

We believe the estimate, 24,419 hours per year, accurately reflects the burden. We recognize that individuals or entities less familiar with FDA forms and the Clinical Trials Data Bank may require greater than 15 and 45 minutes (depending on the type of application/submission) per response.

Dated: December 6, 2007.

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: 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 (OMB), 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 OMB for review under the Paperwork Reduction Act of 1995:

Proposed Project: Ryan White HIV/AIDS Program Annual Data Report: Data Report Form: (OMB No. 0915-0253)—Revision

The Ryan White HIV/AIDS Program Annual Data Report, formerly called the CARE Act Data Report (CADR), was first implemented in 2002 by HRSA's HIV/AIDS Bureau. It has undergone revisions to incorporate the legislative changes that occurred in 2006. Grantees and their subcontracted service providers who are funded under Parts A, B, C, and D of Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006, (Ryan White HIV/AIDS Program), fill out the report. All Parts of the Ryan White HIV/AIDS Program 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 Ryan White HIV/AIDS Program 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. Ryan White HIV/AIDS

Program Grantees are required to report aggregate data to HRSA annually. The Data Report form is filled out by grantees and their subcontracted service providers. The report has seven different sections containing demographic information about the service providers, as well as the clients served, information about the type of core and support services provided, as well as the number of clients served, information about counseling and testing services, clinical information about the clients served, demographic tables for Parts C and D, and information about the Health Insurance Program. The primary purposes of the Data Report are to: (1) Characterize the organizations where clients receive services; (2) provide information on the number and characteristics of clients who receive Ryan White HIV/AIDS Program 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 the Congress, clients, advocacy groups, and the general public, information collected on the Data Report is critical for HRSA, State, and local grantees, and individual providers to assess the status of existing HIV-related service delivery systems.

The response burden for grantees is estimated as:

Program under which grantee is funded	Number of grantees	Number of responses	# of hours per response	Total hour response burden
Part A Only	56	1	40	2,240
Part B Only	59	1	40	2,360
Part C Only	361	1	20	7,220
Part D Only	90	1	20	1,800
Subtotal	566	13,620

The response burden for service providers is estimated as:

Program under which grantee is funded	Number of providers	Number of responses	# of hours per response	Total hour response burden
Part A Only	792	1	26	20,592
Part B Only	653	1	26	16,978
Part C Only	108	1	44	4,752
Part D Only	75	1	42	3,150
Funded under more than one program	703	1	50	35,150
Subtotal	2,331	80,622
Total for Both Grantees & Providers	2,897	94,242

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to OIRA_submission@omb.eop.gov or by fax to 202-395-6974. Please direct

all correspondence to the "attention of the desk officer for HRSA."

Dated: December 6, 2007.

Alexandra Huttinger,

Acting Director, Division of Policy Review and Coordination.

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