

the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on August 21, 2025.

Jennifer M. Jones,

Deputy Executive Secretary.

[FR Doc. 2025–16200 Filed 8–22–25; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10434 #26 and #47]

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

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

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance related to the “generic” clearance process. Generally, this is an expedited process by which agencies may obtain OMB’s approval of collection of information requests that are “usually voluntary, low-burden, and uncontroversial collections,” do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that would fall under its umbrella. This **Federal Register** notice seeks public comment on one or more of our collection of information requests that we believe are generic and fall within the scope of the umbrella. Interested persons are invited to submit comments regarding our burden estimates 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 must be received by September 8, 2025.

ADDRESSES: When commenting, please reference the applicable form number (CMS–10434 #____) and the OMB control number (0938–1188). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–10434____/OMB control number: 0938–1188, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pralisting>.

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

SUPPLEMENTARY INFORMATION: Following is a summary of the use and burden associated with the subject information collection(s). More detailed information can be found in the collection’s supporting statement and associated materials (see **ADDRESSES**).

Generic Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Child and Adult Core Set Measures; *Use:* CMS is required annually to revise and update the Child and Adult Core Sets. The review for the 2025 Core Set resulted in several substantive changes to the templates used for state Core Set reporting to CMS. State reporting of the Core Sets in the Quality Measurement

Reporting system opens for 2025 Core Set reporting on September 3, 2025. *Form Number:* CMS–10434 #26 (OMB control number: 0938–1188); *Frequency:* Yearly, once, and occasionally; *Affected Public:* Individuals or households and State, Local, or Tribal Governments; *Number of Respondents:* 61,293; *Total Annual Responses:* 61,455; *Total Annual Hours:* 99,977. (For policy questions regarding this collection contact: Virginia (Gigi) Raney at 410–786–6117.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Health Home Core Sets Measures; *Use:* CMS is required annually to revise and update the Health Home Core Sets. The review for the 2025 Core Set resulted in several substantive changes to the templates used for state Core Set reporting to CMS. State reporting of the Core Sets in the Quality Measurement Reporting system opens for 2025 Core Set reporting on September 3, 2025. *Form Number:* CMS–10434 #47 (OMB control number: 0938–1188); *Frequency:* Yearly, once, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 4,620. (For policy questions regarding this collection contact: Sara Rhoades at 410–786–4484.)

Evell Barco Holland,

Senior Technical Advisor, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–16171 Filed 8–22–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2962]

Prescription Drug User Fee Act and Biosimilar User Fee Amendments Hiring and Retention Assessment; 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, the Agency, or we) is announcing the following public meeting entitled “Prescription Drug User Fee Act and Biosimilar User Fee Amendments Hiring and Retention Assessment.” The topic to be discussed is a hiring and retention assessment

which was performed by an independent contractor.

DATES: The public meeting will be held in person and virtually on September 24, 2025, from 9 a.m. to 12 p.m. Eastern Time. Either electronic or written comments on this public meeting must be submitted by October 24, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held in person at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD 20993-0002 and virtually using the Microsoft Teams platform. Participants must be REAL ID compliant to access federal facilities. For additional information regarding REAL ID, refer to <https://www.dhs.gov/real-id/real-id-faqs>. Entrance for the public meeting 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>. Any changes to the public meeting location and remote information, as appropriate, will be posted to <https://www.fda.gov/drugs/news-events-human-drugs/prescription-drug-user-fee-act-and-biosimilar-user-fee-amendments-hiring-and-retention-assessment> in advance of the meeting.

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 24, 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-2025-N-2962 for "Prescription Drug User Fee Act and Biosimilar User Fee Amendments Hiring and Retention Assessment; 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:

Thamar Bailey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4103, Silver Spring, MD 20993-0002, 301-796-6645, CDERProgramEvaluation@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is holding a public meeting to meet performance commitments included in the Prescription Drug User Fee Act (PDUFA VII) and the Biosimilar User Fee Amendments (BsUFA III). These user fee programs were reauthorized for fiscal years 2023-2027 as part of the FDA User Fee Reauthorization Act of 2022 (Pub. L. 117-180) enacted on September 30, 2022. The complete set of performance goals for each program is available at:

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

During the public meeting, FDA will share high-level findings from a recently completed assessment of FDA's hiring and retention of staff for the human drug review program. This assessment was conducted by a qualified, independent contractor with expertise in assessing Human Resource (HR) and Human Capital (HC) operations as agreed to in the PDUFA VII and BsUFA III commitment letters. Previously, as part of PDUFA VI and BsUFA II, independent contractors conducted a series of three assessments that aimed to capture the status of FDA's HR and HC operations, identify challenges, and provide actionable recommendations. The previous reports are available at:

- *Initial assessment report:* <https://www.fda.gov/media/108866/download>
- *Interim assessment report:* <https://www.fda.gov/media/138662/download>
- *Final assessment report:* <https://www.fda.gov/media/154873/download>

The initial assessment served as a baseline, evaluated the state of FDA human resource operations, identified root causes of challenges, and provided recommendations related to recruitment and hiring. Unlike the subsequent evaluations, the initial assessment did not evaluate employee retention efforts. The interim and final assessments documented progress from the previous assessment(s) related to recommendations from the initial assessment, program milestones, metrics, and other aggregated feedback from internal HR/HC customers and participants and provided additional recommendations. The current assessment builds upon the findings from the three previous assessments with a focus on changes that have improved FDA's hiring and retention outcomes and challenges that remain. The current assessment also expands beyond the scope of the previous assessments to include the pre-employment onboarding process. This assessment report includes metrics related to recruiting and retention in the human drug review program, including specific targeted scientific disciplines, attrition, and utilization of pay authorities. The report also includes the contractor's findings and recommendations on further enhancements to hiring and retention of staff for the human drug review program. To view the assessment report, please visit: <https://www.fda.gov/media/188083>.

II. Topics for Discussion at the Public Meeting

This public meeting will provide FDA the opportunity to update interested public stakeholders on topics related to hiring and retention in the FDA human drug review program. The independent contractor will present their findings and recommendations that are outlined in the hiring and retention assessment report, and FDA will provide its perspective on the independent contractor's findings and recommendations. To view the assessment report, please visit: <https://www.fda.gov/media/188083>.

III. Participating in the Public Meeting

Registration: To register for this hybrid public meeting, please visit the

following website: https://FDAPublicMeeting_PDUFAVII_BsUFAlII_HiringandRetention.eventbrite.com.

Please provide complete contact information for each attendee, including attendance format (in-person or virtual), name, title, affiliation, and email.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending the public meeting must register by September 15, 2025, 11:59 p.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 meeting will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Tamar Bailey, 301-796-6645, CDERProgramEvaluation@fda.hhs.gov no later than September 15, 2025, 11:59 p.m. Eastern Time.

Opportunity for Public Comment: During online registration, you may indicate if you wish to present during a public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. All requests to make oral presentations during the meeting must be received via registration by September 15, 11:59 p.m. Eastern Time. Onsite registration for public comments on the day of the public meeting will not be provided. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by September 17, 2025. If selected to present at the public comment session, any presentation materials must be emailed to CDERProgramEvaluation@fda.hhs.gov by September 19, 11:59 p.m. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast to registered attendees. To view the webcast of this public meeting, please register at https://FDAPublicMeeting_PDUFAVII_BsUFAlII_HiringandRetention.eventbrite.com (see "Registration"). Please provide complete contact information for each

attendee, including name, title, affiliation, and email.

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 be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/drugs/news-events-human-drugs/prescription-drug-user-fee-act-and-biosimilar-user-fee-amendments-hiring-and-retention-assessment>.

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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-16245 Filed 8-22-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Supporting Fairness and Originality in NIH Research Applications

AGENCY: National Institutes of Health, HHS.

ACTION: Notice; correction.

SUMMARY: The Department of Health and Human Services, National Institutes of Health published a Notice in the **Federal Register** on August 5, 2025. That notice requires a correction in the **SUPPLEMENTARY INFORMATION** section.

DATES: This policy is effective for applications submitted to the September 25, 2025, receipt date and beyond.

FOR FURTHER INFORMATION CONTACT: Further information about this policy notice may be directed to Dr. Lyric Jorgenson, NIH Office of Science Policy, at (301) 496-6837 or (SciencePolicy@od.nih.gov).

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of August 5, 2025, in FR Doc. 2025-14744, on page 37531, as found within the **SUPPLEMENTARY INFORMATION** section. Currently reads "https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.1.2_recipient_staff.htm" and is corrected to read: "https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.1.2_recipient_staff.htm". Also "https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.27_research_misconduct.htm" and is corrected to read: "https://grants.nih.gov/grants/