



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10079, CMS-855S, CMS-10052 and CMS-10495]

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:* Extension of a currently approved collection; *Title:* Hospital Wage Index Occupational Mix Survey; *Use:* Section 304(c) of Public Law 106-554 amended section 1886(d)(3)(E) of the Social Security Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated

with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

CMS takes the data collected from the approximately 3,200 IPPS providers participating in the Medicare program and runs the data through mathematical formulas to create the occupational mix adjustment to the wage index. CMS informs hospitals of the occupational mix adjusted wage indexes through notice and comment rulemaking each year. *Form Number:* CMS-10079 (OMB control number: 0938-0907); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 3,100; *Number of Responses:* 3,100; *Total Annual Hours:* 1,488,000. (For policy questions regarding this collection contact Noel Manlove at 410-786-5161.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Enrollment Application—Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers; *Use:* The primary function of the Form CMS-855S Medicare enrollment application for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) is to gather information from the supplier that tells us who the supplier is, whether the supplier meets certain qualifications to be a Medicare DMEPOS supplier, where the supplier practices or renders services, and other information necessary to establish correct claims payments. *Form Number:* CMS-855S (OMB control number: 0938-1056); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 32,790; *Total Annual Responses:* 32,790; *Total Annual Hours:* 67,886. (For policy questions regarding this collection contact Frank Whelan at 410-786-1302.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Recognition of Pass-Through Payment for Additional (New) Categories of Devices under the Outpatient Prospective Payment System and Supporting Regulations; *Use:* The transitional pass-through provision provides a way for ensuring

appropriate payment for new technologies whose use and costs are not adequately represented in the base year claims data on which the outpatient PPS is constructed as required by law. Categories of medical devices will receive transitional pass-through payments for 2 to 3 years from the date payments are initiated for the category. However, the underlying provision is permanent and provides an on-going mechanism for reflecting timely introduction of new items into the payment structure.

Interested parties such as hospitals, device manufacturers, pharmaceutical companies, and physicians apply for transitional pass-through payment for certain items used with services covered in the outpatient PPS. After we receive all requested information, we evaluate the information to determine if the creation of an additional category of medical devices for transitional pass-through payments is justified. We may request additional information related to the proposed new device category, as needed. We advise the applicant of our decision, and update the outpatient PPS during its next scheduled quarterly payment update cycle to reflect any newly approved device categories. We list below the information that we require from all applicants. The following information is required to process requests for additional categories of medical devices for transitional pass-through payments. *Form Number:* CMS-10052 (OMB control number: 0938-0857); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 16; *Number of Responses:* 16; *Total Annual Hours:* 16. (For questions regarding this collection contact Amanda Rhee at 410-786-3888.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Registration, Attestation, Dispute Resolution and Correction, Assumptions Document and Data Retention Requirements for Open Payments; *Use:* The Patient Protection and Affordable Care Act was enacted on March 23, 2010 (Pub. L. 111-148). This statute amended section 1128 of the Social Security Act (the Act) by adding a new subsection G that requires applicable manufacturers of drugs, devices, biologics, or medical supplies covered under title XVIII of the Act (Medicare) or a State plan under title XIX

(Medicaid) or XXI of the Act (the Children's Health Insurance Program, or CHIP) to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals. Section 1128G of the Act also requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities, as well as any payments provided to such physicians.

The submitted information facilitates various aspects of the program. The information collected through the registration process is used by CMS to validate registration for applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors that are registering for Open Payments. Details collected during the dispute resolution and correction process allows CMS to notify applicable manufacturers and applicable GPOs that a covered recipient or physician owner or investor is initiating a dispute regarding data submitted about them and allow CMS to relay the nature of the dispute. The assumptions documents submitted by applicable manufacturers or applicable GPOs assist CMS in providing guidance (for example, determining form and nature of payment categories, calculating the value of a payment, determining the date of payment, and reporting the terms of an ownership or investment interest). *Form Number:* CMS-10495 (OMB control number: 0938-1237); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 1,788; *Total Annual Responses:* 1,788; *Total Annual Hours:* 1,950,948. (For policy questions regarding this collection contact Kathleen Ott at 410-786-4246.)

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