Dated: October 16, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–30333 Filed 11–18–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Document Identifier: HCFA–R–94

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:* Medicaid Sterilization Regulations 45 CFR 96.73, 42 CFR 441 subpart F and Consent Form; *Form No.:* HCFA–R–94 OMB 0938–0481; *Use:* All Medicaid-eligible individuals seeking sterilization are required to sign the federally mandated consent form, acknowledging that they understand the benefits and risks of sterilization, and have received oral information concerning the sterilization operation from the provider. *Frequency:* Other (each time sterilization is sought); *Affected Public:* Individuals or Households; *Number of Respondents:* 112,526; *Total Annual Responses:* 112,526; *Total Annual Hours:* 140,658.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, 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, D.C. 20503.

Dated: October 6, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services,Information Technology Investment Management Group,Division of HCFA Enterprise Standards.

[FR Doc. 97–30368 Filed 11–18–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–200]

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 Request: Revision of a currently approved collection; *Title of Information Collection:* HEDIS 3.0 (Health Plan Data and Information Set), including the Health of Seniors and Consumer Assessment of Health Plans Study (CAHPS) surveys and supporting regulations 42 CFR 417.470, and 42 CFR 417.126; *Form Number:* HCFA–R–200 (OMB #0938–0701); Use: HEDIS and CAHPS will be used for 3 purposes: (1) To provide summary comparative data to the Medicare beneficiary to assist them in choosing among health plans; (2) to provide information to health plans for internal quality improvement activity; and (3) to provide HCFA, as purchaser, information useful for monitoring quality of and access to care provided by the plans; *Frequency:* Annually; *Affected Public:* Individuals or Households, non-profit and for profit HMOs which contract with HCFA to provide managed health care to Medicare beneficiaries; *Number of Respondents:* 293,834; *Total Annual Responses:* 293,834; *Total Annual Hours Requested:* 181,520.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, 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, D.C. 20503.

Dated: October 21, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 97–30369 Filed 11–18–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Drug Accountability Record; Submission of OMB Review; Comment Request

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Cancer Institute, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 10, 1997, page 37069 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 (NIH form 2564) and Transfer Investigational Drug Record (NIH form 2564–1). *Type of Information Collection Request:* Revision of a currently approved collection, OMB No. 0925–0240, Expiration Date 1/31/98. *Need and Use of Information Collection:* Food and Drug Administration (FDA) regulations 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 trails, has the responsibility to assure the FDA that investigators in its clinical trials program are maintaining systems for drug accountability. In order to fulfill these requirements, a standard Investigational Drug Accountability Report Form (NIH 2564) was designed to account for drug inventories and usage by protocols. The Transfer Investigational Drug Form (NIH 2564–1) permits intra-institutional transfer of drugs to other approved investigators for other approved protocols. The data obtained from the drug accountability record will be used to keep track of the dispensing of investigational anticancer agents to patients. It is used by NCI management to ensure that investigational drug supplies are not diverted for inappropriate protocol or patient use. The information is also compared to patient flow sheets (protocol reporting forms) during site visits conducted for each investigator once every three years. All comparison are done with the intention of ensuring protocol, patient and drug compliance for patient safety and protections. *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. *Type of Respondents:* Investigators, pharmacist; nurses, pharmacy technicians, data managers. The annual reporting burden is as follows: The annualized burden estimate for record keeping is estimated to require 3,650 hours for drug accountability and 120 hours for drug transfer. The annualized cost to the respondents is estimated at $94,500. The reporting burden is the average time (4 minutes or 0.0666 hour) 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 0.0666 hour 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 36,500 items shipped by PMB and the 1,200 items transfer approvals in calendar year 1996. Cost estimates are based upon burden hours at an average cost of $25.00 per hour.

Drug Accountability Form:
No. Of Respondents—4560
No. Of responses per respondent—8
Average Burden per response—0.0666
Annual Burden hours—2430

Drug Transfer Form:
No. Of respondents—1200
No. Of responses per respondent—1
Average burden per response—0.0666
Annual Burden hours—80

Total Annualized Burden For Record Keeping and Reporting: 2,510.

There are no Capital Costs, Operating Costs, and/or Maintenance Cost to report.

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 is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the 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 the 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.

Direct Comments To OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, D.C. 20503, Attention: Desk Officer for NIH. To request information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Joseph High, Head, Drug Management and Authorization Section, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division Cancer Therapy, Diagnosis, and Centers, National Cancer Institute, Executive Plaza North, Room 707, 9000 Rockville Pike, Bethesda, MD 20892 or call non-toll-free number (301) 496–5725 or E-mail your request, including your address to: JoeHigh@nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before December 19, 1997.

Dated: November 12, 1997.

Nancie L. Bliss,

OMB Project Clearance Liaison.

[FR Doc. 97–30322 Filed 11–18–97; 8:45 am]

BILLING CODE 4140–07–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Meeting of the Board of Scientific Counselors

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Institute of Child Health and Human Development, December 5, 1997, in Building 31, Room 2A52.

This meeting will be open to the public from 8:00 a.m. to 12 noon on December 5 for the review of the Intramural Research Program and scientific presentations. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in section 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public on December 5 from 1:00 p.m. to adjournment of the review, discussion, and evaluation of individual programs and projects conducted by the National Institutes of Health, including consideration of personnel qualifications and performance, the competence of individual investigators, and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Ms. Catherine O'Connor, Senior Biomedical Research Program Assistant, NICHD, Building 31, Room 2A50, National Institutes of Health, Bethesda, Maryland, 20892–2425, 301–496–2133, will provide a summary of the meeting, a roster of Board members, and substantive program information upon request. Individuals who plan to attend