with the statute, for CY 2025. We also note that, even if notice and comment procedures were required for this notice, we would find good cause, for the previously stated reason, to waive the delay in effective date of the notice, as additional delay would be contrary to the public interest under section 1871(e)(1)(B)(ii) of the Act. Publication of this notice is consistent with section 1839 of the Act, and we believe that any potential delay in the effective date of the notice, if such delay were required at all, could cause unnecessary confusion for both the agency and Medicare beneficiaries.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 31, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–26474 Filed 11–8–24; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8087–N]

RIN 0938–AV37

Medicare Program; CY 2025 Part A Premiums for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of 2025 Medicare Part A premium for uninsured enrollees.

SUMMARY: This notice announces Medicare's Hospital Insurance Program (Medicare Part A) premium for uninsured enrollees in calendar year (CY) 2025. This premium is paid by enrollees aged 65 and over who are not otherwise eligible for benefits under Medicare Part A (hereafter known as the ''uninsured aged'') and by certain individuals with disabilities who have exhausted other entitlement. The monthly Medicare Part A premium for the 12 months beginning January 1, 2025, for these individuals will be $518. The premium for certain other individuals as described in this notice will be $285.

DATES: The premium announced in this notice is effective on January 1, 2025.

FOR FURTHER INFORMATION CONTACT: Yaminee Thaker, (410) 786–7921.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1818 of the Social Security Act (the Act) provides for voluntary enrollment in Medicare Part A, subject to payment of a monthly premium, of certain persons aged 65 and older who are uninsured under the Old-Age, Survivors, and Disability Insurance (OASDI) program or the Railroad Retirement Act and do not otherwise meet the requirements for entitlement to Medicare Part A. These ''uninsured aged'' individuals are uninsured under the OASDI program or the Railroad Retirement Act, because they do not have 40 quarters of coverage under Title II of the Act (or are/were not married to someone who did). (Persons insured under the OASDI program or the Railroad Retirement Act and certain others do not have to pay premiums for Medicare Part A.)

Section 1818A of the Act provides for voluntary enrollment in Medicare Part A, subject to payment of a monthly premium for certain individuals with disabilities who have exhausted other entitlement. These are individuals who were entitled to coverage due to a disabling impairment under section 226(b) of the Act, but who are no longer entitled to disability benefits and premium-free Medicare Part A coverage because they have gone back to work and their earnings exceed the statutorily defined ''substantial gainful activity'' amount (section 223(d)(4) of the Act).

Section 1818A(d)(2) of the Act specifies that the provisions relating to premiums for the aged under section 1818(d) through section 1818(f) of the Act will also apply to certain individuals with disabilities as described above.

Section 1818(d)(1) of the Act requires us to estimate, on an average per capita basis, the amount to be paid from the Federal Hospital Insurance Trust Fund for services incurred in the upcoming calendar year (CY) (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A. We must then determine the monthly actuarial rate for the following year (the per capita amount estimated above divided by 12) and publish the dollar amount for the monthly premium in the succeeding CY. If the premium is not a multiple of $1, the premium is rounded to the nearest multiple of $1 (or, if it is a multiple of 50 cents but not of $1, it is rounded to the next highest $1).

Section 13508 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) amended section 1818(d) of the Act to provide for a reduction in the premium amount for certain voluntary enrollees (sections 1818 and 1818A of the Act). The reduction applies to an individual who is eligible to buy into the Medicare Part A program and who, as of the last day of the previous month:

- Had at least 30 quarters of coverage under Title II of the Act;
- Was married, and had been married for the previous 1-year period, to a person who had at least 30 quarters of coverage;
- Had been married to a person for at least 1 year at the time of the person's death if, at the time of death, the person had at least 30 quarters of coverage; or
- Is divorced from a person and had been married to the person for at least 10 years at the time of the divorce if, at the time of the divorce, the person had at least 30 quarters of coverage.

Section 1818(d)(4)(A) of the Act specifies that the premium that these individuals will pay for CY 2025 will be equal to the premium for uninsured aged enrollees reduced by 45 percent.

Section 1818(g) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary), at the request of a state, to enter into a Medicare Part A buy-in agreement with a state to pay Medicare Part A premiums for Qualified Medicare Beneficiaries (QMBs). Under the QMB program, state Medicaid agencies must pay the Medicare Part A premium for those not eligible for premium-free Medicare Part A if those individuals meet all of the eligibility requirements for the QMB program under the state's Medicaid state plan. (Entering into a Medicare Part A buy-in agreement would permit a state to avoid any Medicare Part A late enrollment penalties that the individual may owe and would allow states to enroll persons in Medicare Part A at any time of the year, without regard to Medicare enrollment periods.) Other individuals may be eligible for the Qualified Disabled Working Individuals program, through which state Medicaid programs provide coverage of Medicare Part A premiums for individuals eligible to enroll in Medicare Part A by virtue of section 1818A of the Act who meet certain financial eligibility criteria.

II. Monthly Premium Amount for CY 2025

The monthly premium for the uninsured aged and certain individuals with disabilities who have exhausted other entitlement for the 12 months beginning January 1, 2025, is $518. The monthly premium for the individuals eligible under section 1818(d)(4)(B) of the Act, and therefore, subject to the 45

percent reduction in the monthly premium, is $285.

III. Monthly Premium Rate Calculation

As discussed in section I of this notice, the monthly Medicare Part A premium is equal to the estimated monthly actuarial rate for CY 2025 rounded to the nearest multiple of $1 and equals one-twelfth of the average per capita amount, which is determined by projecting the number of Medicare Part A enrollees aged 65 years and over, as well as the benefits and administrative costs that will be incurred on their behalf.

The steps involved in projecting these future costs to the Federal Hospital Insurance Trust Fund are:

- Establishing the present cost of services furnished to beneficiaries, by type of service, to serve as a projection base;
- Projecting increases in payment amounts for each of the service types; and
- Projecting increases in administrative costs.

We base our projections for CY 2025 on—(1) current historical data; and (2) projection assumptions derived from current law and the President's Fiscal Year 2025 Budget.

For CY 2025, we estimate that 61,199,491 people aged 65 years and over will be entitled to (enrolled in) benefits (without premium payment) and that they will incur about $380.149 billion in benefits and related administrative costs. Thus, the estimated monthly average per capita amount is $517.64 and the monthly premium is $518. Subsequently, the full monthly premium reduced by 45 percent is $285.

IV. Costs to Beneficiaries

The CY 2025 monthly premium of $518 is approximately 2.6 percent higher than the CY 2024 premium of $505. We estimate that approximately 756,000 enrollees will voluntarily enroll in Medicare Part A by paying the full premium. We estimate that over 90 percent of these individuals will have their Medicare Part A premium paid for by states, since they are enrolled in the QMB program. Furthermore, the CY 2025 reduced monthly premium of $285 is approximately 2.5 percent higher than the CY 2024 premium of $278. We estimate that an additional 97,000 enrollees will pay the reduced premium. Therefore, we estimate that the total aggregate cost to enrollees paying these premiums in CY 2025, compared to the amount that they paid in CY 2024, will be about $126 million.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment prior to a rule taking effect in accordance with section 1871 of the Act and section 553(b) of the Administrative Procedure Act (APA). Section 1871(a)(2) of the Act provides that no rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under Medicare shall take effect unless it is promulgated through notice and comment rulemaking. Unless there is a statutory exception, section 1871(b)(1) of the Act generally requires the Secretary to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment before establishing or changing a substantive legal standard regarding the matters enumerated by the statute. Similarly, under 5 U.S.C. 553(b) of the APA, the agency is required to publish a notice of proposed rulemaking in the **Federal Register** before a substantive rule takes effect. Section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act usually require a 30-day delay in effective date after issuance or publication of a rule, subject to exceptions. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the advance notice and comment requirement and the delay in effective date requirements. Sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act also provide exceptions from the notice and 60-day comment period and the 30-day delay in effective date. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act expressly authorize an agency to dispense with notice and comment rulemaking for good cause if the agency makes a finding that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest.

The annual Medicare Part A premium announcement set forth in this notice does not establish or change a substantive legal standard regarding the matters enumerated by the statute or constitute a substantive rule which would be subject to the notice requirements in section 553(b) of the APA. However, to the extent that an opportunity for public notice and comment could be construed as required for this notice, we find good cause to waive this requirement. Section 1818(d) of the Act requires the Secretary during September of each year to determine and publish the amount to be paid, on an average per capita basis, from the Federal Hospital Insurance Trust Fund for services incurred in the impending CY (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A. Further, the statute requires that the agency determine the applicable premium amount for each CY in accordance with the statutory formula, and we are simply notifying the public of the changes to the Medicare Part A premiums for CY 2025. We have calculated the Medicare Part A premiums as directed by the statute; the statute establishes both when the premium amounts must be published and the information that the Secretary must factor into the premium amounts, so we do not have any discretion in that regard. We find notice and comment procedures to be unnecessary for this notice and we find good cause to waive such procedures under section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act, if such procedures may be construed to be required at all. Through this notice, we are simply notifying the public of the updates to the Medicare Part A premiums, in accordance with the statute, for CY 2025. As such, we also note that even if notice and comment procedures were required for this notice, for the reasons stated above, we would find good cause to waive the delay in effective date of the notice, as additional delay would be contrary to the public interest under section 1871(e)(1)(B)(ii) of the Act. Publication of this notice is consistent with section 1818(d) of the Act, and we believe that any potential delay in the effective date of the notice, if such delay were required at all, could cause unnecessary confusion both for the agency and Medicare beneficiaries.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. *3501 et seq.*).

VII. Regulatory Impact Analysis

Although this notice does not constitute a significant regulatory action (defined below), we nevertheless prepared this Regulatory Impact

Analysis (RIA) section in the interest of ensuring that the impacts of this notice are fully understood.

A. Statement of Need

This notice announces the CY 2025 Medicare Part A premiums for the uninsured aged and for certain disabled individuals who have exhausted other entitlement, as required by sections 1818 and 1818A of the Act. It also responds to section 1818(d) of the Act, which requires the Secretary to provide for publication of these amounts in the **Federal Register** during the September that precedes the start of each CY. As this statutory provision prescribes a detailed methodology for calculating these amounts, we do not have the discretion to adopt an alternative approach on these issues.

B. Overall Impact

We have examined the impacts of this 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 titled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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

A regulatory impact analysis (RIA) must be prepared for rules with significant regulatory action(s) as per section 3(f)(1) of Executive Order 12866 ($200 million or more in any one year). Based on our estimates, OIRA has determined that this notice is not significant per section 3(f)(1) of E.O. 12866 as measured by the $200 million or more impact in any one year.

In accordance with the Congressional Review Act, OIRA has determined that this notice meets the criteria set forth in 5 U.S.C. 804(2). Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of this notice.

As stated in section IV. of this notice, we estimate that the overall effect of the changes in the Medicare Part A premium will be a cost to voluntary enrollees (sections 1818 and 1818A of the Act) of about $126 million.

C. Accounting Statement and Table

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*), in the table 1, we have prepared an accounting statement showing the total aggregate cost to enrollees paying premiums in CY 2025, compared to the amount that they paid in CY 2024. This amount is approximately $126 million. As stated in section IV. of this notice, the CY 2025 premium of $518 is approximately 2.6 percent higher than the CY 2024 premium of $505. We estimate that approximately 756,000 enrollees will voluntarily enroll in Medicare Part A by paying the full premium. We estimate that over 90 percent of these individuals will have their Medicare Part A premium paid for by states, since they are enrolled in the QMB program. Furthermore, the CY 2025 reduced premium of $285 is approximately 2.5 percent higher than the CY 2024 premium of $278.

TABLE 1—ESTIMATED TRANSFERS FOR CY 2025 MEDICARE PART A PREMIUMS

Category	Transfers	Period covered
Annualized Monetized Transfers.	$126 million	2025
From Whom to Whom.	Beneficiaries to Federal Government.	.....

D. Regulatory Flexibility Act

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. Most hospitals and most other providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration's (SBA) definition of a small business (having revenues of less than $9.0 million to $47 million in any 1 year). Individuals and states are not included in the definition of a small entity. This annual notice announces the Medicare Part A premiums for CY 2025 and will have an impact on certain Medicare beneficiaries, but not on small entities as defined by the SBA. As a result, we are not preparing an analysis for the RFA because the Secretary has certified that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This annual notice announces the Medicare Part A premiums for CY 2025 and will have an impact on certain Medicare beneficiaries. As a result, we are not preparing an analysis for section 1102(b) of the Act, because the Secretary has certified that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any

rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately $183 million. This notice would not impose a mandate that will result in the expenditure by state, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $183 million in any 1 year.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This notice will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have federalism implications.

G. Congressional Review

This notice is subject to the Congressional Review Act and has been transmitted to the Congress and the Government Accountability Office's Comptroller General for review.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 31, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–26473 Filed 11–8–24; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4815]

Patient-Focused Drug Development: Workshop To Discuss Methodologic and Other Challenges Related to Patient Experience Data; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following virtual public workshop entitled ''Patient-Focused Drug Development: Workshop to Discuss Methodologic and Other Challenges Related to Patient Experience Data.'' The purpose of the public workshop is to discuss methodological challenges related to patient experience data, and other areas of greatest interest or concern to public stakeholders.

DATES: The public workshop will be held virtually on December 13, 2024, from 10 a.m. to 5 p.m. Eastern Time. Either electronic or written comments on this public meeting must be submitted by February 11, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held virtually using the Zoom platform.

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 February 11, 2025. 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–N–4815 for ''Patient-Focused Drug Development: Workshop to Discuss Methodologic and Other Challenges Related to Patient Experience Data.'' 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 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.