

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-8003, CMS-10185 and CMS-10164]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Home and Community Based Waiver Requests and Supporting Regulations in 42 CFR 440.180 and 441.300-310; *Use:* Under a Secretarial waiver, States may offer a wide array of home and community-based services to individuals who would otherwise require institutionalization. States requesting a waiver must provide certain assurances, documentation and cost and utilization estimates which are reviewed, approved and maintained for the purpose of identifying/verifying States' compliance with such statutory and regulatory requirements. CMS has recently revised this data collection tool, as well as the methodology by which the data is collected. *Form Number:* CMS-8003 (OMB # 0938-0449); *Frequency:* Annually; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 49; *Total Annual Responses:* 71; *Total Annual Hours:* 9,059.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part D

Reporting Requirements and Supporting Regulations under 42 CFR 423.505; *Form Number:* CMS-10185 (OMB # 0938-0992); *Use:* Title I, Part 423, § 423.514 describes CMS' regulatory authority to establish requirements for Part D sponsors. It is noted that each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, its enrollees, and the general public, at the times and in the manner that CMS requires, statistics in the following areas: (1) The cost of its operations; (2) The availability of utilization of its services; (3) The availability, accessibility; and acceptability of its services; (4) Information demonstrating that the Part D plan sponsor has a fiscally sound operation; and (5) other matters that CMS may require. Subsection 423.505 of the Medicare Prescription Drug Modernization and Modernization Act establishes as a contract provision that Part D Sponsors must comply with the reporting requirements for submitting drug claims and related information to CMS. Data collected via Medicare Part D Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. Refer to the "Crosswalk of Changes between the CY2009 and CY2010 Part D Reporting Requirements" document to view a list of current changes. *Frequency:* Reporting—yearly, quarterly and semi-annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 4,526; *Total Annual Responses:* 343,976; *Total Annual Hours:* 154,610.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Electronic Data Interchange (EDI Enrollment Form and Medicare EDI Registration Form; *Form No.:* CMS-10164 (OMB # 0938-983); *Use:* Federal law requires that CMS take precautions to minimize the security risk to Federal information systems. Accordingly, CMS is requiring that trading partners who wish to conduct the Electronic Data Interchange (EDI) transactions provide certain assurances as a condition of receiving access to the Medicare system for the purpose of conducting EDI exchanges. Health care providers, clearinghouses, and health plans that wish to access the Medicare system are required to complete this form. The information will be used to assure that those entities that access the Medicare system are aware of applicable provisions and penalties; *Frequency:*

Recordkeeping and Reporting—Other (one-time only); *Affected Public:* Business or other for-profit, not-for-profit institutions; *Number of Respondents:* 240,000; *Total Annual Responses:* 240,000; *Total Annual Hours:* 80,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *March 17, 2009*:

1. *Electronically.* You may submit 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) 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.

Dated: January 8, 2009.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3210-N]

Medicare Program; Meeting of the Medicare Evidence Development & Coverage Advisory Committee—March 18, 2009

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces that a public meeting of the Medicare