

Responses: 6,050; Total Annual Hours: 42,350.

### 3. Type of Information Collection

*Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Authorization to Disclose Personal Health Information; *Form Number:* CMS-10106 (OMB#: 0938-931); *Use:* Unless permitted or required by law, § 164.508 of the Standards for Privacy of Individually Identifiable Health Information final rule (67 FR 53182) prohibits Medicare, a Health Insurance Portability and Accountability (HIPAA) covered entity, from disclosing an individual's protected health information without a valid authorization. In order to be valid, an authorization must include specified core elements and statements. Medicare will make available to Medicare beneficiaries a standard, valid authorization to enable beneficiaries to request the disclosure of their protected health information. This standard authorization will simplify the process of requesting information disclosure for beneficiaries and minimize the response time for Medicare. The completed authorization will allow Medicare to disclose an individual's personal health information to a third party at the individual's request. *Frequency:* Reporting—On occasion; *Affected Public:* Individuals or households; *Number of Respondents:* 1,000,000; *Total Annual Responses:* 1,000,000; *Total Annual Hours:* 250,000.

### 4. Type of Information Collection

*Request:* Revision of a currently approved collection. In this revision, a number of changes were made to the form and accompanying instructions to facilitate the completion and data entry of the form. Specifically, the enumeration of individuals involved in laboratory testing was eliminated, and the reporting of hours of laboratory operations was streamlined. Some fields were expanded to reflect changes in laboratory demographics (added prison and assisted living facility to location of laboratory testing) and to collect complete information on the number of tests performed in laboratories. There are no program changes; *Title of Information Collection:* Clinical Laboratory Improvement Amendments Application Form and Supporting Regulations at 42 CFR 493.1-2001; *Form Number:* CMS-116 (OMB#: 0938-0581); *Use:* The application must be completed by entities performing laboratory's testing specimens for diagnostic or treatment purposes. This information is vital to the certification process. *Frequency:* Reporting—Biennially; *Affected Public:* Business or other for-

profit and Not-for-profit institutions; *Number of Respondents:* 187,000; *Total Annual Responses:* 17,960; *Total Annual Hours:* 22,450.

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 August 7, 2007.

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

Dated: May 31, 2007.

#### 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-10137, CMS-10069 and CMS-R-246]

#### 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:* Revision of a currently approved collection; *Title of Information Collection:* Application for Prescription Drug Plans (PDP); Application for Medicare Advantage Prescription Drug (MA-PD); Application for Cost Plans to Offer Qualified Prescription Drug Coverage; Application for Employer Group Waiver Plans to Offer Prescription Drug Coverage; Service Area Expansion Application for Prescription Drug Coverage; *Use:* Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The application requirements are codified in Subpart K of 42 CFR part 423. Coverage for the prescription drug benefit is provided through prescription drug plans (PDPs) that offer drug-only coverage, or through Medicare Advantage (MA) organizations that offer integrated prescription drug and health care coverage (MA-PD plans). PDPs must offer a basic drug benefit. Medicare Advantage Coordinated Care Plans (MA-CCPs) must offer either a basic benefit or may offer broader coverage for no additional cost. Medicare Advantage Private Fee for Service Plans (MA-PFFS) may choose to offer a Part D benefit. Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Plans may also provide a Part D benefit. If any of the contracting organizations meet basic requirements, they may also offer supplemental benefits through enhanced alternative coverage for an additional premium.

The information will be collected under the solicitation of proposals from PDP, MA-PD, Cost Plan, and Employer Group Waiver Plans applicants. The collected information will be used by CMS to: (1) Insure that applicants meet CMS requirements, and (2) support the determination of contract awards.

The major program change that has occurred in Part D applications was that CMS removed several attestations related to Health Insurance Portability and Accountability Act (HIPAA), bids and privacy; *Form Number:* CMS-10137 (OMB#: 0938-0936); *Frequency:* Reporting: Once; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 857; *Total Annual Responses:* 857; *Total Annual Hours:* 28,122.

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare Waiver Demonstration Application; *Use:* The Medicare Waiver Demonstration Application will be used to collect standard information needed to implement congressionally mandated and administration high priority demonstrations. The application will be used to gather information about the characteristics of the applicant's organization, benefits, and services they propose to offer, success in operating the model, and evidence that the model is likely to be successful in the Medicare program. The standard application will be used for all waiver demonstrations and will reduce the burden on applicants, provide for consistent and timely information collections across demonstrations, and provide a user-friendly format for respondents; *Form Number:* CMS-10069 (OMB#: 0938-0880); *Frequency:* Reporting: Once; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 75; *Total Annual Responses:* 75; *Total Annual Hours:* 6000.

3. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare CAHPS Survey; *Use:* The collection of Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey measures is necessary to hold health and prescription drug plans accountable for the quality of care and services they deliver. This requirement will allow CMS to obtain information for the proper oversight of the program. This information is used to help beneficiaries choose among plans, contribute to improved quality of care through identification of quality improvement opportunities, and assist CMS in carrying out its responsibilities; *Form Number:* CMS-R-246 (OMB#: 0938-0732); *Frequency:* Reporting: Yearly; *Affected Public:* Individuals or households; *Number of Respondents:* 660,000; *Total Annual Responses:* 660,000; *Total Annual Hours:* 217,800.

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.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: May 31, 2007.

**Michelle Shortt,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Request for Notification From Industry Organizations Interested in Participating in Selection Process for Nonvoting Industry Representatives on Public Advisory Committees and Request for Nominations for Nonvoting Industry Representatives on Public Advisory Committees

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on its public advisory committees for the Center for Drug Evaluation Research (CDER) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on CDER's public advisory committees. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

**DATES:** Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by July 9, 2007, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by July 9, 2007.

**ADDRESSES:** All letters of interest and nominations should be submitted in writing to Jayne Peterson (see **FOR FURTHER INFORMATION CONTACT**).

**FOR FURTHER INFORMATION CONTACT:** Jayne Peterson, Advisors and

Consultants Staff (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: [jayne.peterson@fda.hhs.gov](mailto:jayne.peterson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Section 120 of the FDA Modernization Act of 1997 (FDAMA) (21 U.S.C. 355) requires that newly formed FDA advisory committees include representatives from the drug manufacturing industries. Although not required for committees existing prior to the passage of FDAMA, to keep within the spirit of FDAMA, the agency has added nonvoting industry representatives to CDER advisory committees identified in the following paragraphs.

#### I. CDER Advisory Committees

##### 1. *Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (Formerly Advisory Committee for Pharmaceutical Science)*

Advises on scientific and technical issues concerning the safety and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases.

##### 2. *Advisory Committee for Reproductive Health Drugs*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in obstetrics, gynecology, and contraception.

##### 3. *Anesthetic and Life Support Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in anesthesiology and surgery.

##### 4. *Anti-Infective Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

##### 5. *Antiviral Drugs Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), HIV-related illnesses, and other viral, fungal, and mycobacterial infections.

##### 6. *Arthritis Advisory Committee*

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human