withdraw, revoke, or limit accreditation of a laboratory as appropriate and report the action to HCFA within 30 days. ASHI also provides an appeal process for laboratories that have had accreditation denied, revoked, suspended, or limited.

We have determined that ASHI's laboratory enforcement and appeal policies are equivalent to the requirements of this subpart as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of ASHI accredited laboratories may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (complaint inspections). The outcome of those validation inspections, performed by HCFA or our agent, or the State survey agency, will be HCFA's principal means for verifying that the laboratories accredited by ASHI remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide, in part, that we may remove the approval of an accreditation organization, such as that of ASHI, for cause, before the end of the effective date of approval. If validation inspection outcomes and the comparability or validation review produce findings as described in § 493.573 (Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure programs), HCFA will conduct a review of an approved accreditation organization's program. We also conduct a review when the validation review findings, irrespective of the rate of disparity (as defined in § 493.2 (Definitions)), indicate widespread or systemic problems in the organization's accreditation processes that provide evidence that the organization's requirements, taken as a whole, are no longer equivalent to the CLIA requirements, taken as a whole. If validation inspection results over a 1-year period indicate a rate of disparity of 20 percent or more between the findings of the organization and those of HCFA, HCFA will conduct a review under § 493.575(a)(4).

If HCFA determines that ASHI has failed to adopt or maintain requirements that are equal to or more stringent than the CLIA requirements, or systematic problems exist in its inspection process, a probationary period as determined by HCFA, not to exceed 1 year, may be given to ASHI to adopt equal or more stringent requirements. HCFA will make a final determination as to whether or not ASHI retains its approved status as an accreditation organization under CLIA. If approved status is withdrawn, an accreditation organization such as ASHI may resubmit its application if it revises its program to address the rationale for the withdrawal, demonstrates that it can reasonably assure that its accredited laboratories meet CLIA condition level requirements, and resubmits its application for approval as an accreditation organization in its entirety. If, however, an approved accreditation organization requests reconsideration of an adverse determination in accordance with subpart D (Reconsideration of Adverse Determinations—Deeming Authority for Accreditation Organizations and CLIA Exemption of Laboratories Under State Programs) of part 488 (Survey, Certification, and Enforcement Procedures) of our regulations, it may not submit a new application until HCFA issues a final reconsideration determination.

Should circumstances result in ASHI having its approval withdrawn, HCFA will publish a notice in the **Federal Register** explaining the basis for removing its approval.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management of Budget.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: February 2, 2001.

Michael McMullan,

Acting Deputy Administrator, Health Care Financing Administration.

[FR Doc. 01–4928 Filed 3–2–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft 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

Clinical Pharmacy Demonstration Project Evaluation: NEW

The Clinical Pharmacy Demonstration Projects, a supplemental grant opportunity for health center networks, were established to evaluate the impact of comprehensive pharmacy services on the patients served by Health Resources and Services Administration (HRSA) supported programs. The overarching mission is to demonstrate the effect of implementing comprehensive pharmacy services in underserved populations. By collecting data regarding health outcomes and the level of pharmacy services provided, the Office of Pharmacy Affairs hopes to establish the provision of comprehensive pharmacy services as a key to improving access and eliminating health disparities.

The grantee networks will provide valuable pharmacy services to patients, and in the process generate data that will demonstrate the effect of the projects on health outcomes. Patient encounter data will be collected (baseline and semi-annual) for diabetic patients who receive clinical pharmacy services. In addition, each participating pharmacy will complete survey instruments (baseline, annual) for utilization, financial, and process data which describe the program. These data will result in the following: the creation of a database to document the nationwide impact of implementing comprehensive pharmacy services through the Clinical Pharmacy Demonstration Projects in underserved areas; and, information sources for the sharing of best practices, with the ultimate goal of aiding other health

center networks in the implementation of comprehensive pharmacy services.

The estimated burden is as follows:

Form name	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Baseline	1400	1	.33	462
Encounter data	1400	4	.16	933
Pharmacy Survey	14	3	1	42
Total	1414			1437

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–22, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 27, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–5224 Filed 3–2–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Drug Accountability Record

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on December 14, 2000, pages 78175–78176, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Drug Accountability Record. *Type of Information Collection Request:* Revision. (OMB No. 0925–0240, expires 3/31/2001). *Need and use of Information Collection:* The regulations of the Food and Drug Administration (FDA) require investigators to establish a record of the receipt, use, and disposition of all investigational agents. The National Cancer Institute (NCI), as a sponsor of investigational drug trials, has the responsibility for assuring to the FDA that systems for drug accountability are being maintained by investigators in its clinical trials program. In order to fulfill these requirements, we have developed two standardized forms. One, the investigational Drug Accountability Report Form (NIH 2564) designed to account for drug inventories and usage by protocol and the other, Transfer Investigational Drug Form (NIH–2564–1) that permits intra-institutional transfer of agents to NCI approved protocols for use by the investigator or other NCI registered investigators on approved protocols. The data obtained from the drug accountability record is used to track the dispensing of investigational anticancer drugs from receipt from NCI to dispensing or administration to patients. NCI uses the accountability data to ensure that investigational drug supplies are not diverted for inappropriate protocol or patient use. The drug accountability information is used to validate patient protocol reporting forms during site audits conducted at each of the Cooperative Groups. The intent is to ensure the investigational agents are used according to protocol guidelines and to ensure the patient's safety and protection. *Frequency of response:* Daily. *Affected public:* State or local governments, businesses or other for-profit, Federal agencies or employees, non-profit institutions, and small business or organizations. *Types of Respondents:* Investigators and their designees, pharmacists, nurses, pharmacy technicians, data managers. The annual reporting burden is divided into two major areas. These are the audits of Drug Accountability Forms by Government and its contractors and the use of the forms by clinical research sites. The burden is as follows: The annualized respondents' burden for record keeping is estimated to require 2,436 hours for drug accountability and 80 hours for drug transfer. The reporting burden is the average time (4 minutes or 0.0668 hours) required to complete the transfer investigational drug form multiplied by the number of forms completed annually. The record keeping burden represents an average time required for multiple entries (4 minutes or 0.0668 hours per entry) on the drug accountability form, the average number of forms maintained by each record keeper and the number of record keepers. These estimates are based on the items shipped by the PMB and the number of transfer approvals in the calendar year 1999.

Type of respondents	Est. number of respondents	Est. number of responses/ respondents	Avg. burden hours per response	Avg. burden hours	Est. total annual burden hours requested
Drug transfer, form	1,200	1	0.0668	80	80
Drug, accountability, form	4,560	8	0.0668	2,436	2,436
Total	5,760				2,516