



Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10110]

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 (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-10110 Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B
Drugs and Biologicals

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:* Revision of currently approved collection; *Title of Information Collection:* Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals; *Use:* Section 1847A of the Act requires that the Medicare Part B payment amounts for covered drugs and biologicals not paid on a cost or prospective payment basis be based upon manufacturers' average sales price data submitted quarterly to the Centers for Medicare & Medicaid Services (CMS). The reporting requirements are specified in 42 CFR part 414 subpart J.

CMS, specifically, the Division of Data Analysis and Market-based Pricing (DDAMBP) will utilize the ASP data (ASP and number of units sold as specific in section 1847A of the Act) to determine the Medicare Part B drug payment amounts for CY 2005 and beyond. The manufacturers submit their ASP data for all of their National Drug Codes (NDC) for Part B drugs. DDAMBP compiles the data, analyzes the data and runs the data through software to calculate the volume-weighted ASP for all of the NDCs that are grouped within a given HCPCS code. The formula to calculate the volume-weighted ASP is the Sum (ASP * units) for all NDCs/Sum (units * bill units per pkg) for all NDCs. DDAMBP provides ASP payment amounts for several components within CMS that utilize 1847(A) payment methodologies to implement various payment policies including, but not limited to, ESRD, OPSS, OTP and payment models. CMS will also use reported ASP and units to calculate inflation adjusted coinsurance and rebates. The Department of Health and Human Services' Office of the Inspector General also uses the ASP data in conducting studies. *Form Number:* CMS-10110 (OMB Control Number: 0938-0921); *Frequency:* Quarterly; *Affected Public:* Private and Business or other for-profits; *Number of Respondents:* 500; *Number of Responses:* 2,00; *Total Annual Hours:* 26,000.

(For policy questions regarding this collection contact Felicia Brown at (410) 786-9287 or

Felicia.brown@cms.hhs.gov).

William N. Parham, III,

Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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