4120-01-U-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10110]

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 also required to publish notice in the **Federal Register** concerning each proposed collection of information before the agency's request is submitted to OMB for approval.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 60 days of publication of this notice to www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting "Currently under 60-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.

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.

Information Collection

1. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR 414.800-806; *Use*: The revisions in this iteration are associated with our November 5, 2025 (90 FR 49266) CY 2026 Physician Fee Schedule (PFS) final rule (CMS-1832-F, OMB 0938-AV50). In this Federal Register notice we are soliciting public comment on the subject ASP collection of information request that is set out in the aforementioned supporting statement and associated attachments (see DATES and ADDRESSES for details).

This solicitation for public review and comment is an additional comment period that is specific to the aforementioned supporting statement and attachments. This notice provides an additional 60-day comment period that will not be supplemented with a subsequent 30-day notice or comment period.

The CY 2026 PFS final rule revised § 414.804(a)(5) adding submission requirements for ASP data reporting to include: (1) reasonable assumptions for calculating the manufacturer's ASP, including a summary of the methodology used to determine fair market value for fee

arrangements as described at § 414.804 and (2) warranty or certification letter from the recipient of a fee from a manufacturer as evidence that a fee was not passed on in accordance with submission requirements at § 414.804.

Currently, in the absence of specific guidance in statute or Federal regulations, the manufacturer may make reasonable assumptions in its calculations of the manufacturer's ASP, consistent with the general requirements and intent of the law, Federal regulations, and the manufacturer's customary business practices. The reasonable assumptions explain the methodology used by the manufacturer to calculate ASP.

The rule specifies that for sales beginning January 1, 2026, the reasonable assumptions document, which is currently submitted voluntarily by some manufacturers along with ASP data, is a required component of the quarterly ASP data submission. The warranty or certification from the recipient of a bona fide service fee is a new document that we finalized to be required as evidence of whether or not a fee was passed on. As discussed in the final rule, the new requirements are effective for sales occurring on or after January 1, 2026; that data would be due to CMS by April 30, 2026, and used in the July 2026 Medicare Part B Drug Payment Limit File.

Form Number: CMS-10110 (OMB control number: 0938-0921); *Frequency*: Quarterly; *Affected Public*: Private Sector; *Number of Respondents*: 500; *Total Annual Responses*: 2,000; *Total Annual Hours*: 33,495. (For policy questions regarding this collection contact: Rebecca Ray at 667-414-0879 or Laura Kennedy at 410-786-3377.)

William N. Parham, III

Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

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