

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 N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: In the FR Doc. 2025-09144 of May 21, 2025 (90 FR 21775), we published a Paperwork Reduction Act notice requesting a 30-day public comment period for the document entitled “State-based Exchange, SBE, SBE Budget Template, SBE Enrollment Metrics, Open Enrollment.” There were technical delays associated with making the information collection request publicly available; therefore, in this notice we are extending the comment period from the date originally listed in the May 21, 2025, notice.

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 Identifier: CMS-2552-10, CMS-10662 and CMS-10799]

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 July 11, 2025.

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:* Revision of a currently approved collection; *Title of Information Collection:* Hospital and Health Care Complex Cost Report; *Use:* CMS requires the Form CMS-2552-10 to determine a hospital’s reasonable cost incurred in furnishing medical services to Medicare beneficiaries and calculate

the hospital reimbursement. Hospitals paid under a prospective payment system (PPS) may receive reimbursement in addition to the PPS for hospital-specific adjustments such as Medicare reimbursable bad debts, disproportionate share, uncompensated care, direct and indirect medical education costs, and organ acquisition costs. CMS uses the Form CMS-2552-10 for rate setting; payment refinement activities, including developing a hospital market basket; and Medicare Trust Fund projections; and to support program operations. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the hospital cost report data to calculate Medicare margins (a measure of the relationship between Medicare’s payments and providers’ Medicare costs) and analyze data to formulate Medicare Program recommendations to Congress. This submission seeks to revise the information collection request. The changes for Form CMS-2552-10 are as follows:

- add Worksheet E-90, Payment Adjustment For Establishing And Maintaining Access to a Buffer Stock Of Essential Medicines
 - add Worksheet E-95, Payment Adjustments For Domestic NIOSH-Approved Surgical N-95 Respirators
- Form Number:* CMS-2552-10 (OMB control number: 0938-0050); *Frequency:* Occasionally; *Affected Public:* Private Sector; Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 6,044; *Total Annual Responses:* 6,044; *Total Annual Hours:* 4,079,700. (For policy questions regarding this collection contact Gail Duncan at 410-786-7278.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* D-SNP Enrollee Advisory Committee; *Use:* CMS established paragraph (f) at § 422.107 under our authority at section 1856(b)(1) of the Act to establish in regulation other standards not otherwise specified in statute that are both consistent with Part C statutory requirements and necessary to carry out the MA program and our authority at section 1857(e) of the Act to adopt other terms and conditions not inconsistent with Part C as the Secretary may find necessary and appropriate. MA organizations with D-SNPs would use the information collected from enrollees in the enrollee advisory committee to help identify and address barriers to high-quality, coordinated care for enrollees. Any collection of information directly from MA organizations offering a D-SNPs

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.)

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.