

1. *Type of Information Collection Request:* Extension of currently approved collection.

Title of Information Collection: Hospice Cost Report and Supporting Regulations Contained in 42 CFR 413.20 and 413.24.

Use: The hospice cost report is the mechanism used to collect data from providers for rate evaluations for the Prospective Payment System (PPS). Once CMS obtains this information, we will update the PPS as mandated by Congress.

Form Number: CMS-R-249 (OMB#: 0938-0758).

Frequency: Annually.

Affected Public: Not-for-profit Institutions and Business or other for-profit.

Number of Respondents: 1,720.

Total Annual Responses: 1,720.

Total Annual Hours: 302,720.

2. *Type of Information Collection*

Request: Extension of currently approved collection.

Title of Information Collection: Outpatient Rehabilitation Cost Report and Supporting Regulations Contained in 42 CFR 413.20 and 413.24.

Use: This form is used by community mental health centers to report their health care costs to determine the amount of reimbursement for services furnished to Medicare beneficiaries.

Form Number: CMS-2088-92 (OMB#: 0938-0037).

Frequency: Annually.

Affected Public: Business or other for-profit; Not-for profit Institutions, State, Local or Tribal governments.

Number of Respondents: 618.

Total Annual Responses: 618.

Total Annual Hours: 61,800.

3. *Type of Information Collection*

Request: Extension of a currently approved collection.

Title of Information Collection: Hospital Conditions of Participation (COP) and Supporting Regulations in 42 CFR 482.12, 482.13, 482.21, 482.22, 482.27, 482.30, 482.41, 482.43, 482.45, 482.53, 482.56, 482.57, 482.60, 482.61, 482.62, 485.618 and 485.631.

Use: Hospitals seeking to participate in the Medicare and Medicaid programs must meet the Conditions of Participation (COP) for Hospitals, 42 CFR Part 482. The information collection requirements contained in this package are needed to implement the Medicare and Medicaid COP for hospitals and critical access hospitals (CAHs).

Form Number: CMS-R-48 (OMB# 0938-0328).

Frequency: Annually.

Affected Public: Business or other for-profit, Not-for-profit institutions,

Federal Government, and State, Local or Tribal Gov.

Number of Respondents: 6,085.

Total Annual Responses: 6,085.

Total Annual Hours: 5,511,544.

4. *Type of Information Collection*

Request: Revision of currently approved collection.

Title of Information Collection: ESRD Beneficiary Selection and Supporting Regulations Contained in 42 CFR 414.330.

Use: ESRD facilities have each new home dialysis patient select one of two methods to handle Medicare reimbursement. The intermediaries pay for the beneficiaries selecting Method I and the carriers pay for the beneficiaries selecting Method II. This system was developed to avoid duplicate billing by both intermediaries and carriers.

Form Number: CMS-382 (OMB#: 0938-0372).

Frequency: Other: One time only.

Affected Public: Individuals or Households, Business or other for-profit, and Not-for profit Institutions.

Number of Respondents: 7,400.

Total Annual Responses: 7,400.

Total Annual Hours: 617.

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/pral/>, 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: November 18, 2004.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0114]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Protection of Human Subjects; Recordkeeping Requirements for Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Protection of Human Subjects; Recordkeeping Requirements for Institutional Review Boards" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of July 22, 2004, (69 FR 43852) the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0130. The approval expires on November 30, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: November 26, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.