

±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, 1996.

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.