

first Monday in June of 2007. In order to meet the Medicare Prescription Drug Improvement and Modernization Act requirements, key preceding events must occur. If these events do not occur according to the statutorily mandated timeline, other statutory requirements will not be met.

For the 2008 contract year, CMS is implementing several steps to reduce the person-hours necessary to complete the Part C solicitations. These steps include automating substantial portions of the Part C Plan solicitations within CMS' Health Plan Management System (HPMS) and streamlining key information previously requested by attachments.

*Type of Information Collection Request:* Revision of a currently approved collection.

*Title of Information Collection; Medicare Advantage Applications:* Medicare Advantage (MA) Application Coordinated Care Plans (CMS-10117); Medicare Advantage (MA) Application Private Fee-For-Service Plans (CMS-10118); Medicare Advantage (MA) Application Regional PPO Plans (CMS-10119); Medicare Advantage (MA) Application Service Area Expansion (SAE) for Coordinated Care Plans; Private Fee Service Plans (CMS-10135); Medical Savings Account Plans (CMS-10136); and Employer Group Waiver Plans (CMS-10214).

*Form Number:* CMS-10117, 10118, 10119, 10135, 10136 and 10214 (OMB#: 0938-0935).

*Use:* An entity seeking a contract as an MA organization must be able to provide Medicare's basic benefits plus meet the organizational requirements set out under the regulations at 42 CFR Part 422. An applicant must demonstrate that it can meet the benefit and other requirements within the specific geographic area it is requesting. The application forms are designed to give CMS the information needed to determine a health plan's compliance with the regulations at 42 CFR Part 422. The MA application forms will be used by CMS to determine whether an entity is eligible to enter into a contract to provide services to Medicare beneficiaries.

*Frequency:* Reporting—Once.

*Affected Public:* Business or other for-profit and Not-for-profit institutions.

*Number of Respondents:* 220.

*Total Annual Responses:* 220.

*Total Annual Hours:* 5580.

CMS is requesting OMB review and approval of this collection by *January 5, 2007*, with a 180-day approval period. Written comments and recommendation will be considered from the public if

received by the individuals designated below by December 22, 2006.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address 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](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by December 22, 2006:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Attn: Bonnie L. Harkless, Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850, and, OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503. Fax Number: (202) 395-6974.

Dated: November 30, 2006.

**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

**[Document Identifier: CMS-10215 and CMS-10148]**

#### 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:* New collection; *Title of Information Collection:* Collection of Physician Administered Drug National Drug Code (NDC) Numbers on State Medicaid Claims and Supporting Regulations at 42 CFR 447.520. *Use:* Section 6002 of the Deficit Reduction Act of 2005 (DRA) added provisions under Section 1927 of the Social Security Act to require physicians in their offices and hospital outpatient settings or other entities (e.g., non-profit facilities) to collect and submit the drug NDC numbers on Medicaid claims to their State within specified timeframes. We estimate that there are 20,000 physician offices, hospital outpatient settings or other entities concentrating in the specialties of oncology, rheumatology and urology that will be required by their State Medicaid Programs to collect and submit "J" drug code data match with NDC numbers. *Form Number:* CMS-10215 (OMB#: 0938-NEW); *Frequency:* Reporting—weekly; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 20,000; *Total Annual Responses:* 3,910,000; *Total Annual Hours:* 15,836.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* HIPAA Administrative Simplification Enforcement Non-Privacy Enforcement; *Use:* The Health Insurance Portability and Accountability Act (HIPAA) became law in 1996 (Pub. L. 104-191). Subtitle F of Title II of HIPAA, entitled "Administrative Simplification," requires the Secretary of HHS to adopt national standards for certain information-related activities of the health care industry. The HIPAA provisions, by statute, apply only to "covered entities" referred to in section 1320d-2(a)(1) of this title. Responsibility for administering and enforcing the HIPAA Administrative Simplification Transactions, Code Sets, Identifiers and Security rules has been delegated to CMS. The initial information collected to enforce these rules will be used to initiate enforcement actions. This information

collection change clarifies the “Identify the HIPAA Non-Privacy complaint category” section of the complaint form. In this section, complainants are given an opportunity to check the “Unique Identifiers” option to categorize the type of HIPAA complaint being filed. The revised form now includes a “For a Unique Identifier Complaint” section, that allows a complaint to further categorize their identifier complaint as either a “National Provider Identifier (NPI)” or an “Employer Identification Number (EIN)” complaint. *Form Number: CMS-10148 (OMB#: 0938-948); Frequency: Reporting—On occasion; Affected Public: Individuals or Households, Business or other for-profit, Not-for-profit institutions, and State, Local, or Tribal governments; Number of Respondents: 500; Total Annual Responses: 500; Total Annual Hours: 500.*

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS’ Web site address 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](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on February 6, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—A, Attention: Melissa Musotto, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: November 30, 2006.

**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

[Document Identifier: CMS-10209, CMS-R-282, CMS-10197, and CMS-R-240]

#### Agency Information Collection Activities: Submission for OMB Review; 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), 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:* New collection; *Title of Information Collection:* Chronic Care Improvement Program (CCIP) and Medicare Advantage Quality Improvement Project (QIP); *Use:* 42 CFR 422.152 requires each Medicare Advantage Organization (MAOs) (other than Medicare Advantage (MA) private fee for service and Medical Savings Account (MSA) plans) that offers one or more MA plan to have an ongoing quality assessment and performance improvement program. Information collected in the QIP and CCIP Reporting Templates will be an integral resource for oversight, monitoring compliance and auditing activities necessary to ensure high quality provision of general health services and chronic care services to Medicare beneficiaries. *Form Number:* CMS-10209 (OMB#: 0938-New); *Frequency:* Recordkeeping, and Reporting—Annually; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 426; *Total Annual Responses:* 852; *Total Annual Hours:* 38,050.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Health Plan Appeals and Grievance Data Collection and Reporting Requirements, Data Disclosure Requirements § 422.111; *Use:* Medicare Advantage (MA) organizations and demonstrations are required to disclose information pertaining to the number of disputes, and their disposition in the aggregate. Organizations provide appeals and grievance information to individuals eligible to elect an MA organization, or persons or entities making the request

on behalf of the individuals who request this information. MA eligible individuals will use this information to help them make informed decisions about their organization’s performance in the area of appeals and grievances. *Form Number:* CMS-R-0282 (OMB#: 0938-0778); *Frequency:* Recordkeeping, Third Party Disclosure and Reporting—Semi-annually; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 434; *Total Annual Responses:* 868; *Total Annual Hours:* 876.

3. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Evaluation of the Medicare National Competitive Bidding Program for DME; *Use:* Section 302(b) of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires the Centers for Medicare and Medicaid Services (CMS) to begin a program of competitive bidding for durable medical equipment (DME), supplies, certain orthotics, and enteral nutrients and related equipment and supplies. Section 303(d) of the MMA requires a Report to Congress on the program, covering program savings, reductions in cost sharing, impacts on access to and quality of affected goods and services, and beneficiary satisfaction. This project’s purpose is to provide information for this Report to Congress. *Form Number:* CMS-10197 (OMB#: 0938-New); *Frequency:* Reporting—Other: Baseline and Follow-up; *Affected Public:* Individuals or Households, Business or other for-profit, Federal Government and Not-for-profit institutions; *Number of Respondents:* 12,671; *Total Annual Responses:* 12,671; *Total Annual Hours:* 6,557.

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Provider-based Status Regulations in 42 CFR 413.24 and 413.65; *Use:* Section 1833(t) of the Social Security Act (of the Act), as amended by section 4523 of the Balanced Budget Act of 1997 (the BBA) requires the Secretary to establish a prospective payment system (PPS) for hospital outpatient services. Successful implementation of an outpatient PPS requires that CMS distinguish facilities or organizations that function as departments of hospitals from those that are freestanding, so that CMS can determine which services should be paid under the PPS. Regulations found at 42 CFR 413.65(b)(3) and (c) require the submission of the information CMS needs to make the determination of whether an organization functions as a department of a hospital or functions as