

have been refined. CMS is also preparing a system of records (SOR) notice.

Applications are received, and distributed to all workgroup members. Workgroup members review the material and provide comments at the HCPCS workgroup meetings. Discussions are posted to CMS' HCPCS website. Final decisions are released to the applicant via letter; and all resulting modifications to the HCPCS codes are reflected on the HCPCS update. *Form Number:* CMS-10224 (OMB#: 0938-New); *Frequency:* Reporting: Occasionally; *Affected Public:* Business or other for-profit and State, Local or Tribal Government; *Number of Respondents:* 300; *Total Annual Responses:* 300; *Total Annual Hours:* 3,300.

**2. Type of Information Collection**  
*Request:* New collection; *Title of Information Collection:* Data Collection for the Nursing Home Value-Based Purchasing (NHVBP) Demonstration; *Use:* The NHVBP Demonstration is a CMS "pay-for-performance" initiative to improve the quality of care furnished to Medicare beneficiaries residing in nursing homes. Under this three-year demonstration project, CMS will assess the performance of nursing homes based on selected quality measures, and then make additional payments to those nursing homes that achieve a higher performance based on those measures. In the first year of the demonstration, quality will be assessed based on the following four domains: staffing, appropriate hospitalizations, outcome measures from the minimum data set (MDS), and survey deficiencies. Additional quality measures may be added in the second and third years of the demonstration as deemed appropriate.

The main purpose of the NHVBP data collection effort is to gather information that will enable CMS to determine which nursing homes will be eligible to receive incentive payments under the NHVBP Demonstration. All measures included in the MDS outcomes, survey deficiency, and appropriate hospitalization domains can be calculated from existing secondary data sources, such as the MDS, annual nursing home certification surveys, and Medicare claims data. However, for the staffing domain, no satisfactory alternative source for these data has been identified. Therefore, CMS will collect payroll-based staffing and resident census information to help assess the quality of care in participating nursing homes. CMS will additionally collect data on two measures, staff immunization status and

use of resident care experience surveys, which may be included in the payment determination during the second and third years of the demonstration. *Form Number:* CMS-10240 (OMB#: 0938-New); *Frequency:* Reporting: Once; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 1,250; *Total Annual Responses:* 2,000; *Total Annual Hours:* 49,170.

**3. Type of Information Collection**  
*Request:* Extension of a currently approved collection; *Title of Information Collection:* Recognition of pass-through payment for additional (new) categories of devices under the Outpatient Prospective Payment System and Supporting Regulations in 42 CFR, Part 419; *Use:* Section 201(b) of the Balanced Budget Act of 1999 amended section 1833(t) of the Social Security Act (the Act) by adding new section 1833(t)(6). This provision requires the Secretary to make additional payments to hospitals for a period of 2 to 3 years for certain drugs, radiopharmaceuticals, biological agents, medical devices and brachytherapy devices. Section 1833(t)(6)(A)(iv) establishes the criteria for determining the application of this provision to new items. Section 1833(t)(6)(C)(ii) provides that the additional payment for medical devices be the amount by which the hospital's charges for the device, adjusted to cost, exceed the portion of the otherwise applicable hospital outpatient department fee schedule amount determined by the Secretary to be associated with the device. Section 402 of the Benefits Improvement and Protection Act of 2000 made changes to the transitional pass-through provision for medical devices. The most significant change is the required use of categories as the basis for determining transitional pass-through eligibility for medical devices, through the addition of section 1833(t)(6)(B) of the Act.

Interested parties such as hospitals, device manufacturers, pharmaceutical companies, and physicians apply for transitional pass-through payment for certain items used with services covered in the outpatient prospective payment system. After CMS receives all requested information, CMS will evaluate the information to determine if the creation of an additional category of medical devices for transitional pass-through payments is justified. *Form Number:* CMS-10052 (OMB#: 0938-0857); *Frequency:* Reporting: Yearly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 160.

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 September 18, 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: July 12, 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-R-244 and CMS-18F5]

### 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:* Extension of a currently approved collection; *Title of Information Collection:* The Medicare and Medicaid Programs: Programs of All-inclusive Care for the Elderly (PACE); *Form Number:* CMS-R-244 (OMB#: 0938-0790); *Use:* PACE organizations must demonstrate their ability to provide quality community-based care for the frail elderly who meet their State's nursing home eligibility standards using capitated payments from Medicare and the State. PACE programs must provide all Medicare and Medicaid covered services including hospital, nursing home, home health, and other specialized services. This collection is necessary to ensure that only appropriate organizations are selected to become PACE organizations and that CMS has the information necessary to monitor the care they provide; *Frequency:* Reporting—Once and on occasion; *Affected Public:* Not-for-profit institutions and State, Local, or Tribal Governments; *Number of Respondents:* 54; *Total Annual Responses:* 108; *Total Annual Hours:* 44131.50.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Application for Hospital Insurance Benefits; *Form Number:* CMS-18F5 (OMB#: 0938-0251); *Use:* The CMS-18F5 form is used to establish entitlement to and enrollment in Part A of Medicare for beneficiaries who are not automatically entitled to Medicare Part A under Title XVIII of the Social Security Act and must file an application. Sections 226(a), 227 and 1818A of the Social Security Act and sections 42 CFR 406.10, 406.11 and 406.20 outline the requirements for entitlement to Medicare hospital insurance (Part A). Section 42 CFR 406.6 provides information about who needs to file an application for Part A and who does not. Section 42 CFR 406.7 lists the CMS-18F5 form as the application to be used by individuals applying for Part A of Medicare. The CMS-18F5 form was designed to capture all the information needed to make a determination of an individual's entitlement to hospital insurance (Part A); *Frequency:* Reporting—once; *Affected Public:* Individuals or households; *Number of Respondents:* 50,000; *Total Annual Responses:* 50,000; *Total Annual Hours:* 12,495.

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: July 12, 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

#### Blood Products Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Blood Products Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on August 16, 2007, from 8 a.m. to 5 p.m.

*Location:* Doubletree Hotel and Executive Meeting Center, 8120 Wisconsin Ave., Bethesda, MD 20814.

*Contact Person:* Donald W. Jehn or Pearlina K. Muckelvene, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike (HFM-71), Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal**

**Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On August 16, 2007, the Committee will hear updates on the following topics: (1) Summary of the May 10 through 11, 2007, and the August 6 through 7, 2007, meetings of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability; (2) summary of the April 25 through 26, 2007, FDA Workshop on Immune Globulins for Primary Immune Deficiency Diseases: Antibody Specificity, Potency and Testing; and (3) summary of the August 15, 2007, FDA Workshop on Licensure of Apheresis Blood Products. The Committee will then hear informational presentations relating to World Health Organization (WHO) biological standards on the following topics: (1) Summary of the January 29 through 30, 2007, WHO meeting with WHO collaborating centers for biological standards and standardization to support the development of WHO biological reference preparations for high risk blood safety-related in vitro diagnostics; (2) potency and safety standards for plasma derivatives; and (3) joint FDA/WHO minimum potency standards for certain blood grouping reagents. The Committee will hear the response of the Office of Blood Research and Review to their office level site visit of July 22, 2005. In the afternoon the Committee will discuss measles antibody levels in U.S. Immune Globulin products.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2007 and scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 8, 2007. Oral presentations from the public will be