

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Persons interested in obtaining a copy of the draft guidance may also do so using the Internet.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Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by August 1, 2001.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.

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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.

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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