

ADDRESSES: You may submit comments by mail to: Rashaun Roberts, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226.

Meeting Information: Audio Conference Call via FTS Conferencing. The USA toll-free dial-in number is 1–866–659–0537; the pass code is 9933701.

FOR FURTHER INFORMATION CONTACT:

Rashaun Roberts, Ph.D., Designated Federal Officer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226. Telephone (513) 533–6800; Email ocas@cdc.gov.

SUPPLEMENTARY INFORMATION:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC.

The charter was issued on August 3, 2001, renewed at appropriate intervals, and rechartered under Executive Order 13889 on March 22, 2022, and will terminate on March 22, 2024.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their

radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters To Be Considered: The agenda will include discussions on the following: Work Group and Subcommittee Reports; Update on the Status of SEC Petitions; and plans for the August 2023 Advisory Board Meeting. Agenda items are subject to change as priorities dictate. For additional information, please contact toll free 1 (800) 232–4636.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

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Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–08003 Filed 4–14–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10110, CMS–10537, CMS–10344 and CMS–10527]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information

collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *May 17, 2023*.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals; *Use:* Section 401 of

Division CC of Title IV of the Consolidated Appropriations Act (CAA), 2021 amended section 1847A of the Social Security Act (the Act) to add new section 1847A(f)(2) of the Act, which requires manufacturers without a Medicaid drug rebate agreement to report average sales price (ASP) information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological. The reported ASP data are used to establish the Medicare payment amounts. *Form Number:* CMS–10110 (OMB control number: 0938–0921); *Frequency:* Quarterly; *Affected Public:* Private sector, Business or other for-profit; *Number of Respondents:* 500; *Total Annual Responses:* 2,000; *Total Annual Hours:* 26,000. (For policy questions regarding this collection contact Felicia Brown at 410–786–9287)

2. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection:* CAHPS Hospice Survey; *Use:* CMS is required to collect and publicly report information on the quality of services provided by hospices under provisions in the Social Security Act. Specifically, sections 1814(i)(5)(A) through (C) of the Act, as added by section 3132(a) of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148), required hospices to begin submitting quality data, based on measures specified by the Secretary of the Department of Health and Human Services (the Secretary) for FY 2014 and subsequent FYs.

The goal of the survey is to measure the experiences of patients and their caregivers with hospice care. The survey was developed to:

- Provide a source of information from which selected measures could be publicly reported to beneficiaries and their family members as a decision aid for selection of a hospice program;
- Aid hospices with their internal quality improvement efforts and external benchmarking with other facilities;
- Provide CMS with information for monitoring the care provided.

Form Number: CMS–10537 (OMB control number: 0938–1257); *Frequency:* Once; *Affected Public:* Individuals and Households; *Number of Respondents:* 1,140,695; *Total Annual Responses:* 1,140,695; *Total Annual Hours:* 198,481. (For policy questions regarding this collection contact Lauren Fuentes at 410–786 2290 or 443–618–2123.)

3. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection:* Elimination of Cost-Sharing for full benefit dual-eligible Individuals Receiving Home and Community-Based Services; *Use:* Section 1860 D–14 of the Social Security Act sets forth requirements for premium and cost-sharing subsidies for low-income beneficiaries enrolled in Medicare Part D. Based on this statute, 42 CFR 423.771, provides guidance concerning limitations for payments made by and on behalf of low-income Medicare beneficiaries who enroll in Part D plans. 42 CFR 423.771 (b) establishes requirements for determining a beneficiary's eligibility for full subsidy under the Part D program. Regulations set forth in 423.780 and 423.782 outline premium and cost sharing subsidies to which full subsidy eligible are entitled under the Part D program

Each month CMS deems individuals automatically eligible for the full subsidy, based on data from State Medicaid Agencies and the Social Security Administration (SSA). The SSA sends a monthly file of Supplementary Security Income-eligible beneficiaries to CMS. Similarly, the State Medicaid agencies submit Medicare Modernization Act files to CMS that identify full subsidy beneficiaries. CMS deems the beneficiaries as having full subsidy and auto-assigns these beneficiaries to benchmark Part D plans. Part D plans receive premium amounts based on the monthly assessments. *Form Number:* CMS–10344 (OMB control number 0938–1127); *Frequency:* Monthly; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents:* 51; *Number of Responses:* 612; *Total Annual Hours:* 621. (For policy questions regarding this collection contact Roland Herrera at 410–786–0668).

4. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection:* Annual Eligibility Redetermination, Product Discontinuation and Renewal Notices; *Use:* Section 1411(f)(1)(B) of the Affordable Care Act directs the Secretary of Health and Human Services (the Secretary) to establish procedures to redetermine the eligibility of individuals for premium tax credits on a periodic basis in appropriate circumstances. Section 1321(a) of the Affordable Care Act provides authority for the Secretary to establish standards and regulations to implement the statutory requirements related to

Exchanges, qualified health plans (QHPs) and other components of title I of the Affordable Care Act. Under section 2703 of the Public Health Service Act (PHS Act), as added by the Affordable Care Act, and former section 2712 and section 2741 of the PHS Act, enacted by the Health Insurance Portability and Accountability Act of 1996, health insurance issuers in the group and individual markets must guarantee the renewability of coverage unless an exception applies.

The 2014 final rule “Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges” (79 FR 52994, September 5, 2014), provides that an Exchange may choose to conduct the annual redetermination process for a plan year (1) in accordance with the existing procedures described in 45 CFR 155.335; (2) in accordance with procedures described in guidance issued by the Secretary for the applicable benefit year; or (3) using an alternative procedure proposed by the Exchange and approved by the Secretary. The 2014 final rule established a renewal and reenrollment hierarchy at 45 CFR 155.335(j) to minimize potential enrollment disruptions. The 2016 final rule “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017” (81 FR 12204, March 8, 2016) amended the enrollment hierarchy to further minimize potential disruptions of enrollee eligibility for cost-sharing reductions. The final rule “Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2024” adopted changes to 45 CFR 155.335(j) to allow the Exchange, beginning in the 2024 plan year, to direct re-enrollment for enrollees who are eligible for cost-sharing reductions in accordance with § 155.305(g) from a bronze QHP to a silver QHP with a lower or equivalent premium after advance payments of the premium tax credit within the same product and QHP issuer, regardless of whether their current plan is available or not, if certain conditions are met (referred to here as the “bronze to silver crosswalk policy”).

The guidance document “Guidance on Annual Eligibility Redetermination and Re-enrollment for Exchange Coverage for 2019 and Later Years” contains the procedures that the Secretary specified for the coverage year, as noted in (2) above, and specified that these procedures will be

used by all Exchanges using the Federal eligibility and enrollment platform, unless otherwise specified in future guidance or rulemaking.

The 2014 final rule also amended the requirements for product renewal and re-enrollment (or non-renewal) notices to be sent by QHP issuers in the Exchanges and specifies content for these notices. The guidance document “Updated Federal Standard Renewal and Product Discontinuation Notices, and Enforcement Safe Harbor for Product Discontinuation Notices in Connection with the Open Enrollment Period for Coverage in the Individual Market in the 2020 Benefit Year” provides standard notices for product discontinuation and renewal to be sent by issuers of individual market QHPs and issuers in the individual market.

The Federal standard notices to be sent by issuers of individual market QHPs and issuers in the individual market have been revised to improve consumer understanding and update out-of-date information, and to include language to reference the potential for a bronze to silver crosswalk under 45 CFR 155.335(j)(4). The revised notices in this information collection will be required for notices provided in connection with coverage beginning in the 2024 plan year.

Issuers in the small group market may use the draft Federal standard small group notices released in the June 26, 2014 bulletin “Draft Standard Notices When Discontinuing or Renewing a Product in the Small Group or Individual Market”, or any forms of the notice otherwise permitted by applicable laws and regulations. States that are enforcing the guaranteed renewability provisions of the Affordable Care Act may develop their own standard notices for product discontinuances, renewals, or both, provided the state-developed notices are at least as protective as the Federal standard notices. *Form Number:* CMS–10527 (OMB Control Number 0938–1254); *Frequency:* Annually; *Affected Public:* Private Sector, State Governments; *Number of Respondents:* 1,340; *Total Annual Responses:* 5,881; *Total Annual Hours:* 72,147. (For policy questions regarding this collection contact Russell Tipps at 301–492–4371.)

Dated: April 12, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–08069 Filed 4–14–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10398 #37]

Medicaid and Children’s Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request; Correction

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: On April 10, 2023, we published a collection of information notice in the **Federal Register** concerning our revised Managed Care Rate Setting Guidance. The notice included an incorrect web address for obtaining copies of the supporting statement, the revised guide, and supporting documents.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of April 10, 2023, in FR Doc. 2023–07473, on page 21191, in the third column, correct the fourth paragraph under the **ADDRESSES** caption to read as follows:

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pralisting>.

Dated: April 12, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–08062 Filed 4–14–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2480]

Rare Disease Endpoint Advancement Pilot Program Workshop: Novel Endpoints for Rare Disease Drug Development; 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 a public workshop entitled “Rare Disease Endpoint Advancement Pilot Program Workshop: Novel Endpoints for Rare Disease Drug Development.” Convened by the Duke-Robert J. Margolis, MD Center for Health Policy (Duke-Margolis) and supported by a cooperative agreement between FDA and Duke-Margolis, the workshop will include discussions of the Rare Disease Endpoint Advancement (RDEA) Pilot Program and novel endpoint development for rare disease drug development.

DATES: The public workshop will be held virtually on June 7, 2023, and June 8, 2023, from 1 p.m. to 5 p.m., Eastern Time. Either electronic or written comments on this public workshop must be submitted by July 23, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held virtually using the Zoom platform. The link for the public workshop will be sent to registrants upon registration.

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 on July 23, 2023. 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>.