

Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the dispute before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 13, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301-594-1283, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 11, 2003.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

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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, 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: AIDS Drug Assistance Program (ADAP): ADAP Monthly Client Utilization and Program Expenditures Report (OMB No. 0915-0219)—Extension**

The Division of Service Systems (DSS)/Health Resources and Services Administration (HRSA) collects aggregated information on the number of clients being served by ADAPs, monthly expenditures by State ADAPs, and the purchase price of HIV/AIDS medications. State AIDS Drug Assistance Program (ADAPs), funded under the Title II of the Ryan White Comprehensive AIDS Resource Emergency (CARE) Act, as amended (Part B of Title XXVI of the Public Health Service Act), are designed to provide low income, uninsured, and underinsured individuals with access to HIV/AIDS medication that prevent serious deterioration of health arising from HIV disease, including the prevention and treatment of opportunistic infections.

During the last several years, there has been an increasing need for pharmaceuticals among uninsured and underinsured low income individuals who are HIV positive or diagnosed with AIDS. Due to the increasing demand, DSS/HRSA recognizes the importance of program planning and budget forecasting in order to maximize resources, and proposed to extend the current data collection form to collect relevant client utilization data and

program expenditure information from State ADAPs. This data collection effort is designed to allow DSS/HRSA (the funding agency) to continue monitoring nationwide trends in program growth, client utilization, expenditures and to assess the capacity of State ADAPs to maintain client services for clients throughout the fiscal year. The form will improve DSS/HRSA's ability to track the prices of HIV/AIDS drugs in order to ensure that State ADAPs are receiving the best price possible, to identify emerging issues and technical assistance needs and to share information among State ADAPs. It will also assist Title II grantees, State ADAPs, DSS/HRSA staff and policy makers at both the Federal and State level to understand the level of client demand for medications and the resources needed to meet those needs.

This report will collect time-specific data for the number of enrolled clients, the number of new clients, and the number of utilizing clients, the level of funds expended, and the price of HIV/AIDS drugs. A text box is provided to allow State ADAPs to report significant changes to their program, such as projected budget shortfall, program restrictions, client waiting lists, a change in eligibility criteria, or formulary changes. On a quarterly basis, State ADAPs will report the purchase price paid on a select number of HIV pharmaceuticals dispensed by each program. DSS/HRSA will continue to compile summary reports that are distributed back to grantees and State ADAPs on a quarterly basis. The data collected is used to guide program planning, formulate budget recommendations, and monitor State ADAPs, especially monitoring the balance between an individual State ADAPs available resources against the client demand for medications. The burden estimates are as follows:

HRSA forms title II ADAP grantees	Number of respondents	Responses per respondent	Total responses	Hour per responses	Total burden hours
Client and Expenditures .....	54	12	648	0.75	486
Drug Pricing .....	54	4	216	0.75	162
Total .....	54	.....	864	.....	648