

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:** Health Care Reform Insurance Web Portal Requirements 45 CFR part 159; **Use:** In accordance with sections 1103 and 10102 of The Patient Protection and Affordability Care Act, Public Law 111–148 (2010) (Affordable Care Act) the U.S. Department of Health and Human Services (HHS) is tasked with developing and implementing an internet website portal to assist consumers with identifying affordable and comprehensive health insurance coverage options that are available in their State. Consistent with minimizing burden and providing consistency in data collection, the Centers for Medicare & Medicaid Services (CMS) updates its *HealthCare.gov* collection requirements as regulatory developments occur. There have been no developments since the last approved collection that require changes to the Paperwork Reduction Act (PRA) package. Therefore, we are submitting this request as an extension of the currently approved information collection. **Form Number:** CMS–10320 (OMB control number 0938–1086); **Frequency:** Occasionally; **Affected Public:** State, Local, and Tribal Governments; **Number of Respondents:** 814; **Number of Responses:** 814; **Total Annual Hours:** 50,653. (For questions regarding this collection contact Kimberlee Heckstall at 410–786–1647.)

2. Type of Information Collection

Request: Reinstatement without change of a previously approved information collection; **Title of Information Collection:** Supporting Statement for Essential Community Provider Data Collection to Support QHP Certification; **Use:** Standards for Essential Community Provider (ECP) requirements are codified at 45 CFR 156.235. Issuers must contract with a certain percentage, as determined by Health and Human Services (HHS), of the available ECPs in the plan's service area. HHS will continue to collect more complete data from such providers so that all issuers are held to a more uniform ECP standard. HHS achieves this outcome by soliciting qualified ECPs throughout the year to complete and submit the ECP application in order to be added to the HHS ECP list or update required data fields to remain on the list. In soliciting updates directly from providers, HHS routinely performs research and outreach to providers on the ECP List to verify information about ECPs collected via the ECP application and annual renewal form. These ongoing efforts will

result in a more accurate listing of the universe of available ECPs from which issuers select to satisfy the ECP standard. **Form Number:** CMS–10561 (OMB control number: 0938–1295); **Frequency:** Annually; **Affected Public:** Private Sector—Business or other for-profits and Not-for-profits institutions; **Number of Respondents:** 19,020; **Number of Responses:** 19,020; **Total Annual Hours:** 4,913.75. (For questions regarding this collection, contact Samantha Nguyen Kella at 816–426–6339).

3. Type of Information Collection

Request: New collection (Request for a new OMB control number); **Title of Information Collection:** 13th SOW QIN–QIO and AI/AN Advancing Healthcare Quality through Technology (AHQT) Readiness Assessment; **Use:** This is a new information collection request. The Quality Improvement Network—Quality Improvement Organization (QIN–QIO) program and American Indian/Alaska Native (AI/AN) program assists providers/practices with high-quality, hands-on quality improvement assistance toward meeting their needs, and the healthcare quality and safety goals for beneficiaries. The purpose of this new information collection within these programs is to assess the readiness of participating nursing homes, hospitals, outpatient clinical practices, and AIAN facilities to access, share, and use data electronically for quality improvement and quality reporting. Use of health information technology (HIT) is imperative to assess, monitor, and improve healthcare quality, patient safety, and care coordination.

Many providers/practices continue to lack basic knowledge and capacity to implement HIT to support data exchange between providers/practices, payers, and patients, and to use data for improving quality and outcomes. This “digital divide” creates burden for patients, families, caregivers, providers/practices and increases costs and administrative waste. This burden is disproportionate for underserved populations. Advancing the use of technology and using interoperable standards can reduce the overall cost and burden associated with data collection and supports communication across the care continuum and is an agency priority.

CMS has developed a 41-item Assessment of Health care Quality Technical Readiness (AHQT) for use with participating providers/practices under the QIN–QIO 13th SOW. Provider/practice burden associated with the collection and reporting of quality measurement data has historically been a pain point for the

QIN–QIO and AI/AN programs, especially in outpatient clinical practices and critical access hospitals; this burden has been a barrier to both achievement of quality improvement contract goals and proper evaluation of their impact.

The results of the assessment will be used to determine which providers/practices may benefit from participation in a technical assistance pilot specific during the QIN–QIO 13th SOW intended to advance provider/practice capacity for engaging in quality improvement and reporting activities facilitated by HIT. **Form Number:** CMS–10916 (OMB control number: 0938–NEW); **Frequency:** Occasionally; **Affected Public:** Private Sector (Business or other for-profit and Not-for-profit institutions); **Number of Respondents:** 53,000; **Total Annual Responses:** 10,600; **Total Annual Hours:** 10,600. (For policy questions regarding this collection contact Geoffrey Berryman at 410–299–7390).

William N. Parham, III,

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

[FR Doc. 2025–15935 Filed 8–20–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1875]

Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following public meeting entitled “Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments.” The topic to be discussed is the financial transparency and efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments.

DATES: The public meeting will be held on September 30, 2025, from 9:30 a.m. to 10:40 a.m. via Microsoft Teams. Either electronic or written comments

on this public meeting must be submitted by October 30, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held as a hybrid event with a virtual option and in-person option at the FDA White Oak Campus, Great Room, Section A.

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 October 30, 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-2019-N-1875 for "Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments; Public Meeting; Request for Comments." 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: Kichelle Joseph, Office of Finance, Budget, Acquisitions, and Planning, Food and Drug Administration, 4041

Powder Mill Rd., Rm. 72064, Beltsville, MD 20705, 301-796-7251, OFBABusinessManagementServices@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The meeting will include presentations from FDA on: (1) the 5-year plan for the Prescription Drug User Fee Act (PDUFA) VII, Biosimilar User Fee Act (BsUFA) III, and Generic Drug User Fee Amendments (GDUFA) III; and (2) the Agency's progress in implementing resource capacity planning as part of fee setting and modernized time reporting. This meeting is intended to satisfy FDA's commitment to host an annual public meeting in the third quarter of each fiscal year and can be found in the Commitment Letters listed below (sections II.B.2 of PDUFA VII (p. 58), III.B.2 of BsUFA III (p. 33), and VIII.D.3 of GDUFA III (p. 40-41)).

PDUFA VII, BsUFA III, and GDUFA III represent the reauthorization of these user fee programs for FYs 2023-2027 as part of the FDA User Fee Reauthorization Act of 2022, which was signed by the President on September 30, 2022. The complete set of performance goals for each program are available at:

- **PDUFA VII:** <https://www.fda.gov/media/151712/download>.
- **BsUFA III:** <https://www.fda.gov/media/152279/download>.
- **GDUFA III:** <https://www.fda.gov/media/153631/download>.

Each of these user fee programs' Commitment Letters included a set of commitments related to financial management. These included commitments to publish a 5-year financial plan and update that plan annually, continue activities to mature FDA's resource capacity planning capability, and modernize time reporting practices. In addition, each user fee program includes a commitment to host a public meeting in the third quarter of each fiscal year to discuss specific topics.

II. Topics for Discussion at the Public Meeting

This meeting will provide FDA with the opportunity to update interested public stakeholders on topics related to the financial management of PDUFA VII, BsUFA III, and GDUFA III. These topics include the 5-year financial plans for each of these programs and FDA's progress toward implementing resource capacity planning as part of fee setting and modernized time reporting.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: <https://events.gcc.teams.microsoft.com/event/516d6231-aede-4035-88cd-c307c6dda9a5@7d2fdb41-339c-4257-87f2-a665730b31fc>. Please provide complete contact information for each attendee, including name, title, affiliation, and email.

Persons interested in attending this public meeting must register by September 20, 2025 at 11:59 p.m. Eastern Time. If registration closes before the day of the public meeting, the Webinar Registration website will be updated.

If you need special accommodations due to a disability, please indicate this during registration or contact Kichelle Joseph at OFBABusinessManagementServices@fda.hhs.gov no later than September 20, 2025.

Streaming Webcast of the Public Meeting: This public meeting will be webcast. To register for the public meeting and obtain the webcast information, please visit the following website: <https://events.gcc.teams.microsoft.com/event/516d6231-aede-4035-88cd-c307c6dda9a5@7d2fdb41-339c-4257-87f2-a665730b31fc>.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may also be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: August 15, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-15936 Filed 8-20-25; 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 & Human Development; Notice of Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors *Eunice Kennedy Shriver National Institute of Child Health and Human Development*.

The meeting will be open to the public as indicated below. Individuals who plan to attend and need special assistance, such as sign language

interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting website (<http://videocast.nih.gov/>).

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the *Eunice Kennedy Shriver National Institute of Child Health & Human Development*, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors *Eunice Kennedy Shriver National Institute of Child Health and Human Development*.

Date: June 5, 2026.

Closed: 10:00 a.m. to 1:30 p.m.

Agenda: Scientific Director's Report on the status of the NICHD Division of Intramural Research and current organizational structure.

Address: *Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Room 2A03, 31 Center Drive, Bethesda, MD 20892 (Virtual Meeting).*

Open: 1:30 p.m. to 3:45 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Address: *Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Room 2A03, 31 Center Drive, Bethesda, MD 20892 (Virtual Meeting).*

Contact Person: Chris J. McBain, Ph.D., Scientific Director, *Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 10 Center Drive, Room 10D39, Bethesda, MD 20892, (301) 594-5984, mcbainc@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: <https://www.nichd.nih.gov/about/advisory/bsc>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: August 19, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-16001 Filed 8-20-25; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Docket ID: FEMA-2025-0114; OMB No. 1660-0024]

Agency Information Collection Activities: Proposed Collection, Comment Request; Federal Assistance for Offsite Radiological Emergency Preparedness and Planning

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 60-Day notice of extension and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on an extension of a currently approved information collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, this notice seeks comments concerning all information collections related to FEMA Radiological Emergency Preparedness Program requirements.

DATES: Comments must be submitted on or before October 20, 2025.

ADDRESSES: To avoid duplicate submissions to the docket, please submit comments at <http://www.regulations.gov> under Docket ID FEMA-2025-0114. Follow the instructions for submitting comments.

All submissions received must include the Agency name and Docket ID. Regardless of the method used to submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy and Security Notice that is available via a link on the homepage of <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Renae Connell, Emergency Management Specialist, FEMA/National Preparedness Division (NPD)/ Technological Hazards Division (THD), 202.657.2294 and renae.connell@fema.dhs.gov. You may contact the Information Management Division for copies of the proposed collection of information at email address: FEMA-Information-Collections-Management@fema.dhs.gov.