DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–R–136]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (CMS)), 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: Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Proper Claim Not Filed and Supporting Regulation Contained in 42 CFR 411.32(c); *Form No.:* CMS–R–136) (OMB# 0938–0564); *Use:* Section 411.32(c) requires a provider, supplier, or beneficiary to notify Medicare that a claim to a third party was improperly filed; *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Individuals or households; *Number of Respondents:* 13,311; *Total Annual Responses:* 13,311; *Total Annual Hours:* 0.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://cms.hhs.gov/regulations/pra/default.asp*, or E-mail your request, including your address, phone number, OMB number, and CMS 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 CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willinghan, Room: C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 25, 2003.

Julie Brown,

Acting, Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–10838 Filed 5–1–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 29, 2003, from 8 a.m. to 5 p.m. and on May 30, 2003, from 8 a.m. to 12 noon.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, petersonj@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting. When available, background materials for this meeting will be posted 1 business day prior to the meeting on the FDA Web site at: www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2003 and scroll down to Cardiovascular and Renal Drugs Advisory Committee meetings.)

Agenda: On May 29, 2003, the committee will discuss QT prolongation issues associated with two new drug applications (NDAs): (1) NDA 21–287, (alfuzosin HCl), Sanofi-Synthelabo Inc., for the proposed indication of treatment of the signs and symptoms of benign prostatic hyperplasia; and (2) NDA 21–400, Levitra (vardenafil HCl), Bayer Corp., proposed for the indication of treatment of erectile dysfunction. The discussion will focus on: (1) Clinical trial designs for assessment of QT prolongation; (2) approaches to the correction of QT interval for drugs that affect the heart rate; and (3) risks of cardiac arrythmias associated with different degrees of QT prolongation. Premarketing clinical safety data from these applications and postmarketing safety data relevant to cardiac QT prolongation from drugs in the same two drug classes (i.e., alpha adrenergic blockers and phosphodiesterase type 5 inhibitors) will be considered.

On May 30, 2003, the meeting will be closed to permit discussion and review of trade secret and/or confidential information.

Procedure: On May 29, 2003, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 21, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on May 29, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 21, 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.

Closed Presentation of Data: On May 30, 2003, the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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 Jayne

Peterson 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: April 24, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–10805 Filed 5–1–03; 8:45 am]

BILLING CODE 4160–01–S

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 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 OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (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 on 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: 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 Amendments of 1996 and 2000. (Pub. L. 104–146), 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 proposes to extend the current data collection from to collect relevant and 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 policymakers 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 project budget shortfall, program restrictions, client waiting lists, a change in eligibility criteria, or formulary charges. 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 for 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

Send comments to Susan G. Queen, Ph.D, HRSA Reports Clearance Officer, Room 14–45, Parklawn Building, 5600 Fishers Lane, Rockville MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 23, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–10877 Filed 5–1–03; 8:45 am]

BILLING CODE 4165–15–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Mental Health and Community Safety Initiative for American Indian and Alaska Native Children, Youth, and Families

AGENCY: Indian Health Service, HHS.