

the system. At the second voice prompt press 1 to order a document. Enter the document number (1332) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Guidance documents are also available on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/default.htm>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by August 1, 2001. Submit two copies of any comments, 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 document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 30, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01-11231 Filed 5-1-01; 12:40 pm]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-116]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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:* Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations in 42 CFR 493.1—.2001; *Form No.:* HCFA-116 (OMB# 0938-0581); *Use:* Certification requirements have been established for any entity that performs testing on human beings for diagnostic or treatment purposes. Laboratories must apply for and obtain a certificate in order to perform this testing; *Frequency:* Biennially; *Affected Public:* Business or other for profit, Not for profit institutions, Federal Government, and State, local or tribal government; *Number of Respondents:* 16,000; *Total Annual Responses:* 16,000; *Total Annual Hours:* 20,000.

To obtain copies of the supporting statement and any related forms 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, phone number, OMB number, and HCFA document identifier, 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 23, 2001.

John P. Burke III,

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

[FR Doc. 01-11044 Filed 5-2-01; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-18]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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:* Application for Hospital Insurance in 42 CFR 406.7; *Form No.:* HCFA-18 (OMB# 0938-0251); *Use:* The HCFA-18F5 is used to establish entitlement to hospital insurance and supplementary medical insurance for beneficiaries entitled under title XVIII of the Social Security Act; *Frequency:* On occasion; *Affected Public:* Individuals or households; *Number of Respondents:* 50,000; *Total Annual Responses:* 50,000; *Total Annual Hours:* 12,500.

To obtain copies of the supporting statement and any related forms 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, phone

number, OMB number, and HCFA document identifier, 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Attn: HCFA-18, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 26, 2001.

John P. Burke, III,

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

[FR Doc. 01-11118 Filed 5-2-01; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Organ Procurement and Transplantation Network (42 CFR Part 121, OMB No. 0915-0184)—Revision

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain recordkeeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. This is a request for a revision of the current recordkeeping and reporting requirements associated with the OPTN. These data will be used by HRSA in monitoring the contracts for the OPTN and the Scientific Registry and in carrying out other statutory responsibilities. Information is needed to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, and to ensure that all qualified entities are accepted for membership in the OPTN.

The estimated annual response burden is as follows:

ESTIMATED ANNUAL REPORTING AND RECORD KEEPING BURDEN

Section and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
121.3(b) (2)—OPTN membership and application requirements for OPOs, hospitals, histocompatibility laboratories	30	1	30	40	1,200
121.6(c)—Submitting criteria for organ acceptance	900	1	900	0.1	90
121.6(c)—Sending criteria to OPOs	900	1	900	0.1	90
121.7(b)4—Reasons for refusal	900	0.5	34,200	0.1	3,420
121.7(e)—Transplant to prevent organ wastage	900	0.5	420	0.1	42
121.9(b)—Designated transplant program requirements	10	1	10	2	20
Total	940	38.8	36,460	.1	4,862

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 26, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01-11074 Filed 5-2-01; 8:45 am]

BILLING CODE 4160-15-U

DEPARTMENT OF THE INTERIOR

U.S. Geological Survey

Request for Public Comments on Extension of Existing Information Collection To Be Submitted to OMB for Review Under the Paperwork Reduction Act

A request extending the information collection described below will be submitted to the Office of Management and Budget (OMB) for approval under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)). Copies of the proposed collection may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments on the proposal should be made within 60 days to the Bureau Clearance Officer, U.S. Geological Survey, 807 National Center, Reston, VA 20192.

As required by OMB regulations at 5 CFR 1320.8(d)(1), the U.S. Geological Survey solicits specific public comments as to:

1. Whether the collection of information is necessary for the proper performance of the functions on the bureaus, including whether the information will have practical utility;
2. The accuracy of the bureau's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
3. The quality, utility, and clarity of the information to be collected; and
4. How 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 forms of information technology.

Title: User Survey for National Biological Information Infrastructure (NBII).

OMB Approval No.: 1028-0069.