

functional status and other factors related to outcomes and resource utilization at admission, discharge, and interim times during post acute treatment, and (3) understand the relationship between severity of illness, functional status, social support factors, and resource utilization. The CARE instrument will be used in the Post-Acute Care (PAC) Payment Reform Demonstration program mandated by Section 5008 of the Deficit Reduction Act of 2005 to develop payment groups that reflect patient severity and related cost and resource use across post acute settings. Specifically, the data collected using the CARE instrument during the Post-Acute Care Payment Demonstration will be used by CMS to develop a setting neutral post-acute care payment model as mandated by the Congress. The data will be used to characterize patient severity of illness and level of function in order to predict resource use, post-acute care discharge placement, and beneficiary outcomes. CMS will use the data from the CARE instrument to examine the degree to which the items on the instrument can be used to predict beneficiary resource use and outcomes.

CMS made over 150 changes and improvements to the CARE instrument following the 60 day public comment period. Many revisions were minor word changes or clarifications to item-coding instructions. A significant number of changes were made to delete unnecessary items and to add skip patterns to allow respondents to skip over items/sections that do not apply to a particular condition. The revised version of CARE retains its clinical integrity while allowing for greater response specificity. *Form Number:* CMS-10243 (OMB#: 0938-NEW); *Frequency:* Reporting—Daily; *Affected Public:* Private Sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 388; *Total Annual Responses:* 244,292; *Total Annual Hours:* 179,341.

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, 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 December 10, 2007. 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 2, 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-10239 and CMS-R-48]

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:* Conditions of Participation for Critical Access Hospitals; *Use:* With this submission, we are creating a new information collection request for critical access hospitals (CAH). Currently, the information collection requirements associated with the critical access hospital (CAH) conditions of participation (CoPs) are included with the hospital CoPs reported under CMS-R-48 (0938-0328). Because the CAH program has grown in scope of services and the number of providers, we have removed the CAH burden from the

CMS-R-48 with the exception of the burden associated with the 101 CAHs that have distinct part units (DPUs), and created a separate information collection request for OMB review and approval. Section 1820(c)(2)(E)(i) of the Social Security Act states that if a CAH operates a distinct part psychiatric or rehabilitation unit it must have 10 beds or less in the DPU and it must comply with the hospital requirements specified in 42 CFR Subpart A, B, C, and D of part 482. Based on 2007 data from HRSA, 81 CAHs have psychiatric distinct part units (DPUs) and 20 CAHs have rehabilitation DPUs. The burden associated with the 101 CAHs with DPUs is reported in CMS-R-48. *Form Number:* CMS-10239 (OMB#: 0938-NEW); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profit; *Number of Respondents:* 1,189; *Total Annual Responses:* 137,990; *Total Annual Hours:* 23,291.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Hospital Conditions of Participation and Supporting Regulations in 42 CFR 482.12, 482.13, 482.21, 482.22, 482.23, 482.24, 482.27, 482.30, 482.41, 482.43, 482.45, 482.53, 482.56, 482.57, 482.60, 482.61, 482.62, and 485.616 and 485.631; *Use:* The information collection requirements described in this information collection request are needed to implement the Medicare and Medicaid conditions of participation (CoP) for 4,890 accredited and non-accredited hospitals and an additional 101 critical access hospitals (CAHs) that have distinct part psychiatric or rehabilitation units (DPUs). CAHs that have DPUs must comply with all of the hospital CoPs on these units. Thus, this package reflects the paperwork burden for a total of 4,991 (that is, 4,890 hospitals and 101 CAHs which include 81 CAHs that have psychiatric DPUs and 20 CAHs that have rehabilitation DPUs). The information collection requirements for the remaining 1,183 CAHs have been reported in a separate package under CMS-10239.

The CoPs and accompanying requirements specified in the regulations are used by our surveyors as a basis for determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid. CMS and the health care 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. *Form Number:* CMS-R-48 (OMB#: 0938-328); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profit; *Number of Respondents:* 4,991; *Total Annual Responses:* 1,120,817; *Total Annual Hours:* 9,151,200.57.

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, 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 January 8, 2008. CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: November 2, 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

[Docket No. 2007N-0422]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in the Medical Device Fellowship Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the application for participation in the Medical Device Fellowship Program (MDFP).

DATES: Submit written or electronic comments on the collection of information by January 8, 2008.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each

proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Application for Participation in the Medical Device Fellowship Program; 5 U.S.C. 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 (OMB Control Number 0910-0551)—Extension

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code, authorize Federal agencies to rate applicants for Federal jobs. Collecting applications for the MDFP will allow FDA's Center for Devices and Radiological Health (CDRH) to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in CDRH activities. The process will reduce the time and cost of submitting written documentation to the agency and lessen the likelihood of applications being misrouted within the agency mail system. It will assist the agency in promoting and protecting the public health by encouraging outside persons to share their expertise with CDRH.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

5 U.S.C. Section/ FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1104, 1302, 3301, 3304, 3320, 3361, 3393, 3394/ Form No. 3608	250	1	250	1	250

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.