

which repeats the AP criteria set out in section II of this document. In addition, the guidance provides other useful information such as suggestions about the format and content of the accreditation applications.

The guidance represents the agency's current thinking on the "Implementation of the Inspection by Accredited Persons Program under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties." The issuance of this guidance is consistent with FDA's good guidance practices regulation (21 CFR 10.115). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

This document and the guidance entitled "Implementation of the Inspection by Accredited Persons Program under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties" contain a proposed collection of information that requires clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995. In a document found elsewhere in this issue of the **Federal Register**, FDA is announcing that this proposed collection of information has been submitted to OMB for emergency processing. The document also solicits comments concerning the proposed collection of information.

FDA will publish a separate document in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions contained in this document and the guidance. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

V. Comments

Interested persons may submit their written or electronic comments regarding the guidance at any time to Dockets Management Branch (see **ADDRESSES**). Submit either a single copy of the electronic comments to: <http://www.fda.gov/dockets/ecomments> or send two paper copies of any mailed comments (individuals may submit only one copy). Identify comments with the docket number found in brackets in the

heading of this document. Comments received will be made available in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

To receive "Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties" by fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1200) followed by the pound sign (1). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by 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 device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets>.

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Jeffrey Shuren,

Assistant Commissioner for Policy.

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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 the 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 the Office of Management and Budget (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 at (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: Ryan White Comprehensive AIDS Resources Emergency (CARE) Act: CARE Act Data Report (CADR) Form: Extension (OMB No. 0915-0253)

The CARE Act Data Report (CADR) form, created in 1999 by the HIV/AIDS Bureau of the Health Resources and Services Administration (HRSA), is designed to collect information from grantees, as well as their subcontracted service providers, funded under titles I, II, III and IV of the Ryan White (CARE) Act of 1990, as amended by the Ryan White CARE Act Amendments of 1996 and 2000 (codified under title XXVI of the Public Health Services Act). All titles of the CARE Act specify HRSA's responsibilities in the administration of grant funds, the allocation of funds, the evaluation of programs for the population served, and the improvement of the quantity and quality of care. Accurate records of the providers receiving CARE Act funding, the services provided, and the clients served continue to be critical to the implementation of the legislation and thus are necessary for HRSA to fulfill its responsibilities.

CARE Act grantees are required to report aggregate data to HRSA annually. The CADR form is used by grantees and their subcontracted service providers to report data on six different areas: service provider information, client information, services provided/clients served, demographic information, AIDS