



4169-69-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10174]

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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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 web site by copying and pasting the following web address into your web browser:

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing](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.

Information Collections

1. *Type of Information Collection Request:* Revision with change of currently approved collection; *Title of Information Collection:* Collection of Prescription Drug Event Data from Contracted Part D Providers for Payment; *Use:* CMS fundamental goal is to have the least burdensome data submission requirements necessary to acquire the data needed for accurate Medicare Part D payment and appropriate program oversight. CMS believes that claims data provide the most reliable approach to ensuring that payment calculations are accurate. Without claims-level data, we cannot verify the accuracy of payments related to reinsurance, risk corridors, low-income subsidies, CGDP reconciliation, MDP reconciliation, IRASA, and Selected Drug Subsidy.

This claims-level information is reported by Part D sponsors to CMS on the PDE record. CMS limits there data collection to only those critical data elements necessary for accurate payment-related calculations, along with other elements required for validation of the PDE record, quality monitoring, and program integrity and oversight.

The information users will be pharmacy benefit managers (PBMs), third party administrators and pharmacies, PDPs, MA-PDs, Fallbacks, and other plans that offer coverage of outpatient prescription drugs under the Medicare Part D benefit to Medicare beneficiaries. The statutorily required data is used primarily for payment and is used for

claim validation as well as for other legislated functions such as quality monitoring, program integrity and oversight. In addition, the PDE data are used to support operations and program development *Form Number*: CMS-10174 (OMB control number: 0938-0982); *Frequency*: Yearly; *Affected Public*: Private sector, Federal Government profits; *Number of Respondents*: 994; *Total Annual Responses*: 1,627,798,686; *Total Annual Hours*: 11,208. (For policy questions regarding this collection contact Shelly Winston at (443) 934-3621.)

William N. Parham, III,

Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

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