

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 December 31, 2024.

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-10520 Marketplace Quality Standards

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:* Marketplace Quality Standards; *Use:* The Patient Protection and Affordable Care Act establishes requirements to support the delivery of quality health care coverage for health insurance issuers offering QHPs in Exchanges. Section 1311(c)(3) of the Patient Protection and Affordable Care Act directs the Secretary to develop a system to rate QHPs on the basis of quality and price and requires Exchanges to display this quality rating information on their respective websites. Section 1311(c)(4) of the Patient Protection and Affordable Care Act requires the Secretary to develop an enrollee satisfaction survey system to assess enrollee experience with each QHP (with more than 500 enrollees in the previous year) offered through an Exchange. Section 1311(h) requires QHPs to contract with certain hospitals that meet specific patient safety and health care quality standards beginning January 1, 2015.

This collection of information is necessary to provide adequate and timely health care quality information for consumers, regulators, and Exchanges in the initial years of Exchange implementation. It is also necessary to collect information to appropriately monitor and provide a process for a survey vendor to appeal HHS' decision to not approve a QHP Enrollee Survey vendor application.

Form Number: CMS-10114 (OMB control number: 0938-1249); *Frequency:* Annually; *Affected Public:* Public sector (Individuals and Households), Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 380; *Total Annual Responses:* 380; *Total Annual Hours:* 138,112. (For policy questions regarding this collection contact Preeti Hands at 301-492-5144.)

William N. Parham III,

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

[FR Doc. 2024-25505 Filed 10-31-24; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10398 #86]

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 November 15, 2024.

ADDRESSES: When commenting, please reference the applicable form number (CMS-10398 #86) and the OMB control number (0938-1148). 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-10398 #86/OMB control number: 0938-1148, 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/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. *Title of Information Collection:* Section 1115 Reentry Demonstration Initiative; *Type of Information Collection Request:* New information collection request; *Use:* On April 17, 2023, CMS released a State Medicaid Directors Letter (SMDL #23-003) announcing a demonstration opportunity to support community reentry and improve care transitions for individuals who are incarcerated and who are otherwise eligible for Medicaid to receive medical assistance under title XIX. The Section 1115 Reentry Demonstration Opportunity (hereinafter, “the Reentry Demonstration Initiative”) will allow states to offer coverage for

certain pre-release services for up to 90 days prior to the individual’s expected release date that could not otherwise be covered by Medicaid due to the Medicaid inmate exclusion policy. The provision is consistent with section 5032 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115-271), “Promoting State Innovations to Ease Transitions Integration to the Community for Certain Individuals.”

States applying for the Reentry Demonstration Initiative must provide a minimum set of pre-release services called the “pre-release benefit package.” The benefit package aims to improve transitions for individuals being released from jails or prisons and returning to their communities. The benefit package must include: (1) case management to assess and address physical and behavioral health needs and health-related social needs; and (2) medication-assisted treatment services for all types of substance use disorders as clinically appropriate, with accompanying counseling. Also required in the minimum set of services is a 30-day supply of all prescription medications that have been prescribed for the beneficiary.

This collection of information request includes three templates that are intended to expedite CMS’s review of reentry demonstration initiative applications and to support state implementation planning and related transparency by standardizing the presentation of key information necessary for approvals, thereby reducing rounds of clarifying questions with state applicants. The three templates include the: (1) reentry demonstration initiative preprint, (2) reentry implementation plan template, and (3) reentry budget neutrality formulation workbook. The templates are strongly encouraged but optional and described in the following section.

Form Number: CMS-10398 #86 (OMB control number: 0938-1148); *Frequency:* Annual and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 10; *Total Annual Responses:* 30; *Total Annual Hours:* 300. (For policy questions regarding this collection contact: Raven Smith at 410-786-3731.)

William N. Parham III,

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

[FR Doc. 2024-25503 Filed 10-31-24; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-3575]

Reauthorization of the Over-The-Counter Monograph Drug User Fee Program; 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 public meeting to discuss proposed recommendations for the reauthorization of the Over-The-Counter [OTC] Monograph Drug User Fee Program (OMUFA) for fiscal years (FYs) 2026 through 2030. Under OMUFA, FDA collects user fees to support OTC monograph drug activities. The current legislative authority for OMUFA expires September 30, 2025. At that time, new legislation will be required to reauthorize OMUFA for future fiscal years. Following negotiations with the regulated industry and consultation with interested members of the public, the Federal Food, Drug, and Cosmetic Act (FD&C Act) directs FDA to publish recommendations for the reauthorization of the OMUFA program in the **Federal Register**, provide for a period of 30 days for the public to provide written comments on such recommendations, and hold a meeting at which the public may present its views on such recommendations. FDA will then consider such public views and comments and revise such recommendations as necessary.

DATES: The public meeting will be held on November 20, 2024, from 9 a.m. to 12:30 p.m. Submit either electronic or written comments on this public meeting by December 20, 2024. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting is scheduled to be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Rm. 1503, Silver Spring, MD 20993. 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/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/>