

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 (DDMBP) 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. DDMBP 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. DDMBP 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, OPPS, 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10466]

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 March 21, 2024.

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 website 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*: Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; *Use*: The data collection and reporting requirements in "Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions" (78 FR 39494 (July 1, 2013)), address Federal requirements that states must meet with regard to the Exchange minimum function of performing eligibility determinations and issuing certificates of exemption from the shared responsibility payment. In the final regulation, CMS addresses standards related to eligibility, including the verification and eligibility determination process, eligibility redeterminations, options for states to rely on HHS to make eligibility determinations for certificates of exemption, and reporting. CMS developed four appendices of

application materials to illustrate the process applicants use to apply for exemptions from the shared responsibility payment. This information collection requests seeks approval for the requirements associated with the collection of information associated with these four appendices. No comments were received in response to the 60-day comment period. *Form Number:* CMS–10466 (OMB control number 0938–1190); *Frequency:* Annually; *Affected Public:* Individuals and Households—State, Local, or Tribal Governments; *Number of Respondents:* 849; *Total Annual Responses:* 849; *Total Annual Hours:* 1,962. (For policy questions regarding this collection contact John Kenna at 301–492–4452.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10662 and CMS–10219]

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 March 21, 2024.

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 website 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:* Administrative Simplification HIPAA Compliance Review; *Use:* Section 1173 of the Social Security Act (the Act), 42 U.S.C. 1320d–2, and section 264 of HIPAA require the Secretary to adopt a number of national standards to facilitate the exchange of certain health information and to protect the privacy and security of such information.

The Secretary promulgated rules that relate to compliance with, and enforcement of, the HIPAA rules, which are codified at 45 CFR part 160, subparts C, D, and E and collectively referred to as the Enforcement Rule. The Secretary first issued an interim final rule promulgating the procedural requirements for imposition of civil money penalties on violations of the privacy standards on April 17, 2003, Civil Money Penalties: Procedures for Investigations, Imposition of Penalties (68 FR 18896). The Secretary subsequently proposed a rule on April 18, 2005, HIPAA Administrative Simplification: Enforcement; Proposed Rule (70 FR 20224), proposing the amendment of 45 CFR part 160, subparts A (General Provisions), C (Compliance and Enforcement), and E (Procedures for Hearing), and proposing a new subpart D (Imposition of Civil Money Penalties) that addressed the substantive issues related to the imposition of civil money penalties and proposing the above provisions be applied to all HIPAA rules.

The purpose of this collection is to retrieve information necessary to conduct a compliance review and carry out the authority delegated to CMS as described in CMS–0014–N (68 FR 60694). These forms will be submitted to the Centers for Medicare & Medicaid Services (CMS), National Standards Group, from entities covered by HIPAA Administrative Simplification regulations. This collection is not applicable to HIPAA Privacy and Security Rules. *Form Number:* CMS–10662 (OMB Control Number: 0938–1390); *Frequency:* Weekly; *Affected Public:* Private, State, Local, or Tribal Governments, Federal Government, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 500. (For policy questions regarding this collection contact Kevin Stewart at (410) 786–6149.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* HEDIS Data Collection for Medicare Advantage; *Use:* Sections 422.152 and 422.516 of title 42 of the Code of Federal Regulations (CFR) specify that MAOs must submit quality performance measures as specified by the Secretary of the Department of Health and Human Services and by CMS. These quality performance measures include HEDIS®. HEDIS® data are used in the Medicare Part C Star Ratings which are used to determine Quality Bonus Payments to Medicare Advantage contracts.