

regarding the enrollee advisory committee requirement § 422.107(f) will be included in a separate PRA package. CMS is collecting data on D-SNP enrollee advisory committees as part of the CY 2025 Part C Reporting Requirements. *Form Number:* CMS-10799 (OMB control number 0938-1422); *Frequency:* Occasionally; *Affected Public:* Private Sector and Business or other for-profits; *Number of Respondents:* 398; *Number of Responses:* 398; *Total Annual Hours:* 15,920. (For questions regarding this collection contact Melissa Maker at 212-616-2329.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Administrative Simplification HIPAA Compliance Review; *Use:* The purpose of this collection is to retrieve information necessary to conduct a compliance review and carry out the authority delegated to CMS as described in CMS-0014-N (68 FR 60694). These forms will be submitted to the Centers for Medicare & Medicaid Services (CMS), National Standards Group, from entities covered by HIPAA Administrative Simplification regulations. This collection is not applicable to HIPAA Privacy and Security Rules. *Form Number:* CMS-10662 (OMB control number 0938-1390); *Frequency:* Biennially; *Affected Public:* Private Sector—State, Local, or Tribal Governments; and Business or other for-profits, Not-for-profits institutions and Federal Government; *Number of Respondents:* 100; *Total Annual Responses:* 140; *Total Annual Hours:* 3,040. (For policy questions regarding this collection contact Kevin Stewart at 410-786-6149 or [Kevin.stewart@cms.hhs.gov](mailto:Kevin.stewart@cms.hhs.gov).)

**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-2025-N-1157]

### Reauthorization of the Medical Device 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, the Agency, or we) is hosting a hybrid public meeting entitled “Medical Device User Fee Amendments.” The purpose of the public meeting is to discuss proposed recommendations for the reauthorization of the Medical Device User Fee Amendments (MDUFA) for fiscal years (FYs) 2028 through 2032. MDUFA authorizes FDA to collect fees and use them for the process for the review of device applications. The current legislative authority for MDUFA expires September 30, 2027. At that time, new legislation will be required for FDA to continue collecting device user fees in future fiscal years. The Federal Food, Drug, and Cosmetic Act (FD&C Act) directs that FDA begin reauthorization by publishing a notice in the **Federal Register** requesting public input and holding a meeting where the public may present its views on the reauthorization. FDA invites public comment as the Agency begins the process to reauthorize the program in FYs 2028 through 2032. These comments will be published and available on FDA’s website.

**DATES:** The public meeting will be held on August 4, 2025, from 10 a.m. to 3 p.m. Eastern Time and will take place in-person with a webcast option. Submit electronic or written comments on this public meeting by September 4, 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., Building 31 Conference Center, the White Oak Great Room, Silver Spring, MD 20993-0002 and virtually using the Microsoft Teams platform. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. 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>. For security and parking information, please refer to <https://www.fda.gov/about-fda/visitor-information/public-meeting-information> and <https://www.fda.gov/about-fda/visitor-information/visitor-parking-and-campus-map>.

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 September 4, 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-1157 for “Reauthorization of the Medical Device 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 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:** Nia Benjamin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Room 5422, Silver Spring, MD 20993-0002, 301-796-5424, [MDUFARVReauthorization@fda.hhs.gov](mailto:MDUFARVReauthorization@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing a hybrid public meeting to begin the reauthorization process for MDUFA, the legislation that authorizes FDA to collect user fees to support the process for the review of medical device applications, which reaches various components in FDA, including the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), the Office of the Commissioner

(OC), and the Office of Inspections and Investigations (OII). The current authorization of the program (MDUFA V) expires September 30, 2027.

Section 738A(b)(2) of the FD&C Act (21 U.S.C. 379j-1(b)(2)) requires that, before FDA begins negotiations with regulated industry on MDUFA reauthorization, the Agency performs the following: (1) publish a notice in the **Federal Register** requesting public input on the reauthorization; (2) hold a public meeting where the public may present its views on the reauthorization; (3) provide a period of 30 days after the public meeting to obtain written comments from the public; and (4) publish the comments on FDA’s website. This notice, the public meeting, the 30-day comment period after the meeting, and the posting of the comments on the FDA’s website will satisfy these requirements. The purpose of the meeting is to hear stakeholder views on MDUFA as we consider the features to propose, update, discontinue, or add in the next MDUFA. FDA is interested in responses to the following questions and welcomes any other pertinent information stakeholders would like to share:

(1) What is your assessment of the overall performance of MDUFA V thus far?

(2) What current features of MDUFA should be reduced or discontinued to ensure the continued efficiency and effectiveness of the medical device review process?

(3) What new features should FDA consider adding to the program to enhance the efficiency and effectiveness of the medical devices review process?

(4) What changes, if any, could be made to the current fee structures and amounts to better advance the goals of the agreement, including facilitating product development and timely access for consumers?

##### II. Public Meeting Information

###### A. Purpose and Scope of the Meeting

In general, the public meeting’s format will include presentations by FDA and other interested parties, which may include scientific and academic experts, healthcare professionals, representatives of patient and consumer advocacy groups, the medical device industry, and the general public. A draft agenda and other background information for the public meeting will be posted at: <https://www.fda.gov/medical-devices/medical-devices-news-and-events/register-fdas-public-meeting-reauthorization-medical-device-user-fee-amendments-08042025>.

###### B. Participating in the Public Meeting

**Registration:** To register for the public meeting, please visit the following web page: <https://www.fda.gov/medical-devices/medical-devices-news-and-events/register-fdas-public-meeting-reauthorization-medical-device-user-fee-amendments-08042025>. Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number.

Registration is free for both in-person and virtual attendance. In-person attendance is based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact [MDUFARVReauthorization@fda.hhs.gov](mailto:MDUFARVReauthorization@fda.hhs.gov) no later than July 25, 2025.

**Opportunity for Public Comment:** Those who register online by June 30, 2025, at 11:59 p.m. Eastern Time will receive a notification about an opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify which topic(s) you wish to address. All requests to make public comments during the meeting must be received by July 7, 2025, at 11:59 p.m. Eastern Time. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate comment and request time jointly. We will determine the amount of time allotted to each commenter, and the approximate time each comment is to begin, and will select and notify participants by July 14, 2025. No commercial or promotional material will be permitted to be presented at the public meeting.

**Streaming Webcast of the Public Meeting:** This public meeting will also be webcast. The meeting web page link is: [https://teams.microsoft.com/l/meetup-join/19%3ameeting\\_ODQ3YzUwMDEtODk3Zi00YTFlLWlwYzAtMmFjMzlkYzYzM5YzVh%40thread.v2/0?context=%7b%22Tid%22%3a%227d2fdb41-339c-4257-87f2-a665730b31fc%22%2c%22Oid%22%3a%22b991a8ee-e689-4dc1-bd5d-afa310d67246%22%7d](https://teams.microsoft.com/l/meetup-join/19%3ameeting_ODQ3YzUwMDEtODk3Zi00YTFlLWlwYzAtMmFjMzlkYzYzM5YzVh%40thread.v2/0?context=%7b%22Tid%22%3a%227d2fdb41-339c-4257-87f2-a665730b31fc%22%2c%22Oid%22%3a%22b991a8ee-e689-4dc1-bd5d-afa310d67246%22%7d).

**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/medical-devices/workshops-conferences-medical-devices/public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-04192022>.

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

Dated: June 4, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–10551 Filed 6–10–25; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Nurse Corps Scholarship Program

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than August 11, 2025.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA

Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the ICR title for reference.

*Information Collection Request Title:* Nurse Corps Scholarship Program, OMB No. 0915–0301—Revision.

*Abstract:* The Nurse Corps Scholarship Program (Nurse Corps SP), administered by HRSA, provides scholarships to nursing students in exchange for a minimum 2-year full-time service commitment (or part-time equivalent), at an eligible health care facility with a critical shortage of nurses (*i.e.*, Critical Shortage Facility [CSF]). The scholarship consists of payment of tuition, fees, other reasonable educational costs, and a monthly support stipend. Program recipients are required to fulfill Nurse Corps SP service commitments at CSFs located in the 50 states, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

*Need and Proposed Use of the Information:* The Nurse Corps SP collects data to determine an applicant's eligibility for the program, monitor a participant's continued enrollment in a school of nursing, monitor the participant's compliance with the Nurse Corps SP service obligation, and prepare annual reports to Congress. The following information will be collected (1) from the applicants to determine

their eligibility—an application form consisting of personal (such as proof of citizenship, references, and personal essay), financial (such as the Student Aid Index), and educational information (including verification of acceptance and good standing, tuition costs, and transcripts); (2) from the schools, on a quarterly basis—general applicant and nursing school data such as full name, location, tuition/fees, and enrollment status; (3) from the schools, on an annual basis—data concerning tuition/fees and overall student enrollment status; and (4) from the participants and their employing CSF on a biannual basis—data concerning the participant's employment status, work schedule, and leave usage.

There will be minor changes to this information collection, including replacing “gender” with “sex” and a discontinuation of the collection of resumes within the application as they are not used to determine eligibility.

*Likely Respondents:* Nurse Corps SP applicants, participants who are in school, graduates, educational institutions, and CSFs.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

#### TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Nurse Corps Scholarship Program Application .....	3,300	1	3,300	2.00	6,600
School Enrollment Verification Form .....	600	2	1,200	0.33	396
Confirmation of Interest Form .....	200	1	200	0.20	40
Data Collection Worksheet Form .....	600	1	600	1.00	600
Graduation Close Out Form .....	200	1	200	0.17	34
Employment Verification Form .....	500	2	1,000	0.42	420
In-Service Verification Form .....	1,000	2	2,000	0.12	240
Verification of Acceptance Form .....	3,300	2	6,600	0.33	2,178
Authorization to Release Information Form .....	3,300	1	3,300	0.20	660