



Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10279, CMS-10316 and CMS-10008]

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-10279 Ambulatory Surgical Center Conditions for Coverage

CMS-10316 Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey

CMS-10008 Transitional Pass-through payments related to Drugs, Biologicals, and Radiopharmaceuticals to determine eligibility under the Outpatient Prospective Payment System

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:* Reinstatement with changes to a previously approved collection; *Title of Information Collection:* Ambulatory Surgical Center Conditions for Coverage; *Use:* The purpose of this package is to request from the Office of Management and Budget (OMB) the approval to reinstate, with changes, the collection of information. The Cfc for ASCs are regulation based on criteria described and codified at § 42 CFR 416. The Cfc establish standards designed to ensure that each ASC has properly trained staff to provide the appropriate type and level of care for the environment of ASC patients.

To determine ASC compliance with CMS standards, CMS, via the Secretary, authorizes States, through contracts, to survey ASC facilities. For Medicare purposes, certification is based on the State survey agency's recording of an ASC provider's compliance or non-compliance with the health and safety Cfc as published and codified in 42 CFR 416.40 to 485.54. The information collections aid surveyors as they assess ASC compliance or non-compliance.

The previous iteration of this information collection request had a burden of 262,946 annual hours at an annual cost of \$28,144,370. For this requested reinstatement, with changes, the adjusted annual hourly burden is 97,527 hours at a cost of \$11,089,427. The reasons for this change, is the previous iteration of this IC assumed the development associated with IC-1 and IC-2 occurred frequently. We have revised this as development of drafts only occur on a one-time basis. *Form Number:* CMS-10279 (OMB control number: 0938-1071); *Frequency:* Annual; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of*

Respondents: 6,257; Total Annual Responses: 6,257; Total Annual Hours: 97,527. (For policy questions regarding this collection contact Claudia Molinar at 410-786-8445.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey; *Use:* Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provides a requirement to collect and report performance data for Part D prescription drug plans. Specifically, the MMA under Sec. 1860D-4 (Information to Facilitate Enrollment) requires CMS to conduct consumer satisfaction surveys regarding the PDP and MA contracts pursuant to section 1860D-4(d). Plan disenrollment is generally believed to be a broad indicator of beneficiary dissatisfaction with some aspect of plan services, such as access to care, customer service, cost of the plan, services, benefits provided, or quality of care.

This data collection complements the enrollee beneficiary experience data collected through the Medicare Consumer Assessment of Healthcare Providers and Systems (Medicare CAHPS) survey by providing information on the reasons for disenrollment from a Medicare Advantage (with or without prescription drug coverage) or Prescription Drug Plan.

The Disenrollment Survey results are an important source of information used by CMS to monitor contract performance and to identify potential problems (e.g., plans providing incorrect information to beneficiaries or creating access problems). CMS uses the results to monitor the quality of service that Medicare beneficiaries get from contracted plans and their providers and to understand beneficiaries' expectations relative to provided benefits and services for MA and PDPs. CMS uses information from the Disenrollment Survey to support quality improvement efforts of individual contracts. *Form Number:* CMS-10316 (OMB control number: 0938-1113); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:*

36,050; *Total Annual Responses*: 36,050; *Total Annual Hours*: 6,730. (For policy questions regarding this collection contact Beth Simon at 415-744-3780.)

3. *Type of Information Collection Request*: Extension currently approved collection; *Title of Information Collection*: Transitional Pass through payments related to Drugs, Biologicals, and Radiopharmaceuticals to determine eligibility under the Outpatient Prospective Payment System; *Use*: Section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs and biologicals (assuming that no pro rata reduction in pass-through payment is necessary) as the amount determined under section 1842(o) of the Act. Section 303(c) of Pub. L. 108-173 amended Title XVIII of the Act by adding new section 1847A. This new section establishes the use of the average sales price (ASP) methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. Therefore, as we stated in the November 15, 2004 Federal Register (69 FR 65776), in CY 2005, we will pay under the OPPS for drugs, biologicals and radiopharmaceuticals with pass-through status consistent with the provisions of section 1842(o) of the Act as amended by Pub. L. 108-173 at a rate that is equivalent to the payment these drugs and biologicals will receive in the physician office setting, and established in accordance with the methodology described in the CY 2005 Physician Fee Schedule final rule.

Interested parties such as hospitals, pharmaceutical companies, and physicians will apply for transitional pass-through payment for drugs, biologicals, and radiopharmaceuticals used with services covered under the hospital OPPS. After we receive all requested information, we will evaluate the information to determine if the criteria for making a transitional pass-through payment are met and if an interim healthcare common procedure coding system (HCPCS) code for a new drug, biological, or radiopharmaceutical is necessary. We will advise the applicant of our decision, and update the hospital OPPS during its next scheduled quarterly update to reflect any newly approved drug, biological, or radiopharmaceutical. Based on experience gained in processing transitional pass-through and new technology applications, we have reworded some

of the statements for clarity and have more clearly requested information in a format that will allow us to determine if the drug, biological, or radiopharmaceutical meets the cost significance test, as well as to estimate the associated pass-through payment amount. In addition, we have also eliminated the requirement for applicants to obtain a national Level II HCPCS code prior to seeking transitional pass-through payment eligibility, or provide us with a copy of their application for a national HCPCS code, as we had originally required in the April 7, 2000 final rule. *Form Number:* CMS-10008 (OMB control number: 0938-0802); *Frequency:* Once; *Affected Public:* Private Sector, Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 35; *Total Annual Responses:* 35; *Total Annual Hours:* 560. (For policy questions regarding this collection contact Andrew Wang at 410-786-8233.)

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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