

these categories of registrants is provided below.

Based on an evaluation of U.S. Census data, a certain percentage of manufacturers, hospitals/clinics, and pharmacies, narcotic treatment programs and all practitioners that are registrants with the DEA are likely to be small, as defined by the Small Business Administration. All distributors, importers and exporters are likely to be large. All exporters are likely to be large as they usually are also distributors or manufacturers, and only large manufacturers are likely to be involved in exporting. Researchers, teaching institutions, and analytical labs are assumed to be associated with large institutions or government entities and therefore not qualifying as small businesses.

Manufacturers fall into one of two industry classifications: pharmaceutical preparation or medicinal and botanical manufacturing. Based on DEA data on registered manufacturers, DEA estimates that 381 of the 460 manufacturers registered with DEA qualify as small businesses (Small Business Administration definition of less than 750 employees). For manufacturers in the small business category of 20–49 employees, the fee of \$1,625 represents less than 0.02% of the average annual sales of \$9.7 million (U.S. Census figures).

There are 61,463 pharmacies registered with the DEA and eligible to handle controlled substances. According to the National Association of Chain Drug Stores (NACDS) and census data on mail order prescription firms, there were 35,428 chain pharmacies, mass merchant pharmacies, supermarket pharmacies, and mail order pharmacies in 2001 (latest data available). It is assumed that the remaining 26,035 DEA registrants are independent pharmacies and that these independent pharmacies are small businesses. The chain drug stores, mass merchant pharmacies, supermarket pharmacies, and mail order pharmacies are assumed to be large establishments. For pharmacies in the \$250,000–\$499,000 category of annual sales, a fee of \$130 per year represents 0.05% of average annual sales. In this category, the mean value of annual sales is \$429,853 according to the U.S. Census data of which the annual registration fee represents 0.03%.

There are 14,796 hospitals registered with DEA to handle controlled substances. U.S. Census data indicate there are 6,590 hospitals; thus the remaining 8,206 registrants are assumed to be clinics. Census data also indicate there are 4,434 large hospitals; therefore,

assuming all hospitals are registered with the DEA, DEA estimates there are 2,156 small hospitals. There are 3,260 clinics that can be defined as large. Thus, assuming that all large clinics are registered with DEA, DEA assumes that the remaining 4,946 clinics that are DEA registrants are small. For hospitals in the small business category of \$1 million–\$2.5 million in annual revenue, the annual fee of \$130 represents less than 0.01% of average annual revenues. For clinics and narcotic treatment programs with annual revenues of less than \$100,000 the annual fee of \$130 represents 0.13% of annual revenue. Or for entities with the mean annual revenue of \$61,909 in this group, the fee represents 0.21% of annual revenue. There are 1,166 narcotic treatment programs registered with the DEA.

Finally, there are 1,038,000 practitioners registered with the DEA to handle controlled substances—the largest registrant category. Because practitioners may hold multiple registrations and because practitioners register for three-year cycles, this figure may double count some practitioners and, accordingly, represents a high estimate. The majority of registered practitioners are physicians, followed by dentists and veterinarians. As of May 2003, there are 736,449 physician registrants, 164,630 dentist registrants, 51,101 veterinarian registrants, 44,800 nurse practitioner registrants, and 24,077 physician assistant registrants. Other practitioner registrants include optometrists, nursing homes, animal shelters, ambulances, naturopaths, euthanasia technicians, certain pharmacists in the state of Washington, certain veterinarian technicians in the state of California, and doctors of oriental medicine.

For the three largest groups of registrants in this category, data from the Bureau of Labor Statistics (2001 survey data) indicate the average annual salary of physicians to be \$110,020, of dentists to be \$110,790 and of veterinarians to be \$69,150. For practitioners with average annual salaries of less than \$100,000 the annual fee of \$130 represents 0.13% of annual revenue. Of the mean annual salary of practitioners in this category (\$63,688 per U.S. Census data), the fee represents 0.20%. For physicians and dentists which account for 87% of practitioner registrants, the fee represents 0.12% of annual average salary.

In summary, while the changes in fee structure will affect a substantial number of individual entities that qualify as small businesses, the impact will be minimal when evaluated as a percentage of average annual sales,

revenue or income. Consequently, this rule does not create a significant adverse effect on a substantial number of small entities. In addition, the rule is not a discretionary action but rather responds to a statutory mandate to fully fund the costs of the Diversion Control Program through registrant fees.

VII. Registration Fee

A. Effective Date of New Fee Structure

Based on the methodology described in section V–D of this rulemaking and current calculations, to recover the full costs of the DCP as required by law, DEA plans to incrementally raise the fees in accordance the fee structure summarized in Section V. This fee structure replaces the fee structure proposed in the February 18, 2003 Notice of Proposed Rulemaking.

This fee schedule will go into effect on December 1, 2003. To be as clear as possible about the effective date and to ease processing, this effective date represents the first day of the month following the mandatory 30 days after the publication of the final rule in the **Federal Register**. The new fee schedule will be in effect for all new registration applications postmarked on or after December 1, 2003 and all reregistration applications postmarked on or after December 1, 2003. Registration or reregistration applications postmarked on or after this date must, therefore, include the new fee payment.

Because DEA is required by statute to recover through fees the “full costs” of the DCP, DEA will continue to monitor the costs and expenditures of the DCP and will revise the fee structure as necessary. DEA does not expect to revise the fee structure again until Fiscal Year 2006 (to be effective Fiscal Year 2007); however, DEA cannot anticipate events or other catalysts that may necessitate major diversion control initiatives by the DEA in future years.

B. Individual Registrations

Several comments were received relating to the use of individual registrations for practitioners as opposed to clinics or medical facilities. One pharmacist commenter objected to the ability of residents and hospital- and clinic-based physicians to use their employer's registration number instead of being required by DEA to maintain individual registrations. The commenter noted that use of an employer's number leads to confusion among pharmacists when the computer, cross-checking the number against the practitioner's name, indicates that they do not match. The commenter argued that the ability to use employer's registration numbers is