



Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10174 and CMS-R-64]

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 with change of a currently approved collection; *Title of Information Collection:* Collection of Prescription Drug Data from MA-PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments; *Use:* The PDE data is used in the Payment Reconciliation System to perform the annual Part D payment reconciliation, any PDE data within the Coverage Gap Phase of the Part D benefit is used for invoicing in the CGDP, and the data are part of the report provided to the Secretary of the Treasury for Section 9008.

Sections 11001 through 11004 of the Inflation Reduction Act of 2022 establish a Medicare Drug Negotiation Program for high-expenditure drugs. Section 11102 of the Inflation Reduction Act of 2022 establishes a Part D inflation rebate by manufacturers of certain single

source drugs and biologicals with prices increasing at a rate faster than the rate of inflation. CMS will use data reported under sections 1860D-15(c)(1)(C) and (d)(2), in part, to rank drugs by total expenditures under Part D in order to select drugs for negotiation and to identify units to calculate inflation rebates.

The information users will be pharmacy benefit managers (PBMs), third party administrators and pharmacies, and the PDPs, MA-PDs, Fallbacks, and other plans that offer coverage of outpatient prescription drugs under the Medicare Part D benefit to Medicare beneficiaries. The statutorily required data is used primarily for payment and is used for claim validation as well as for other legislated functions such as quality monitoring, program integrity and oversight. In addition, the PDE data are used to support operations and program development. *Form Number:* CMS-10174 (OMB control number: 0938-0982); *Frequency:* Monthly; *Affected Public:* Private sector and Federal Government; *Number of Respondents:* 856; *Total Annual Responses:* 1,499,064,780; *Total Annual Hours:* 62,918. (For policy questions regarding this collection contact Shelly Winston at 410-786-3694.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Indirect Medical Education and Direct Graduate Medical Education; *Use:* Section 1886(d)(5)(B) of the Social Security Act requires additional payments to be made under the Medicare Prospective Payment System (PPS) for the indirect medical educational costs a hospital incurs in connection with interns and residents (IRs) in approved teaching programs. In addition, title 42, part 413, sections 75 through 83 implement section 1886(d) of the Act by establishing the methodology for Medicare payment for the costs of direct graduate medical educational activities.

The information collected on IRs is used by Part- A Medicare Administrative Contractors (MAC) to verify the number of IRs FTE used in the calculation of Medicare payments for IME and GME. The IR data submitted by the hospitals to the MACs is uploaded into CMS' Intern and Resident Information System (IRIS) database to identify duplicate FTEs reported for any IR.

The MACs use the information collected on IRs to ensure that all program payments for IME and GME are accurate and are in accordance with Medicare regulations. The IR data submitted by the hospitals to the MACs are used to audit the Medicare cost reports filed by the hospitals. *Form Number:* CMS-R-64 (OMB control number: 0938-0456); *Frequency:* Monthly; *Affected Public:* Private sector and Federal Government; *Number of Respondents:* 1,245; *Total Annual Responses:* 1,245; *Total Annual Hours:* 2,490. (For policy questions regarding this collection contact Owen Osaghae at 410-786-7550.)

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Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

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