



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10185]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid 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 THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

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, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>
1. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).
2. Call the Reports Clearance Office at (410) 786-1326.

**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 with change of a currently approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements; *Use:* Data collected via Medicare Part D Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. For all reporting sections, data are reported electronically to CMS. Each reporting section is reported at one of the following levels: Contract (data should be entered at the H#, S#, R#, or E# level) or Plan (data should be entered at the Plan Benefit Package (PBP level, e.g. Plan 001 for contract H#, R#, S#, or E). Sponsors should retain documentation and data records related to their data submissions. Data will be validated, analyzed, and utilized for trend reporting by the Division of Clinical and Operational Performance (DCOP) within the Medicare Drug Benefit and C & D Data Group. If outliers or other data anomalies are detected, DCOP will work in collaboration with other Divisions within CMS for follow-up and resolution.

In accordance with Title I, Part 423, Subpart K (§ 423.514), the Act requires each Part D

Sponsor to have an effective procedure to provide statistics indicating:

- the cost of its operations
- the patterns of utilization of its services
- the availability, accessibility, and acceptability of its services
- information demonstrating it has a fiscally sound operation
- other matters as required by CMS

Subsection 423.505 of the MMA regulation establishes as a contract provision that Part D Sponsors must comply with the reporting requirements for submitting drug claims and related information to CMS. *Form Number:* CMS-10185 (OMB control number: 0938-0992); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 744; *Total Annual Responses:* 17,080; *Total Annual Hours:* 25,256. (For policy questions regarding this collection contact Chanelle Jones at 410-786-8008.)

Dated: May 22, 2020

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William N. Parham, III

Director, Paperwork Reduction Staff

Office of Strategic Operations and Regulatory Affairs

4120-01-U-P

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