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.

Dated: June 26, 2001.

John P. Burke III,

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

[FR Doc. 01–17515 Filed 7–12–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Survey on Drug Use and Health Clinical Validation Study of the Substance Dependence and Abuse Measures—(New)—The Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health (NSDUH), formerly the National Household Survey on Drug Abuse, is a survey of the civilian, noninstitutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, the Office of National Drug Control Policy, other Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

From 2001–2003, the NSDUH plans a two or three-phase Clinical Validation Study of Substance Dependence and Abuse Measures. Specific aims are to achieve the best overarching format, and the best wording and ordering for the assessment questions. The goal is quicker administration time, improved validity, and reduced respondent burden.

Half of all subject will be between 12 and 17, and half 18 years of age or older; subjects will be recruited from the Research Triangle and the Triad areas of North Carolina. In Phase 1, subjects, recruited through fliers and newspaper ads, will be asked (1) demographic information and (2) questions from two self-administered sections of the NSDUH questionnaire: Questions about the quantity and frequency of use of drugs and alcohol, and questions about symptoms of substance dependence and abuse.

A semi-structured clinical interview will then be administered to these same subjects by a trained clinician to determine the presence or absence of substance dependence and abuse. The clinical instruments used to assess subjects will be the substance abuse modules from the Structured Clinical Interview for DSM–IV (SCID) (for adults) and the Kiddie Schedule for Affective Disorders and Schizophrenia (K–SADS) (for those between 12 and 17 years of age). The correspondence of the diagnosis of substance dependence and abuse between the clinical and survey interview will then be compared.

Information from Phase 1 will then be used to assess if a lack of correspondence exists between the clinical and survey measures. If there is a lack of sufficient correspondence, we will then examine reasons for any lack of correspondence, and make decisions about how to modify the NSDUH questions on substance dependence and abuse to achieve better correspondence. This information will then be used to develop a revised NSDUH substance dependence and abuse module.

In Phase 2, a second clinical validation study will be conducted using the same procedures as Phase 1. This will allow a determination of the correspondence (kappa) between the revised diagnosis obtained from the NSDUH substance dependence and abuse module and the diagnosis from the structured clinical interviews. Final revisions to the survey instrument will be made based on findings from Phase 2.

Finally, if the revised NSDUH survey assessment of substance dependence and abuse still does not have sufficient correspondence with a structured clinical interview, overall, or for certain groups (for example, youth or marijuana users) or for certain criteria (withdrawal symptoms or substance abuse without dependence), then an additional phase of the study will be undertaken. Even if the overall correspondence from Phase 2 is good, for example, additional small validation studies might be conducted for specific groups (e.g., adolescent females, Hispanics) for whom there was not good correspondence as a result of small sample sizes or real differences in interpretation of the questionnaire items. All decisions about final revisions to the module will balance the need for correspondence across different groups.

	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Phase I				
Screener only	60	1	.08	5
Screener and Interview	270	1	1.5	405
Phase II				
Screener only	100	1	.08	8
Screener and Interview	455	1	1.5	683
Phase III				
Screener only	100	1	.08	8
Screener and Interview	455	1	1.5	683
Total	1,440	.....	.....	1,792