

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>.

Dated: April 23, 2003.

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

Pharmaceutical Assistance and AIDS Drug Assistance Program, and the Health Insurance Program. The primary purposes of the CADR are to: (1) Characterize the organizations from which clients receive services; (2) provide information on the number and

characteristics of clients who receive CARE Act services; and (3) enable HAB to describe the type and amount of services a client receives. In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information

collected on the CADR is critical for HRSA, State and local grantees, and individual providers to assess the status of existing HIV-related service delivery systems.

The estimated response burden for CARE Act grantees is estimated as:

Title under which grantee is funded	Estimated number of grantees	Estimated (median) number of providers	Estimated hours to coordinate receipt of data reports from providers	Estimated total hour burden for grantees
Title I only	51	107	40	2,040
Title II only	59	112	40	2,360
Title III only	337	1	8	2,696
Title IV only	90	1	16	1,440
Total	537	8,536

The estimated response burden for service providers is estimated as:

Title under which provider is funded	Estimated number of provider respondents	Estimated responses per provider	Estimated hours per response	Estimated total hour burden
Title I only	1,175	1	24	28,200
Title II only	995	1	24	23,880
Title III only	248	1	40	4,800
Title IV only	98	1	40	3,920
Funded under multiple titles	394	1	40	15,760
Total	2,782	76,560

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 21, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry.

Date and Time: May 29, 2003, 8:30 a.m.–4:30 p.m.; May 30, 2003, 8 a.m.–2 p.m.

Place: The Holiday Inn Select, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

Status: The meeting will be open to the public.

Purpose: The Advisory Committee provides advice and recommendations on a broad range of issues dealing with programs and activities authorized under section 747 of the Public Health Service Act as amended by The Health Professions Education Partnership Act of 1998, Pub. L. 105-392. At this meeting the Advisory Committee will continue working on its third report which will be submitted to Congress and the Secretary of the Department of Health and Human Services in November 2003. The third report focuses on disparities in health care and their implications for primary care medical education.

Agenda: The meeting on Thursday, May 29, will begin with welcoming and opening comments from the Chair and Executive Secretary of the Advisory Committee. A plenary session will follow in which the Advisory Committee members will work on drafting various sections of the third report. The Advisory Committee will also discuss various partnership opportunities with the National Advisory Council of the National Health Service Corps.

On Friday, May 30, the Advisory Committee will meet in plenary session to

discuss outcome measures for programs under section 47 of the Public Health Service Act and will make plans for the October 2003 meeting. An opportunity will be provided for public comment.

For Further Information Contact: Anyone interested in obtaining a roster of members or other relevant information should write or contact Stan Bastacky, D.M.D., M.H.S.A., Acting Deputy Executive Secretary, Advisory Committee on Training in Primary Care Medicine and Dentistry, Parklawn Building, Room 9A-21, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-6326. The web address for information on the Advisory Committee is <http://bhpr.hrsa.gov/medicine-dentistry/actpcmd>.

Dated: April 21, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

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