

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 November 14, 2022.

**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](http://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:* Solicitation for Applications for Medicare Prescription Drug Plan 2024 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:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 783; *Number of Responses:* 425 *Total Annual Hours:* 1,861. (For policy questions regarding this collection contact Arianne Spaccarelli at 410-786-5715.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title:* Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits; *Use:* Collection of this information is mandated by the Code of Federal Regulations, MMA, and CMS

regulations at 42 CFR 422, subpart K, in "Application Procedures and Contracts for Medicare Advantage Organizations." In addition, the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) further amended titles XVII and XIX of the Social Security Act.

This information collection includes the process for organizations wishing to provide healthcare services under MA plans. These organizations must complete an application annually (if required), file a bid, and receive final approval from CMS. The MA application process has two options for applicants that include (1) request for new MA product or (2) request for expanding the service area of an existing product. CMS utilizes the application process as the means to review, assess and determine if applicants are compliant with the current requirements for participation in the MA program and to make a decision related to contract award. This collection process is the only mechanism for organizations to complete the required MA application process. *Form Number:* CMS-10237 (OMB Control Number: 0938-0935); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 500; *Number of Responses:* 500 *Total Annual Hours:* 9,173. (For policy questions regarding this collection contact Keith Penn-Jones at 410-786-3104 or [Keith.Penn-Jones@cms.hhs.gov](mailto:Keith.Penn-Jones@cms.hhs.gov).)

Dated: October 5, 2022.

**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, 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-10628]

#### 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 (the 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 December 12, 2022.

**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-10628—Initial Request for State Implemented Moratorium Form**

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 Collection**

1. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Initial Request for State Implemented Moratorium Form; *Use:* Congress has enacted section 1866 (j)(7) of the Social Security Act, which allows for the imposition of temporary moratorium. CMS promulgated 42 CFR 424.570 in order to comply with that statute, which requires that prior to implementing state Medicaid moratoria the state Medicaid agency must notify the Secretary in writing, including all of the details of the moratoria, and obtain the Secretary's concurrence with the imposition of the moratoria.

The Initial Request for State Medicaid Implemented Moratorium, named the "Initial Request for State Medicaid Implemented Moratorium" has been created to collect that data, in a uniform manner, which the states report to CMS when they request a moratorium. Currently, CMS is collecting this data on an ad-hoc basis, however this process needs to be standardized so that moratoria decisions are being made based on the same criteria each time. The form may be used by states and territories who wish to impose a Medicaid or Children's Health Insurance Program moratorium. CMS will use this information as a standardized method to collect and track state-imposed moratoria requests.

*Form number:* CMS-10628 (OMB control number: 0938-1328); *Frequency:* Occasionally; *Affected Public:* State,

Local, or Tribal Governments; *Number of Respondents:* 5; *Number of Responses:* 5; *Total Burden Hours:* 25. (For questions regarding this collection contact Alisha Jacobs at 410-786-0671).

Dated: October 5, 2022.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration.**

[Docket No. FDA-2022-N-2354]

**Generic Drug User Fee Rates for Fiscal Year 2023**

**AGENCY:** Food and Drug Administration, Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Federal Food, Drug, and Cosmetic Act (FD&C Act or statute), as amended by the Generic Drug User Fee Amendments of 2022 (GDUFA III), authorizes the Food and Drug Administration (FDA, Agency, or we) to assess and collect fees for abbreviated new drug applications (ANDAs); drug master files (DMFs); generic drug active pharmaceutical ingredient (API) facilities, finished dosage form (FDF) facilities, and contract manufacturing organization (CMO) facilities; and generic drug applicant program user fees. In this document, FDA is announcing fiscal year (FY) 2023 rates for GDUFA III fees. These fees are effective on October 1, 2022, and will remain in effect through September 30, 2023.

**FOR FURTHER INFORMATION CONTACT:** Robert Marcarelli, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705-4304, and the User Fees Support Staff at [OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov](mailto:OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov), 301-796-7223.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j-41 and 379j-42), as amended by GDUFA III, authorize FDA to assess and collect fees associated with human generic drug products. Fees are assessed on: (1) certain types of applications for human generic drug products; (2) certain facilities where APIs and FDFs are produced; (3) certain