Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement (which contains more detail about the information collection and burden estimates than this notice), and other documentation, will be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportingforms/review* or may be requested from the agency clearance officer, whose name appears above. On the page displayed at the link above, you can find the supporting information by referencing the collection identifier, CFPB E. Final versions of these documents will be made available at *https://www.reginfo.gov/public/do/PRAMain*, if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed 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;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, With Revision, the Following Information Collection

Collection title: Recordkeeping and Disclosure Requirements Associated with the CFPB's Regulation E.

Collection identifier: CFPB E.

OMB control number: 7100–0200.

General description of collection: Board-supervised institutions must provide meaningful disclosures about the basic terms, costs, and rights relating to electronic fund transfer services involving a customer's account and must maintain certain records.

Proposed revisions: The Board proposes to revise the CFPB E to account for one recordkeeping provision in Section 1005.13(b) of Regulation E that has not previously been cleared by the Board under the PRA.

Frequency: Event-generated, monthly, and annually.

Respondents: State member banks and their subsidiaries, subsidiaries of bank holding companies, U.S. branches and agencies of foreign banks (other than federal branches, federal agencies, and insured state branches of foreign banks), commercial lending companies owned or controlled by foreign banks, and organizations operating under section 25 or 25A of the Federal Reserve Act (12 U.S.C. 601–604a; 611–631).

Total estimated number of respondents: 815.

Total estimated change in burden: 0.

Total estimated annual burden hours: 165,426.

Board of Governors of the Federal Reserve System, July 28, 2025.

Benjamin W. McDonough,

Deputy Secretary and Ombuds of the Board.

[FR Doc. 2025–14464 Filed 7–30–25; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10287, CMS–10137 and CMS–10824]

Agency Information Collection Activities: Proposed Collection; 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 60 days for public comment on the proposed action. Interested persons are invited to send 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 29, 2025.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. 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: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 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/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

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

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10287 Medicare Quality of Care Complaint Form

CMS–10137 Solicitation for Applications for Medicare Prescription Drug Plan 2027 Contracts

CMS–10824 Annual Notice of Change and Evidence of Coverage for Applicable Integrated Plans in States that Require Integrated Materials

Under the 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 requires federal agencies to publish a 60-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.

Information Collections

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Quality of Care Complaint Form; *Use:* This is a reinstatement with changes. Since 1986, Quality Improvement Organizations (QIO) have been responsible for conducting appropriate reviews of written complaints submitted by beneficiaries about the quality of care they have received. In order to receive these written complaints, each QIO has developed its own unique form on which beneficiaries can submit their complaints. CMS has initiated several efforts aimed at increasing the standardization of all QIO activities, and the development of a single, standardized Medicare Quality of Care Complaint Form beneficiaries can use to submit complaints is a key step towards attaining this increased standardization. The form was updated to remove lengthy instructions, provide clarification and ensure demographic data collection aligns with statistical Policy Directive 15. *Form Number:* CMS–10287 (OMB control number: 0938–1102); *Frequency:* Occasionally; *Affected Public:* Individuals and Households; *Number of Respondents:* 3,369; *Total Annual Responses:* 3,369; *Total Annual Hours:* 562. (For policy questions regarding this collection contact Kellie Leveille at 929–548–5297.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Solicitation for Applications for Medicare Prescription Drug Plan 2027 Contracts; *Use:* Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application.

Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) in Subpart 3. The application requirements are codified in Subpart K of 42 CFR 423 entitled ''Application Procedures and Contracts with PDP Sponsors.''

The information will be collected under the solicitation of proposals from PDP, MA–PD, Cost Plan, Program of All-Inclusive Care for the Elderly (PACE), and EGWP applicants. The collected information will be used by CMS to: (1) ensure that applicants meet CMS requirements for offering Part D plans (including network adequacy, contracting requirements, and compliance program requirements, as described in the application), (2) support the determination of contract awards *Form Number:* CMS–10137 (OMB control number: 0938–0936); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for profits, Not for profits institutions; *Number of Respondents:* 785; *Total Annual Responses:* 402; *Total Annual Hours:* 1,723. (For policy questions regarding this collection contact April Forsythe at 410–786–8493 or *April.Forsythe@cms.hhs.gov.*)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual Notice of Change and Evidence of Coverage for Applicable Integrated Plans in States that Require Integrated Materials; *Use:* CMS requires MA organizations and Part D sponsors to use the standardized documents being submitted for OMB approval to satisfy disclosure requirements mandated by section 1851(d)(3)(A) of the Act and § 422.111 for MA organizations and section 1860D–1(c) of the Act and § 423.128(a)(3) for Part D sponsors. The regulatory provisions at §§ 422.111(b) and 423.128(b) require MA organizations and Part D sponsors to disclose plan information, including: service area, benefits, access, grievance and appeals procedures, and quality improvement/assurance requirements. MA organizations and sponsors may send the ANOC separately from the EOC but must send the ANOC for enrollee receipt by September 30. The required due date for the EOC is 15 days prior to the start of the AEP.

This information collection maintains standardized EOC and ANOC models for Dual Eligible Special Needs Plan (D–SNP) applicable integrated plans (AIPs), as defined at § 422.561, in certain States that chose to require that plans issue an integrated EOC and ANOC that covers the Medicare and Medicaid benefits. The models reflect revisions to the D–SNP models under CMS–10260 to include information on Medicaid benefits that State Medicaid agencies can customize. *Form Number:* CMS–10824 (OMB control number: 0938–1444); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for profits; *Number of Respondents:* 109; *Total Annual Responses:* 109; *Total Annual Hours:* 1,308. (For policy questions regarding this collection

contact Julie Jones at 312–353–9850 or *Julie.Jones@cms.hhs.gov*.)

William N. Parham, III,

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

[FR Doc. 2025–14479 Filed 7–30–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1873]

Medical Device User Fee Small Business Qualification and Determination Guidance Final Guidance for Industry and Food and Drug Administration Staff and Foreign Governments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Medical Device User Fee Small Business Qualification and Determination Guidance.'' This guidance updates the previous version of the guidance, titled ''Medical Device User Fee Small Business Qualification and Certification Guidance'', issued on August 1, 2018. The guidance includes updates which describe how FDA plans to determine if a small business is experiencing ''financial hardship'' which makes them eligible for a waiver of their registration fee. The guidance details what information FDA intends to review and consider in making this determination.

DATES: The announcement of the guidance is published in the **Federal Register** on July 31, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2018–D–1873 for ''Medical Device User Fee Small Business Qualification and Determination Guidance.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Medical Device User Fee Small Business Qualification and Determination Guidance'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Medical Device User Fee Small Business Qualification and Determination Guidance''. On December 29, 2022, the Food and Drug Omnibus Reform Act of 2022 was signed into law as part of the Consolidated Appropriations Act, 2023, Public Law 117–328. Section 3309 of the Omnibus—''Small Business Fee Waiver''—amended section 738(a)(3)(B) of the Federal Food, Drug, and Cosmetic