DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Federal Allotments to States for Social Services Expenditures, Pursuant to Title XX, Block Grants to States for Social Services; Promulgation for Fiscal Year 1997

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notification of allocation of title XX—social services block grant allotments for Fiscal Year 1997.

SUMMARY: This issuance sets forth the individual allotments to States for Fiscal Year 1997, pursuant to title XX of the Social Security Act, as amended (Act). The allotments to the States published herein are based upon the authorization set forth in section 2003 of the Act and are contingent upon Congressional appropriations for the fiscal year. If Congress enacts and the President approves a different authorization or appropriation amount, the allotments will be adjusted proportionately.

FOR FURTHER INFORMATION CONTACT: Frank A. Burns, (202) 401–5536.

SUPPLEMENTARY INFORMATION: Section 2003 of the Act authorizes $2.8 billion for Fiscal Year 1997 and provides that it be allocated as follows:

(1) Puerto Rico, Guam, the Virgin Islands, and the Northern Mariana Islands each receives an amount which bears the same ratio to $2.8 billion as its allocation for Fiscal Year 1981 bore to $2.9 billion.

(2) American Samoa receives an amount which bears the same ratio to the amount allotted to the Northern Mariana Islands as the population of American Samoa bears to the population of the Northern Mariana Islands determined on the basis of the most recent data available at the time such allotment is determined.

(3) The remainder of the $2.8 billion is allotted to each State in the same proportion as that State's population is to the population of all States, based upon the most recent data available from the Department of Commerce.

For Fiscal Year 1997, the allotments are based upon the Bureau of Census population statistics contained in its reports ''Updated National and State Population Estimates'' (CB95–39 Table 1) released March 1, 1995, and ''1990 Census of Population and Housing'' (CPH–6–AS and CPH–6–CNMI) published April 1992, which are the most recent data available from the Department of Commerce at this time as to the population of each State and each Territory.

EFFECTIVE DATE: The allotments shall be effective October 1, 1996.

Fiscal Year 1997 Federal Allotments to States for Social Services—Title XX Block Grants

Total	$2,800,000,000
Alabama	45,122,270
Alaska	6,481,179
American Samoa	104,188
Arizona	43,582,187
Arkansas	26,234,873
California	336,155,028
Colorado	39,100,976
Connecticut	35,026,175
Delaware	7,550,681
Dist. of Col	6,096,159
Florida	149,227,549
Georgia	75,453,333
Guam	482,759
Hawaii	12,609,423
Idaho	12,117,452
Illinois	125,687,820
Indiana	61,517,728
Iowa	30,256,198
Kansas	27,315,069
Kentucky	40,929,824
Louisiana	46,148,991
Maine	13,261,819
Maryland	53,539,247
Massachusetts	64,608,588
Michigan	101,559,865
Minnesota	48,844,135
Mississippi	28,544,996
Missouri	56,448,291
Montana	9,154,933
Nebraska	17,358,010
Nevada	15,582,637
New Hampshire	12,160,232
New Jersey	84,533,401
New Mexico	17,689,555
New York	194,317,733
North Carolina	75,613,758
North Dakota	6,823,420
No. Mariana Islands	96,552
Ohio	118,736,060
Oklahoma	34,844,360
Oregon	33,004,817
Pennsylvania	128,896,325
Puerto Rico	14,482,759
Rhode Island	10,662,930
South Carolina	39,186,536
South Dakota	7,711,106
Tennessee	55,346,704
Texas	196,552,992
Utah	20,406,089
Vermont	6,203,109
Virgin Islands	482,759
Virginia	70,073,740
Washington	57,143,467
West Virginia	19,486,318
Wisconsin	54,352,068
Wyoming	5,090,827

Dated: November 21, 1995.

Dr. Thornell Page,

Special Assistant to the Director, Office of Community Services.

[FR Doc. 95–29346 Filed 11–30–95; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment Prescription Drug User Fee Revenues and Rates Fiscal Year 1996

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is establishing user fee revenues and rates for Fiscal Year (FY) 1996. The Prescription Drug User Fee Act of 1992 (the PDUFA) authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such marketed products. Fees for applications, establishments, and products for FY 1993 were established by the PDUFA. Fees for future years are to be determined by FDA using criteria delineated in the statute.

FOR FURTHER INFORMATION CONTACT: Michael E. Roosevelt, Office of Financial Management (HFA–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4872.

SUPPLEMENTARY INFORMATION:

I. Background

The PDUFA (Pub. L. 102–571) establishes three different kinds of user fees. Fees are assessed on: (1) Certain types of applications and supplements for approval of drug and biologic products, (2) certain establishments where such products are made, and (3) certain marketed products (21 U.S.C. 379h(a))). When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379h(d)). Under the PDUFA, one-third of the total user fee revenue for each FY must come from each of the three types of fees.

For FY 1993, the total revenues to be derived from fees and the fee rates for each of the categories were established in the PDUFA (21 U.S.C. 379h(b)(1)). For FY 1994 through 1997, however, the PDUFA establishes only target total fee revenues and fees. For these years, FDA is authorized to increase the total fee revenues and to establish new fee rates for each of the three categories so that the revised total fee revenues are realized (21 U.S.C. 379h(c)).

This notice establishes total fee rates for FY 1996. These fees are retroactive to October 1, 1995, and will remain in effect through September 30, 1996. For fees already paid on applications and

supplements submitted on or after October 1, 1995, FDA will refund applicants for the difference between fees paid and fees due under the new fee schedules. For applications and supplements submitted after December 31, 1995, the new fee schedule should be used. Invoices for establishment and product fees for FY 1996 will be issued in December 1995, using the new fee schedules.

I. Revenue Increase and Fee Adjustment Process

The PDUFA provides that total fee revenues for each FY, as set out in the original fee schedule (see 21 U.S.C. 379h(b)(1)), shall be increased by notice in the Federal Register. The increase must reflect the greater of : (1) The total percentage increase that occurred during the FY in the Consumer Price Index (the CPI) (all items; U.S. city average), or (2) the total percentage pay increase for that FY for Federal employees, as adjusted for any locality-based payment applicable to employees stationed in the District of Columbia (see 21 U.S.C. 379h(c)(1)). The PDUFA also provides that within 60 days after the end of each FY, FDA shall adjust the user fee rates in each of the three categories of fees (application, establishment, and product) to achieve the revised total fee revenues. The new individual user fees must be adjusted in a manner that maintains the proportions established in the original fee schedules, so that approximately one-third of the revenues will come each from applications, establishments, and product fees (21 U.S.C. 379h(c)(2)).

III. Total Fee Revenue Adjustment

For FY 1995, the total percentage increase in the CPI was 2.54 percent, whereas the increase in applicable Federal salaries for FY 1996 is 2.54 percent. Thus, for computing the total fee revenues for FY 1996, the percentage is 2.54. The new adjusted total fee revenue is computed by applying the increase as a percentage (102.54 percent) to the FY 1996 target fee revenue amount from the PDUFA schedule ($78 million). The FY 1996 total adjusted fee revenue amount then totals $79,981,200.

IV. Fee Calculations for Application, Establishment, and Product Fees

The PDUFA provides that in making adjustments to the user fee rates, the one-third proportionality must be maintained among application, product, and establishment fees. Thus, the amount of revenues to be obtained from each category are $26,660,400 ($79,981,200 divided by 3).

A. Application Fees

Application fees are assessed on each ''human drug application,'' as defined in the PDUFA (see 21 U.S.C. 379g(1)). Application fees are levied for: (1) Review of certain new drug applications submitted after September 1, 1992, under section 505(b)(1) of the act (21 U.S.C. 355(b)(1)); (2) for review of an application for certain molecular entities or indications for use submitted after September 30, 1992, under section 505(b)(2) of the act; (3) review of applications for initial certifications or approvals of antibiotic drugs submitted after September 1, 1992, under section 507 of the act (21 U.S.C. 357); and (4) for review of applications for licensure of certain biological products under the Public Health Service Act (42 U.S.C. 262).

Fees are assessed at different rates for qualifying applications depending on whether the applications require clinical data on safety and effectiveness (other than bioavailability or bioequivalence studies) (21 U.S.C. 379h(a)(1)(A) and 379h(b)). Applications that require clinical data are subject to the full application fee. Applications that do not require clinical data and supplements that require clinical data are assessed one-half the fee of applications with clinical data.

In most cases, a first payment of 50 percent of an application or supplement fee is due at the time the application or supplement is submitted (21 U.S.C. 379h(a)(1)(B)(i)). The final payment is due 30 days from the date FDA issues an invoice after issuance of an action letter for the application (see 21 U.S.C. 379g(6)(B)), or at the time an application is withdrawn, unless FDA waives this portion of the fee (21 U.S.C. 379h(a)(1)(A)(ii)). If FDA refuses to file an application or supplement, one-half of the first payment is refunded to the applicant (21 U.S.C. 379h(a)(1)(D)).

In setting the specific rate for each type of fee, FDA is required to estimate the numbers of applications, supplements, establishments, and products that it expects will qualify for fees in FY 1996. FDA makes this estimate based on the number of products, establishments, or applications subject to fees in FY 1995.

For FY 1995, FDA received and assessed fees for 87 filed applications that require clinical data, 36 applications that did not require clinical data, and 62 supplements that require clinical data. Because applications that do not require clinical data and supplements that require clinical data are assessed only one-half the full fee (that is, one-half the fee due on an application that requires clinical data), the equivalent number of these applications subject to the full fee is determined by summing these categories and dividing by 2. This amount is then added to the number of applications that require clinical data to arrive at the equivalent number of applications subject to full application fees.

In addition, as of September 30, 1995, FDA refused to file, or there were withdrawn before filing, two applications that required clinical data, and four applications that did not require clinical data. After refunds, each of the former applications paid one-fourth the full application fee and are counted as one-fourth of an application. Similarly, after refunds, each of the latter applications paid one-eighth of the full application fee rate and are counted as one-eighth of an application.

Using this methodology, the approximate equivalent number of applications that required clinical data and were assessed fees in FY 1995 was 137, before any further decisions were made on requests for waivers or reductions. Additional waivers or reductions of FY 1995 fees are expected to account for approximately 6 equivalents of applications that require clinical data. Therefore, FDA estimates that approximately 131 equivalent applications that require clinical data will qualify for fees in FY 1996, after allowing for possible waivers or reductions. Thus, the FY 1996 application fee rate is determined by dividing the adjusted total fee revenue to be derived from applications ($26,660,400) by the equivalent number of applications projected to qualify for fees in FY 1996 (131), for a fee of $204,000 per application that requires clinical data (rounded to the nearest $1,000). A fee of one-half this amount or $102,000 applies to applications that do not require clinical data and to supplements that require clinical data. The following calculations summarize the determination of FY 1996 application fee rates:

- 87 applications that require clinical data, + (36÷2) applications that do not require clinical data, + (62÷2) supplements that require clinical data, + (2÷4) applications that require clinical data and which FDA refuses to file or the sponsor withdraws before filing, + (4÷8) other applications that FDA refuses to file or the sponsor withdraws before filing minus 6 waivers or reductions = 131 (the estimated number of ''full fee'' applications for FY 1996 based on FY 1995 experience).
- $26,660,400 (FY 1996 estimated revenue to be derived from applications)

÷131 (the estimated number of applications for FY 1996) = $204,000 per application (rounded to the nearest $1,000).

• For applications that do not require clinical data and supplements that require clinical data, the rate will be one-half the full application fee or $102,000.

B. Establishment Fees

The FY 1995 establishment fee was based on an estimate of 200 establishments subject to fees. In FY 1995, 203 establishments qualified for fees before any decisions on requests for waivers or reductions were made. FDA estimates that approximately 197 establishments will qualify for fees in FY 1996 after allowing for possible waivers or reductions. Thus, the number 197 was used in setting the new establishment fee rate. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments ($26,660,400), by the estimated 197 establishments, for an establishment fee rate for FY 1996 of $135,300 (rounded to the nearest $100).

C. Product Fees

The FY 1995 product fee was based on an estimate that 2,116 products would be subject to product fees in FY 1995. For FY 1995, 2,135 products qualified for fees before any decisions on requests for waivers or reductions were made. However, FDA estimates that only 2,115 products will qualify for product fees in FY 1996, after allowing for estimated waivers or reductions. Accordingly, the FY 1996 product fee rate was determined by dividing the adjusted total fee revenue to be derived from product fees ($26,660,400) by the estimated 2,115 products for a product fee rate of $12,600 (rounded to the nearest $100).

V. Adjusted Fee Schedules for FY 1996

The fee rates for FY 1996 are set out in the following table:

Fee category	Fee rates for FY 1996
Applications	
Requiring clinical data	$204,000
Not requiring clinical data	102,000
Supplements requiring clinical data	102,000
Establishments	135,300
Products	12,600

VI. Implementation of Adjusted Fee Schedule

A. Application Fees

Any application or supplement subject to fees under the PDUFA that is submitted after December 31, 1995, must be accompanied by the appropriate application fee established in the new fee schedule. FDA will refund applicants who submitted application fees between October 1, 1995, and December 31, 1995, based on the adjusted rate schedule.

B. Establishment and Product Fees

By December 31, 1995, FDA will issue invoices for establishments and product fees for FY 1996 under the new fee schedules. Payment will be due by January 31, 1996. FDA will issue invoices in October 1996 for any products and establishments subject to fees for FY 1996 that qualify for fees after the December 1995 billing.

Dated: November 28, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–29420 Filed 11–29–95; 11:13 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[OPL–008–N]

Medicare Program; Request for Nominations for Members for the Practicing Physicians Advisory Council

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: In accordance with section 1868(a) of the Social Security Act, this notice requests nominations from medical organizations representing physicians for individuals to serve on the Practicing Physicians Advisory Council. There will be four vacancies on February 29, 1996.

DATES: Nominations from medical organizations will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 5, l996.

ADDRESSES: Mail or deliver nominations for membership to the following address: Health Care Financing Administration, Office of the Associate Administrator for External Affairs, Attention: Sam S. Shekar, M.D., Room 425H, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Sam S. Shekar, M.D., (202) 260–5463.

SUPPLEMENTARY INFORMATION: Section 4112 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101–508), enacted on November 5, 1990, added a new section 1868 to the Social Security Act (the Act), which established the Practicing Physicians Advisory Council (the Council). The Council advises the Secretary (the Secretary) of the Department of Health and Human Services on proposed regulations and manual issuances related to physicians' services. An advisory committee created by the Congress, such as this one, is subject to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2), and, since this committee advises the Secretary, it is also subject to our regulations in 45 CFR Part 11—Committee Management.

Section 1868(a) of the Act requires the Council consist of 15 physicians, each of whom must have submitted at least 250 claims for physicians' services under Medicare in the previous year. At least 11 Council members must be physicians as defined in section 1861(r)(1) of the Act; that is, State-licensed physicians of medicine or osteopathy. The other four Council members may include dentists, podiatrists, optometrists, and chiropractors. The Council must include both participating and nonparticipating physicians as well as physicians practicing in rural and underserved urban areas. In addition, section 1868(a) of the Act provides that nominations to the Secretary for Council membership must be made by medical organizations representing physicians.

This notice is an invitation to all medical organizations representing physicians to submit nominees for membership on the Council. Current members whose terms expire in 1996 will be considered for reappointment, if renominated. The Secretary will appoint the new members to the Council from among those candidates determined to have the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of membership.

Each nomination must state that the nominee has expressed a willingness to serve as a Council member and must be accompanied by a short resume or description of the nominee's experience. To permit evaluation of possible sources of conflict of interest, potential candidates will be asked to provide detailed information concerning financial holdings, consultant positions, research grants, and contracts.