

Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street NW., Washington, DC 20503, (202) 395-4718.

Dated: May 28, 2009.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10050 and CMS-10174]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

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 the currently approved collection; *Title of Information Collection:* New Enrollee Survey; *Use:* The New Enrollee survey was developed to gather information from newly enrolled Medicare beneficiaries about their Medicare knowledge and needs. CMS is seeking understanding about what types of information new enrollees need and what they know about Medicare. Included in the survey are questions regarding how well informed new enrollees are about Medicare and what information they have received about the Medicare program. Information gathered in this survey will be used only for purposes of targeting and improving communications with newly

eligible Medicare beneficiaries. *Form Number:* CMS-10050 (OMB#: 0938-0869); *Frequency:* Reporting—Quarterly; *Affected Public:* Individuals or Households; *Number of Respondents:* 1200; *Total Annual Responses:* 1200; *Total Annual Hours:* 300. (For policy questions regarding this collection contact Renee Clark at 410-786-0006. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* Revision of the currently approved collection; *Title of Information Collection:* Collection of Drug Event Data From Contracted Part D Providers For Payment; *Use:* In December 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 referred to as the Medicare Modernization Act (MMA). The Medicare Prescription Drug Benefit program (Part D) was established by section 101 of the MMA and is codified in section 1860D-1 through 1860D-41 of the Social Security Act. Effective January 1, 2006, the Part D program establishes an optional prescription drug benefit for individuals who are entitled to Medicare Part A and/or enrolled in Part B. Part D plans have flexibility in terms of benefit design. This flexibility includes, but is not limited to, authority to establish a formulary that limits coverage to specific drugs within each therapeutic class of drugs, and the ability to have a cost-sharing structure other than the statutorily defined structure (subject to certain actuarial tests). Coverage under the new prescription drug benefit is provided predominately through private at-risk prescription drug plans that offer drug-only coverage (PDPs), Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans) or Cost Plans that offer prescription drug benefits.

The transmission of the data will be in an electronic format. The information users will be Pharmacy Benefit Managers (PBM), 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 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. *Form Number:* CMS-10174 (OMB#: 0938-0982); *Frequency:* Reporting—Monthly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 747; *Total Annual Responses:* 947,881,770; *Total Annual*

Hours: 1896. (For policy questions regarding this collection contact Bobbie Knickman at 410-786-4161. For all other issues call 410-786-1326.)

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 *August 4, 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 (CMS-10078), Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 28, 2009.

Michelle Shortt,

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

[FR Doc. E9-13150 Filed 6-4-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10133, CMS-10279, CMS-250-254, CMS-10277, CMS-10157 and CMS-10273]

Agency Information Collection Activities: Submission for OMB Review; 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), Department of Health

and Human Services, 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 function; (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:* Extension of a currently approved collection; *Title of Information Collection:* Competitive Acquisition Program (CAP) for Medicare Part B Drugs: Vendor Application and Bid Form; *Use:* Section 303(d) of the Medicare Modernization Act (MMA) requires the implementation of a competitive acquisition program for Medicare Part B drugs and biologicals not paid on a cost or prospective payment system basis. The CAP is an alternative to the Average Sales Price (ASP or "buy and bill") method of acquiring many Part B drugs and biologicals administered incident to a physician's services. The CAP Vendor Application and Bid Form, is used by bidders to provide a response to CMS' solicitation for approved CAP vendor bids and to submit their bid prices for CAP drugs. Though the program is currently on hold and a timeline for the resumption of the CAP has not been established, the CAP Vendor Application and Bid Form will be required to conduct the next round of vendor bidding. *Form Number:* CMS-10133 (OMB#: 0938-0955); *Frequency:* Reporting—Occasionally; *Affected Public:* Private Sector; Business or other for-profits; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 1. (For policy questions regarding this collection contact Bonny Dahm at 410-786-4006. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Ambulatory Surgical Center Conditions for Coverage; *Form Number:* CMS-10279 (OMB#: 0938-New); *Use:* The Ambulatory Surgical Center (ASC) Conditions for Coverage (CfCs) focus on a patient-centered, outcome-oriented, and transparent processes that promote, quality patient care. The CfCs are designed to ensure that each facility has

properly trained staff to provide the appropriate type and level of care for that facility and provide a safe physical environment for patients. The CfCs are used by Federal or State surveyors as a basis for determining whether an ASC qualifies for approval or re-approval under Medicare. CMS and the healthcare industry believe that the availability to the facility of the type of records and general content of records, which this regulation specifies, is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. *Frequency:* Recordkeeping and Reporting—One time; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 5,100; *Total Annual Responses:* 5,100; *Total Annual Hours:* 193,800. (For policy questions regarding this collection contact Jacqueline Morgan at 410-786-4282. For all other issues call 410-786-1326.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Secondary Payer Information Collection and Supporting Regulations in 42 CFR 411.25, 489.2, and 489.20; *Form Number:* CMS 250-254 (OMB#: 0938-0214); *Use:* Medicare Secondary Payer Information (MSP) is essentially the same concept known in the private insurance industry as coordination of benefits, and refers to those situations where Medicare does not have primary responsibility for paying the medical expenses of a Medicare beneficiary. Medicare Fiscal Intermediaries, Carriers, and now Part D plans, need information about primary payers in order to perform various tasks to detect and process MSP cases and make recoveries. MSP information is collected at various times and from numerous parties during a beneficiary's membership in the Medicare Program. Collecting MSP information in a timely manner means that claims are processed correctly the first time, decreasing the costs associated with adjusting claims and recovering mistaken payments. *Frequency:* Reporting—On occasion; *Affected Public:* Individuals or Households, Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 143,070,217; *Total Annual Responses:* 143,070,217; *Total Annual Hours:* 1,788,057. (For policy questions regarding this collection contact John Albert at 410-786-7457. For all other issues call 410-786-1326.)

4. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Hospice

Conditions of Participation and Supporting Regulations in 42 CFR 418.52, 418.54, 418.56, 418.58, 418.60, 418.64, 418.66, 418.70, 418.72, 418.74, 418.76, 418.78, 418.100, 418.106, 418.108, 418.110, 418.112, and 418.114; *Use:* The Conditions of Participation and accompanying requirements are used by Federal or State surveyors as a basis for determining whether a hospice qualifies for approval or re-approval under Medicare. The healthcare industry and CMS believe that the availability to the hospice of the type of records and general content of records, which the final rule (72 FR 32088) specifies, is standard medical practice, and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. *Form Number:* CMS-10277 (OMB#: 0938-New); *Frequency:* Reporting and Recordkeeping—Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 2,872; *Total Annual Responses:* 1,808,345; *Total Annual Hours:* 2,152,396. (For policy questions regarding this collection contact Danielle Shearer at 410-786-6617. For all other issues call 410-786-1326.)

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* CMS Real-time Eligibility Agreement and Access Request; *Form Number:* CMS-10157 (OMB#: 0938-0960); *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 eligibility transaction on a real-time basis to access Medicare beneficiary information provide certain assurances as a condition of receiving access to the Medicare database for the purpose of conducting eligibility verification. Health care providers, clearinghouses, and health plans that wish access to the Medicare database are required to complete this form. The information will be used to assure that those entities that access the Medicare database are aware of applicable provisions and penalties. *Frequency:* Recordkeeping and Reporting—One time; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 2,000; *Total Annual Responses:* 500; *Total Annual Hours:* 500. (For policy questions regarding this collection contact Vivian Rogers at 410-786-8142. For all other issues call 410-786-1326.)

6. *Type of Information Collection Request:* New collection; *Title of*

Information Collection: Evaluation of the Medicare Care Management Performance Demonstration (MCMP) and the Electronic Health Records Demonstration (EHRD); **Use:** The MCMP demonstration was authorized under Section 649 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This is a three year pay for performance demonstration with physicians to promote the adoption and use of health information technology (HIT) to improve the quality of care for eligible chronically ill Medicare beneficiaries. MCMP targets small to medium sized primary care practices with up to 10 physicians. Practices must provide care to at least 50 Medicare beneficiaries. Physicians will receive payments for meeting or exceeding performance standards for quality of care. They will also receive an additional incentive payment for electronic submission of performance measures via their electronic health record (EHR) system. These payments are in addition to their normal payments for providing service to Medicare beneficiaries. The Office System Survey (OSS) will be used to assess progress of physician practices in implementation and use of EHRs and related HIT functionalities.

The EHR demonstration is authorized under Section 402 of the Medicare Waiver Authority. The goal of this five year pay for performance demonstration is to foster the implementation and adoption of EHRs and HIT in order to improve the quality of care provided by physician practices. The EHRD expands upon the MCMP Demonstration and will test whether performance-based financial incentives (1) increase physician practices' adoption and use of electronic health records (EHRs), and (2) improve the quality of care that practices deliver to chronically ill patients. The EHRD targets small to medium sized primary care practices with up to 20 physicians. Practices must provide care to at least 50 Medicare beneficiaries. Approximately 800 practices will be enrolled in the demonstration across four sites. Practices will be randomly assigned to

a treatment and a control group. The OSS will be used to assess progress of physician practices in implementation and use of EHRs and related HIT functionalities, and to determine incentive payments for treatment practices. In-person and telephone discussions with community partners and physician practices will be used to learn about practices' experiences and strategies in adopting and using EHRs, as well as the factors that help or hinder their efforts. Refer to the supporting document "High-Level Summary of Changes" for a list of changes. *Form Number:* CMS-10273 (OMB# 0938-New); *Frequency:* Annually, Biennially and Once; *Affected Public:* Business or other for-profit; *Number of Respondents:* 4,123; *Total Annual Responses:* 1,659; *Total Annual Hours:* 934. (For policy questions regarding this collection contact Lorraine Johnson at 410-786-9457. For all other issues call 410-786-1326.)

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *July 6, 2009*. OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, E-mail: OIRA_submission@omb.eop.gov.

Dated: May 28, 2009.

Michelle Shortt,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Supporting Healthy Marriage (SHM) Demonstration and Evaluation Project—Wave 2 Survey

OMB No.: 0970-0339.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is conducting a demonstration and evaluation called the Supporting Healthy Marriage (SHM) Project. SHM is a test of marriage education demonstration programs in eight sites that will enroll about 800 couples per site, with half assigned to participate in the SHM program and the other half assigned to the control group.

SHM is designed to inform program operators and policymakers of the effectiveness of programs designed to help low-income married couples strengthen and maintain healthy marriages and improve outcomes for adults and children.

This notice of information collection is for two activities. One is a second adult survey and new instruments to obtain information from children and youth about 30 months after study entry. The other is for an extension of the period of approval for the first survey and observation instruments used to obtain information from research participants about 12 months after study entry.

The proposed second wave of information collection will involve:

- An adult survey instrument to assess study participants' longer term marital status and stability, quality of relationships, and a range of other measures.
- A survey of focal children of study participants in both the program and control groups who are over 8 years of age (the youth survey).
- A direct child assessment of focal children of study participants in both the program and control groups who are 8 years of age or younger.

Respondents: Low-income married couples and their children in the SHM evaluation research sample.

ANNUAL BURDEN ESTIMATE

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per respondent	Estimated annual burden hours
Adult Survey Wave 1	4,267	1	.83	3,542
Adult-Child Observation Study Wave 1	2,448	1	.55	1,346
Total Wave 1 Burden				4,888
Adult Survey Wave 2	4,267	1	.83	3,542