4120-01-U-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10185 and CMS-10008]

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-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 of Information Collection*: Medicare Part D Reporting Requirements; *Use*: Section 1860D–12(b)(3)(D) of the Act provides broad authority for the Secretary to add terms to the contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary with information as the Secretary may find necessary and appropriate. Pursuant to our statutory authority, we codified these information collection requirements for Part D sponsors in regulation at 42 CFR 423.514(a).

Data collected via the 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 (Enrollment and Disenrollment, Medication Therapy Management (MTM) Programs, Grievances, Improving Drug Utilization Review Controls, Coverage Determinations and Redeterminations, and Employer/Union Sponsored Sponsors, and Medicare Prescription Payment Plan), data are reported electronically to CMS. The data collected via the MTM and Grievances reporting sections are used in the Medicare Part C and D Star Ratings and Display Measures. The other reporting sections' data are analyzed for program oversight to ensure the availability, accessibility, and acceptability of sponsors' services, such as coverage determinations and appeals processes, and opioid safety edits at the time of dispensing. *Form Number*: CMS-10185 (OMB Control Number: 0938-0992); *Frequency*: Yearly; *Affected Public*: Business or other for-profits; *Number of Respondents*: 1,019; *Number of Responses*: 14,325; *Total Annual Hours*: 23,094. (For policy questions regarding this collection contact Abigale Sanft at 410-786-6068.)

2. *Type of Information Collection Request*: Extension currently approved collection; *Title of Information Collection*: Transitional Pass through payments related to Drugs, Biologicals, and Radiopharmaceuticals to determine eligibility under the Outpatient Prospective Payment System; *Use*: Section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs and biologicals (assuming that no pro rata reduction in pass-through payment is necessary) as the amount determined under section 1842(o) of the Act. Section 303(c) of Pub. L. 108-173 amended Title XVIII of the Act by adding new section 1847A. This new section establishes the use of the average sales price (ASP) methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. Therefore, as we stated in the November 15, 2004 **Federal Register** (69 FR 65776), in CY 2005, we will pay under the OPPS for drugs, biologicals and radiopharmaceuticals with pass-through status consistent with the provisions of section 1842(o) of the Act as amended by Pub. L. 108-173 at a rate that is equivalent to the payment these drugs and biologicals will receive in the physician

office setting, and established in accordance with the methodology described in the CY 2005 Physician Fee Schedule final rule.

Interested parties such as hospitals, pharmaceutical companies, and physicians will apply for transitional pass-through payment for drugs, biologicals, and radiopharmaceuticals used with services covered under the hospital OPPS. After we receive all requested information, we will evaluate the information to determine if the criteria for making a transitional pass-through payment are met and if an interim healthcare common procedure coding system (HCPCS) code for a new drug, biological, or radiopharmaceutical is necessary. We will advise the applicant of our decision and update the hospital OPPS during its next scheduled quarterly update to reflect any newly approved drug, biological, or radiopharmaceutical. Based on experience gained in processing transitional pass-through and new technology applications, we have reworded some of the statements for clarity and have more clearly requested information in a format that will allow us to determine if the drug, biological, or radiopharmaceutical meets the cost significance test, as well as to estimate the associated pass-through payment amount. In addition, we have also eliminated the requirement for applicants to obtain a national Level II HCPCS code prior to seeking transitional pass-through payment eligibility or provide us with a copy of their application for a national HCPCS code, as we had originally required in the April 7, 2000, final rule. *Form Number*: CMS-10008 (OMB control number: 0938-0802); *Frequency*: Once; *Affected Public*: Private Sector, Business or other for-profit and Not-for-profit institutions; *Number of Respondents*: 35; *Total Annual Responses*: 35; *Total Annual Hours*: 560. (For policy questions regarding this collection contact Andrew Wang at 410-786-8233.)

William N. Parham, III,

Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-11397 Filed: 5/23/2024 8:45 am; Publication Date: 5/24/2024]