

*Respondents: 2,700,000; Total Annual Responses: 2,700,000; Total Annual Hours: 1,360,000.* (For policy questions regarding this collection contact Debbie Skinner at 410-786-7480. 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 address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email 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.

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 **June 26, 2012**:

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: April 24, 2012.

**Martique Jones,**

*Director, Regulations Development Group, Division B 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-10102, CMS-R-263 and CMS-855(O)]**

**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:* National Implementation of Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS); *Use:* The HCAHPS (*Hospital Consumer Assessment of Healthcare Providers and Systems*) survey is the first national, standardized, publicly reported survey of patients' perspectives of hospital care. HCAHPS (pronounced "*H-caps*"), also known as the CAHPS® Hospital Survey, is a survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience. While many hospitals have collected information on patient satisfaction for their own internal use, until HCAHPS there was no national standard for collecting and publicly reporting information about patient experience of care that allowed valid comparisons to be made across hospitals locally, regionally and nationally.

Three broad goals have shaped HCAHPS. First, the survey is designed to produce data about patients' perspectives of care that allow objective and meaningful comparisons of hospitals on topics that are important to consumers. Second, public reporting of the survey results creates new incentives for hospitals to improve quality of care. Third, public reporting serves to enhance accountability in health care by increasing transparency of the quality of hospital care provided in return for the public investment. With these goals in mind, the Centers for Medicare & Medicaid Services (CMS) has taken substantial steps to assure that the survey is credible, useful, and practical. Hospitals implement HCAHPS under the auspices of the Hospital Quality Alliance (HQA), a private/public partnership that includes major hospital and medical associations,

consumer groups, measurement and accrediting bodies, government, and other groups that share an interest in improving hospital quality. Both the HQA and the National Quality Forum have endorsed HCAHPS.

The enactment of the Deficit Reduction Act of 2005 created an additional incentive for acute care hospitals to participate in HCAHPS. Since July 2007, hospitals subject to the Inpatient Prospective Payment System (IPPS) annual payment update provisions ("subsection (d) hospitals") must collect and submit HCAHPS data in order to receive their full IPPS annual payment update. IPPS hospitals that fail to publicly report the required quality measures, which include the HCAHPS survey, may receive an annual payment update that is reduced by 2.0 percentage points. Non-IPPS hospitals, such as Critical Access Hospitals, may voluntarily participate in HCAHPS.

The Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) includes HCAHPS among the measures to be used to calculate value-based incentive payments in the Hospital Value-Based Purchasing program, beginning with discharges in October 2012.

Currently the HCAHPS survey asks discharged patients 27 questions about their recent hospital stay. The survey contains 18 core questions about critical aspects of patients' hospital experiences (communication with nurses and doctors, the responsiveness of hospital staff, the cleanliness and quietness of the hospital environment, pain management, communication about medicines, discharge information, overall rating of hospital, and would they recommend the hospital). The survey also includes four items to direct patients to relevant questions, three items to adjust for the mix of patients across hospitals, and two items that support Congressionally-mandated reports.

This revision is being submitted in order to add five new items to the survey: three items that comprise a Care Transitions composite; one item that asks whether the patient was admitted through the emergency room; and one item that asks about the patient's overall mental health. This marks the first addition of items to the HCAHPS Survey since its national implementation in 2006. *Form Number:* CMS-10102 (OCN: 0938-0981); *Frequency:* Occasionally; *Affected Public:* Individuals or Households, Private Sector—Business or other for-profits and not-for-profit institutions. *Number of Respondents:* 2,713,812; *Total Annual Responses:* 2,713,812;

*Total Annual Hours:* 365,136. (For policy questions regarding this collection contact William Lehrman at 410-786-1037. For all other issues call 410-786-1326.)

### 2. Type of Information Collection

*Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Site Investigation for Durable Medical Equipment (DME) Suppliers; *Use:* CMS is mandated to identify and implement measures to prevent fraud and abuse in the Medicare program. To meet this challenge, CMS has moved forward to improve the quality of the process for enrolling suppliers into the Medicare program by establishing a uniform application for enumerating suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Implementation of enhanced procedures for verifying the enrollment information has also improved the enrollment process. As part of this process, verification of compliance with supplier standards is necessary. The site investigation form has been used in the past to aid the Medicare contractor (the National Supplier Clearinghouse and/or its subcontractors) in verifying compliance with the required supplier standards found in 42 CFR 424.57(c). The primary function of the site investigation form is to provide a standardized, uniform tool to gather information from a DMEPOS supplier (as found in 42 CFR 424.57(c)) and where it practices or renders its services.

This site investigation form collects the same information as its predecessor, with the exception of one new yes/no question under the "Records and Telephone" section (question 11(a)) used to verify if the DMEPOS supplier maintains physician ordering/referring records for the supplies and/or services it renders to Medicare beneficiaries (if applicable). This information is required by section 1833(g) of the Social Security Act (the Act) which states that all physicians and non-physician practitioners that meet the definitions at section 1861(r) and 1842(b)(18)(C) of the Act, be uniquely identified for all claims for services that are ordered or referred. Other information collected on this site investigation remains unchanged, but has been reformatted for greater functionality. *Form Number:* CMS-R-263 (OCN: 0938-0749); *Frequency:* Once; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 30,000; *Total Annual Responses:* 30,000; *Total Annual Hours:*

15,000. (For policy questions regarding this collection contact Kimberly McPhillips at 410-786-5374. For all other issues call 410-786-1326.)

### 3. Type of Information Collection

*Request:* Revision of a currently approved collection;

*Title of Information Collection:* Medicare Registration Application; *Use:* The CMS 855O allows a physician to receive a Medicare identification number (without being approved for billing privileges) for the sole purpose of ordering and referring Medicare beneficiaries to Medicare approved providers and suppliers. This new Medicare registration application form allows physicians who do not provide services to Medicare beneficiaries to be given a Medicare identification number without having to supply all the data required for the submission of Medicare claims. It also allows the Medicare program to identify ordering and referring physicians without having to validate the amount of data necessary to determine claims payment eligibility (such as banking information), while continuing to identify the physician's credentials as valid for ordering and referring purposes. Since the physicians and non-physician practitioners submitting this application are not enrolling in Medicare to submit claims but are only registering with Medicare as eligible to order and refer, CMS believes changing the title from Medicare Enrollment Application to Medicare Registration Application better captures the actual purpose of this form.

Where appropriate, CMS has changed all references to enrollment or enrolling to registration and registering and Medicare billing number to National Provider Identifier. CMS also added a check box to allow physicians and non-physician practitioners to withdraw from the ordering and referring registry. A section to collect information on professional certifications was added for those practitioners who are not professionally licensed. Editorial and formatting corrections were made in response to prior comments received during the approval of the current version of this application. Other minor editorial and formatting corrections were made to better clarify the purpose of this application. *Form Number:* CMS-855(O) (OCN: 0938-1135); *Frequency:* Occasionally; *Affected Public:* Individuals; *Number of Respondents:* 48,500; *Total Annual Responses:* 48,500; *Total Annual Hours:* 24,125. (For policy questions regarding this collection contact Kimberly McPhillips at 410-786-5374. 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 address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email 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 by the OMB desk officer at the address below, no later than 5 p.m. on May 29, 2012.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

Dated: April 24, 2012.

#### Martique Jones,

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

#### Circulatory System Devices Panel of the Medical Devices 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:* Circulatory System Devices Panel of the Medical Devices 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 June 13, 2012, from 8 a.m. to 6 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is 301-977-8900.

*Contact Person:* Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product