

on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: July 9, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-17538 Filed 7-12-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-339]

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare Provider Cost Report Reimbursement Questionnaire and Supporting Regulations in 42 CFR 413.20, 413.24, 415.50, 415.55, 415.60, 415.70, 415.150,

415.152, 415.160, and 415.162; *Form No.:* HCFA-339 (OMB# 0938-0301); *Use:* The Medicare Provider Cost Report Reimbursement Questionnaire must be completed by all providers to assist in preparing an acceptable cost report, to ensure proper Medicare reimbursement, and to minimize subsequent contact between the provider and its fiscal intermediary. It is designed to answer pertinent questions about key reimbursement concepts found in the cost report and to gather information necessary to support certain financial and statistical entries on the cost report. In addition, it provides an audit trail for the fiscal intermediary; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, local and tribal government; *Number of Respondents:* 33,144; *Total Annual Responses:* 33,144; *Total Annual Hours:* 1,342,332.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web Site Address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address and phone number, to Paperwork@hcfa.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 designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: June 19, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01-17514 Filed 7-12-01; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-10036]

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget

(OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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.

Type of Information Collection

Request: New Collection;

Title of Information Collection:

Request to Use Inpatient Rehabilitation Assessment Instrument and Data Set for PPS for Inpatient Rehabilitation Facilities: Implementation Phase and Supporting Regulations in 42 CFR, Parts 412 and 413;

Form No.: HCFA-10036 (OMB# 0938-NEW); *Use:* This is a request to use a modification of an instrument currently in use by the majority of inpatient rehabilitation facilities for the implementation phase of the prospective payment system. Use of this instrument will enable HCFA to implement a classification and payment system for the legislatively mandated inpatient rehabilitation hospital and exempt units prospective payment system.;

Frequency: On occasion; *Affected Public:* Business or other for-profit, and Not-for-profit institutions;

Number of Respondents: 359,000;

Total Annual Responses: 359,000;

Total Annual Hours: 269,250.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address and phone number, to Paperwork@hcfa.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 designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.