market. In an effort to distribute costs more equitably among the various types and sizes of laboratories, while generating sufficient revenue, we now rely more heavily on average annual test volumes to determine certificate fees. The fees for certificate of waiver or PPM procedures have been, and will continue to be, a flat fee irrespective of volume of testing performed. The $50 fee increase for these laboratories is based on expenditures related to these types of certificates. These costs include: reviewing test systems for categorization as waived or PPM procedures; maintaining and updating the data systems; issuing certificates; issuing test categorization notices; collecting fees; and analyzing data.

For other certificate types, instead of using the three-tiered fee schedule based on general ranges of test volume, we are maintaining the 11 laboratory schedules, LVA through J, previously established on February 28, 1992. The new biennial certificate fees for each schedule are computed using a decreasing per test rate as the volume of tests increases. This per-test rate is multiplied by the average annual test volume performed in each schedule, with the exception of the smallest laboratories, LVA through B, being charged a certificate fee of $150. Laboratories in Schedules C through G, which encompass test volumes up to 100,000, each will pay a certificate fee based on the per-test rate. (See Table III) Between Schedules G and H laboratories, the per-test rate is being reduced by almost one half, because of the dramatic increase in volume for Schedule H laboratories. These test volumes range from more than 100,000 to 500,000. Another very large increase in volume occurs for Schedule J laboratories, which perform over 1 million tests annually. Between Schedules I and J laboratories, the per-test rate is being reduced by approximately three-fourths, in recognition of the large increase in the test volume of these laboratories.

The revisions to the CLIA certificate fees will significantly alter the biennial certificate fees for some laboratories. Table III presents the approximate number of laboratories in each laboratory type and their new biennial certificate fees.

The effect of this new fee schedule will vary widely among clinical laboratories. Nearly 62 percent of the laboratories now hold certificate of waiver or certificate for PPM procedures and pay a flat certificate fee. For certificates of waiver, laboratories will pay $150 biennially and for certificates for PPM procedures, the biennial fee will be $200. These $50 biennial increases amount to less than $0.07 per day per laboratory. The new fees take into account the increased number of tests that may be performed under these types of certificates.

Laboratories with a change in name, location or in any of the conditions specified in § 493.639 of our regulations will find the fee for a revised certificate increased by $25, from $50 to $75.

As previously stated, we are required by statute to establish fees to support the CLIA program. Although certificate fees increase proportionately, we believe that by relating the fee more precisely to the number of tests a laboratory performs each year, the costs of administering CLIA will be distributed more equitably across all laboratories. The laboratories bearing the largest increase in certificate fees, Schedules C through J, account for more than 90 percent of the annual test volume in this country. Because of their large test volumes we have applied the lowest possible per-test rates to those laboratories, consistent with generating sufficient revenues. We concluded that basing certificate fees on the average annual test volume for each schedule and a decreasing per-test rate was the most equitable and practical method for constructing the fee schedule. (See Table III) This approach has the merit of charging larger laboratories less per test performed, while still basing the overall fees directly on the volume of testing. These fees will result in large increases in certificate fees for the laboratories with the highest test volumes. These differences are directly proportional to test volumes, resulting in laboratories with similar volumes paying similar fees.

For the reasons given above, we certify that this proposed fee schedule would not have a significant effect on a substantial number of small entities and that a regulatory flexibility analysis is not needed.

B. Rural Hospital Impact Statement

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. We are not preparing a rural impact statement since we have determined, and certify, that this notice would not have a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93–778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93–774, Medicare—Supplementary Medical Insurance Program)

Dated: December 20, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: December 11, 1996.

David A. Satcher,

Director, Centers for Disease Control and Prevention.

Dated: March 26, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–23084 Filed 8–28–97; 8:45 am]

BILLING CODE 4210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Translation Advisory Committee for Diabetes Prevention and Control Programs: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Translation Advisory Committee for Diabetes Prevention and Control Programs.

Times and Dates: 9 a.m.–6 p.m., September 16, 1997. 9 a.m.–12 noon, September 17, 1997.

Place: Crown Plaza Ravinia, 4355 Ashford-Dunwoody Road, Atlanta, Georgia 30346, telephone 770/395-7700.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: This committee is charged with advising the Director, CDC, regarding policy issues and broad strategies for diabetes translation activities and control programs designed to reduce risk factors, health services utilization, costs, morbidity, and mortality associated with diabetes and its complications. The Committee identifies research advances and technologies ready for translation into widespread community practice; recommends broad public health strategies to be implemented through public health interventions; identifies opportunities for surveillance and epidemiologic assessment of diabetes and related complications; and for the purpose of assuring the most effective use and

organization of resources, maintains liaison and coordination of programs within the Federal, voluntary, and private sectors involved in the provision of services to people with diabetes.

Matters to be Discussed: Agenda items include a discussion of public health issues pertinent to the role of economic analysis in the Division of Diabetes Translation (DDT) priorities, as well as, the challenges of diabetes in Latino/Hispanic communities. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Margaret Hurd, Committee Management Specialist, DDT, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, NE, M/S K–10, Atlanta, Georgia 30341–3724, telephone 770/488–5505.

Dated: August 25, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–23189 Filed 8–28–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects: *Title:* Request for State Data to Determine the Tribal Family Assistance Grant Amount.

OMB No: New Request.

Description: This information collection will be used to request data from States that will be used to determine the amount of Tribal Family Assistance Grants. The data requested is the data required to be used by Section 412(a)(1)(B) of the Social Security Act, as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

Respondents: State Govts.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Request	18	1	42	756.

Estimated Total Annual Burden Hours: 756

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: August 25, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–23088 Filed 8–28–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: Immunology Devices Panel of the Medical Devices Advisory Committee.

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

Date and Time: The meeting will be held on September 19, 1997, 9:30 a.m. to 5 p.m.

Location: Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Contact Person: Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12516. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear presentations from FDA staff regarding new review initiatives pertinent to types of submissions generally reviewed by the committee. FDA will also present a first year summary of activities associated with the down classification of tumor markers used for monitoring cancer patients. FDA seeks to obtain committee input on the data requirements for class II submissions of tumor markers with the intent of modifying the guidance document that serves as a special control for these class II products. Single copies of the guidance document entitled ''Guidance For Submission Of Tumor Marker Premarket Notifications'' can be obtained by contacting the Division of Small Manufacturers Assistance, 1350 Piccard Dr., Rockville, MD 20851, 1–800–638–2041 or 301–443–6597, or on the Internet using the World Wide Web (WWW) (http://www.fda.gov/cdrh/draftgui.html).

Procedure: On September 19, 1997, from 10 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending