

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/, 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.

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.

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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, 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