

collection contact Valerie Yingling at 667-290-8657.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare Request for Retirement Benefit Information; *Use:* Medicare Premium Part A is a voluntary program that is financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government. Form CMS-R-285, "Medicare Request for Retirement Benefit Information," is used to obtain information regarding whether a beneficiary currently purchasing Medicare Premium Part A coverage is receiving retirement payments based on State or local government employment, how long the claimant worked for the State or local government employer, and whether the former employer or pension plan is subsidizing the individual's Part A premium.

Form CMS-R-285 provides the necessary information regarding the prior state or local government employment to process the individual's request for premium Part A reduction based on their employment by a state or local government. The form is completed by the state or local government employer on behalf of the individual seeking the Medicare premium reduction. The SSA, CMS' agent for processing Medicare enrollments and premium amount determinations, will use this information to help determine whether a beneficiary meets the requirements for reduction of the Part A premium. The form is owned by CMS but not completed by CMS staff. *Form Number:* CMS-R-285 (OMB control number: 0938-0769); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 125. (For policy questions regarding this collection contact Candace Carter at 410-786-8446.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10695]

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 September 6, 2024.

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:* Extension of a currently approved collection; *Title of Information Collection:* Quality Payment Program/Merit-Based Incentive Payment System (MIPS) Surveys and Feedback Collections; *Use:* The purpose of this submission is to request approval for generic clearance of a program of survey and feedback collections supporting the Quality Payment Program which includes the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (AAPMs). MIPS is a program for certain eligible clinicians that makes Medicare payment adjustments based on performance on quality, cost and other measures and activities, and that consolidates components of three precursor programs—the Physician Quality Reporting system (PQRS), the Value Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for eligible professionals. AAPMs are a track of the Quality Payment Program that offer incentives for achieving threshold levels of payments or patients in Advanced APMs or Other Payer Advanced APMs. Under the AAPM path, eligible clinicians may become Qualifying APM Participants (QPs) and are excluded from MIPS. Partial Qualifying APM Participants (Partial QPs) may opt to report and be scored under MIPS.

This generic clearance will cover a program of surveys and feedback collections designed to strategically obtain data and feedback from MIPS

eligible clinicians, third-party intermediaries, Medicare beneficiaries, and any other audiences that would support the Agency in improving MIPS or the Quality Payment Program. The specific collections we intend to conduct are: Human Centered Design (HCD) User Testing Volunteer Sign-Up Survey; HCD User Satisfaction, Product Usage, and Benchmarking Surveys; and Physician Compare (and/or successor website) User Testing. *Form Number:* CMS-10695 (OMB control number: 0938-1399); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions and Individuals; *Number of Respondents:* 630,300; *Total Annual Responses:* 630,300; *Total Annual Hours:* 61,035. (For policy questions regarding this collection, contact Renee O'Neill at 410-786-8821.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-0001]

Enhancing Diversity in Therapeutics Development for Pediatric Patients; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled "Enhancing Diversity in Therapeutics Development for Pediatric Patients." The aim of the public workshop is to explore strategies to increase the enrollment of historically underrepresented populations in pediatric clinical trials and to help improve the strength and generalizability of the evidence for the intended use population.

DATES: The public workshop will be held on September 6, 2024, from 9 a.m. to 5 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for the registered public

workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/about-fda/visitor-information>. The workshop will also be streamed online.

FOR FURTHER INFORMATION CONTACT: Julie Levin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6481, Silver Spring, MD 20993, 202-567-7565, or ONDPublicMTGSupport@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Clinical trials in children are essential for obtaining data on the safety and effectiveness of medical products in children and to protect children from the risks associated with exposure to medical products that may be unsafe or ineffective for their intended uses in children. In some therapeutic areas, participation in clinical trials may be an important component of a participant's clinical care. Pediatric drug development programs should consider the clinical and demographic factors that impact the generalizability of study results with respect to the patient population that will use the product once it is approved.

II. Topics for Discussion at the Public Workshop

FDA, in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation, is convening a 1-day workshop to explore strategies for enrolling historically underrepresented populations in pediatric clinical trials. The specific topics to be covered include, but are not limited to, the following:

- Understanding the current state and challenges of pediatric clinical trial participation;
- Understanding metrics for assessing representative clinical study enrollment, including considerations of disease prevalence and incidence across subgroups of the pediatric population; and
- Discussing key elements of a strategy to include a more representative population, including trial design and methodological considerations, community engagement, recruitment and retention practices, and other related topics.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following

website: <https://www.fda.gov/drugs/news-events-human-drugs/adept-9-public-workshop-enhancing-diversity-therapeutics-development-pediatric-patients-09062024>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop in person must register by August 23, 2024, at 5 p.m. Eastern Time; virtual attendees may register by September 6, 2024, at 9 a.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8:15 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Julie Levin at 202-567-7565 or ONDPublicMTGSupport@fda.hhs.gov no later than August 16, 2024.

Streaming Webcast of the Public Workshop: This public workshop will also be streamed virtually via Zoom. A link will be provided via email to registered participants. If you have never attended a Zoom event before, test your connection at <https://zoom.us/test>. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible on the workshop website.

(Notice of this meeting is given pursuant to 21 CFR 10.65.)

Dated: July 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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