

program in question; that office or organization has the responsibility for making decisions about such definitions (to the extent that the definition is not already contained in legislation or regulations).

Dated: February 14, 2005.

**Michael O. Leavitt,**

*Secretary of Health and Human Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

[Document Identifier: CMS-10134 and CMS-10138]

#### Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

**AGENCY:** Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and 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 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.

We are, however, requesting an emergency review of the information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with an initiative of the

Administration and is required in order to meet the demands of new legislation. We cannot reasonably comply with the normal clearance procedures because of statutory deadlines.

The Benefits Improvement & Protection Act of 2000 mandated the Physician Group Practice (PGP) Demonstration and gave the Secretary discretion to use quality measures to assess physician performance in order to reward them for improvements in the quality and efficiency of health care.

The Medicare Care Management Performance (MCMP) Demonstration was authorized by Section 649 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The project requires the Secretary to establish a pay-for-performance 3-year pilot with physicians to promote the adoption and use of health information technology to improve the quality of patient care for chronically ill Medicare patients. The mandate specifies that rewards shall be based on the electronic reporting of clinical quality and outcomes measures in accordance with requirements established by the Secretary under the demonstration program.

CMS is requesting OMB review and approval of this collection by April 1, 2005, with a 180-day approval period. Written comments and recommendation will be considered from the public if received by the individuals designated below by March 18, 2005.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Physician Group Practice (PGP) Standardized Ambulatory Care Quality Measure Collection Initiative; *Use:* The Benefits Improvement & Protection Act of 2000 mandated the Physician Group Practice (PGP) Demonstration and gave the Secretary discretion to use quality measures to assess physician performance in order to reward them for improvements in the quality and efficiency of health care. This demonstration is intended to strengthen the Medicare program by offering innovative models to people on Medicare that improve quality and access and lower costs. As a result, people on Medicare will directly benefit from these innovative models.; *Form Number:* CMS-10134 (OMB#: 0938-NEW); *Frequency:* Annually; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 790.

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Medicare Care

Management Performance (MCMP) Demonstration—Standardized Ambulatory Care Quality Collection Initiative; *Use:* The MCMP Demonstration was authorized by Section 649 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This project requires the Secretary to establish a pay-for-performance 3-year pilot with physicians to promote the adoption and use of health information technology to improve the quality of patient care for chronically ill Medicare patients. This demonstration represents the first pay for performance project fostering the adoption of health information technology in small physician group practices and will enable a test of the concept to improve the quality and efficiency of care in Fee-for-Service (FFS) Medicare.; *Form Number:* CMS-10138 (OMB# 0938-NEW); *Frequency:* Annually; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 800; *Total Annual Responses:* 800; *Total Annual Hours:* 15,200.

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://cms.hhs.gov/regulations/pract/>, 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 received by the designees referenced below by March 18, 2005: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Dawn Willingham, CMS-10134 and CMS-10138, Room C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850; and, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn.: Christopher Martin, Desk Officer, Fax # 202-395-6974.

Dated: February 8, 2005.

**John P. Burke, III,**

*CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10115, CMS-2552 and CMS-R-148]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services.

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:** Federal Funding of Emergency Health Services (Section 1011); Enrollment Application; **Use:** These information collections will allow hospitals and other providers to enroll to receive payment for Section 1011 claim submissions. Section 1011 provides \$250 million per year for fiscal years 2005-2008 for payments to eligible providers for emergency health services provided to undocumented aliens and other specified aliens; **Form Number:** CMS-10115 (OMB#: 0938-0929); **Frequency:** Other: as needed; **Affected Public:** Business or other for-profit, Not-for-profit institutions, and State, local or tribal govt.; **Number of Respondents:** 62,500; **Total Annual**

**Responses:** 62,500; **Total Annual Hours:** 31,250.

**2. Type of Information Collection Request:** Revision of a currently approved collection; **Title of Information Collection:** Hospital and Health Care Complexes Cost Report and Supporting Regulations in 42 CFR 413.20 and 413.24; **Use:** This form is completed by Hospitals and Health Care Complexes participating in the Medicare program. Hospitals and Health Care Complexes use this form to report the health care costs for services they provide. The information reported on this form is used by CMS to determine the amount of reimbursable costs for services rendered to Medicare beneficiaries. The revisions to this form contain the provisions for implementing section 422 of the MMA. Section 422 deals with the calculation of GME and IME payments for redistribution of unused resident slots; **Form Number:** CMS-2552-96 (OMB# 0938-0050); **Frequency:** Annually; **Affected Public:** Business or other for-profit, Not-for-profit institutions, and State, local or tribal government; **Number of Respondents:** 6,111; **Total Annual Responses:** 6,111; **Total Annual Hours:** 4,046,782.

**3. Type of Information Collection Request:** Reinstatement, without change, of a previously approved collection for which approval has expired; **Title of Information Collection:** Limitations on Provider Related Donations and Health Care Related Taxes; Limitation on payments to Disproportionate Share Hospitals; Medicaid and Supporting Regulations in 42 CFR 433.68, 433.74, and 447.272; **Use:** This information collection is necessary to ensure compliance with Sections 1903 and 1923 of the Social Security Act for the purpose of preventing payment of federal financial participation on amounts prohibited by the statute. State Medicaid agencies must report quarterly on the source of provider related donations received by the State or unit of local government, and health care related taxes collected. Failure to collect the funding data on a quarterly basis may result in Federal funds not being returned promptly and properly to the Federal Government; **Form Number:** CMS-R-148 (OMB#: 0938-0618); **Frequency:** Quarterly and as needed; **Affected Public:** State, Local or Tribal Government; **Number of Respondents:** 50; **Total Annual Responses:** 40; **Total Annual Hours:** 3,200.

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/>

[regulations/pa/](mailto:regulations/pa/), 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 within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 11, 2005.

**Michelle Shortt,**

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

[FR Doc. 05-3127 Filed 2-17-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Nonprescription Drugs 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:** Nonprescription Drugs 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 March 23, 2005, from 8 a.m. to 5:30 p.m.

**Location:** Hilton Washington DC North, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

**Contact Person:** Shalini Jain, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery: 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, FAX: 301-827-6801, e-mail: [jains@cder.fda.gov](mailto:jains@cder.fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512541. Please call the Information Line for up-to-date information on this meeting.

**Agenda:** On March 23, 2005, the committee will discuss the microbiologic surrogate endpoints used