



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier CMS-R-64 and CMS-10699]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid 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 (the 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 THE 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, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).
3. Call the Reports Clearance Office at (410) 786-1326.

**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-R-64 Indirect Medical Education and Direct Graduate Medical Education

CMS-10699 Information Collection Requirements Associated with Drug Pricing Transparency and Supporting Regulations in 42 CFR 403.1202

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 a currently 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. These payments, which are adjustments (add-ons) to other payments made to a hospital under PPS, are largely determined by the number of full-time equivalent (FTE) IRs that work at a hospital during its cost reporting period. In Federal fiscal year (FY) 2018, the estimated Medicare program

payments for indirect medical education (IME) costs was \$6.4 billion. Medicare program payment for direct graduate medical education (GME) is also based upon the number of FTE-IRs that work at a hospital. In FY 2018, the estimated Medicare program payments for GME costs was \$3.1 billion. Since it is important to accurately count the number of IRs FTEs working at each hospital, original approval was obtained from the Office of Management and Budget (OMB) in 1985 to collect the IR information required in 42 CFR 412.105(f) and timeframes for filing. All Medicare health plans are required to use these standardized notices. *Form Number:* CMS-R-64 (OMB control number: 0938-0456); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-profit institutions); *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.)

*2. Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Information Collection Requirements Associated with Drug Pricing Transparency and Supporting Regulations in 42 CFR 403.1202; *Use:* The Department of Health and Human Services proposed a rule (78 FR 52789) to revise the Federal Health Insurance Programs for the Aged and Disabled by amending regulations for the Medicare and Medicaid program, to require direct-to-consumer (DTC) television advertisements of prescription drugs and biological products for which payment is available through or under Medicare or Medicaid to include the Wholesale Acquisition Cost (WAC, or list price) of that drug or biological product. This rule is intended to improve the efficient administration of the Medicare and Medicaid programs by ensuring that beneficiaries are provided with relevant information about the costs of prescription drugs and biological products so they can make informed decisions that minimize not only their out-of-pocket costs, but also expenditures borne by Medicare and Medicaid, both of which are

significant problems. It is necessary for manufacturers to display the list price in direct-to-consumer television advertisements of prescription drugs and biological products to provide relevant information to beneficiaries to allow them to work with their prescribers to select the best overall treatment. *Form Number:* CMS-10699 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 25; *Total Annual Responses:* 1,200; *Total Annual Hours:* 300. (For policy questions regarding this collection contact Cheri Rice at 410 786-6499.)

Dated: April 3, 2019.

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**William N. Parham, III,**

*Director,*

*Paperwork Reduction Staff,*

*Office of Strategic Operations and Regulatory Affairs.*

**4120-01-U-P**

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