

“exorbitant.” Multiple commenters noted that physicians and other practitioners have been experiencing declining reimbursements and increasing operating costs, malpractice insurance costs, and costs of complying with other Federal and State requirements combined with high medical school debt. Several commenters suggested that the fee be raised 1.6 percent consistent with the 2003 increase in Medicare reimbursements; others suggested a 3–4 percent annual increase or a flat \$5–10 increase. One commenter questioned how the fee increase compares with the rate of inflation. One commenter alleged that DEA was “arbitrarily” raising fees, and several others commented that DEA had not provided adequate justification for the fee increase.

As described above, DEA’s authority to charge registration fees to support the Diversion Control Program derives from three statutory provisions. DEA is authorized by 21 U.S.C. 821 to collect reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances. Secondly, 21 U.S.C. 958(f) permits DEA to collect reasonable fees relating to the registration of importers and exporters of controlled substances.

Thirdly, the 1993 Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act established the Drug Diversion Control Fee Account (DDCFA) and specifically mandated that fees “shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program.” 21 U.S.C. 886a(3). Congress, in using the mandatory term “shall” as opposed to the discretionary “may,” unambiguously required DEA to increase its then-existing registration fees resulting in registrants fully funding DCP expenses. DEA, therefore, lacks discretion in this matter and must fund its DCP totally from registration fees (that is, not from fines, Congressional appropriations or other potential sources). Assuming for the sake of argument that there is some doubt as to whether Congress intended DEA to entirely fund the DCP from registration fees due to its use of the phrase “various aspects” of the DCP as opposed to something like “all aspects,” the House Conference Report notes that the act’s language “requires the Drug Enforcement Administration to set fees to recover the full cost of their Diversion Control Program.” H.R. Conf. Rep. No. 918, 102nd Cong., 2d Sess. 44 (1992).

Congress also mandated fulfillment of the requirements of the Appropriations

Act “(n)otwithstanding (a)ny (o)ther (p)rovision of (l)aw,” thus making its provisions supersede all other provisions of law that would otherwise prevent or impede DEA’s recovery of the full costs of the DCP through registration fees. H.R. 5678, 102nd Cong., 2d Sess. 111 (1992).

Accordingly, while DEA recognizes the economic pressures facing practitioners such as declining Medicaid reimbursements and increasing operating, equipment, and insurance costs, the current statutory scheme requires DEA to set registration fees to recover the full costs of the DCP, while limiting DEA to charge “reasonable” fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances. DEA does not have the discretion to partially fund the DCP or to find alternative sources of funding for the program. Rather it is mandated by law to fund the DCP fully through registration fees.

DEA has not adjusted the registration and reregistration fees since March 22, 1993 when it published a final rule in the **Federal Register**, establishing registration fees for controlled substances registrants (58 FR 15272). (This fee schedule then went into effect for all registration applications postmarked on April 21, 1993 or later and all renewal applications with an expiration date of May 21, 1993 or later). Following publication of the final rule, the American Medical Association (AMA) and others filed a complaint in the United States District Court for the District of Columbia objecting to the new fees. The district court issued its final order granting the government’s motion for summary judgment and disposing of all claims. Following an appeal by the AMA, the United States Court of Appeals for the District of Columbia Circuit found DEA’s rulemaking to be inadequate and remanded, without vacating, the rule to DEA, requiring the agency to provide an opportunity for meaningful notice and comment on the fee-funded components of the Diversion Control Program. DEA responded to the remand requirement through a final rule published in the **Federal Register** on December 30, 1996 (61 FR 68624). DEA then published its Final Rule on the Drug Diversion Control Fee Account and Diversion Control Program funding, responding to comments and clarifying the activities to be funded as part of the DCP, on August 9, 2002 through publication in the **Federal Register** (67 FR 51988).

Over the period of ten years the costs of operating the Diversion Control

Program (DCP) have increased, necessitating a review of fees and an increase in those fees that support the program as mandated by statute. Such increase in operating costs, detailed below, include a greater number of diversion investigators, increased investigation costs, additional diversion control efforts such as controlling diversion of licit controlled substances on the Internet, inflation, and increases in salaries and compensation for employees. In setting the fees, DEA is mandated to recover the “full costs” (emphasis added) of the DCP and does not have the discretion to adjust the fees according to Medicare reimbursements or inflation as suggested by some commenters. DEA is also mandated to charge “reasonable” fees. Because the fees do not represent a significant financial burden on registrants (see discussion below regarding the impact on small businesses), DEA has determined that the fees contained in this final rule are reasonable. The individual effect on registrants is minimal, representing from 0.21% to as little as 0.01% of average annual sales (or income) for those registrants qualifying as small businesses. For registrants that are large businesses with higher sales, the impact of the fee is even less.

IV. Fees as a Tax or User Fee

Several commenters inaccurately characterized the registration fee as a tax or user fee. One commenter expressed that the DCP is a program from which the general public benefits and from which physicians do not derive a benefit despite paying a fee. User fees are charges that may be assessed only when a fee-funded service provides special benefits to an identifiable recipient beyond those that accrue to the general public, pursuant to the Independent Offices Appropriations Act (IOAA) (OMB Circular A–25, July 15, 1993). Examples of such services include activities that: Enable the beneficiary to obtain more immediate or substantial gains or values than those that accrue to the general public (e.g., receiving a patent, insurance, or guarantee provision, or a license to carry on a specific activity or business); provide business stability or contributes to public confidence in the business activity of the beneficiary (e.g., insuring deposits in commercial banks); or that are performed at the request of or for the convenience of the recipient, and are beyond the services regularly received by other members of the same industry or group or by the general public (e.g., receiving a passport, visa, airman’s