2,304,450; *Number of Responses:* 2,304,450; *Total Annual Hours:* 282,366. (For policy questions regarding this collection, contact William G. Lehrman at 410–786–1037.)

Dated: August 18, 2023.

William N. Parham, III,

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

[FR Doc. 2023–18151 Filed 8–22–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10809]

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 22, 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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Ambulatory Surgical Center Covered Procedures List (ASC CPL); *Use:* The ASC CPL (Ambulatory Surgical Center Covered Procedures List) was authorized in accordance with section 1833(i)(1) of the Social Security Act, which requires the Secretary to specify surgical procedures which are appropriately performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ASC, critical access hospital, or hospital outpatient department. The statute also requires the Secretary to regularly review and update the ASC CPL.

During rulemaking, CMS receives surgical procedure code nominations from a variety of external interested parties and evaluates them for inclusion to the CPL in the OPPS/ASC proposed rule. After reviewing the nominations and evaluating them against the criteria, CMS proposes the list of procedures that they will add to the CPL for the following calendar year. The public has 60 days to comment on the proposals, CMS takes these perspectives into account, and the final list of procedure nominations are finalized in the OPPS/ASC final rule.

The information collected in this request will be used by CMS annually to determine what covered surgical procedures should be added to the ASC CPL. Specifically, the policy analysts and medical officers in the Division of Outpatient Care will individually review each procedure nomination, as well as any supporting evidence (clinical studies, literature, data or letters of support) submitted. The agency will use this information to propose a list of covered surgical procedures for the OPPS/ASC Proposed Rule starting with the CY 2025 Proposed Rule. *Form Number:* CMS–10809 (OMB control number: 0938–New); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 15; *Total Annual Responses:* 100; *Total Annual Hours:* 50. (For policy questions regarding this collection contact Nate Vercauteren at *Nathan.Vercauteren@cms.hhs.gov.*)

Dated: August 18, 2023.

William N. Parham, III,

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

[FR Doc. 2023–18154 Filed 8–22–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2462]

Workshop To Enhance Clinical Study Diversity; 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 ''Workshop To Enhance Clinical Study Diversity.'' This public workshop will satisfy a mandate of the Food and Drug Omnibus Reform Act of 2022 (FDORA) for FDA to convene one

or more public workshops to solicit input from various stakeholders on enhancing diversity in clinical studies.The public workshop will be convened and supported by a cooperative agreement between FDA and the Clinical Trials Transformation Initiative and will solicit input from interested parties on increasing the enrollment of historically underrepresented populations in clinical studies and encouraging clinical study participation that reflects the prevalence or incidence of the disease or condition among demographic subgroups, where appropriate.

DATES: The public workshop will be held virtually on November 29, 2023, from 10 a.m. to 2 p.m., Eastern Time and November 30, 2023, from 10 a.m. to 2 p.m., Eastern Time. Following the workshop, a public comment period will be established to receive comments related to the topics addressed during the public workshop. Either electronic or written comments on this public workshop must be submitted by January 29, 2024. 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 January 29, 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–2023–N–2462 for ''Workshop To Enhance Clinical Study Diversity.'' 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.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993, 240–402–8962, *Dat.Doan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 3603 of the FDORA requires FDA to convene one or more public workshops to solicit input from various stakeholders on increasing diversity in clinical studies. To meet the FDORA requirement, FDA will convene a workshop with key participants, including drug and device sponsors, clinical research organizations, academia, patients and patient advocates, study site investigators, and the public, to gather input on how to enhance clinical study diversity by discussing ways to (1) increase enrollment of historically underrepresented populations in clinical studies and (2) encourage clinical study participation that reflects the prevalence of the disease or condition among demographic subgroups, where appropriate. The public workshop scheduled for November 29, 2023, and November 30, 2023, will fulfill the requirement to convene a public workshop no later than 1 year after the date of the enactment of FDORA.

II. Topics for Discussion at the Public Workshop

At the public workshop, FDA plans to solicit input from participants on increasing the enrollment of historically underrepresented populations in clinical studies and encouraging clinical study participation that reflects disease prevalence or incidence data, including but not limited to:

1. The collection and presentation of disease prevalence and incidence data by demographic group.

2. The dissemination of information to the public on clinical study enrollment demographic data.

3. The establishment of goals for clinical study enrollment, including the relevance of disease prevalence and incidence.

4. The approaches to include underrepresented populations and encourage participation that reflects the population expected to use the drug or device, if approved, including:

A. The establishment of inclusion and exclusion criteria for certain subgroups, such as pregnant and lactating women and individuals with disabilities, including intellectual or developmental disabilities or mental illness.

B. The considerations regarding informed consent with respect to individuals with intellectual or developmental disabilities or mental illness, including ethical and scientific considerations.

C. The appropriate use of decentralized trials or digital health tools, clinical endpoints, biomarker selection, and studying analysis.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://duke.zoom.us/meeting/register/tJcrceuhqjgvE9zGjDNOURONoJZvxrpK4Rvi#/registration.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free, and persons interested in attending this public workshop must register to receive a link to the meeting. Registrants will receive a confirmation email after they register.

If you need special accommodations due to a disability, please contact Sabrena Mervin-Blake, 919–724–0715, *sabrena.mervin-blake@duke.edu* no later than November 15, 2023. Please note, closed captioning and American Sign Language will be available automatically.

Dated: August 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–18149 Filed 8–22–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; 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: Eunice Kennedy Shriver National Institute of Child Health and Human Development Special Emphasis Panel; PS/Member Conflict.

Date: October 5, 2023.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2137B, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Vera A. Cherkasova, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health, and Human Development National Institutes of Health, 6710B Rockledge Drive, Room 2137B, Bethesda, MD 20892, (240) 478–4580, *vera.cherkasova@nih.gov.*

Name of Committee: Eunice Kennedy Shriver National Institute of Child Health and Human Development Special Emphasis Panel; Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant Review.

Date: November 2–3, 2023.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: North Bethesda Marriott Hotel and Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Christiane M. Robbins, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2125D, Bethesda, MD 20892, (301) 451–4989, *crobbins@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: August 18, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–18145 Filed 8–22–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; External Quality Assurance Program Oversight Laboratory (EQAPOL), RFP: 75N93022R00034.

Date: September 15, 2023.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G21B, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Robert C. Unfer, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G21B, Rockville, MD 20852, 240–669–5035. *unferrc@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 18, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–18147 Filed 8–22–23; 8:45 am]

BILLING CODE 4140–01–P