includes an end-use limitation to appropriately scope this activity to circumstances that could give rise to a particularly acute national security threat, recognizing that similar technologies could have civilian purposes.

AI Systems

Some commenters to the ANPRM noted that the AI definitions under consideration in connection with a *prohibited transaction* could apply broadly and potentially sweep in civilian uses of an *AI system* unnecessarily. As noted above, the policy objective is to cover U.S. investment into entities that develop *AI systems* that have applications that pose a particularly acute national security threat without broadly capturing investments into entities that develop *AI systems* intended only for consumer applications or other civilian end uses that do not have potential national security consequences. To make sure the scope of *prohibited transactions* related to the development of any *AI system* appropriately addresses the national security threat identified in the Outbound Order, the *covered activities* would include any *AI system* that is designed to be exclusively used for, or which the relevant covered foreign

person intends to be used for, any military end use (*e.g.,* for weapons targeting, target identification, combat simulation, military vehicle or weapon control, military decision-making, weapons design, or combat system logistics and maintenance); or government intelligence or mass surveillance end use (*e.g.,* through mining text, audio, or video; image recognition; location tracking; or surreptitious listening devices). Additionally, as discussed above in connection with *notifiable transactions* involving the development of *AI systems,* commenters to the ANPRM recommended, among other things, adding coverage of transactions involving frontier AI models and defined based on a set of technical parameters. The proposed rule offers for comment specific technical parameters in describing any *AI system* that is trained using a certain quantity of computing power generally and separately, any *AI system* that is trained using a certain quantity of computing power using primarily biological sequence data. The Department of the Treasury is considering setting the general computing power threshold for a *prohibited transaction* at one of three levels: 10^24, 10^25, or 10^26 computational operations (*e.g.,* integer or floating-point operations). As discussed above in connection with *notifiable transactions* involving the development of *AI systems,* the Department of the Treasury intends to select one of the general compute power alternates for purposes of the *prohibited transaction* definition and would potentially set the relevant amount of compute power for the corresponding provision in the definition of *notifiable transaction* (at § 850.217(d)(3)) below the amount of compute power in the definition of *prohibited transaction.* With respect to *AI systems* trained primarily using biological sequence data, the Department of the Treasury is considering setting the computing power threshold at one of two levels: 10^23 or 10^24 computational operations. As noted below, the Department of the Treasury is considering whether this approach with respect to biological sequence data should be utilized for the definition of a *notifiable transaction* rather than the definition of a *prohibited transaction.* Regardless, the Department of the Treasury invites comments on the impacts of setting the computing power threshold at the various levels proposed as alternates.

The Department of the Treasury, in consultation with other departments and agencies, has determined that the *covered activities* described in connection with *AI systems* pose a particularly acute threat to the national security of the United States and thus are appropriate for the definition of *prohibited transaction.* The specified end uses relate directly to the national security threats identified in the Outbound Order, and the Department of the Treasury, in consultation with other departments and agencies, has determined that transactions involving either an *AI system* exclusively designed to be deployed for such an end use or the relevant *covered foreign person's* intent to use an *AI system* for such an end use present a particularly acute threat to U.S. national security. Meanwhile, the general computing power thresholds set forth for consideration would cover powerful AI models, which could enable potential applications of concern, such as the design, synthesis, acquisition, or use of chemical, biological, radiological, or nuclear weapons; powerful offensive cyber operations; or the evasion of human control or oversight through deception or obfuscation. Such models can also enable next-generation military capabilities through improving the speed and accuracy of military decision-making and intelligence capabilities. Models trained using a quantity of computing power greater than 10^23 or 10^24 computational operations using primarily biological sequence data could enable potential biotechnology applications of concern, including for the design of biological weapons. The Department of Treasury welcomes comments on whether any transactions involving *AI systems* that could pose a threat to U.S. national security as identified in the Outbound Order would not be covered by the definitions of a *notifiable transaction* or a *prohibited transaction.* The Department of the Treasury invites comments on the impacts of each of these computing power threshold alternates. The Department of the Treasury is also interested in comments on whether and why this approach to biological sequence data should instead be considered for the notification requirement rather than the prohibition.

Cross-Reference to U.S. Government Lists

The definition of *prohibited transaction* would also provide that any *covered transaction* is prohibited when it is with or involves a *covered foreign person* undertaking any *covered activity*—whether referred to in the definition of *prohibited transaction* or in the definition of *notifiable transaction*—if the *covered foreign person* is included on one of several U.S. Government lists, such as the Entity List maintained by the Bureau of Industry and Security within the Department of Commerce. Because the United States has already determined that the inclusion of a person on such a list evidences a threat to the interests of the United States, such as the foreign policy or national security of the United States, if a listed person is a *covered foreign person* engaged in any *covered activity,* then a *U.S. person's covered transaction* with such *covered foreign person* and the transfer of capital and *U.S. person* intangible benefits to them would pose a particularly acute risk to U.S. national security even when such listed person is engaged in what would otherwise qualify as only a *covered activity* under the *notifiable transaction* definition.

§ 850.229—U.S. Person

The proposed rule would apply to the conduct of a *U.S. person* only. In the proposed rule, a *U.S. person* would include any United States citizen or lawful permanent resident, as well as any entity organized under the laws of the United States or any jurisdiction within the United States, including any foreign branch of any such entity, or any person in the United States. This would mean that an entity organized in the United States would be considered a *U.S. person* for purposes of the proposed rule even if its *parent* is a non-*U.S. person.*

Some commenters to the ANPRM raised questions about the potential extraterritorial reach of the proposed rule as it relates to this term. Depending on how *U.S. person* is defined, these commenters noted that the proposed rule could purport to restrict activity taking place outside of the United States. In response to these comments, the Department of the Treasury clarifies two points. First, a non-*U.S. person* that happens to be a *parent* of a *U.S. person* would not be treated as a *U.S. person* for the purposes of this proposed rule solely because of its relationship to the *U.S. person.* Second, while any person in the United States, including personnel of a non-*U.S. person* entity working in a branch office of that entity or otherwise, would be considered a *U.S. person* under the proposed rule based on their presence in the United States, such person's non-*U.S. person* employer would not be considered a *U.S. person* solely because of an employee's presence in the United States. The Department of the Treasury invites comments regarding this proposed approach.

Some commenters to the ANPRM noted that the potential inclusion of ''any person in the United States'' in this definition could scope in a non-*U.S. person* in transit through the United States that takes an action during this transit that could constitute a *covered transaction,* such as signing investment paperwork, and therefore this portion of the definition should be scaled back or removed. However, the inclusion of ''any person in the United States'' mirrors the language used in the definition of ''United States person'' in the Outbound Order. The Department of the Treasury is concerned with persons who are neither citizens nor permanent residents and who are nevertheless able to accrue knowledge, experience, networks, and other intangible assets while they are in the United States that could convey valuable benefits to a *covered foreign person.* The circumstance of a non-U.S. citizen or permanent resident individual in transit through the United States who wishes to enter into a transaction that could trigger program coverage, while possible, is not likely to be a frequent occurrence and can be reasonably managed with advance planning.

Subpart C—Prohibited Transactions and Other Prohibited Activities

This subpart of the proposed rule describes activities that would be prohibited. Such activities would include a *U.S. person* engaging in a *prohibited transaction* unless an exemption has been granted and would include a *U.S. person knowingly directing* an otherwise *prohibited transaction,* as described below. A *U.S. person* would also be required to take all reasonable steps to prohibit and prevent any transaction by its *controlled foreign entity* that would be a *prohibited transaction* if engaged in by a *U.S. person.*

§ 850.303—Knowingly Directing an Otherwise Prohibited Transaction

Subpart C includes a prohibition on a *U.S. person* that possesses authority at a non-*U.S. person* entity from *knowingly directing* a transaction by that non-*U.S. person* entity that would be a *prohibited transaction* if undertaken by a *U.S. person.* This provision is intended to address a potential loophole, such as a *U.S. person* senior manager at a foreign fund that invests in a *covered foreign person* or otherwise directs a transaction that would be prohibited if engaged in by a *U.S. person.*

In the ANPRM, the Department of the Treasury noted that it was considering applying this provision to situations where a *U.S. person,* with knowledge, ''orders, decides, approves, or otherwise causes to be performed a transaction that would be prohibited under these regulations if engaged in by a U.S. person.'' Commenters to the ANPRM sought clarity on this language, including at what stage of an investment such ''directing'' would occur, what level of involvement or responsibility would be required to trigger the definition, and through what types of entities such ''knowingly directing'' would need to occur to be covered. Commenters to the ANPRM also asked for clarification that ordinary banking activities would not be scoped into this definition.

The Department of the Treasury's proposed approach to this provision is guided by several goals: (1) establishing a clear standard so a *U.S. person* (or a non-*U.S. person* employing such *U.S. person*) can determine whether its (or its employee's) conduct is covered; (2) limiting the reach of the provision to minimize the potential impact on non-senior *U.S. person* employees, including administrative staff and individuals not playing a substantial role in an investment decision; and (3) capturing concerning *U.S. person* activities in a targeted manner.

Under the proposed rule, a *U.S. person* ''knowingly directs'' a transaction when such *U.S. person* has authority to make or substantially participate in decisions on behalf of a non-*U.S. person* entity and exercises that authority to direct, order, decide upon, or approve a transaction that would be a *prohibited transaction* if engaged in by a *U.S. person.* The proposed provision specifies that a *U.S. person* would have authority if such *U.S. person* is an officer, director, or senior advisor, or otherwise possesses senior-level authority. The Department of the Treasury requests comments on the impacts of the proposed approach as well as any alternatives that commenters consider appropriate.

In response to commenter questions on the ANPRM about whether this provision would apply only to the activity of *U.S. persons* at non-*U.S. person* funds, or to non-financial entities as well, the proposed rule clarifies that this provision would prohibit a *U.S. person* from *knowingly directing* a transaction via any type of non-*U.S. person* entity if the subject transaction would be a *prohibited transaction* if undertaken by a *U.S. person.* In response to commenter questions on the ANPRM about whether ordinary banking activities would be included in the definition of *knowingly directing,* the Department of the Treasury's proposed approach to this provision is intended to avoid scoping in the provision of third-party services such as banking services, as well as routine administrative work by a *U.S. person* who lacks substantial involvement in an investment decision. Rather, the Department of the Treasury's objective is to address a potential loophole that could otherwise permit a *U.S. person* to transfer capital and intangible benefits to a *covered foreign person* via a non-*U.S. person* entity.

The following example illustrates the application of the proposed definition of *knowingly directing:*

(12) *Example 12.* A *U.S. person* is a senior executive at Company P, a non-*U.S. person* operating company. The *U.S. person's* role includes substantial participation in investment decisions related to Company P's strategic acquisitions. The *U.S. person* participates in deliberations among Company P's leadership about whether to undertake a share purchase in Company Q, a privately-held *covered foreign person* that develops a *quantum computer.* Following these deliberations, the *U.S. person* votes in favor of the share purchase and *knows* at the time of the vote that the share purchase would be a *prohibited transaction* if undertaken by a *U.S. person.* Therefore, the *U.S. person* would have *knowingly directed* an otherwise *prohibited transaction* under the proposed rule.

Wherever possible, consistent with national security objectives, the Department of the Treasury seeks to avoid broad implications on the employment of *U.S. persons.* As a result, the proposed approach would carve out a *U.S. person* who recuses themself from an investment even if that person has the authority to make or substantially participate in decisions on behalf of a non-*U.S. person* entity. The Department of the Treasury invites comments regarding the proposed approach, particularly to what stage of an investment this recusal carveout should apply (*e.g.,* negotiation of a transaction, the decision to undertake the transaction, and/or overseeing the investment after the *completion date*).

Subpart D—Notifiable Transactions and Other Notifiable Activities

This subpart of the proposed rule would require a *U.S. person* to notify the Department of the Treasury in any of the following circumstances:

- If it undertakes a *notifiable transaction* (§ 850.401);
- If its *controlled foreign entity* undertakes a transaction that would be notifiable if undertaken by a *U.S. person* (§ 850.402), or;

• If the *U.S. person* acquires actual knowledge following the *completion date* of a transaction that the transaction would have been a *covered transaction* if the *U.S. person* had *known* of relevant facts or circumstances as of the *completion date* (§ 850.403).

In each of the above circumstances, the *U.S. person* would be required to follow specified procedures that include requirements to submit detailed information to the Department of the Treasury according to set timeframes and to certify as to the completeness and accuracy of the information submitted, as well as to maintain relevant records. A *U.S. person* would also be required to promptly notify the Department of the Treasury of any material omission or inaccuracy that the *U.S. person* learns about following any information submission.

The requirement to notify the Department of the Treasury in § 850.403 would apply to circumstances in which a *U.S. person* acquires actual knowledge after the window in which a § 850.401 notification could have been timely submitted. Specifically, the § 850.403 notification requirement would apply to situations where a *U.S. person* did not possess *knowledge* at the time of the transaction of a fact that, if *known* at the time of the transaction, would have made the transaction a *covered transaction* (such as, for example, the investment target's engagement in a *covered activity*). The information requirements for a § 850.403 notification include an explanation by the *U.S. person* as to why it did not possess or obtain such *knowledge* at the time of the transaction and to describe any pre-transaction diligence.

Some commenters stated that certain of the information considered in the ANPRM as elements of a complete notification could be difficult to obtain or burdensome to provide and cautioned that certain information requirements could have an unintended chilling effect on transactions in the relevant activities described in the ANPRM. The proposed rule seeks to address the national security threat described in the Outbound Order while minimizing unintended consequences. In light of this, the proposed rule contains information requirements for a *notifiable transaction* that would provide important details regarding a transaction, but are more focused than those listed in the ANPRM. The proposed rule also would require the *U.S. person* to maintain a copy of the notification and supporting documentation for ten years (consistent with the 21st Century Peace through Strength Act of 2024 (Sec. 3111, Pub. L. 118–50), which amended section 206 of IEEPA and extended the statute of limitations for violations of IEEPA from five years to ten years), during which period the Department of the Treasury could request such documents.

In response to comments to the ANPRM that a requirement to submit a notification before the *completion date* of a transaction could have the effect of delaying the transaction, the proposed rule would allow a notification to be submitted no later than 30 calendar days following the *completion date* of a *notifiable transaction.* In other words, the *U.S. person* could submit the notification at any point prior to the *completion date* of the *notifiable transaction* or within 30 calendar days following the *completion date.*

The following example illustrates the application of the proposed definition of *completion date* and the submission of a notification in the context of an acquisition of a *contingent equity interest:*

(13) *Example 13.* A *U.S. person* acquires a *contingent equity interest* in a *covered foreign person* in a transaction that is a *notifiable transaction.* One year later, the *contingent equity interest* converts into an equity interest. The *U.S. person's* acquisition of a *contingent equity interest* and subsequent conversion into an equity interest each constitute a separate *covered transaction* under § 850.210(a)(1) and § 850.210(a)(3), respectively. Under § 850.204, § 850.401, and § 850.404, the *U.S. person* would be required to file the first notification with the Department of the Treasury no later than 30 calendar days following the *completion date* of the first *covered transaction,* which would be the earliest date upon which the *contingent equity interest* is conveyed, assigned, delivered, or otherwise transferred to the *U.S. person.* Likewise, the *U.S. person* would be required to file the second notification with the Department of the Treasury no later than 30 calendar days following the *completion date* of the second *covered transaction,* which would be the earliest date upon which the equity interest (resulting from the conversion of the *contingent equity interest*) is conveyed, assigned, delivered, or otherwise transferred to the *U.S. person.*

Subpart E—Exceptions and Exemptions

This subpart of the proposed rule specifies particular factors that would cause an otherwise *covered transaction* to be treated as an *excepted transaction.* This subpart also specifies provisions that would apply when a transaction is a *covered transaction* but a party to that transaction seeks an exemption from certain applicable rules on national interest grounds (which, if granted, would cause the transaction to be an exempted transaction).

§ 850.501—Excepted Transaction

In keeping with the goal of tailoring the proposed rule to address the national security threat described in the Outbound Order while minimizing disruptive effects on *U.S. persons,* the proposed rule would define certain exceptions. A transaction that otherwise would qualify as a *covered transaction* but meets one of the exceptions would be referred to as an *excepted transaction.* The Department of the Treasury considers that a transaction that would qualify as an *excepted transaction* presents a lower likelihood of the transfer of intangible benefits to the *covered foreign person* or is otherwise less likely to present national security concern than a *covered transaction.*

As discussed in detail below, an *excepted transaction* would include the following (subject to conditions in some instances, as explained below):

• An investment by a *U.S. person* in a publicly traded security;

• An investment by a *U.S. person* in a security issued by an investment company, such as an index fund, mutual fund, or exchange traded fund;

• An investment of a certain size by a *U.S. person* LP in a pooled investment fund;

• A *U.S. person's* full buyout of all interests *of any person of a country of concern* in an entity, such that the entity would not constitute a *covered foreign person* following the transaction;

• An intracompany transaction between a *U.S. person parent* and its subsidiary to support ongoing operations (or other activities that are not *covered activities* as defined in § 850.208);

• Fulfillment of a *U.S. person's* binding capital commitment entered into prior to the date of the Outbound Order;

• The acquisition of a voting interest in a *covered foreign person* upon default or other condition involving a loan, where the loan was made by a lending syndicate and a *U.S. person* participates passively in the syndicate; and

• Certain transactions that occur in a country or territory outside the United States that has been designated by the Secretary in accordance with provisions set forth in § 850.501(f) of the proposed rule.

To make sure these exceptions are consistent with the policy objectives, certain of the transactions described

above would cease to qualify as an *excepted transaction* if a *U.S. person* were to obtain certain investor rights beyond standard minority shareholder protections (for example, in connection with publicly traded securities or an LP investment).

The ANPRM proposed an exception for an investment into a publicly traded security, with ''security'' defined as set forth in section 3(a)(1) of the Securities Exchange Act of 1934. In response to the ANPRM, some commenters requested that the definition of ''publicly traded security'' be broadened from the definition of ''security'' used in the discussion of excepted transactions in the ANPRM to align with the definition used by the Department of the Treasury's Office of Foreign Assets Control in connection with the Non-SDN Chinese Military-Industrial Complex Companies List. The proposed rule would effectively broaden the carveout to include a security traded on a non-U.S. exchange, or a security traded ''over-the-counter,'' in addition to a security traded on a U.S. exchange. The proposed rule would adopt this suggestion because a *U.S. person's* purchase of securities traded on a public exchange, whether inside or outside the United States, presents a lower likelihood of transferring intangible benefits to a *covered foreign person.*

The proposed rule also would provide an exception for investment in securities issued by an investment company, such as an index fund, mutual fund, or exchange traded fund, as well as a business development company under the Investment Company Act of 1940, as amended.

Similarly, a *U.S. person* making an LP investment under a specified threshold into a pooled fund that then invests in a *covered foreign person* would, subject to the specified criteria, constitute an *excepted transaction.* The rationale for this approach is that LP transactions above a certain threshold are more likely to involve the transfer of intangible benefits such as those often associated with larger institutional investors, including standing and prominence, managerial assistance, and enhanced access to additional financing. When a *U.S. person's* committed capital to a pooled investment fund as an LP exceeds a certain threshold, the *U.S. person* may have greater incentive and potentially greater ability to impact the success of a *covered foreign person* in which the pooled fund invests. The proposed rule presents two alternate approaches for defining the threshold beneath which a *U.S. person's* LP investment into a pooled fund that then invests in a *covered foreign person* would constitute an *excepted transaction.*

Under proposed Alternate 1, a *U.S. person's* investment made as an LP in a pooled fund would constitute an *excepted transaction* if (1) the LP's rights are consistent with a passive investment and (2) the LP's committed capital is not more than 50 percent of the total assets under management of the pooled fund. If the *U.S. person* LP's committed capital were to constitute more than 50 percent of the total assets under management of the pooled fund, its investment would qualify as an *excepted transaction* only if the *U.S. person* secured a binding agreement that the pooled fund would not use its capital for a *prohibited transaction.* This approach was developed to address the likelihood of intangible benefits being transferred by such an investment if, for example, a *U.S. person's* LP investment is large enough compared to the investable assets of the pooled fund such that the *U.S. person* LP is an anchor investor or otherwise wields substantial influence that would allow it to guide the pooled fund's investment decisions or interact regularly with the pooled fund's investment targets. This approach would also address situations where the *U.S. person's* LP investment falls below the threshold but contains one of several indicia of control or influence over the pooled fund or the ultimate *covered foreign person* investment target by excluding such an investment from the definition of *excepted transaction.*

Under proposed Alternate 2, a *U.S. person's* investment made as an LP in a pooled investment fund would constitute an *excepted transaction* if the LP's committed capital is not more than $1 million. The rationale for this alternate approach is that if an LP investment is above the $1 million threshold, a *U.S. person's* LP investment may be large enough that its investment transfers intangible benefits, such as standing and prominence that an underlying *covered foreign person* investment target could exploit for legitimacy or for further fundraising purposes. Although this alternate may scope in a greater number of LP investments as *covered transactions* compared to Alternate 1, this bright-line approach may be easier to comply with while still addressing the risk of intangible benefits being transferred by such an investment.

An *excepted transaction* also would include a *U.S. person's* full buyout of the interests of a *person of a country of concern* in an entity, where the entity would not constitute a *covered foreign person* following the transaction. As discussed in the ANPRM, the objective of this exception is to carve out from coverage a transaction that eliminates the likelihood that intangible benefits of a *U.S. person* transfer to a *covered foreign person,* because following a full buyout, a *person of a country of concern* will no longer have any interest in the target of the buyout.

An *excepted transaction* would also include certain intracompany transactions—that is, a transaction between a *U.S. person* and its *controlled foreign entity* to support ongoing operations or other activities that are not *covered activities.* The goal of this exception is to avoid unintended interference with the ongoing operations of a *U.S. person's controlled foreign entity* even when that *controlled foreign entity* also meets the definition of *covered foreign person.* The Department of the Treasury expects that the initial acquisition or establishment of the subsidiary would already constitute a *covered transaction,* and where it does not, the potential impacts on the *U.S. person* from covering such intracompany transactions under the proposed rule would likely outweigh the benefit in terms of the objectives of the Outbound Order. Although the definition of *covered transaction* in the proposed rule would not usually apply to most routine intracompany activities such as the sale or purchase of inventory or fixed assets, the provision of paid services, or the licensing of technology, the intracompany transaction exception in the proposed rule nonetheless excepts intracompany transactions that would be *covered transactions* but support activities that are not *covered activities.* To avoid use of the intracompany transaction exception to establish new *covered foreign persons* or to pivot existing subsidiaries into a new *covered activity,* the exception would not apply to greenfield investments, pivots of existing entities' operations into *covered activities,* and joint ventures.

Consistent with the ANPRM, the proposed definition of *excepted transaction* would also include any transaction made in fulfillment of a *U.S. person's* binding capital commitment entered into prior to the effective date of the Outbound Order (August 9, 2023). A *U.S. person* would not have been aware of the scope of the Outbound Order and directive for the implementation of the prohibition and notification requirement before the Outbound Order was issued, and this exception is intended to avoid significant disruption to a *U.S. person* who entered into a binding commitment prior to August 9, 2023. The ANPRM,

issued on the same day as the Outbound Order, also included discussion of a possible exception for fulfillment of ''binding capital commitments . . . made prior to the issuance of the [Outbound] Order.'' The Department of the Treasury proposes to specify that this proposed exception applies to any transaction made in fulfillment of a binding capital commitment entered into prior to the date of the Outbound Order. The intent is to effectively address the national emergency identified in the Outbound Order and avoid creating incentives for *U.S. persons* to enter into new binding commitments for a *covered transaction* after issuance of the proposed rule. The Department of the Treasury requests comment on the scope of the exception, including how to address the timing of binding capital commitments.

The definition of *excepted transaction* would also include the acquisition of a voting interest in a *covered foreign person* by a *U.S. person* upon default or other condition involving a loan or similar financing arrangement where the *U.S. person* lender was part of a syndicate of banks and cannot initiate action vis-à-vis the debtor on its own and does not have a lead role in the syndicate. Consistent with the objectives of the Outbound Order, it would except a narrow set of circumstances in which a *U.S. person* lender has passively received an interest in a *covered foreign person* and, even after receiving such interest, lacks a role in the lending syndicate that could create the opportunity for a *U.S. person* lender's intangible benefits to transfer to the *covered foreign person* debtor.

The Department of the Treasury, together with the Departments of State and Commerce and other agencies, recognize the importance of working with our partners and allies and will continue coordinating closely to address our shared national security concerns posed by outbound investment. In recognition of the shared objectives and in furtherance of the U.S. Government's efforts to encourage partners and allies address risks posed by outbound investment, the proposed rule would also provide for the potential application of the term *excepted transaction* to certain transactions with or involving a person of a country or territory outside of the United States designated by the Secretary in accordance with certain criteria (to be developed) that relate to that country or territory's own measures to address the national security risk related to certain outbound investment. The Department of the Treasury expects that any such country or territory would be designated after accounting for factors such as whether the country or territory is regulating outbound investment transactions involving technologies critical to a country of concern's military, intelligence, surveillance, or cyber-enabled capabilities, which technologies are covered by such regulation, and whether such regulation addresses national security concerns posed by outbound investment similar to those addressed by the U.S. outbound program. The Department of the Treasury is considering taking into account other factors for purposes of designating a country or territory, including the extent to which a country or territory cooperates with the United States on issues of national security and whether it has in place and is using related authorities and tools, such as export controls, to protect sensitive technologies and products.

The proposed rule would provide for the application of this exception only to certain types of transactions with or involving a person of a designated country or territory. The proposed rule anticipates that the Secretary would determine the types of transactions for which the related national security concerns are likely to be adequately addressed by measures taken or that may be taken by the government of a country or territory outside the United States. Once developed, the Department of the Treasury intends to make factors for the designation of a country or territory as well as types of transactions and/or activities that would be subject to the exception publicly available on Treasury's Outbound Investment Security Program website. The Department of the Treasury, along with the Departments of State and Commerce, will continue to work with partners and allies as they explore addressing the national security concerns posed by certain outbound investments. The Department of the Treasury invites comments and input on the proposed factors for the Secretary to consider when designating a country or territory in this context as well as comments on the types of transactions or activities that should be excepted once a country or territory has been designated. Additionally, the Department of the Treasury invites comments more generally on efforts to engage internationally on outbound investment security.

§ 850.502—National Interest Exemption

The Outbound Order authorizes the Secretary to ''exempt from applicable prohibitions or notification requirements any transaction or transactions determined by the Secretary, in consultation with the heads of relevant agencies, as appropriate, to be in the national interest of the United States.''

On a case-by-case basis, the Secretary, in consultation with the Secretary of Commerce, the Secretary of State, and the heads of relevant agencies, as appropriate, may determine that a *covered transaction* is in the national interest of the United States and therefore, exempt it from certain provisions of this proposed rule. The Department of the Treasury anticipates that this exemption of a *covered transaction* would be granted by the Secretary in exceptional circumstances.

This section of the proposed rule describes the process and considerations for such a determination. Any determination that a covered transaction is in the national interest of the United States and therefore exempt from certain provisions will be based on a consideration of the totality of the facts and circumstances. The Department of the Treasury anticipates that such determination may be informed by, among other considerations, the transaction's effect on critical U.S. supply chain needs, domestic production needed for projected national defense requirements, the United States' technological leadership globally in areas affecting U.S. national security, and the impact on national security from prohibiting a given transaction. The Department of the Treasury is *not* considering granting retroactive waivers or exemptions (*i.e.,* waivers or exemptions after a *prohibited transaction* has been completed).

In order to request a national interest exemption, a *U.S. person* would need to submit certain information to the Department of the Treasury, including describing the scope of the relevant transaction, the basis for the request, and an analysis of the transaction's potential impact on the national interest of the United States. The Department of the Treasury may request that a *U.S. person* submit information that may include some or all of the information required by § 850.405, as well as additional details based on the facts and circumstances.

Once developed, the Department of the Treasury anticipates detailing the process and required information for any national interest exemption request on the Department of the Treasury's Outbound Investment Program website.

Subpart F—Violations

This subpart of the proposed rule describes conduct that would be treated as a violation of the proposed rule. Such

conduct would include taking any action prohibited by the proposed rule, failing to take any action required by the proposed rule within the timeframe and in the manner specified, and making materially false or misleading representations to the Department of the Treasury when submitting any information required by the proposed rule. The proposed rule would also prohibit any action that evades or avoids or has the purpose of evading or avoiding any of the prohibitions of the proposed rule.

Subpart G—Penalties and Disclosures

This subpart of the proposed rule describes the penalties that would be applicable to violations of the proposed rule by any person subject to the jurisdiction of the United States, which would include civil and criminal penalties up to the maximum amount set forth in section 206 of IEEPA. Under the proposed rule, the Department of the Treasury may impose a civil penalty on any person that violates the rule, and the Secretary may refer potential criminal violations under the proposed rule to the Attorney General. Further, the proposed rule states that the Secretary, in consultation with the heads of relevant agencies, may take action to nullify, void, or otherwise compel divestment of any *prohibited transaction* entered into after the effective date of the rule. This subpart also describes the process for a person that may have violated applicable rules to submit a voluntary self-disclosure. A *U.S. person* could elect to make such a disclosure of actual or possible violations. The Department of the Treasury would take such disclosure into account as a mitigating factor in determining the appropriate response, including the potential imposition of penalties, if the Department of the Treasury determines that there was, in fact, a violation.

Subpart H—Provision and Handling of Information

This subpart describes the Department of the Treasury's proposal to treat as confidential, subject to limited exceptions, information and documentary materials that are submitted pursuant to the regulations and that are not otherwise publicly available. Except to the extent required by law or in accordance with one of the enumerated exceptions, the Department of the Treasury would not disclose such information publicly.

However, consistent with the exceptions set forth in the proposed rule, the Department of the Treasury would be permitted to disclose information that would otherwise be treated as confidential in certain limited circumstances; for example, the Department of the Treasury could disclose information to U.S. partners and allies where the information is important for the national security analysis or actions of the Department of the Treasury or such partners and allies, and subject to appropriate safeguards. Separately, under the proposed rule, the Department of the Treasury could use information submitted to fulfill its obligations under the Outbound Order, which include the requirement to prepare annual reports to the President in coordination with the Secretary of Commerce and in consultation with the heads of other relevant agencies, as appropriate, and could include anonymized data gathered pursuant to this part.

The Department of the Treasury is considering whether there are additional circumstances where disclosure of otherwise confidential information should be permitted. One proposal under consideration would allow the Department of the Treasury to disclose such information to the public as and when the Secretary determines that such disclosure is in the national interest: for example, to promote compliance with the proposed regulations by sharing with the public information about the activities of particular persons of a country of concern. The Department of the Treasury expects that such an exception would be subject to a high bar and limited to circumstances in which the Secretary identifies a pressing national interest that disclosure could help to address. This exception would not supersede any applicable statutory restrictions that may constrain the sharing of certain categories of information, such as information that a party has identified as protected trade secrets information. The Department of the Treasury invites comments on the considerations that it should take into account in identifying the scope of this potential additional exception to confidential treatment, the standard that should apply to the Secretary's determination, and what safeguards may be applicable to disclosure when such an exception applies.

Subpart I—Other Provisions

This subpart of the proposed rule contains provisions related to the delegation of the Secretary's authorities under the Outbound Order, any amendment to or modification of the proposed rule, and a requirement for certain information regarding any transaction to be furnished upon demand. The proposed rule states that, consistent with the statutory authority on which the Outbound Order and the proposed rule are based, the Department of the Treasury has the power to investigate conduct that may constitute a violation, hold hearings, call witnesses, and require in-person testimony or production of documents, among other powers listed in § 850.904.

Subpart I would also establish, in § 850.903, that the provisions of the rule are severable from one another. If any of the provisions of this rule as finalized, or the application thereof to any person or circumstance, were to be held invalid, such invalidity would not affect other provisions or application of such provisions to other persons or circumstances that can be given effect without the invalid provision or application.

IV. Request for Comment

The Department of the Treasury invites comments on any and all aspects of the proposed rule, including and on the specific provisions discussed above in section III and the questions below. The Department of the Treasury invites comments accompanied by empirical data or other specific information wherever possible.

1. Are there areas where the proposed rule is broader than necessary to address the national security concerns identified in the Outbound Order? Are there areas where it is narrower than necessary or contains loopholes? If so, where and what adjustments should be made?

2. How could the knowledge standard in the proposed rule be clarified? What, if any, alternatives should be considered? What other factors should be considered to assess whether a person conducted a reasonable and diligent inquiry?

3. What considerations should the Department of the Treasury take into account with respect to the ease or difficulty with which a *U.S. person* will be able to comply with the proposed rule, particularly with respect to ascertaining whether an investment target or relevant counterparty is a *person of a country of concern* and engaged in a *covered activity*?

4. Are there adjustments to the scope of *covered activities* identified in the definition of either *notifiable transaction* or *prohibited transaction* in the proposed rule (including addition(s), removal(s), or elaboration(s)) that should be made to help ensure that the definition addresses the national security concerns identified in the Outbound Order and discussed above while minimizing

unintended consequences? If so, what are they?

5. Is the line between the *covered activities* identified in the definition of *notifiable transaction* and those in the definition of *prohibited transaction* (with respect to the products and technologies in the semiconductors and microelectronics and the AI sectors) appropriately drawn? What are the potential consequences of the proposed scope of *covered activities* in the definition of *notifiable transaction* and *prohibited transaction* and how should the distinction between the two be adjusted, if at all?

6. How do *U.S. persons* anticipate ascertaining the information necessary to comply with paragraph (a)(2) of the definition of *covered foreign person* at § 850.209? How, if at all, should this definition be adjusted for a situation in which no financial statement (audited or otherwise) is available for a covered foreign person?

7. Are there adjustments to the types and scope of *covered transactions* identified in the proposed rule (including addition(s), removal(s), or elaboration(s)) that should be made to help ensure it addresses the national security concerns identified in the Outbound Order and discussed above while minimizing unintended consequences? If so, what are they?

8. How, if at all, should the definition of *covered transaction* be modified with respect to the conversion of a contingent equity interest or convertible debt? What are the considerations as to the balance among minimizing compliance costs, avoiding over- or under-inclusiveness, while maintaining U.S. Government visibility into the instances of conversion?

9. How, if at all, should the definition of *covered transaction* be modified with respect to LP investments? What considerations should the Department of the Treasury take into account with respect to a *U.S. person's* LP investment qualifying as a *covered transaction* when the relevant pooled investment fund actually undertakes a transaction that would be a *covered transaction* if undertaken by a *U.S. person?*

10. Could the proposed approach to defining an indirect *controlled foreign entity* be further refined to enhance clarity and facilitate compliance, and if so, how?

11. The definitions of *controlled foreign entity* and *person of a country of concern* discuss application of such terms in the case of a tiered ownership structure. Could either of these definitions be further refined to enhance clarity and facilitate compliance with respect to their application in a tiered ownership structure, and if so, how?

12. The proposed definition of *person of a country of concern* (in § 850.221(d)) and the proposed definition of *covered foreign person* (in § 850.209(a)(2)) could include a *U.S. person* entity. What considerations should the Department of the Treasury take into account with respect to an entity qualifying as a *U.S. person* and also as a *covered foreign person* or *person of a country of concern?* What are the instances in, and what is the frequency with which, this may occur?

13. What are the legal, commercial, practical or other consequences of including in, or conversely excluding from, the definition of *U.S. person* a person who is lawfully present in the United States? What are the consequences of an individual simultaneously being both a *person of a country of concern* and a *U.S. person?* Under what circumstances, and with what frequency, may this occur?

14. What are the considerations for *U.S. person* due diligence related to the specified end uses and computing thresholds in the different alternates for an *AI system* in the definitions of *notifiable transaction* and *prohibited transaction?* How would a *U.S. person* investor determine the computational threshold levels of any *AI system* of an investment target or relevant counterparty? What are the considerations with respect to making such determinations related to an entity of a *country of concern* specifically?

15. What would be the impact of a prohibition on *U.S. person* transactions involving entities that develop an *AI system* trained using a quantity of computing power greater than 10^24, 10^25, or 10^26 computational operations? What, if any, unintended consequences could result from adoption of the alternate definitions of *AI system?*

16. What would be the impact of a prohibition on *U.S. person* transactions involving entities that develop an *AI system* trained using a quantity of computing power greater than 10^23 or 10^24 computational operations applied to biological sequence data? What are the considerations or factors weighing in favor or against requiring notification rather than a prohibition in this instance?

17. How should the Department of the Treasury ensure the regulations remain responsive to changes in the sectors identified in the Outbound Order (*i.e.,* the semiconductors and microelectronics, quantum information technologies, and artificial intelligence sectors)?

18. How, if at all, could the prohibition on *knowingly directing* a transaction be modified to best address national security concerns identified in the Outbound Order and discussed above while maximizing clarity and minimizing adverse impacts on *U.S. persons,* including their employment at foreign companies? What, if any, alternatives should be considered?

19. What is the practical utility of a recusal carveout from the prohibition on *knowingly directing* a transaction? What stage(s) of an investment should the recusal carveout from the prohibition on *knowingly directing* apply to (for example, should it apply to negotiating and decision-making related to an investment, management and oversight of the investment after the *completion date,* or something else), and why? In what ways could the recusal carveout's clarity or usefulness be enhanced?

20. What challenges, if any, are anticipated in connection with the information required to be submitted for a *notifiable transaction?* Are they scoped appropriately to obtain information relevant to the national security concerns identified in the Outbound Order and discussed above, including increasing the U.S. Government's visibility into *U.S. person* transactions involving the relevant technologies and products and highlighting trends with respect to related capital flows? If not, how should the information requirements be modified?

21. Are there categories of transactions that should be added to, or removed from, the definition of *excepted transaction* in light of the national security concerns identified in the Outbound Order? If so, what are they and why? What potential consequences should the Department of the Treasury consider in limiting the applicability of the definition of *excepted transaction* to a transaction made pursuant to a binding, uncalled capital commitment entered into before August 9, 2023?

22. Which of the two proposed alternates for the exception for LP investments in the definition of *excepted transaction* best addresses national security concerns while minimizing disruptive effects? Should either approach and corresponding threshold for the exception be adjusted, and if so, why and how? What consequences could result from basing an exception on either of the proposed thresholds? What are the considerations related to compliance by *U.S. persons?* Where available, please support your answer with data about the type, aggregate number, or total dollar

equivalent amount of investments that would be excepted under each of the two proposed alternates.

23. What adjustments, if any, should be made to the proposed rule to clarify the coverage with respect to a greenfield investment, brownfield investment, or joint venture that is a *covered transaction* versus an intracompany transaction to support ongoing operations or other activities in a *country of concern* that is an *excepted transaction?*

24. What is the value to stakeholders of including a national interest exemption for *notifiable transactions, prohibited transactions,* or both? Under what circumstance might a *U.S. person* request a national interest exemption in general? Specifically with respect to a *notifiable transaction,* under what circumstance might a *U.S. person* request a national interest exemption from the notification requirement, while still needing to provide information about the proposed transaction in the course of seeking the exemption?

25. What specific information should the Department of the Treasury require from a *U.S. person* seeking a national interest exemption in order to evaluate the transaction's potential impact on the national interest of the United States and to substantiate the basis for requesting an exemption from the prohibition or notification requirement?

V. Rulemaking Requirements

This rulemaking pertains to a foreign affairs function of the United States and therefore is not subject to the rulemaking requirements of the Administrative Procedure Act (APA) (5 U.S.C. 553), which exempts a rulemaking from notice and comment requirements ''to the extent there is involved . . . a military or foreign affairs function of the United States.'' 5 U.S.C. 553(a)(1). As required by the Outbound Order, the proposed rule is being issued to assist in addressing the national emergency declared by the President with respect to the national security threat posed by countries of concern developing technologies that are critical to the next generation of military, intelligence, surveillance, or cyber-enabled capabilities. As described in the Outbound Order, this threat to the national security of the United States has its source in whole or substantial part outside the United States. The proposed rule would have a direct impact on foreign affairs concerns, which include the protection of national security against external threats (for example, limiting investment in specific sectors in designated countries of concern). Although the proposed rule is not subject to the notice and comment requirements of the APA, the Department of the Treasury is engaging in notice and comment rulemaking for this proposed rule, consistent with section 1(a) of the Outbound Order. In addition, the proposed rule was designated as significant under Executive Order 12866, as amended, and was reviewed by the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB). The Department of the Treasury has undertaken an analysis of the anticipated costs and benefits of the proposed rule. Following the issuance of the ANPRM, a number of stakeholders commented about the potential burden associated with this program, which is novel in its approach to addressing the national security concern posed by U.S. outbound investments involving a country of concern. The Department of the Treasury, after taking into account these comments and the novelty of the program, conducted an analysis of the relative costs and benefits of the proposed rule. For purposes of this analysis, the Department of the Treasury assessed the costs and benefits of the proposed rule relative to a no-action baseline reflecting *U.S. person* investment behavior in the absence of regulations.

In addition, this section includes the required assessments of the reporting and recordkeeping burdens under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et. seq.,* and the potential impact on small entities pursuant to the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et. seq.,* in each case as discussed below.

A. Executive Orders 12866, 13563, and 14094

Executive Orders 12866, 13563, and 14094 direct agencies to assess the costs and benefits of available regulatory alternatives for certain types of rulemaking in certain circumstances and, if regulation is necessary, to select regulatory approaches that maximize net benefits. The Department of the Treasury has conducted an assessment of the costs and benefits of the proposed rule, as well as the costs and benefits of available regulatory alternatives.

As noted above in section I, the Outbound Order directs the Secretary to establish a program to prohibit *U.S. persons* from engaging in certain transactions and require *U.S. persons* to submit notifications of certain other transactions. These two primary components of the program established by the Outbound Order would serve distinct but interrelated objectives with respect to the relevant technologies and products. The first component would require the Secretary to prohibit certain types of investment by a *U.S. person* in a *covered foreign person* engaged in certain categories of activities related to technologies and products that pose a particularly acute national security threat. The second component would require notification to the Secretary regarding certain types of investments by a *U.S. person* in a *covered foreign person* engaged in other categories of activities related to technologies and products that may contribute to the threat to national security. The focus of both components would be on investments that could enhance a country of concern's military, intelligence, surveillance, or cyber-enabled capabilities through the advancement of technologies and products in particularly sensitive areas. In an Annex to the Outbound Order, the President identified the People's Republic of China, along with the Special Administrative Region of Hong Kong and the Special Administrative Region of Macau, as a *country of concern.*

As described above in section I, this proposed rule is consistent with the President's mandate in the Outbound Order and prescribes procedures and obligations governing the (1) prohibition of certain types of investment by *U.S. persons* into certain entities located in or subject to the jurisdiction of a country of concern, certain other entities owned by *persons of a country of concern,* and certain entities with an interest in and significant financial connection to a *person of a country of concern,* with capabilities or activities related to defined technologies and products; and (2) mandatory notification to the Secretary by *U.S. persons* for certain types of investment into certain entities located in or subject to the jurisdiction of a *country of concern,* certain other entities owned by *persons of a country of concern,* and certain entities with an interest in and significant financial connection to a *person of a country of concern,* with capabilities or activities related to defined technologies and products. The implementation of the Outbound Order through this proposed rule would advance the President's objective of regulating certain investments from the United States into a country of concern.

The proposed rule would cover a defined set of transactions such as certain acquisitions of equity interests (*e.g.,* mergers and acquisitions, private equity, and venture capital) and contingent equity interests, certain debt financing transactions, greenfield and

brownfield investments, joint ventures, and certain LP investments by *U.S. persons.* Given the focus on transactions that could aid in the development of technological advances that pose a risk to U.S. national security, the Department of the Treasury proposes to except from the program certain transactions with a lower likelihood of having that effect. The proposed exceptions extend to certain investments into publicly traded securities or into securities issued by an investment company, such as an index fund, mutual fund, or exchange traded fund.

B. Costs

The primary direct costs to the public associated with the proposed rule would relate to (1) understanding the proposed rule; (2) conducting the transaction-specific diligence that would be needed for a *U.S. person* to determine whether a particular transaction would be either a *notifiable transaction* or a *prohibited transaction* under the proposed rule; and (3) if applicable, preparing and submitting a mandatory notification of certain transactions or other information to the Department of the Treasury pursuant to the proposed rule. The Department of the Treasury invites comment on any of the assumptions and estimates in this analysis.

The proposed rule would apply to all *U.S. persons* who undertake, directly or indirectly, a *covered transaction.* Because of the tailored scoping of the proposed rule, the Department of the Treasury estimates that it would apply to a relatively modest volume of potential *covered transactions.* While precise data that matches the scope of *covered transactions* including the relevant technology and products in the proposed rule is not available—and is one of the reasons for the notification requirement which would increase the U.S. Government's visibility into the relevant transactions—a review of available data appears to support this estimate of a modest volume. For example, to estimate the number of entities that would be potentially affected by the proposed rule and would incur associated direct compliance costs, the Department of the Treasury considered data available through PitchBook from approximately 2021 to 2023.[1] This data indicates that over this three-year period, 180 unique U.S.-based investors made around 318 equity and add-on investment transactions in the semiconductor, AI, and quantum science sectors of the PRC (as defined by PitchBook). This data suggests an annual average of 60 different investors engaging in an annual average of 106 potentially *covered transactions.* Since details of U.S. private investment overseas cannot be determined with precision through the available data, and there are limitations in any dataset based on the parameters set by the provider, the Department of the Treasury has determined this figure to be a lower bound. The Department of the Treasury also acknowledges that some *U.S. person* investors may incur costs even where the rule does not appear to apply directly to their transaction. To clarify, the figure used to estimate the volume of potentially *covered transactions* may not capture all instances of parties who may incur costs as a result of the proposed rule. For example, a *U.S. person* may not always know in advance of the due diligence process whether the *U.S. person* will want or need to collect information related to the proposed rule and then proceed to spend resources on diligence, only to confirm that the relevant transaction is not a *covered transaction.*

For purposes of this analysis, the Department of the Treasury doubled the averages from the available data to account for the likely underrepresentation of potentially relevant transactions. Thus, the Department of the Treasury's analysis is based on the estimate of approximately 120 entities and 212 transactions annually (based on an assumption of an annual average of 1.77 transactions per entity) that may be affected by the proposed rule. The Department of the Treasury is soliciting comments on the reasonableness of this estimate (in terms of the data source and analysis), and whether there are other sources of data that the Department of the Treasury should consider for its cost analysis. The Department of the Treasury also invites comments on whether doubling the averages from publicly available data is a reasonable way to account for any underrepresentation of potentially relevant transactions, or whether a different methodology should be used. For the remainder of this analysis, however, the Department of the Treasury relied on the estimates as described above.

To derive an estimate for the costs related to the proposed rule, the Department of the Treasury first estimated the associated labor costs related to interpreting and applying the proposed rule. The Department of the Treasury expects that individuals and entities reviewing the proposed rule and engaging in potentially relevant transactions would engage on their own and through their own employees as well as hire lawyers or advisors from outside firms.

For a low-end estimate, the Department of the Treasury relied on a figure from the Bureau of Labor Statistics (BLS), which reports the mean hourly wage for Standard Occupational Classification System Code (SOC Code) 231011—Lawyers to be $84.84 per hour and SOC Code 111021—General and Operations Managers to be $62.18 per hour.[2] In each instance the Department of the Treasury tripled the BLS mean hourly wage figure. This adjustment is intended to not only account for employee benefits and overhead, but also to reflect the presumption that hourly labor costs of the investors and their advisors likely to be affected by the proposed rule will often be higher than the hourly mean wage in these occupation categories across the United States. Accordingly, the Department of the Treasury estimates that the impacted entities will each incur costs of $187 per hour for managers and $255 for lawyers. The average of these figures is $221 per hour and, again, this is a low-end estimate.

For a high-end estimate, the Department of the Treasury acknowledges that the hourly rate billed for a lawyer performing the relevant type of work at a private firm may be significantly higher than the average hourly wage of a lawyer from the BLS figure. The global data and business intelligence platform Statista reports that the average hourly attorney billing rate in Washington, DC, in 2023 was $392.[3] The average of the hourly cost of a manager at $187 per hour and the Statista figure of the hourly rate of a lawyer at $392 per hour is $290. The Department of the Treasury invites comments on whether either of these figures (*i.e.,* the low-end or the high-end estimate) are reasonable benchmarks and estimates for this analysis or whether there are other sources of data or estimates that should be considered.

Costs Associated With Understanding the Proposed Rule

Based on the above assumptions and estimates of affected entities, number of transactions and labor costs, the Department of the Treasury has estimated the annual time and cost that would be spent by affected entities in understanding the proposed rule. While

[1] PitchBook, *https://pitchbook.com* (last visited May 24, 2024).

[2] Figures based on May 2023 data.

[3] Statista (Feb. 26, 2024), *https://www.statista.com/statistics/941146/legal-services-hourly-rates-metropolitan-region-united-states/.*

recognizing that the extent of this diligence will necessarily vary from transaction to transaction, the Department of the Treasury arrived at the below estimates for purposes of this regulatory analysis.

The range of estimated aggregate annual costs for understanding the proposed rule begins at $468,520 on the low end and goes up to $614,800 on the high end. This is based on the estimate of an average time burden to be ten total person hours per transaction for understanding the proposed rule. As such, ten total person hours per transaction multiplied by 212 annual transactions and the low-end hourly labor cost range and high-end hourly labor cost range described above, respectively, result in the total cost range for understanding the proposed rule.

Costs Associated With Diligence and Maintaining Records

Based on the above assumptions and estimates of affected entities, number of transactions and labor costs, the Department of the Treasury has estimated the annual time and cost that would be spent by affected entities on conducting additional transactional diligence with respect to this proposed rule. These economic estimates should in no way be construed as relevant to the reasonableness of the inquiry a party would pursue in light of the particular facts and circumstances of a transaction and the requirements of the proposed rule. While recognizing that the extent of this diligence will necessarily vary from transaction to transaction, the Department of the Treasury arrived at the below estimates for purposes of this regulatory analysis.

The Department of the Treasury recognizes that most investment transactions, regardless of whether the investment is potentially subject to this proposed rule, involve some level of review, diligence, assessment, and recordkeeping by the investor. And, for some transactions and investors, the level of information collection, retention, and diligence necessary to comply with the proposed rule may not give rise to any costs beyond what would be incurred in the absence of the proposed rule. This conclusion is reached by focusing on the nature of the information required for a notification, which consists of data typically gathered or available in the process of making an investment. This includes, for example, the proposed information requirements regarding transaction party identifying information as well as the commercial rationale, transaction structure, financial details, and *completion date* of the transaction itself.

The Department of the Treasury assesses that it is reasonable in some cases to assume that customary transactional due diligence would involve the collection and review of this required information, meaning that the only incremental costs would be incurred for the review of the information from the perspective of ensuring compliance with the proposed rule. While the notification requirement would also include (1) information regarding *covered activities* undertaken by the *covered foreign person* that makes the transaction a *notifiable transaction,* as well as a brief description of the known end uses and end users of the covered foreign person's technology, products, or services; (2) a statement of the attributes that cause the entity to be a covered foreign person; and (3) in certain cases, the identification of the technology node(s) at which any applicable product is produced, the due diligence underlying many *covered transactions* would include gathering and reviewing this information even if not specifically to comply with the proposed rule. The proposed rule further states that a *U.S. person* that has failed to conduct a reasonable and diligent inquiry by the time of a given transaction may be assessed to have had awareness or reason to know of a given fact or circumstance, including facts or circumstances that would cause the transaction to be a *covered transaction.* Compliance with this provision and the requirements of the proposed rule may in some cases require enhanced diligence. Recognizing that in some instances, compliance with the proposed rule may not require the collection and retention of additional transaction-related information, this analysis considers reasonable estimates of the additional due diligence and recordkeeping costs that could be associated with the proposed rule as described below.

The range of estimated annual incremental cost for conducting due diligence and recordkeeping associated with the proposed rule runs from $0 on the low end to $2,459,200 on the high end. These are two ends of the range, and it is anticipated that the costs for most transactions would fall between these figures. The Department of the Treasury estimates that the average time burden would likely not exceed 40 total person hours per transaction for conducting additional due diligence and recordkeeping with respect to the proposed rule.

For the low end of this range, it is reasonable to anticipate that some investors, having spent resources learning about the proposed rule, as discussed above, will be able to quickly collect and assess the information needed to determine whether a potential transaction would be a *prohibited transaction.* As such, the low-end estimate is a zero-dollar incremental cost for additional due diligence and recordkeeping. Not all transactions will be this simple, and it is reasonable to anticipate more costs at the higher end of the range. As such, 40 total person hours per transaction multiplied by 212 annual transactions and the high-end hourly labor cost estimate described above results in the high-end estimate for additional due diligence and recordkeeping related to the proposed rule. The Department of the Treasury estimates 40 person hours per transaction, based on approximately a total of eight person hours across all involved general and operations managers and lawyers per business day for one week. However, the cost of a *U.S. person* conducting diligence and the difficulty of that exercise will vary depending on a transaction's complexity, the availability of relevant information, and the incremental person hours may be higher for certain transactions, for example those that involve indirect transactions.

The Department of the Treasury invites comments on whether these figures are reasonable benchmarks and estimates for this analysis or whether there are other sources of data or estimates it should consider.

Costs Associated With Providing Information

The proposed rule would require the submission of information to the Department of the Treasury for notifiable transactions and provides for certain other circumstances that require information submission. The Department of the Treasury intends to require *U.S. persons* to provide notification of certain transactions under the proposed rule. The proposed rule also contemplates that a person seeking a national interest exemption from the proposed rule's notification requirement or prohibition would submit certain information to the Department of the Treasury. The proposed rule would also require a *U.S. person* to make a post-closing submission regarding a transaction that it believed at closing was not a *covered transaction* when the *U.S. person* later discovers information which, had it been known at closing, would have caused the transaction to be a *covered*

transaction. Also, the proposed rule would require a *U.S. person* to inform the Department of the Treasury of any material omission or inaccuracy in any previous representation, statement, or certification. Lastly, the Department of the Treasury anticipates time and cost associated with responding to inquiries by the Department of the Treasury.

The Department of the Treasury expects that of the universe of potentially *covered transactions* for which *U.S. persons* perform due diligence each year, certain transactions will turn out not to be covered, others will turn out to be notifiable, and still others will turn out to be prohibited. For purposes of this analysis, however, the Department of the Treasury has assumed that *U.S. persons* will perform due diligence with respect to the estimated 212 potentially *covered transactions* each year, and that all 212 will turn out to be *notifiable transactions.* The Department of the Treasury took this approach in the interest of estimating a theoretical maximum upper bound, recognizing that the number of actual *notifiable transactions* is likely to be less than 100 percent of potentially *covered transactions.* A *notifiable transaction* would likely cost more in terms of time and resources than a *prohibited transaction,* because, in addition to the due diligence cost, a *notifiable transaction* would entail resources to prepare and submit a notification.

The estimated annual cost range for time spent submitting information would be $2,342,600 to $3,074,000. This estimate assumes 50 person hours per transaction for preparing and submitting a notification through an online portal, combined with the number of transactions per year (212) and the hourly labor cost range described above—$221 to $290. As discussed above, this number reflects the high-end estimate, since this analysis assumes that every potentially relevant transaction would result in a notification.

For purposes of this analysis, the Department of the Treasury estimated only the total annual costs of preparing and submitting a notification under § 850.404 of the proposed rule. The Department of the Treasury anticipates that the time and cost behind preparing and submitting a post-transaction notice, notice of any material omission or inaccuracy in any previous representation, statement, or certification, or responding to agency inquiries may be comparable to the costs of preparing and submitting a notification. Likewise, where a *U.S. person* elects to provide information in seeking a national interest exemption, the Department of the Treasury anticipates that the associated costs would be comparable to or could slightly exceed the costs of preparing and submitting a notification.

Estimated Total Direct Costs

Based on the direct cost estimates above, the total annual direct costs associated with complying with the proposed rule can be expected to have a range of between $2,811,120 and $6,148,000 and the total annual time burden would be approximately 21,200 person hours.

Additional Indirect Costs Associated With Prohibited Transactions and Non-Covered Transactions

With respect to *prohibited transactions,* the Department of the Treasury has no basis to conclude that the proposed rule will have additional direct economic costs to U.S. investors beyond those described above. There may, however, be additional indirect costs associated with *prohibited transactions.* Investors who would have otherwise engaged in a *prohibited transaction* absent the proposed rule may pursue alternative investment opportunities since they would be precluded from undertaking a *prohibited transaction.* These indirect costs amount to the difference, if any, between the return on investment that would have been generated by a *prohibited transaction* and the return on investment that would result from an alternative transaction. Any attempt to quantify this cost would be speculative and difficult to assess in any specificity due to individual decision-making, opportunities available, and market conditions. In addition, while the proposed rule may have an economic impact on investment targets that are *covered foreign persons* because certain transactions would be prohibited, the proposed rule is not designed to nor does it prohibit all *U.S. person* investments into such persons, due to the scope of transactions covered as well as the exceptions provided for in the proposed rule.

Costs to the U.S. Government

Administering the regulation would also entail costs to the U.S. Government. Such costs would include information technology (IT) development and ongoing annual maintenance, as well as processing electronic notifications. The Department of the Treasury estimates that initial IT development costs would be between $4 million and $8 million with an additional $2 million to $3 million required to maintain the systems and the underlying technology being leveraged to support the capabilities. The Department of the Treasury and other relevant agencies, including the Department of Commerce, may incur additional costs, besides those estimated above. This includes other responsibilities related to the implementation of the proposed rule such as analyzing notifications submitted as well as complying with the reporting requirements under the Outbound Order. Furthermore, costs may be associated with efforts to promote compliance with the notification requirement and prohibition requirements, potentially including education on the requirements, development of guidance and frequently asked questions, and conducting stakeholder outreach. The Department of the Treasury does not currently have specific estimates for these costs but estimates that there would be personnel costs of less than $2 million associated with the proposed regulation in Fiscal Year 2024 with additional costs for ongoing outreach and enforcement thereafter.

The Department of the Treasury and other government agencies may also incur costs in enforcing compliance with the regulation. The Department of the Treasury does not currently have estimates for these costs, and they are not included in the estimates above.

The Department of the Treasury plans to monitor compliance with the final regulation by leveraging a variety of data sources, both internal and external. Because the external data sources may include third parties, the Department of the Treasury requests comment on what external data sources would be appropriate to leverage in identifying non-compliance with respect to the regulations and what potential costs may be incurred by such third parties. If the external data sources include third party commercial data, the Department of the Treasury assesses that the cost associated with accessing these databases would be modest and incremental, given that the Department of the Treasury regularly maintains access to such databases in the course of other work but may need to request additional licenses for employees. After identifying an instance of apparent non-compliance, the Department of the Treasury may initiate outreach to the involved entity, work with law enforcement to investigate the apparent non-compliance, or initiate an enforcement action. The Department of the Treasury's enforcement of the proposed regulation would also involve coordination with law enforcement agencies. These law enforcement

agencies may also incur costs (time and resources) while conducting investigations into potential non-compliance.

C. Benefits

The President found in the Outbound Order that the advancement by *countries of concern* in sensitive technologies and products critical for the military, intelligence, surveillance, or cyber-enabled capabilities of such countries constitutes an unusual and extraordinary threat to the national security of the United States, which has its source in whole or substantial part outside the United States, and that certain United States investments risk exacerbating this threat. The potential military, intelligence, surveillance, or cyber-enabled applications of these technologies and products pose risks to U.S. national security particularly when developed by a *country of concern* in which the government seeks to (1) direct entities to obtain technologies to achieve national security objectives; and (2) compel entities to share with or transfer these technologies to the government's military, intelligence, surveillance, or security apparatuses. As part of their strategy of advancing the development of these sensitive technologies and products, *countries of concern* are exploiting or could exploit certain United States outbound investments, including certain intangible benefits that often accompany United States investments and that help companies succeed, such as enhanced standing and prominence, managerial assistance, investment and talent networks, market access, and enhanced access to additional financing. Such investments, therefore, risk exacerbating this threat to U.S. national security. Although the United States has undertaken efforts to enhance existing policy tools and develop new policy initiatives aimed at maintaining U.S. leadership in technologies critical to national security, there remain instances where the risks presented by U.S. investments enabling *countries of concern* to develop critical military, intelligence, surveillance, or cyber-enabled capabilities are not sufficiently addressed by existing tools.

The proposed rule is designed to complement our existing tools and effectively address the threat to the national security of the United States described in the Outbound Order. The benefit of protecting national security is difficult to quantify. Furthermore, the notification component of the proposed rule is intended to provide key information that the Department of the Treasury could use to better inform the development and implementation of the program. These notifications would increase the U.S. Government's visibility into transactions by *U.S. persons* or their *controlled foreign entities* and involving technologies and products relevant to the threat to the national security of the United States due to the policies and actions of *countries of concern*. These notifications would be helpful in highlighting trends with respect to related capital flows and would inform future policy development. The Department of the Treasury expects that the national security benefits, while qualitative, will outweigh the compliance costs of the proposed rule. The Department of the Treasury requests comment on data or methods that may inform estimates of potential costs of the proposed rule.

D. Alternatives

The Outbound Order requires the Secretary of the Treasury to issue implementing regulations subject to public notice and comment. As a result, the Department of the Treasury did not have the discretion to refrain from promulgating the proposed rule or to promulgate it without notice and comment. However, the Department of the Treasury considered different approaches to the proposed rule that would be available under the Outbound Order. Specifically, the Department of the Treasury considered the following potential alternatives to the proposed rule:

- *Scope of covered transaction and excepted transaction.* The Department of the Treasury could have proposed a broader definition of *covered transaction* and/or fewer exceptions and considered certain alternatives to the scope of *covered transaction* and *excepted transaction* in developing the proposed rule. This discussion does not cover each alternative considered for the scope of *covered transaction* but provides a summary of a few alternatives the Department of the Treasury considered.

The Department of the Treasury considered and selected regulatory approaches that maximize net benefits (including effectively addressing the national security threat identified in the Outbound Order) while balancing potential compliance and implementation costs. For example, an alternative that the Department of the Treasury considered in relation to contingent equity interests in particular was to limit the scope of *covered transaction* to just the acquisition of a contingent equity interest and not separately cover the conversion of the contingent equity interest. This would have reduced some of the compliance and resource burden on a *U.S. person,* who would have, in the context of a *notifiable transaction,* been required to submit a notification only at the time of acquisition rather than a notification at the time of acquisition and another notification at the time of conversion of contingent equity. However, this alternative would have reduced the ability of the U.S. Government to observe the frequency and instances in which the relevant contingent interests convert. Additionally, it would not have scoped in circumstances where the acquisition of a contingent equity interest did not involve a *covered foreign person* but then a *covered foreign person* was involved at the time of the conversion of a contingent equity interest, which would have limited the proposed rule's reach and ability to address the national security threat identified in the Outbound Order. Another example is with respect to the exception for LP investments where the proposed rule puts forth two proposed alternatives. As discussed above in the section-by-section analysis with respect to § 850.501 of the proposed rule, the Department of the Treasury, after consulting with the heads of other agencies, is offering and seeking comment on two alternates for this exception. Under proposed Alternate 1, a *U.S. person's* investment made as an LP in a pooled investment fund would constitute an *excepted transaction* if (1) the LP's rights are consistent with a passive investment and (2) the LP's committed capital is not more than 50 percent of the total assets under management of the pooled fund. If the *U.S. person* LP's committed capital were to constitute more than 50 percent of the total assets under management of the pooled fund, its investment would qualify as an *excepted transaction* only if the *U.S. person* secured a binding agreement that the pooled fund would not use its capital for a *prohibited transaction*. This approach would address situations where the *U.S. person's* LP investment falls below the threshold but contains one of several indicia of control or influence over the pooled fund or the ultimate *covered foreign person* investment target. Compared to Alternate 2, Alternate 1 would scope in fewer LP investments as *covered transactions* but could potentially be more challenging for a *U.S. person* to comply with, as it requires a multi-factor analysis for assessing whether a *U.S. person's* LP investment is an *excepted transaction*. Under Alternate 2, a *U.S. person* LP's

committed capital in a pooled fund that then invests in a *covered foreign person* would be an *excepted transaction* only if the committed capital was not more than $1,000,000. Although this alternate would likely scope in a greater number of LP investments as *covered transactions* compared to Alternate 1 (and potentially increase the compliance costs of this program), the bright-line approach may be easier for *U.S. persons* to comply with than Alternate 1.

• *Covered national security technologies using broad definition of sectors rather than specific activities and technologies.* In the proposed rule, the Department of the Treasury proposed to define *notifiable transaction* and *prohibited transaction* in § 850.217 and § 850.224, respectively, by reference to certain technologies and activities, and in some instances, end uses. Alternatively, the Department of the Treasury could have opted for a broad sectoral categorization, such as, for example, all technologies and products in the artificial intelligence sector, regardless of the end use of such artificial intelligence related technologies or products. If the Department of the Treasury had proposed that approach, the Department of the Treasury estimates that the economic impact for *U.S. persons* subject to the rule, and for the overall U.S. economy, would be significantly greater than under the proposed rule. Instead, the Department of the Treasury, along with other relevant agencies, carefully tailored the *covered activities* and technical descriptions under the definitions of *notifiable transaction* and *prohibited transaction*. In the case *of AI systems,* the proposed rule addresses *covered activities* related to certain *AI systems* that would have applications that pose or have the potential to pose national security risks without broadly capturing AI systems intended only for commercial applications or other civilian end uses that do not have potential national security consequences, thereby limiting the additional compliance and implementation burden on *U.S. persons*.

The Department of the Treasury intends that the proposed rule would provide a *U.S. person* with clarity and guidance regarding its obligations with respect to a *covered transaction,* while effectively addressing the national emergency identified in the Outbound Order in a targeted manner. The Department of the Treasury expects that the national security benefits, while qualitative, will outweigh the compliance costs of the proposed rule.

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) (PRA).

The proposed rule would require a *U.S. person* to submit a notification with respect to (1) any *notifiable transaction;* (2) any transaction by a *controlled foreign entity* that would be a *notifiable transaction* if engaged in by a *U.S. person;* and (3) any transaction for which a *U.S. person* acquires actual *knowledge* after the *completion date* of the transaction that the transaction would have been a *prohibited transaction* or a *notifiable transaction* if *knowledge* had been possessed by the relevant *U.S. person* at the time of the transaction. Such notification would include relevant details on the *U.S. person* involved in the transaction as well as information on the transaction and the *covered foreign person* involved. The proposed rule would require any *U.S. person* that has filed a notification to respond to any questions or document requests from the Department of the Treasury related to the transaction or compliance with the proposed rule; any information or documents provided to the Department of the Treasury in response to such request would be deemed part of the notification under the proposed rule.

The proposed rule would also require any *U.S. person* that files a notification to maintain a copy of the notification filed and supporting documentation for a period of ten years from the date of the filing. Further, the proposed rule would require any person who has made any representation, statement, or certification subject to the proposed rule to notify the Department of the Treasury in writing of any material omission or inaccuracy in such representation, statement, or certification. Finally, the proposed rule would also require any *U.S. person* seeking a national interest exemption to submit information to the Department of the Treasury regarding the scope of the transaction including, as applicable, the information that would be required for a notification of a *notifiable transaction*.

The collections of information described would be used by the Department of the Treasury and the Department of Commerce, and, as appropriate, other relevant agencies, in connection with the analysis of notifiable transactions pursuant to the Outbound Order. The information provided in the notifications would increase the U.S. Government's visibility into the volume and nature of *U.S. person* transactions involving the defined technologies and products that may contribute to the threat to the national security of the United States. The information in the notifications will be helpful in highlighting trends with respect to related capital flows. It would also inform future policy development and decisions, including any modifications to the scope of *notifiable transactions* and *prohibited transactions*. Additionally, the information would assist the Secretary in complying with the report requirements in section 4 of the Outbound Order and in determining whether to grant a national interest exemption to a particular *covered transaction*. The proposed rule would prohibit the Department of the Treasury from making public any information or documentary materials submitted to or filed with the Department of the Treasury under the proposed rule unless required by law or otherwise provided in the proposed rule.

Written comments and recommendations for the proposed information collections can be submitted by visiting *https://www.reginfo.gov/public/do/PRAMain*. Information collection requests may be found by selecting ''Currently Under Review—Open for Public Comments'' or by using the search function. Comments on the collections of information should be received by August 4, 2024.

The Department of the Treasury used the methodology described in the previous section to estimate the total annual reporting and recordkeeping burden of the information collections in this proposed rule. The Department of the Treasury estimates that the annual hourly burden would be up to 19,080 hours. This annual total is based on the Department of the Treasury's assumption that: (1) 120 entities per year would respond to the information collections in this proposed rule and each entity would submit an average of 1.77 notifications annually, meaning these respondents would file a total 212 responses to the information collections annually; and (2) each respondent would spend an estimated 50 to 90 person hours per response. The Department of the Treasury estimates that the annual cost burden associated with the information collections and recordkeeping in the proposed rule would range between $2,342,600 and $5,533,200.

In accordance with 5 CFR 1320.8(d)(1), the Department of the Treasury is soliciting comments from

members of the public concerning these collections of information to:

(1) 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;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collections of information;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology.

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the OMB.

Regulatory Flexibility Act

It is hereby certified that the proposed rule would not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

The proposed rule may impact any *U.S. person,* including a small business that engages in a *covered transaction* with a *covered foreign person.* The Department of the Treasury does not anticipate that the proposed rule would affect ''small organizations'' or ''small governmental jurisdiction[s],'' as defined in the RFA.

The Department of the Treasury expects the proposed rule to have a negligible baseline impact on small businesses because the proposed rule's obligations on *U.S. persons* target investments generally associated with larger institutions that more often are involved in cross-border investments related to the sectors under the proposed rule. These larger institutions are more likely to enter into transactions that will trigger the definition of covered transaction. The proposed rule would except specific types of transactions that may be more attractive or accessible to small business investors. And, as discussed below, the Department of the Treasury has assessed that small businesses would be likely to enter into transactions that constitute *excepted transactions.* As an example, the Small Business Administration's (SBA's) Table of Size Standards with respect to NAICS U.S. Industry Sector 52 ''Finance and Insurance'' defines a small business in this sector by dollar value of assets or revenue rather than by number of employees. As discussed below, the Department of the Treasury believes that the relevant SBA thresholds are too low to capture the type of U.S. investor likely to actively invest in an entity that engages in the identified activities related to technologies and products in the semiconductors and microelectronics, quantum information technologies, and artificial intelligence sectors that are critical for the military, intelligence, surveillance, or cyber-enabled capabilities of a country of concern. For example, SBA categories such as ''open end investment funds,'' and ''other financial vehicles'' are not considered small businesses if their average annual receipts exceed $40 million. As a reference point, IBISWorld reports that for NAICS Industry Code 52591 ''Open-End Investment Funds,'' for years 2018 to 2023, there were 825 businesses in this category and a total 2023 revenue across those businesses of $191.1 billion.[4] Extrapolating from this data, the average 2023 revenue per firm in this category would have been $231.5 million.

In fact, the total number of potential investors subject to the regulation is likely limited to a small set of relatively large and sophisticated investors. As discussed above, the Department of the Treasury considered PitchBook Data from approximately 2021 through 2023. Notably, the most common type of U.S. based investors in this survey were identified by PitchBook Data as a venture capital business, corporation, private equity or buyout firm, or comparable investor types.

Given the applications of technologies and products in these sectors, the Department of the Treasury believes investments into these sectors involving a *person of a country of concern* is not typical for a small business, as these investor types are treated in the SBA's Table of Size Standards. Importantly, the proposed rule would also except certain types of transactions, including certain investments into publicly traded securities or into securities issued by an investment company, such as an index fund, mutual fund, or exchange traded fund, where a small business is more likely to consider investing. Given the narrow scoping of what constitutes a *covered transaction* under the proposed rule, the Department of the Treasury expects that few small businesses, as that term is defined by SBA, will be impacted by the proposed rule.

In the unlikely event that a small entity is subject to the requirements of the program, such entity would be expected to incur the costs described in the separate cost benefit analysis above. For submission of notifications, the Department of the Treasury has endeavored to develop information gathering procedures that minimize the burden on *U.S. persons,* both large and small. *U.S. persons* who file a notification will use a fillable form that will be available online and is intended to facilitate submission through an electronic format. This fillable form will benefit anyone who submits a notification, regardless of their size, but may be especially helpful for small businesses who will be able to submit directly to the Department of the Treasury through an online portal.

Notwithstanding this certification, the Department of the Treasury invites comments from the public about the impact the proposed rule on small entities. The proposed rule will be submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business.

List of Subjects in 31 CFR Part 850

Administrative practice and procedure, Artificial intelligence, Business and industry, Confidential business information, Electronic filing, Executive orders, Foreign persons, Hong Kong, Holding companies, Investigations, Investments, Investment companies, Microelectronics, National defense, National security, Macau, Penalties, People's Republic of China, Quantum information technologies, Reporting and recordkeeping requirements, Science and technology, Securities, Semiconductors, U.S. investments abroad.

■ For the reasons set forth in the preamble, the Department of the Treasury proposes to add part 850 of title 31 of the Code of Federal Regulations as follows:

PART 850—PROVISIONS PERTAINING TO U.S. INVESTMENTS IN CERTAIN NATIONAL SECURITY TECHNOLOGIES AND PRODUCTS IN COUNTRIES OF CONCERN

Subpart A—General

Sec.

[4] IBIS World, *https://www.ibisworld.com/united-states/market-research-reports/open-end-investment-funds-industry/#IndustryStatisticsAndTrends* (last visited Mar. 15, 2024).

Authority: 50 U.S.C. 1701 *et seq.;* E.O. 14105, 88 FR 54867.

Subpart A—General

§ 850.101 Scope.

(a) This part implements Executive Order 14105 of August 9, 2023, ''Addressing United States Investments in Certain National Security Technologies and Products in Countries of Concern'' (the Order), directing the Secretary of the Treasury (the Secretary), in consultation with the Secretary of Commerce and, as appropriate, the heads of other relevant executive departments and agencies, to issue, subject to public notice and comment, regulations that require U.S. persons to provide notification of information relative to certain transactions involving covered foreign persons and that prohibit U.S. persons from engaging in certain other transactions involving covered foreign persons.

(b) The regulations identify certain types of transactions that are *covered transactions*—that is, transactions that are either notifiable or prohibited. Additionally, the regulations identify other instances where a U.S. person has obligations with respect to certain transactions. The regulations prescribe exceptions to the definition of *covered transaction*. A transaction that meets an exception is not a *covered transaction* and is referred to as an *excepted transaction*. Finally, the regulations prescribe a process for the Secretary to exempt certain *covered transactions* from the rules otherwise prohibiting or requiring notification of *covered transactions* on a case-by-case basis.

(c) The regulations identify categories of *covered transactions* that are *notifiable transactions*. A *notifiable transaction* is a transaction by a *U.S. person* or its *controlled foreign entity* with or resulting in the establishment of a *covered foreign person* that engages in a *covered activity* or a *person of a country of concern*'s engagement in a new *covered activity* that the Secretary, in consultation with the Secretary of Commerce and, as appropriate, the heads of other *relevant agencies,* has determined may contribute to the threat to the national security of the United States identified in the Order. The regulations require a *U.S. person* to notify the Department of the Treasury of each such notifiable transaction by such *U.S. person* or its *controlled foreign entity*. The regulations also require a *U.S. person* to provide prompt notice to the Department of the Treasury upon acquiring actual knowledge after the *completion date* of a transaction of facts or circumstances that would have caused the transaction to be a *covered transaction* if the *U.S. person* had had such knowledge on the *completion date*. Additionally, any person who makes a representation, statement, or certification under to this part is required to promptly notify the Department of the Treasury upon learning of a material omission or inaccuracy in such representation, statement, or certification.

(d) The regulations identify categories of *covered transactions* that are *prohibited transactions*. A *prohibited transaction* is a transaction by a *U.S. person* with or resulting in the establishment of a *covered foreign person* that engages in a *covered activity* or a *person of a country of concern*'s engagement in a new *covered activity* that the Secretary, in consultation with the Secretary of Commerce and, as appropriate, the heads of other *relevant agencies,* has determined poses a particularly acute national security threat because of its potential to significantly advance the military, intelligence, surveillance, or cyber-enabled capabilities of a country of concern. The regulations prohibit a *U.S. person* from engaging in a *prohibited transaction* and also prohibit a *U.S. person* from *knowingly directing* a transaction that the *U.S. person* knows would be a *prohibited transaction* if engaged in by a *U.S. person*. The regulations also require a *U.S. person* to take all reasonable steps to prohibit and prevent any transaction by its *controlled foreign entity* that would be a *prohibited transaction* if undertaken by a *U.S. person*.

(e) Pursuant to the Order, the Secretary shall, as appropriate:

(1) Communicate with the Congress and the public with respect to the implementation of the Order;

(2) Consult with the Secretary of Commerce on industry engagement and analysis of notifiable transactions;

(3) Consult with the Secretary of State, the Secretary of Defense, the Secretary of Commerce, the Secretary of Energy, and the Director of National Intelligence on the implications for military, intelligence, surveillance, or cyber-enabled capabilities of covered national security technologies and products in the Order and potential

covered national security technologies and products;

(4) Engage, together with the Secretary of State and the Secretary of Commerce, with allies and partners regarding the national security risks posed by countries of concern advancing covered national security technologies and products;

(5) Consult with the Secretary of State on foreign policy considerations related to the implementation of the Order, including but not limited to the issuance and amendment of regulations; and

(6) Investigate, in consultation with the heads of relevant agencies, as appropriate, violations of the Order or the regulations in this part and pursue available civil penalties for such violations.

§ 850.102 Relation of this part to other laws and regulations.

Nothing in this part shall be construed as altering or affecting any other authority, process, regulation, investigation, enforcement measure, license, authorization, or review provided by or established under any other provision of federal law, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), or any other authority of the President or the Congress under the Constitution of the United States. This part is separate from, and independent of, the other parts of this subtitle. Differing foreign policy and national security circumstances may result in differing interpretations of the same or similar language among the parts of this subtitle. No action taken pursuant to any other provision of law or regulation, including the other parts of this subtitle, authorizes any transaction prohibited by this part or alters any other obligation under this part. No action taken pursuant to this part relieves the involved parties from complying with any other applicable laws or regulations.

§ 850.103 Rules of construction and interpretation.

(a) As used in this part, the term ''including'' (or variations such as ''include'') means ''including but not limited to.''

(b) Any term in the singular includes the plural, and the plural includes the singular, if such use would be appropriate.

(c) Section headings are included for convenience of reference only and shall not affect the interpretation of this part.

§ 850.104 Knowledge standard.

(a) Certain provisions of this part apply only if a U.S. person *knows* of a fact or circumstance. The term *knowledge* is defined in § 850.216. In determining whether a U.S. person is complying with this part or has violated any obligation under this part, the Department of the Treasury will assess whether such person has or had knowledge of the relevant facts and circumstances at the specified time.

(b) Such assessment as to whether, at the time of a given transaction, a U.S. person has or had knowledge of a given fact or circumstance will be made based on information a U.S. person had or could have had through a reasonable and diligent inquiry. A U.S. person that has failed to conduct a reasonable and diligent inquiry by the time of a given transaction may be assessed to have had reason to know of a given fact or circumstance, including facts or circumstances that would cause the transaction to be a covered transaction.

(c) In assessing whether a U.S. person has undertaken such a reasonable and diligent inquiry, the Department of the Treasury's considerations will include the following, as applicable, among others that the Department of the Treasury deems relevant, with respect to a particular transaction:

(1) The inquiry a U.S. person, its legal counsel, or its representatives have made on behalf of the U.S. person regarding an investment target or relevant counterparty, including questions asked of the investment target or relevant counterparty, as of the time of the transaction;

(2) The contractual representations or warranties the U.S. person has obtained or attempted to obtain from the investment target or relevant counterparty with respect to the determination of a transaction's status as a covered transaction and an investment target or relevant counterparty's status as a covered foreign person;

(3) The effort by the U.S. person at the time of the transaction to obtain available non-public information relevant to the determination of a transaction's status as a covered transaction and an investment target or relevant counterparty's status as a covered foreign person, and the efforts undertaken by the U.S. person to obtain and review such information;

(4) Available public information, the efforts undertaken by the U.S. person to obtain and review such information, and the degree to which other information available to the U.S. person at the time of the transaction is consistent or inconsistent with such publicly available information;

(5) Whether the U.S. person, its legal counsel, or its representatives have purposefully avoided learning or sharing relevant information;

(6) The presence or absence of warning signs, which may include evasive responses or non-responses from an investment target or relevant counterparty to questions or a refusal to provide information, contractual representations, or warranties; and

(7) The use of public and commercial databases to identify and verify relevant information of an investment target or relevant counterparty.

Subpart B—Definitions

§ 850.201 Advanced packaging.

The term *advanced packaging* means to package integrated circuits in a manner that supports the two-and-one-half-dimensional (2.5D) or three-dimensional (3D) assembly of integrated circuits, such as by directly attaching one or more die or wafer using through-silicon vias, die or wafer bonding, heterogeneous integration, or other advanced methods and materials.

§ 850.202 AI system.

The term *AI system* means:

(a) A machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments—*i.e.,* a system that uses data inputs to:

(1) Perceive real and virtual environments;

(2) Abstract such perceptions into models through automated or algorithmic statistical analysis; and

(3) Use model inference to make a classification, prediction, recommendation, or decision.

(b) Any data system, software, hardware, application, tool, or utility that operates in whole or in part using a system described in (a).

§ 850.203 Certification.

(a) The term *certification* means a written statement signed by the chief executive officer or other duly authorized designee of the person filing a notification or providing other information that certifies under the penalties provided in the False Statements Accountability Act of 1996, as amended (18 U.S.C. 1001) that the notification or other information filed or provided:

(1) Fully complies with the regulations in this part; and

(2) Is accurate and complete in all material respects to the best knowledge of the person filing a notification or other information.

(b) For purposes of this section, a duly authorized designee is:

(1) In the case of a partnership, any general partner thereof;

(2) In the case of a corporation, any officer thereof; and

(3) In the case of any entity lacking partners and officers, any individual within the organization exercising executive functions similar to those of a general partner of a partnership or an officer of a corporation or otherwise authorized by the board of directors or equivalent to provide such certification.

(c) In each case described in paragraphs (b)(1) through (3) of this section, such designee must possess actual authority to make the certification on behalf of the person filing a notification or other information.

Note 1 to § 850.203: A template for certifications may be found at the Outbound Investment Security Program section of the Department of the Treasury website.

§ 850.204 Completion date.

The term *completion date* means:

(a) With respect to a covered transaction other than under § 850.210(a)(6), the earliest date upon which any interest, asset, property, or right is conveyed, assigned, delivered, or otherwise transferred to a U.S. person, or as applicable, its controlled foreign entity; or

(b) With respect to a covered transaction under § 850.210(a)(6), the earliest date upon which any interest, asset, property, or right in the relevant covered foreign person is conveyed, assigned, delivered, or otherwise transferred to the applicable fund.

§ 850.205 Contingent equity interest.

The term *contingent equity interest* means a financial instrument that currently does not constitute an equity interest but is convertible into, or provides the right to acquire, an equity interest upon the occurrence of a contingency or defined event.

§ 850.206 Controlled foreign entity.

(a) The term *controlled foreign entity* means any entity incorporated in, or otherwise organized under the laws of, a country other than the United States of which a U.S. person is a parent.

(b) For purposes of this term, the following rules shall apply in determining whether an entity is a parent of another entity in a tiered ownership structure:

(1) Where the relationship between an entity and another entity is that of parent and subsidiary, the holdings of voting interest or voting power of the board, as applicable, of a subsidiary shall be fully attributed to the parent.

(2) Where the relationship between an entity and another entity is not that of parent and subsidiary (*i.e.,* because the holdings of voting interest or voting power of the board, as applicable, of the first entity in the second entity is 50 percent or less), then the indirect downstream holdings of voting interest or voting power of the board, as applicable, attributed to the first entity shall be determined proportionately.

(3) Where the circumstances in paragraphs (b)(1) and (2) of this section apply (*i.e.,* because a U.S. person holds both direct and indirect downstream holdings in the same entity), any holdings of voting interest shall be aggregated for the purposes of applying this definition, and any holdings of voting power of the board shall be aggregated for the purposes of applying this definition. Voting interest shall not be aggregated with voting power of the board for the purposes of applying this definition.

§ 850.207 Country of concern.

The term *country of concern* has the meaning given to it in the Annex to the Order.

§ 850.208 Covered activity.

The term *covered activity* means, in the context of a particular transaction, any of the activities referred to in the definition of notifiable transaction in § 850.217 or prohibited transaction in § 850.224.

§ 850.209 Covered foreign person.

(a) The term *covered foreign person* means:

(1) A person of a country of concern that engages in a covered activity; or

(2) A person that directly or indirectly holds any voting interest, board seat, or equity interest in any person described in paragraph (a)(1) of this section, or holds any power to direct or cause the direction of the management or policies of any person described in paragraph (a)(1) of this section through one or more contractual arrangements, including, for the avoidance of doubt, variable interest entities; and where the person, based the relevant financial statement described in paragraph (b) of this section:

(i) Derives more than 50 percent of its revenue from any person described in paragraph (a)(1) of this section, individually or in the aggregate;

(ii) Derives more than 50 percent of its net income from any person described in paragraph (a)(1) of this section, individually or in the aggregate;

(iii) Incurs more than 50 percent of its capital expenditure through any person described in paragraph (a)(1) of this section, individually or in the aggregate; or

(iv) Incurs more than 50 percent of its operating expenses through any person described in paragraph (a)(1) of this section, individually or in the aggregate.

(3) With respect to a covered transaction described in § 850.210(a)(5), the person of a country of concern that participates in the joint venture is deemed to be a covered foreign person by virtue of its participation in the joint venture.

(b) Determination of whether a person is a covered foreign person within the meaning of paragraph (a)(2) of this section shall be made based on an annual financial statement from the most recent year for which an audited financial statement of such person is available at the time of a given transaction. If an audited financial statement is not available, the most recent unaudited financial statement shall be used instead.

§ 850.210 Covered transaction.

(a) The term *covered transaction* means a U.S. person's direct or indirect:

(1) Acquisition of an equity interest or a contingent equity interest (or interest equivalent to an equity or contingent equity interest) in a person that the U.S. person knows at the time of the acquisition is a covered foreign person;

(2) Provision of a loan or a similar debt financing arrangement to a person that the U.S. person knows at the time of the provision is a covered foreign person, where such debt financing:

(i) Is convertible to an equity interest; or

(ii) Affords or will afford the U.S. person the right to make management decisions with respect to or on behalf of the covered foreign person or the right to appoint members of the board of directors (or equivalent) of the covered foreign person;

(3) Conversion of a contingent equity interest (or interest equivalent to a contingent equity interest) or conversion of debt to an equity interest in a person that the U.S. person knows at the time of the conversion is a covered foreign person;

(4) Acquisition, leasing, or other development of operations, land, property, or other assets in a country of concern that the U.S. person knows at the time of such acquisition, leasing, or other development will result in, or that the U.S. person intends to result in:

(i) The establishment of a covered foreign person; or

(ii) The engagement of a person of a country of concern in a covered activity where it was not previously engaged in such covered activity;

(5) Entrance into a joint venture, wherever located, that is formed with a person of a country of concern and that the subject U.S. person knows at the time of entrance into the joint venture will engage in or the U.S. person intends to engage in a covered activity; or

(6) Acquisition of a limited partner or equivalent interest in a venture capital fund, private equity fund, fund of funds, or other pooled investment fund (in each case where the fund is not a U.S. person) that a U.S. person knows at the time of the acquisition likely will invest in a person of a country of concern that is in the semiconductors and microelectronics, quantum information technologies, or artificial intelligence sectors, and such fund undertakes a transaction that would be a covered transaction if undertaken by a U.S. person.

(b) Notwithstanding paragraph (a) of this section, a transaction is not a covered transaction if it is:

(1) An excepted transaction as set forth in § 850.501; or

(2) For the conduct of the official business of the United States Government by employees, grantees, or contractors thereof.

(c) The acquisition of a convertible or contingent interest described in paragraph (a)(1) or (2) of this section may constitute a covered transaction, and the subsequent occurrence of a conversion event described in paragraph (a)(3) of this section may constitute a separate covered transaction. A U.S. person should assess each of the acquisition and the conversion to determine the applicability of this part.

Note 1 to § 850.210: For the avoidance of doubt, in the context of a debt financing, a lender's foreclosure on collateral that constitutes an equity interest is an acquisition of such equity interest by the lender.

§ 850.211 Develop.

The term *develop* means to engage in any stages prior to serial production, such as design or modification, design research, design analyses, design concepts, assembly and testing of prototypes, pilot production schemes, design data, process of transforming design data into a product, configuration design, integration design, and layouts.

§ 850.212 Entity.

The term *entity* means any branch, partnership, association, estate, joint venture, trust, corporation or division of a corporation, group, sub-group, or other organization (whether or not organized under the laws of any State or foreign state).

§ 850.213 Excepted transaction.

The term *excepted transaction* means a transaction that meets the criteria in § 850.501.

§ 850.214 Fabricate.

The term *fabricate* means to form devices such as transistors, poly capacitors, non-metal resistors, and diodes on a wafer of semiconductor material.

§ 850.215 Knowingly directing.

The term *knowingly directing* has the definition set forth in § 850.303.

§ 850.216 Knowledge.

Knowledge of a fact or circumstance (the term may be a variant, such as ''know'') means:

(a) Actual knowledge that a fact or circumstance exists or is substantially certain to occur;

(b) An awareness of a high probability of a fact or circumstance's existence or future occurrence; or

(c) Reason to know of a fact or circumstance's existence.

Note 1 to § 850.216: See the discussion of the knowledge standard in § 850.104 for more information about how this term is applied in this part.

§ 850.217 Notifiable transaction.

The term *notifiable transaction* means a covered transaction (that is not a prohibited transaction) in which the relevant covered foreign person or, with respect to a covered transaction described in § 850.210(a)(5), the relevant joint venture:

(a) Designs any integrated circuit that is not described in § 850.224(c);

(b) Fabricates any integrated circuit that is not described in § 850.224(d);

(c) Packages any integrated circuit that is not described in § 850.224(e); or

(d) Develops any AI system that is not described in § 850.224(j) or (k) and that is:

(1) Designed to be used for any government intelligence or mass-surveillance end use (*e.g.,* through mining text, audio, or video; image recognition; location tracking; or surreptitious listening devices) or military end use (*e.g.,* for weapons targeting, target identification, combat simulation, military vehicle or weapons control, military decision-making, weapons design, or combat system logistics and maintenance);

(2) Intended by the covered foreign person to be used for cybersecurity applications, digital forensics tools, and penetration testing tools, or the control of robotic systems; or

Alternate 1

(3) Trained using a quantity of computing power greater than 10^23 computational operations (*e.g.,* integer or floating-point operations).

Alternate 2

(3) Trained using a quantity of computing power greater than 10^24 computational operations (*e.g.,* integer or floating-point operations).

Alternate 3

(3) Trained using a quantity of computing power greater than 10^25 computational operations (*e.g.,* integer or floating-point operations).

Note 1 to § 850.217: Consistent with section 3 of the Order, the Secretary, in consultation with the Secretary of Commerce, and, as appropriate, the heads of other relevant agencies, shall periodically assess whether the quantity of computing power described in paragraph (d)(3) remains effective in addressing threats to the national security of the United States described in the Order and make updates, as appropriate, through public notice.

§ 850.218 Package.

The term *package* means to assemble various components, such as the integrated circuit die, lead frames, interconnects, and substrate materials to safeguard the semiconductor device and provide electrical connections between different parts of the die.

§ 850.219 Parent.

The term *parent* means, with respect to an entity:

(a) A person who or which directly or indirectly holds more than 50 percent of:

(1) The outstanding voting interest in the entity; or

(2) The voting power of the board of the entity;

(b) The general partner, managing member, or equivalent of the entity; or

(c) The investment adviser to any entity that is a pooled investment fund, with ''investment adviser'' as defined in the Investment Advisers Act of 1940 (15 U.S.C. 80b–2(a)(11)).

§ 850.220 Person.

The term *person* means any individual or entity.

§ 850.221 Person of a country of concern.

The term *person of a country of concern* means:

(a) Any individual that:

(1) Is a citizen or permanent resident of a country of concern;

(2) Is not a U.S. citizen; and

(3) Is not a permanent resident of the United States.

(b) An entity with a principal place of business in, headquartered in, or

incorporated in or otherwise organized under the laws of, a country of concern;

(c) The government of a country of concern, including any political subdivision, political party, agency, or instrumentality thereof; any person acting for or on behalf of the government of such country of concern; or any entity with respect to which the government of such country of concern holds individually or in the aggregate, directly or indirectly, 50 percent or more of the entity's outstanding voting interest, voting power of the board, or equity interest, or otherwise possesses the power to direct or cause the direction of the management and policies of such entity (whether through the ownership of voting securities, by contract, or otherwise);

(d) Any entity in which one or more persons identified in paragraph (a), (b), or (c) of this section, individually or in the aggregate, directly or indirectly, holds at least 50 percent of any of the following interests of such entity: outstanding voting interest, voting power of the board, or equity interest; or

(e) Any entity in which one or more persons identified in paragraph (d) of this section, individually or in the aggregate, directly or indirectly, holds at least 50 percent of any of the following interests of such entity: outstanding voting interest, voting power of the board, or equity interest.

§ 850.222 Principal place of business.

The term *principal place of business* means the primary location where an entity's management directs, controls, or coordinates the entity's activities, or, in the case of an investment fund, where the fund's activities are primarily directed, controlled, or coordinated by or on behalf of the general partner, managing member, or equivalent.

§ 850.223 Produce.

The term *produce* means to engage in any of the post-development stages of realizing the relevant technology or product, such as engineering, manufacture, integration, assembly, inspection, testing, and quality assurance.

§ 850.224 Prohibited transaction.

The term *prohibited transaction* means a covered transaction in which the relevant covered foreign person or, with respect to a covered transaction described in § 850.210(a)(5), the relevant joint venture:

(a) Develops or produces any electronic design automation software for the design of integrated circuits or advanced packaging;

(b) Develops or produces any:

(1) Front-end semiconductor fabrication equipment designed for performing the volume fabrication of integrated circuits, including equipment used in the production stages from a blank wafer or substrate to a completed wafer or substrate (*i.e.,* the integrated circuits are processed but they are still on the wafer or substrate);

(2) Equipment for performing volume advanced packaging; or

(3) Commodity, material, software, or technology designed exclusively for use in or with extreme ultraviolet lithography fabrication equipment.

(c) Designs any integrated circuit that meets or exceeds the performance parameters in Export Control Classification Number 3A090.a in supplement No. 1 to 15 CFR part 774, or integrated circuits designed for operation at or below 4.5 Kelvin;

(d) Fabricates any integrated circuit that meets any of the following criteria:

(1) Logic integrated circuits using a non-planar transistor architecture or with a production technology node of 16/14 nanometers or less, including fully depleted silicon-on-insulator (FDSOI) integrated circuits;

(2) NOT–AND (NAND) memory integrated circuits with 128 layers or more;

(3) Dynamic random-access memory (DRAM) integrated circuits using a technology node of 18 nanometer half-pitch or less;

(4) Integrated circuits manufactured from a gallium-based compound semiconductor;

(5) Integrated circuits using graphene transistors or carbon nanotubes; or

(6) Integrated circuits designed for operation at or below 4.5 Kelvin;

(e) Packages any integrated circuit using advanced packaging techniques;

(f) Develops, installs, sells, or produces any supercomputer enabled by advanced integrated circuits that can provide a theoretical compute capacity of 100 or more double-precision (64-bit) petaflops or 200 or more single-precision (32-bit) petaflops of processing power within a 41,600 cubic foot or smaller envelope;

(g) Develops a quantum computer or produces any of the critical components required to produce a quantum computer such as a dilution refrigerator or two-stage pulse tube cryocooler;

(h) Develops or produces any quantum sensing platform designed for, or which the relevant covered foreign person intends to be used for, any military, government intelligence, or mass-surveillance end use;

(i) Develops or produces any quantum network or quantum communication system designed for, or which the relevant covered foreign person intends to be used for:

(1) Networking to scale up the capabilities of quantum computers, such as for the purposes of breaking or compromising encryption;

(2) Secure communications, such as quantum key distribution; or

(3) Any other application that has any military, government intelligence, or mass-surveillance end use;

(j) Develops any AI system that is designed to be exclusively used for, or which the relevant covered foreign person intends to be used for, any:

(1) Military end use (*e.g.,* for weapons targeting, target identification, combat simulation, military vehicle or weapon control, military decision-making, weapons design, or combat system logistics and maintenance); or

(2) Government intelligence or mass surveillance end use (*e.g.,* through mining text, audio, or video; image recognition; location tracking; or surreptitious listening devices);

(k) Develops any AI system that is trained using a quantity of computing power greater than:

Alternate 1 for paragraph (k)(1)

(1) 10^24 computational operations (*e.g.,* integer or floating-point operations); or

Alternate 2 for paragraph (k)(1)

(1) 10^25 computational operations (*e.g.,* integer or floating-point operations); or

Alternate 3 for paragraph (k)(1)

(1) 10^26 computational operations (*e.g.,* integer or floating-point operations); or

Alternate 1 for paragraph (k)(2)

(2) 10^23 computational operations (*e.g.,* integer or floating-point operations) using primarily biological sequence data;

Alternate 2 for paragraph (k)(2)

(2) 10^24 computational operations (*e.g.,* integer or floating-point operations) using primarily biological sequence data;

(l) Meets the conditions set forth in § 850.209(a)(2) because of its relationship to one or more covered foreign persons engaged in any covered activity described in any of paragraphs (a) through (k) of this section; or

(m) Engages in a covered activity, whether referenced in this section or § 850.217 and is:

(1) Included on the Bureau of Industry and Security's Entity List (15 CFR part 744, supplement no. 4);

(2) Included on the Bureau of Industry and Security's Military End User List (15 CFR part 744, supplement no. 7);

(3) Meets the definition of ''Military Intelligence End-User'' by the Bureau of

Industry and Security in 15 CFR 744.22(f)(2);

(4) Included on the Department of the Treasury's list of Specially Designated Nationals and Blocked Persons (SDN List), or is an entity in which one or more individuals or entities included on the SDN List, individually or in the aggregate, directly or indirectly, own a 50 percent or greater interest;

(5) Included on the Department of the Treasury's list of Non-SDN Chinese Military-Industrial Complex Companies (NS–CMIC List); or

(6) Designated as a foreign terrorist organization by the Secretary of State under 8 U.S.C. 1189.

Note 1 to § 850.224: Consistent with section 3 of the Order, the Secretary, in consultation with the Secretary of Commerce and, as appropriate, the heads of other relevant agencies, shall periodically assess whether the quantities of computing power described in paragraph (k) of this section remain effective in addressing threats to the national security of the United States described in the Order and make updates, as appropriate, through public notice.

§ 850.225 Quantum computer.

The term *quantum computer* means a computer that performs computations that harness the collective properties of quantum states, such as superposition, interference, or entanglement.

§ 850.226 Relevant agencies.

The term *relevant agencies* means the Departments of State, Defense, Justice, Commerce, Energy, and Homeland Security, the Office of the United States Trade Representative, the Office of Science and Technology Policy, the Office of the Director of National Intelligence, the Office of the National Cyber Director, and any other department, agency, or office the Secretary determines appropriate.

§ 850.227 Subsidiary.

The term *subsidiary* means, with respect to a person, an entity of which such person is a parent.

§ 850.228 United States.

The term *United States* or *U.S.* means the United States of America, the States of the United States of America, the District of Columbia, and any commonwealth, territory, dependency, or possession of the United States of America, or any subdivision of the foregoing, and includes the territorial sea of the United States of America. For purposes of this part, an entity organized under the laws of the United States of America, one of the States, the District of Columbia, or a commonwealth, territory, dependency, or possession of the United States is an entity organized ''in the United States.''

§ 850.229 U.S. person.

The term *U.S. person* means any United States citizen, lawful permanent resident, entity organized under the laws of the United States or any jurisdiction within the United States, including any foreign branch of any such entity, or any person in the United States.

Subpart C—Prohibited Transactions and Other Prohibited Activities

§ 850.301 Undertaking a prohibited transaction.

A U.S. person may not engage in a prohibited transaction unless an exemption for that transaction has been granted under § 850.502.

§ 850.302 Actions of a controlled foreign entity.

(a) A U.S. person shall take all reasonable steps to prohibit and prevent any transaction by its controlled foreign entity that would be a prohibited transaction if engaged in by a U.S. person.

(b) If a controlled foreign entity engages in a transaction that would be a prohibited transaction if engaged in by a U.S. person, in determining whether the relevant U.S. person took all reasonable steps to prohibit and prevent such transaction, the Department of the Treasury will consider, among other factors, any of the following with respect to a U.S. person and its controlled foreign entity:

(1) The execution of agreements with respect to compliance with this part between the subject U.S. person and its controlled foreign entity;

(2) The existence and exercise of governance or shareholder rights by the U.S. person with respect to the controlled foreign entity, where applicable;

(3) The existence and implementation of periodic training and internal reporting requirements by the U.S. person and its controlled foreign entity with respect to compliance with this part;

(4) The implementation of appropriate and documented internal controls, including internal policies, procedures, or guidelines that are periodically reviewed internally, by the U.S. person and its controlled foreign entity; and

(5) Implementation of a documented testing and/or auditing process of internal policies, procedures, or guidelines.

Note 1 to § 850.302: Findings of violations of this section and decisions related to enforcement and penalties will be made based on a consideration of the totality of relevant facts and circumstances, including whether the U.S. person has taken the steps described in paragraph (b) of this section and whether such steps were reasonable given the size and sophistication of the U.S. person.

§ 850.303 Knowingly directing an otherwise prohibited transaction.

(a) A U.S. person is prohibited from knowingly directing a transaction by a non-U.S. person that the U.S. person knows at the time of the transaction would be a prohibited transaction if engaged in by a U.S. person. For purposes of this section, a U.S. person ''knowingly directs'' a transaction when the U.S. person has authority, individually or as part of a group, to make or substantially participate in decisions on behalf of a non-U.S. person, and exercises that authority to direct, order, decide upon, or approve a transaction. Such authority exists when a U.S. person is an officer, director, or senior advisor, or otherwise possesses senior-level authority at a non-U.S. person.

(b) A U.S. person that has the authority described in paragraph (a) of this section and recuses themself from an investment will not be considered to have exercised their authority to direct, order, decide upon, or approve a transaction.

Subpart D—Notifiable Transactions and Other Notifiable Activities

§ 850.401 Undertaking a notifiable transaction.

A U.S. person that undertakes a notifiable transaction shall file a notification of that transaction with the Department of the Treasury pursuant to § 850.404.

§ 850.402 Notification of actions of a controlled foreign entity.

A U.S. person shall file a notification with the Department of the Treasury pursuant to § 850.404 with respect to any transaction by a controlled foreign entity of that U.S. person that would be a notifiable transaction if engaged in by a U.S. person.

§ 850.403 Notification of post-transaction knowledge.

A U.S. person that acquires actual knowledge after the completion date of a transaction of a fact or circumstance such that the transaction would have been a covered transaction if such knowledge had been possessed by the relevant U.S. person at the time of the transaction shall promptly, and in no event later than 30 calendar days following the acquisition of such

knowledge, submit a notification pursuant to § 850.404. This requirement applies regardless of whether the transaction would have been a notifiable transaction or a prohibited transaction.

Note 1 to § 850.403: For the avoidance of doubt, a U.S. person's submission of a notification pursuant to this section shall not preclude a finding by the Department of the Treasury that as a factual matter the U.S. person had relevant knowledge of the transaction's status at the time of the transaction.

§ 850.404 Procedures for notifications.

(a) A U.S. person that has an obligation under §§ 850.401, 850.402, or 850.403 shall file an electronic copy of the notification of the transaction with the Department of the Treasury including the information set out in § 850.405 and the certification referred to in § 850.203. The U.S. person shall follow the electronic filing instructions posted on the Department of the Treasury's Outbound Investment Security Program website. No communications or submissions other than those described in this section shall constitute the filing of a notification for purposes of this part.

(b) The Department of the Treasury may contact a U.S. person that has filed a notification with questions or document requests related to the transaction or compliance with this part. The U.S. person shall respond to any such questions or requests within the time frame and in the manner specified by the Department of the Treasury. Information and other documents provided by the U.S. person to the Department of the Treasury after the filing of the notification under this section shall be deemed part of the notification and shall be subject to the certification referred to in § 850.203.

(c) A U.S. person shall file a notification under § 850.401 or § 850.402 with the Department of the Treasury no later than 30 calendar days following the completion date of a notifiable transaction. A U.S. person shall file a notification required under § 850.403 with the Department of the Treasury no later than 30 calendar days after it acquires the knowledge referred to in § 850.403.

(d) If a U.S. person files a notification prior to the completion date of the notifiable transaction, the U.S. person shall update such notification no later than 30 calendar days following the completion date of the notifiable transaction if information in the original filing has materially changed.

(e) A U.S. person shall inform the Department of the Treasury in writing no later than 30 calendar days following the acquisition of previously unavailable information required under § 850.405.

Note 1 to § 850.404: While the Department of the Treasury may engage with the U.S. person following notification, it is also possible the U.S. person will receive no communication from the Department of the Treasury other than an electronic acknowledgment of receipt after notification is submitted.

§ 850.405 Content of notifications.

(a) A U.S. person that has an obligation under this part to file a notification shall provide the information set forth in this section, which must be accurate and complete in all material respects.

(b) A notification shall provide, as applicable:

(1) The contact information of a representative of the U.S. person filing the notification who is available to communicate with the Department of the Treasury about the notification including such representative's name, title, email address, mailing address, phone number, and employer;

(2) A description of the U.S. person, including name, and as applicable, principal place of business and place of incorporation or legal organization, company address, website, and, if the U.S. person is an entity, such U.S. person's ultimate owner;

(3) A post-transaction organizational chart of the U.S. person that includes its relationship with any controlled foreign entity or entities of the U.S. person and that identifies the covered foreign person and other relevant persons involved in the transaction;

(4) A brief description of the commercial rationale for the transaction;

(5) A brief description of why the U.S. person has determined the transaction is a covered transaction that includes a discussion of the nature of the transaction, its structure, reference to the paragraph of § 850.210(a) that best describes the transaction type, and whether the notification is being submitted pursuant to §§ 850.401, 850.402, or 850.403;

(6) The status of the transaction, including the actual or expected completion date of the transaction;

(7) The total transaction value in U.S. dollars or U.S. dollar equivalent, an explanation of how the transaction value was determined, and a description of the consideration for the transaction (including cash, securities, other assets, and debt forgiveness);

(8) The aggregate equity interest, voting interest, board seats (or equivalent holdings) of the U.S. person and its affiliates in the covered foreign person (or in the joint venture, as applicable) following the completion date of the transaction, including a description of any agreements or commitments for future investment or options to make future investments in the covered foreign person (or joint venture);

(9) Information about the covered foreign person, including its name, and as applicable, principal place of business and place of incorporation or legal organization, company address, website, and if the covered foreign person is an entity, such covered foreign person's ultimate owner, and the full legal names and titles of each officer, director, and other member of management of the covered foreign person, and a post-transaction organizational chart of the covered foreign person;

(10) Identification and description of each of the covered activity or activities undertaken by the covered foreign person that makes the transaction a covered transaction, as well as a brief description of the known end use(s) and end user(s) of the covered foreign person's technology, products, or services;

(11) A statement describing the attributes that cause the entity to be a covered foreign person, and any other relevant information regarding the covered foreign person and covered activity or activities;

(12) If a transaction involves a covered activity identified in § 850.217(a), (b), or (c), identification of the technology node(s) at which any applicable product is produced; and;

(13) If the notification is required under § 850.403:

(i) Identification of the fact or circumstance of which the U.S. person acquired knowledge post-transaction;

(ii) The date upon which the U.S. person acquired such knowledge;

(iii) A statement explaining why the U.S. person did not possess or obtain such knowledge at the time of the transaction; and

(iv) A description of any pre-transaction diligence undertaken by the U.S. person, including, as applicable, any steps described in § 850.104(c).

(c) The U.S. person shall maintain a copy of the notification filed and supporting documentation for a period of ten years from the date of the filing. Such supporting documentation shall include, as applicable, any pitch decks, marketing letters, and offering memorandums; transaction documents including side letters and investment agreements; and due diligence materials related to the transaction. The U.S. person shall make all supporting

documentation available upon request by the Department of the Treasury.

(d) If the U.S. person does not provide responses to the information required in paragraph (b) of this section, the U.S. person shall provide sufficient explanation for why the information is unavailable or otherwise cannot be obtained and explain the U.S. person's efforts to obtain such information. If such information subsequently becomes available, the U.S. person shall provide such information to the Department of the Treasury promptly, and in no event later than 30 calendar days following the availability of such information.

§ 850.406 Notice of material omission or inaccuracy.

A person who has made any representation, statement, or certification subject to this part shall inform the Department of the Treasury in writing promptly, and in no event later than 30 calendar days after learning of a material omission or inaccuracy in such representation, statement, or certification.

Subpart E—Exceptions and Exemptions

§ 850.501 Excepted transaction.

A transaction that would be either a prohibited transaction or a notifiable transaction if engaged in by a U.S. person but for this section is not a prohibited transaction or a notifiable transaction if the conditions set forth in this section are met. In that case, the transaction is an excepted transaction.

(a) The following transactions are excepted transactions:

(1) An investment by a U.S. person:

(i) In any publicly traded security, with ''security'' as defined in section 3(a)(10) of the Securities Exchange Act of 1934, as amended, at 15 U.S.C. 78c(a)(10), denominated in any currency, and that trades on a securities exchange or through the method of trading that is commonly referred to as ''over-the-counter,'' in any jurisdiction;

(ii) In a security issued by (1) any ''investment company'' as defined in section 3(a)(1) of the Investment Company Act of 1940, as amended, at 15 U.S.C. 80a–3(a)(1), that is registered with the U.S. Securities and Exchange Commission, such as index funds, mutual funds, or exchange traded funds, or (2) any company that has elected to be a business development company pursuant to section 54 of the Investment Company Act of 1940 (15 U.S.C. 8a–54); or any derivative thereon; or

Alternate 1 for paragraph (a)(1)(iii)

(iii) Made as a limited partner or equivalent in a venture capital fund, private equity fund, fund of funds, or other pooled investment fund other than as described in paragraph (a)(1)(ii) of this section where:

(A) The limited partner's contribution is solely capital and the limited partner:

(*1*) Is not responsible for any debts or other financial obligations with respect to the fund beyond its investment including any uncalled capital commitments related thereto;

(*2*) Cannot approve, disapprove, or otherwise influence or participate in the investment decisions of the fund;

(*3*) Cannot approve, disapprove, or otherwise influence or participate in the decisions made by the general partner, managing member, or equivalent related to entities in which the fund is invested;

(*4*) Cannot unilaterally dismiss, prevent the dismissal of, select, or determine the compensation of the general partner, managing member, or equivalent of the fund; and

(*5*) Cannot participate in, and has no right or ability, by virtue of its status as a limited partner or any other contractual relationship, to influence the decision-making or operations of any covered foreign person in which the fund is invested; and;

(B)(*1*) The limited partner's committed capital is not more than 50 percent of the total assets under management of the fund, aggregated across any investment and co-investment vehicles that comprise the fund; or,

(*2*) Where the fund is not a U.S. person or a controlled foreign entity, the limited partner has secured a binding contractual assurance that its capital will not be used to engage in a transaction that would cause the limited partner to have made an indirect prohibited transaction.

Alternate 2 for paragraph (a)(1)(iii)

(iii) Made as a limited partner or equivalent in a venture capital fund, private equity fund, fund of funds, or other pooled investment fund other than as described in paragraph (a)(1)(ii) of this section where the limited partner's committed capital is not more than $1,000,000, aggregated across any investment and co-investment vehicles that comprise the fund.

(2) Notwithstanding paragraph (a)(1) of this section, an investment is not an excepted transaction if it affords the U.S. person rights beyond standard minority shareholder protections with respect to the covered foreign person. Such protections include:

(i) The power to prevent the sale or pledge of all or substantially all of the assets of an entity or a voluntary filing for bankruptcy or liquidation;

(ii) The power to prevent an entity from entering into contracts with majority investors or their affiliates;

(iii) The power to prevent an entity from guaranteeing the obligations of majority investors or their affiliates;

(iv) The right to purchase an additional interest in an entity to prevent the dilution of an investor's pro rata interest in that entity in the event that the entity issues additional instruments conveying interests in the entity;

(v) The power to prevent the change of existing legal rights or preferences of the particular class of stock held by minority investors, as provided in the relevant corporate documents governing such stock; and

(vi) The power to prevent the amendment of the Articles of Incorporation, constituent agreement, or other organizational documents of an entity with respect to the matters described in paragraphs (a)(2)(i) through (v) of this section;

(b) The acquisition by a U.S. person of equity or other interests in an entity held by one or more persons of a country of concern; *provided that:*

(1) The U.S. person is acquiring all equity or other interests in such entity held by all persons of a country of concern; and

(2) Following such acquisition, the entity does not constitute a covered foreign person.

(c) A transaction that, but for this paragraph, would be a covered transaction between a U.S. person and its controlled foreign entity that supports ongoing operations or other activities that are not covered activities as defined in § 850.208; *provided that* this exception shall not apply when the transaction is a covered transaction pursuant to § 850.210(a)(4) or (a)(5);

(d) A transaction made after the effective date of this part pursuant to a binding, uncalled, capital commitment entered into before August 9, 2023; or

(e) The acquisition of a voting interest in a covered foreign person by a U.S. person upon default or other condition involving a loan or a similar financing arrangement, where the loan was made by a syndicate of banks in a loan participation where the U.S. person lender(s) in the syndicate:

(1) Cannot on its own initiate any action vis-à-vis the debtor; and

(2) Does not have a lead role in the syndicate; or

(f)(1) A transaction that is:

(i) With or involving a person of a country or territory outside of the United States designated by the Secretary, after taking into account whether the country or territory is

addressing national security concerns posed by outbound investment; and

(ii) Of a type for which the Secretary has determined that the related national security concerns are likely to be adequately addressed by measures taken or that may be taken by the government of the relevant country or territory.

(2) Prior to making a designation or determination under this paragraph (f), the Secretary shall consult with the Secretary of State, the Secretary of Commerce, and, as appropriate, the heads of other relevant agencies.

(3) The Secretary's designations and determinations under paragraph (f) of this section shall be made available through public notice.

Note 1 to § 850.501: A limited partner's participation on an advisory board or a committee of an investment fund shall not constitute having the ability to undertake the actions referred to in Alternate 1 paragraphs (a)(1)(iii)(A)(*1*) to (*5*) of this section if the advisory board or committee does not have the ability to approve, disapprove, or otherwise control: (i) investment decisions of the investment fund; or (ii) decisions made by the general partner, managing member, or equivalent related to entities in which the investment fund is invested.

§ 850.502 National interest exemption.

(a) The Secretary, in consultation with the Secretary of Commerce, the Secretary of State, and the heads of relevant agencies, as appropriate, may determine that a covered transaction is in the national interest of the United States and therefore is exempt from applicable provisions in Subparts C and D of this part (excluding §§ 850.406, 850.603, and 850.604). Such a determination may be made following a request by a U.S. person on its own behalf or on behalf of its controlled foreign entity.

(b) Any determination pursuant to paragraph (a) of this section will be based on a consideration of the totality of the relevant facts and circumstances and may be informed by, among other considerations, the transaction's effect on critical U.S. supply chain needs; domestic production needs in the United States for projected national defense requirements; United States' technological leadership globally in areas affecting U.S. national security; and impact on U.S. national security if the U.S. person is prohibited from undertaking the transaction.

(c) A U.S. person seeking a national interest exemption shall submit relevant information to the Department of the Treasury regarding the transaction and shall articulate the basis for the request, including the U.S. person's analysis of the transaction's potential impact on the national interest of the United States. The Department of the Treasury may request additional information that may include some or all of the information required under § 850.405.

(d) A determination that a covered transaction is exempt under this section may be subject to binding conditions.

(e) No determination pursuant to paragraph (a) of this section will be valid unless provided to the subject U.S. person in writing and signed by the Assistant Secretary or Deputy Assistant Secretary of the Treasury for Investment Security.

Note 1 to § 850.502: A process and related information for exemption requests will be made available on the Department of the Treasury's Outbound Investment Security Program website.

§ 850.503 IEEPA statutory exception.

Conduct referred to in 50 U.S.C. 1702(b) shall not be regulated or prohibited, directly or indirectly, by this part.

Subpart F—Violations

§ 850.601 Taking actions prohibited by this part.

The taking of any action prohibited by this part is a violation of this part.

§ 850.602 Failure to fulfill requirements.

Failure to take any action required by this part, and within the time frame and in the manner specified by this part, as applicable, is a violation of this part.

§ 850.603 Misrepresentation and concealment of facts.

With respect to any information submission to or communication with the Department of the Treasury pursuant to any provision of this part, the making of any materially false or misleading representation, statement, or certification, or falsifying or concealing any material fact is a violation of this part.

§ 850.604 Evasions; attempts; causing violations; conspiracies.

(a) Any action on or after the effective date of this part that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in this part is prohibited.

(b) Any conspiracy formed to violate the prohibitions set forth in this part is prohibited.

Subpart G—Penalties and Disclosures

§ 850.701 Penalties.

(a) Section 206 of IEEPA applies to any person subject to the jurisdiction of the United States who violates, attempts to violate, conspires to violate, or causes a violation of any order, regulation, or prohibition issued by or pursuant to the direction or authorization of the Secretary pursuant to this part or otherwise under IEEPA.

(1) A civil penalty not to exceed the maximum amount set forth in section 206 of IEEPA may be imposed on any person who violates, attempts to violate, conspires to violate, or causes a violation of any order, regulation, or prohibition issued under IEEPA, including any provision of this part.

(2) A person who willfully commits, willfully attempts to commit, willfully conspires to commit, or aids or abets in the commission of a violation, attempt to violate, conspiracy to violate, or causing of a violation of any order, regulation, or prohibition issued under IEEPA, including any provision of this part, shall, upon conviction, be fined not more than $1,000,000, or if a natural person, be imprisoned for not more than 20 years, or both.

(b) The Secretary may refer potential criminal violations of the Order, or of this part, to the Attorney General.

(c) The civil penalties provided for in IEEPA are subject to adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended (Pub. L. 101–410, 28 U.S.C. 2461 note).

(d) The criminal penalties provided for in IEEPA are subject to adjustment pursuant to 18 U.S.C. 3571.

(e) The penalties available under this section are without prejudice to other penalties, civil or criminal, and forfeiture of property, available under other applicable law.

(f) Pursuant to 18 U.S.C. 1001, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact; makes any materially false, fictitious, or fraudulent statement or representation; or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry shall be fined under title 18, United States Code, or imprisoned not more than 5 years, or both.

§ 850.702 Administrative collection; referral to United States Department of Justice.

The imposition of a monetary penalty under this part creates a debt due to the U.S. Government. The Department of the Treasury may take action to collect the penalty assessed if not paid. In addition or instead, the matter may be

referred to the Department of Justice for appropriate action to recover the penalty.

§ 850.703 Divestment.

(a) The Secretary, in consultation with the heads of relevant agencies, as appropriate, may take any action authorized under IEEPA to nullify, void, or otherwise compel the divestment of any prohibited transaction entered into after the effective date of this part.

(b) The Secretary may refer any action taken under paragraph (a) of this section to the Attorney General to seek appropriate relief to enforce such action.

§ 850.704 Voluntary self-disclosure.

(a) Any person who has engaged in conduct that may constitute a violation of this part may submit a voluntary self-disclosure of that conduct to the Department of the Treasury.

(b) In determining the appropriate response to any violation, the Department of the Treasury will consider the submission and the timeliness of any voluntary self-disclosure.

(c) In assessing the timeliness of a voluntary self-disclosure, the Department of the Treasury will consider whether it has learned of the conduct prior to the voluntary self-disclosure. The Department of the Treasury may consider disclosure of a violation to another government agency other than the Department of the Treasury as a voluntary self-disclosure based on a case-by-case assessment.

(d) Notwithstanding the foregoing, identification to the Department of the Treasury of conduct that may constitute a violation of this part may not be assessed to be a voluntary self-disclosure in one or more of the following circumstances:

(1) A third party has provided a prior disclosure to the Department of the Treasury of the conduct or similar conduct related to the same pattern or practice, regardless of whether the disclosing person knew of the third party's prior disclosure;

(2) The disclosure includes materially false or misleading information;

(3) The disclosure, when considered along with supplemental information timely provided by the disclosing person, is materially incomplete;

(4) The disclosure is not self-initiated, including when the disclosure results from a suggestion or order of a federal or state agency or official;

(5) The disclosure is a response to an administrative subpoena or other inquiry from the Department of the Treasury or another government agency;

(6) The disclosure is made about the conduct of an entity by an individual in such entity without the authorization of such entity's senior management; or

(7) The filing is made pursuant to a required notification under this part, including § 850.403 or § 850.406.

(e) A voluntary self-disclosure to the Department of the Treasury must take the form of a written notice describing the conduct that may constitute a violation and each of the persons involved. A voluntary self-disclosure must include, or be followed within a reasonable period of time by, a report of sufficient detail to afford a complete understanding of the conduct that may constitute the violation. A person making a voluntary self-disclosure must respond in a timely manner to any follow-up inquiries by the Department of the Treasury.

Subpart H—Provision and Handling of Information

§ 850.801 Confidentiality.

(a) Except to the extent required by law or otherwise provided in paragraphs (b) and (c) of this section, information or documentary materials not otherwise publicly available that are submitted to the Department of the Treasury under this part shall not be disclosed to the public.

(b) Notwithstanding paragraph (a) of this section, except to the extent prohibited by law, the Department of the Treasury may disclose information or documentary materials that are not otherwise publicly available, subject to appropriate confidentiality and classification requirements, when such information or documentary materials are:

(1) Relevant to any judicial or administrative action or proceeding;

(2) Provided to Congress or to any duly authorized committee or subcommittee of Congress; or

(3) Provided to any domestic governmental entity, or to any foreign governmental entity of a United States partner or ally, where the information or documentary materials are important to the national security analysis or actions of such governmental entity or the Department of the Treasury.

(c) Notwithstanding paragraph (a) of this section, the Department of the Treasury may disclose to third parties information or documentary materials that are not otherwise publicly available when the person who submitted or filed the information or documentary materials has consented to its disclosure to such third parties.

(d) The Department of the Treasury may use the information gathered pursuant to this part to fulfill its obligations under the Order, which may include publication of anonymized data.

§ 850.802 Language of information.

All materials or information filed with the Department of the Treasury under this part shall be submitted in English. If supplementary or additional materials were originally written in a foreign language, they shall be submitted in their original language. Where English versions of those documents exist, they shall also be submitted.

Subpart I—Other Provisions

§ 850.901 Delegation of authorities of the Secretary of the Treasury.

Any action that the Secretary is authorized to take pursuant to the Order and any further executive orders relating to the national emergency declared in the Order may be taken by the Assistant Secretary of the Treasury for Investment Security or their designee or by any other person to whom the Secretary has delegated the authority so to act, as appropriate.

§ 850.902 Amendment, modification, or revocation.

(a) Except as otherwise provided by law, and in consultation with the Secretary of Commerce and, as appropriate, the heads of other relevant agencies, the Secretary may amend, modify, or revoke provisions of this part at any time.

(b) Except as otherwise provided by law, any instructions, orders, forms, regulations, or rulings issued pursuant to this part may be amended, modified, or revoked at any time.

(c) Unless otherwise specifically provided, any amendment, modification, or revocation of any provision in or appendix to this part does not affect any act done or omitted, or any civil or criminal proceeding commenced or pending, prior to such amendment, modification, or revocation. All penalties, forfeitures, and liabilities under any such instructions, orders, forms, regulations, or rulings pursuant to this part continue and may be enforced as if such amendment, modification, or revocation had not been made.

§ 850.903 Severability.

The provisions of this part are separate and severable from one another. If any of the provisions of this part, or the application thereof to any person or circumstance, is held to be invalid, such invalidity shall not affect other provisions or application of such provisions to other persons or circumstances that can be given effect

without the invalid provision or application.

§ 850.904 Reports to be furnished on demand.

(a) Any person is required to furnish under oath, in the form of reports or otherwise, at any time as may be required by the Department of the Treasury, complete information regarding any act or transaction subject to the provisions of this part, regardless of whether such act or transaction is effected pursuant to a national interest exemption under § 850.502. Except as provided otherwise, the Department of the Treasury may, through any person or agency, conduct investigations, hold hearings, administer oaths, examine witnesses, receive evidence, take depositions, and require by subpoena the attendance and testimony of witnesses and the production of any books, contracts, letters, papers, and other hard copy or electronic documents relating to any matter under investigation, regardless of whether any report has been required or filed under this section.

(b) For purposes of paragraph (a) of this section, the term *document* includes any written, recorded, or graphic matter or other means of preserving thought or expression (including in electronic format), and all tangible things stored in any medium from which information can be processed, transcribed, or obtained directly or indirectly.

(c) Persons providing documents to the Department of the Treasury pursuant to this section must do so in a usable format agreed upon by the Department of the Treasury.

Paul M. Rosen,

Assistant Secretary for Investment Security.

[FR Doc. 2024–13923 Filed 7–3–24; 8:45 am]

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Federal Register

Vol. 89, No. 129

Friday, July 5, 2024

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