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Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10834]

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 **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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 web site 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-10834 Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

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*: New collection (Request for a new OMB control number); *Title of Information Collection:* Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan; *Use*: Section 2003 of the SUPPORT for Patients and Communities Act of 2018 requires that prescribing of a Schedule II, III, IV, and V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. In the calendar year (CY) 2021 and 2022 Physician Fee Schedule (PFS) final rules, CMS finalized the electronic prescribing for controlled substances (EPCS) requirements and exceptions at 42 CFR 423.160(a)(5). Compliance for prescribers not in long-term care facilities begins in CY 2023. Compliance for prescribers in long-term care facilities begins in CY 2025.

EPCS requirements do not require prescribers or pharmacies to submit additional data to CMS; however, CMS did finalize one exception that requires data collection. The EPCS exception, at § 423.160(a)(5)(iv), requires a prescriber to apply for a waiver if the prescriber is unable to conduct EPCS due to circumstances beyond the prescriber's control. This collection of information is necessary to provide adequate and timely exception from the EPCS requirements if the prescriber is unable to conduct EPCS due to circumstances beyond the prescriber's control. *Form Number*: CMS-10834 (OMB control number: 0938-NEW); *Frequency:* Annually; *Affected Public*: Private Sector (Business or other for-profits, Not-for-Profit Institutions), and Public sector (State, Local or Tribal Governments); *Number of Respondents:* 100; *Total Annual Responses*: 100; *Total Annual Hours:* 17. (For policy questions regarding this collection contact Mei Zhang at (410) 786-7837).

Dated: March 7, 2023.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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