

instruments, call the HRSA Reports Clearance Officer on (301) 443-1129. Comments are invited on: (a) Whether the proposed collection of information is 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: Impact of Accreditation on BPHC-Supported Health Centers—NEW**

The Bureau of Primary Health Care (BPHC) will conduct an evaluation of the impact of JCAHO accreditation on BPHC-supported health centers. This study will assess the impact in health centers that are accredited by the Joint Commission and those that are not,

including migrant health centers, school-based health centers, health centers for the homeless and public housing health centers. This study aims to address a key purpose of the BPHC/JCAHO Accreditation initiative: How effective is accreditation in providing a structure for health centers to integrate ongoing quality improvement into their daily operations. The assessment will be conducted by administering a mailed questionnaire to all health centers that were funded by HRSA/BPHC as of September 30, 2002.

**ESTIMATED BURDEN HOURS**

Survey	Number of respondents	Responses per respondents	Total responses	Hours per responses	Total burden hours
Assessment of Quality Structure in Health Centers .....	843	1	843	.45	380

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 18, 2004.

**Tina M. Cheatham,**  
Director, Division of Policy Review and Coordination.

[FR Doc. 04-6635 Filed 3-24-04; 8:45 am]

BILLING CODE 4165-15-P

8982, in the third column, lines 8 and 9 under the section "Application Requests, Dates and Addresses" are corrected to read: "or delivered no later than September 30, 2004 to: Division of Commissioned."

Dated: March 17, 2004.

**Tina M. Cheatham,**  
Director, Division of Policy Review and Coordination.

[FR Doc. 04-6633 Filed 3-24-04; 8:45 am]

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*Information Request:* Revision. (OMB No. 0925-0334). *Need and Use of Information Collection:* This study will quantify associations between conventional and hypothetical risk factors and coronary heart disease (CHD) and stroke in people age 65 years and older. The primary objectives include quantifying associations of risk factors with subclinical disease; characterize the natural history of CHD and stroke; and identify factors associated with clinical course. The findings will provide important information on cardiovascular disease in an older U.S. population and lead to early treatment of risk factors associated with disease and identification of factors which may be important in disease prevention. *Frequency of response:* twice a year (participants) or once per cardiovascular disease event (proxies and physicians); *Affected public:* Individuals. *Types of Respondents:* Individuals recruited for CHS and their selected proxies and physicians. The annual reporting burden is as follows: *Estimated Number of Respondents:* 3,330; *Estimated Number of Responses per respondent:* 3.76; and *Estimated Total Annual Burden Hours Requested:* 1,029. *The annualized cost to respondents is estimated at:* \$55,633.

There are no capital, operating, or maintenance costs to report.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Recruitment of Clinicians To Become Commissioned Officers; Recruitment of Sites for Assignment of Commissioned Officers; Correction**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** General notice; correction.

**SUMMARY:** The Health Resources and Services Administration published a document in the **Federal Register** of February 26, 2004, containing an incorrect deadline for clinicians to submit applications.

In FR Doc. 04-4204, in the **Federal Register** of February 26, 2004, on page

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; Comment Request; The Cardiovascular Health Study (CHS)**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* The Cardiovascular Health Study. *Type of*

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent*	Average burden hours per response	Estimated total annual burden hours requested
Participants .....	2,196	5.8	0.25	992
Physicians .....	343	1.0	0.10	11

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent*	Average burden hours per response	Estimated total annual burden hours requested
Participant proxies .....	102	1.0	0.25	26
Total .....	3,330	3.76	0.246	1,029

\* Total for 3 years.

**Request for Comments:** Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information will have practical utility; (2) The accuracy of the agency's estimate of burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of data collection plans and instruments, contact Dr. Jean Olson, Epidemiology and Biometry Program, Division of Clinical Applications, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, MSC #7934, Bethesda, MD 20892-7934, or call non-toll-free number (301) 435-0707, or e-mail your request, including your address to: [OlsonJ@nhlbi.nih.gov](mailto:OlsonJ@nhlbi.nih.gov).

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: March 16, 2004.

**Peter Savage,**

Director, DECA.

[FR Doc. 04-6732 Filed 3-24-04; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Proposed Collection; Comment Request; the Drug Accountability Record

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995,

for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**Proposed Collection: Title:** The Drug Accountability Record. **Type of Information Collection Request:** Revision. **Need and Use of Information Collection:** FDA regulations require **investigators:** To maintain adequate records of the disposition of all investigational drugs received from the sponsor; to prepare and maintain adequate case histories of treated patients and controls; and to furnish reports to the drug sponsor who is responsible for evaluating the results of the investigation. Similarly, 21 CFR 312.1 includes requirements for **sponsors** to maintain adequate records on the shipment of drugs to investigators; to make individual patient records available to the FDA for inspection; and to submit accurate progress reports of the drug investigation to the FDA. The NCI, as an IND sponsor has developed the "Drug Accountability Record" form (DARF: NIH 2564) to help investigators using NCI sponsored drugs under NCI protocols to meet FDA requirements. **Frequency of Response:** Daily. **Affected Public:** Individuals or households; businesses or other for-profit; not-for-profit institutions; Federal Government; State, local or tribal government. **Type of Respondents:** Pharmacists, nurses and investigators or their designee at medical institutions to keep track of the dispensing of investigational anticancer drugs to patients use the information entered onto the DARF. NCI uses the data from the DARF to ensure compliance with NCI's responsibilities as an IND sponsor. NCI Management request copies of the DARF at any time for audit and review and DARFs are reviewed at least once every 3 years during site audits. The information contained in the DARF is compared to PMB-IMS Inventory Module histories

for each investigator and clinical site to ensure no diversion of investigational drug supplies to inappropriate protocol or patient use. The accountability information is also compared to patient flow sheets (protocol reporting forms) during site visits conducted for each investigator. All comparisons are completed with the intention of ensuring protocol integrity, patient safety, and compliance with FDA regulations. Record keeping of drug accountability information in a standard format is required to allow an investigator to receive, and continue to receive NCI-sponsored drugs. This information is reviewed at the time of site visit audits, which currently occur at least once every 3 years. The IND sponsor may also request the DARF at any time. This requirement is an essential part of investigational agent accountability process and motivates the investigator to maintain accurate, appropriate records. The record keeping retention period is specified by FDA regulation, and the NCI does not deviate from that requirement. As noted above, the FDA requires IND sponsors to maintain adequate records on the shipment and disposition of drugs to investigators. Permitting intra-institutional transfer of drugs to other NCI sponsored protocols and other approved investigators necessitates that NCI be notified of these transfers. It is for this purpose and use that the Transfer of Investigational Drug form (TID: NIH 2564-1) was developed. The annual reporting burden is as follows: **Estimated Number of Respondents:** 7,371; **Estimated Number of Responses per Respondent:** 8; **Average Burden Hours Per Response:** 0.67; and **Estimated Total Annual Burden Hours Requested:** 3,378. The annualized respondent's burden for record keeping is estimated to require 3,298 hours for the DARF and 80 hours for the TID form. The annualized cost to the respondents is estimated at \$84,450.00. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.