DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301 and 1309

[Docket No. DEA–346P]

RIN 1117–AB32

Controlled Substances and List I Chemical Registration and Reregistration Fees

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: DEA proposes adjusting the fee schedule for DEA registration and reregistration fees necessary to recover the costs of its Diversion Control Program relating to the registration and control of the manufacture, distribution, dispensing, importation and exportation of controlled substances and List I chemicals as mandated by the Controlled Substances Act.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before September 6, 2011. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–346'' on all electronic and written correspondence. DEA encourages all comments be submitted electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document and supplemental information to this proposed rule are also available at the *http://www.regulations.gov* Web site for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to *http://www.regulations.gov* will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone (202) 307–7165.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the ''For Further Information'' paragraph.

Background

Legal Authority

The Drug Enforcement Administration (DEA) is a component of the Department of Justice and is the primary agency responsible for coordinating the drug law enforcement activities of the United States. DEA also assists in the implementation of the President's National Drug Control Strategy. DEA's mission is to enforce U.S. controlled substances laws and regulations and bring to the criminal and civil justice system those organizations and individuals involved in the growing, manufacturing or distribution of controlled substances and listed chemicals appearing in or destined for illicit traffic in the U.S., including organizations that use drug trafficking proceeds to finance terrorism. The diversion control program (DCP) is a strategic component of the DEA's law enforcement mission. The DCP carries out the mandates of the Controlled Substances and Chemical Diversion and Trafficking Acts. It is primarily the DCP within DEA that implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801–971), as amended (hereinafter, ''CSA'').[1] DEA drafts and publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1321. The CSA together with these regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes.

Pursuant to the CSA, controlled substances are classified in one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. 21 U.S.C. 812. Likewise, under the CSA, listed chemicals are separately classified based on their importance to the manufacture of controlled substances (List I chemicals) or their use in manufacturing controlled substances (List II chemicals). 21 U.S.C. 802(33)–(35). The CSA mandates that DEA register persons or entities who manufacture, distribute, dispense, import, export, or conduct research or chemical analysis with controlled substances and listed chemicals. These registrants are permitted to handle controlled substances and listed chemicals as authorized by their registration and are required to comply with the applicable requirements associated with their registration. 21 U.S.C. 822. The identification and registration of all individuals and entities authorized to handle controlled substances and listed chemicals establishes a closed system over which DEA is charged to inspect, investigate, and enforce applicable federal law.

[1] The Attorney General's delegation of authority to DEA may be found at 28 CFR 0.100.

Under the CSA, DEA is authorized to charge reasonable fees relating to the registration and control of the manufacture, distribution, dispensing, import, and export of controlled substances and listed chemicals. 21 U.S.C. 821 and 958(f). DEA must set fees at a level that ensures the recovery of the full costs of operating the various aspects of its DCP. 21 U.S.C. 886a. Each year, DEA is required by statute to transfer the first $15 million of fee revenues into the general fund of the Treasury and the remainder of the fee revenues is deposited into a separate fund of the Treasury called the Diversion Control Fee Account (DCFA). 21 U.S.C. 886a(1). On at least a quarterly basis, the Secretary of the Treasury is required to reimburse DEA an amount from the DCFA ''in accordance with estimates made in the budget request of the Attorney General for those fiscal years'' for the operation of the DCP.[2] 21 U.S.C. 886a(1)(B) and (D). The first $15 million of fee revenues that are transferred to the Treasury do not support any DCP activities.

History of Fees

In 1970, Congress consolidated more than 50 laws related to the control of legitimate channels of narcotics and dangerous drugs into one statute—the CSA. The statute was ''designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a 'closed' system of drug distribution for legitimate handlers of such drugs'' with criminal penalties for transactions outside the legitimate chain.[3] With enactment of the CSA, the Bureau of Narcotics and Dangerous Drugs (BNDD) was also granted authority to charge reasonable fees relating to the registration and control of the manufacture, distribution, dispensing, export, and import of controlled substances.[4] To this end, BNDD established a three-tiered fee structure for companies and individuals wishing to participate in the U.S. controlled substance industry.[5] Before the enactment of the CSA, the U.S. House of Representatives held hearings to discuss the proposed Controlled Substances Act. In these hearings, there was a discussion about whether the Attorney General should be allowed to charge reasonable fees relating to both registration and control (including enforcement costs) or just registration.[6] In the end, Congress enacted the CSA and allowed the Attorney General to charge reasonable fees relating to both registration and control.[7]

In 1973, the BNDD was abolished and all BNDD functions were transferred to DEA, including the authority to charge registrants reasonable fees.[8] In 1982, a General Accounting Office (GAO) report[9] advised that the 1971 fee schedule did not adequately recover the costs for the DCP administered by DEA. An increase in fees was proposed and finalized in the **Federal Register** in 1983.[10] All fees collected from 1971 through 1992 were deposited into the general fund of the United States Treasury.

In the 1993 appropriations for DEA, Congress determined that the DCP would be fully funded by fees and no longer by appropriations.[11] Congress established the DCFA as a separate account of the Treasury to ''ensure the recovery of the full costs of operating the various aspects of [the Diversion Control Program]'' by those participating in the closed system established by the CSA. 21 U.S.C. 886a(1)(C). Congress specified the general operation of the DCFA. Each fiscal year, the first $15 million of deposited fees are retained in the general fund of the Treasury and are not available for use by the DCP. The amounts in excess of $15 million are deposited into the DCFA for the operation of DEA's diversion control program. The funds in the DCFA remain available until expended and are paid by the Secretary of the Treasury to reimburse DEA for expenses incurred in the operation of the DCP in accordance with estimates made in the budget request of the Attorney General. 21 U.S.C. 886a(1). Thus, specific statutory authorizations set the parameters of the DCFA, but not the details of the application of those standards to the activities of DEA.

Shortly after the 1993 Appropriations Act, DEA published a proposed rule proposing to increase the existing fee schedule to comply with Congress' direction to set fees at a level that ensures the recovery of the full costs of operating the DCP.[12] After a comment period, a final rule was published on March 22, 1993, implementing changes to the fee structure and excluding chemical control costs from the calculation of fees.[13] Several members of the registrant population impacted by the fee increase challenged the new fee, first in federal district court, where it was upheld, and subsequently on appeal to the U.S. Court of Appeals where it was remanded without being vacated for inadequate information supporting the selected fees.[14]

In December of 1993, the Domestic Chemical Diversion Control Act of 1993 was passed by Congress to amend the CSA to require that manufacturers, distributors, importers, and exporters of List I chemicals obtain a registration from DEA. Coincident with the new registration requirements, DEA was also authorized to charge ''reasonable fees relating * * * to the registration and control of regulated persons and regulated transactions.'' [15] (Congress modified this language in 2004, as it currently reads at 21 U.S.C. 821, to make it uniform with other provisions

[2] The diversion control program (DCP) consists of the controlled substance and chemical diversion control activities of DEA. These activities are related to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and listed chemicals (21 U.S.C. 886a(2)).

[3] H.R. Rep. No. 91–1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4571–4572.

[4] DEA's authority to charge reasonable fees was later expanded to include manufacturers, distributors, importers and exporters of List I chemicals. The Domestic Chemical Diversion Control Act of 1993, Pub. L. 103–200, 107 Stat. 2333.

[5] 36 FR 4928, March 13, 1971, 36 FR 7776, April 24, 1971.

[6] Drug Abuse Control Amendments of 1970: Hearing on H.R. 1170 and H.R. 13743 Before Subcomm. on Public Health and Welfare of the H. Comm. on Interstate and Foreign Commerce, 91st Cong. 145–148, 359–365, and 412–414 (Feb. 3 & 20, 1970) and Controlled Dangerous Substances, Narcotics and Drug Control Laws: Hearings Before H. Comm. on Ways and Means, 91st Cong. 211–214 and 468–474 (July 20 & 21, 1970).

[7] The term ''control'' as defined in 21 U.S.C. 802(5) specifically applies to Part B of Title II of the CSA only (21 U.S.C. 811–814). In general, ''diversion control'' is a broad term encompassing activities related to preventing and detecting the diversion of controlled substances and listed chemicals from legitimate commerce into the illicit market. In 1992, Congress established the Diversion Control Fee Account (DCFA) and required that the fees charged by DEA under its diversion control program be set at a level that ensures the recovery of the full costs of operating the various aspects of that program (Pub. L. 102–395, 106 Stat. 1843). In 2004, Congress amended the CSA and defined ''diversion control program'' and ''controlled substance and chemical diversion control activities'' (Pub. L. 108–447, 118 Stat. 2921, codified in 21 U.S.C. 886a). The ''diversion control program'' means the controlled substance and chemical diversion control activities of the Drug Enforcement Administration. 21 U.S.C. 886a(2)(A).

[8] Reorganization Plan No. 2 of 1973, 38 FR 18380 (July 2, 1973).

[9] GAO/GGD–83–2, October 29, 1982.

[10] 48 FR 14640, April 5, 1983; 48 FR 56043, December 19, 1983.

[11] Departments of Commerce, Justice, and State, the Judiciary and Related Agencies Appropriations Act of 1993, Public Law 102–395, codified in relevant part at 21 U.S.C. 886a.

[12] 57 FR 60148–01, December 18, 1992.

[13] 58 FR 15272–01, March 22, 1993.

[14] *American Medical Association* v. *Reno,* 857 F.Supp. 80 (D.D.C. 1994); *American Medical Association* v. *Reno,* 57 F.3d 1129 (D.C. Cir. 1995).

[15] The Domestic Chemical Diversion Control Act of 1993, Public Law 103–200, 107 Stat. 2333.

of the CSA.[16]) This amendment to the CSA was made after publication of DEA's March 22, 1993 final rule and the commencement of the legal challenges. List I chemical registration and reregistration fees were not addressed in the DCFA until the fee calculation initiated with a proposed rule published November 2005.[17]

The fee was finalized in 1996 with a request for further comment.[18] DEA instituted studies and internal reorganizations to enable DEA to better identify DCP activities and costs. Additional information on the components and activities of the fee-funded DCP and what was deemed to be part of that program as well as DEA's response to comments received was published in 2002 for additional public comment.[19] After that publication, a review of DEA's DCP by the Office of the Inspector General, Department of Justice (OIG) concluded DEA was not adequately supporting the DCP program.[20]

In February 2003, DEA published a proposed rule to raise registration and reregistration fees in an effort to comply with the statutory requirement to charge fees at a level that ensures the recovery of the full costs of operating the various aspects of the DCP.[21] Shortly thereafter, DEA created an organization within headquarters known as the Validation Unit. This Unit reviews and ensures that every DCFA expenditure over $500 is in support of diversion control-related activities. The Validation Unit is independent of the Office of Diversion Control and reports directly to the DEA Deputy Administrator. If an expense only partially supports the DCP, such as a field office's rent or utility cost, the Validation Unit determines the portion of the expense that should be funded by the DCFA. A new fee was finalized by publication of a final rule on October 10, 2003.[22]

In 2004, Congress provided additional guidance in the relevant 2005 Appropriations Act.[23] Specifically, the CSA was amended to define the DCP as ''the controlled substance and chemical diversion control activities of the Drug Enforcement Administration.'' 21 U.S.C. 886a(2)(A). Furthermore, ''controlled substance and chemical diversion control activities'' means ''those activities related to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and listed chemicals.'' 21 U.S.C. 886a(2)(B). Congress further provided that reimbursements from the DCFA ''shall be made without distinguishing between expenses related to controlled substance activities and expenses related to chemical activities'' (21 U.S.C. 886a(1)(B)) and amended the language of 21 U.S.C. 821 and 958(f) to be consistent with the definition of the DCP articulated in 21 U.S.C. 886a(2). As a result, all registration and reregistration fees for controlled substances and chemicals are deposited into the DCFA and reimbursements by the Secretary of the Treasury are made without distinction.

In 2005, based upon the internal organizational changes and the 2005 Appropriations Act, DEA proposed an adjusted fee schedule to appropriately reflect all costs associated with the DCP.[24] In July 2006, the OIG reported on its *Follow-up Review of DEA's Efforts to Control the Diversion of Controlled Pharmaceuticals* and recommended that DEA apply more resources to diversion control.[25] The OIG also recommended that DEA provide more Special Agent support to the DCP and increase training for those individuals who support the program. The OIG also noted that the diversion of controlled substance pharmaceuticals had dramatically increased over recent years and that the increase coincided with the use of emerging technologies such as the Internet. Twelve comments were received and analyzed in response to DEA's proposed fee rule and DEA published the final rule on August 29, 2006.[26]

The OIG completed a *Review of DEA's Use of the Diversion Control Fee Account* in 2008 and did not find any misused DCFA funds for non-diversion control activities between FY 2004 and FY 2007. To the contrary, the OIG found that DEA did not fully fund all diversion control costs with the DCFA as required by law.[27] It has been approximately five years since the last fee adjustment. It should be noted, however, that collections associated with the last fee adjustment did not begin until FY 2007.

Diversion Control Program (DCP)—Scope

The scope of the DCP has evolved since its inception. In late 1971, the BNDD's Compliance Program was created to provide a specialized work force that could focus exclusively on controlled substance diversion and take full advantage of the controls and penalties established by the CSA. The program was placed under the BNDD's Office of Enforcement and staffed by compliance investigators, later called diversion investigators. In 1973, the BNDD was abolished and all BNDD functions were transferred to DEA.[28]

From 1971 to 1983, DEA's legal authority with regard to diversion and abuse of drugs remained relatively unchanged. The CSA originally provided DEA with substantially more authority to regulate controlled substance manufacturers and distributors than retail dispensers such as medical professionals and retail pharmacies. Congress, acknowledging that registration is the cornerstone of the closed system of distribution, required DEA to find that manufacturer and distributor registrations are consistent with a specifically defined public interest and with U.S. international obligations as a prerequisite to granting such registrations.[29] In contrast, practitioners were entitled to a registration if they were authorized to handle controlled substances by the state in which they practiced. Furthermore, a practitioner's registration could be revoked only on the following three bases: conviction of a drug-related felony; revocation of a state license; or submission of a materially falsified application. There was also great disparity in the recordkeeping and security requirements applicable to the two groups, with manufacturers and distributors subject to the tighter

[16] It authorizes ''reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.'' 21 U.S.C. 821.

[17] 70 FR 69474, November 16, 2005. See also 108 H. Rpt. 576, July 1, 2004.

[18] 61 FR 68624, December 30, 1996.

[19] 67 FR 51988, August 9, 2002.

[20] ''Review of the Drug Enforcement Administration's Control of the Diversion of Controlled Pharmaceuticals,'' I–2002–010, October 2002, *http://www.usdoj.gov/oig/reports/DEA/e0210/index.htm.*

[21] 68 FR 7728, February 18, 2003.

[22] 68 FR 58587, October 10, 2003. DEA published a correction to this final rule where the internal DEA computer system, Firebird, was identified as being solely funded through appropriations. The Firebird system costs are properly apportioned as a DCP cost as well as a non-DCP appropriations expense. 69 FR 34568, June 22, 2004.

[23] Public Law 108–447, Departments of Commerce, Justice and State, the Judiciary and Related Agencies Appropriations Act of 2005, signed into law on December 8, 2004.

[24] 70 FR 69474, November 16, 2005.

[25] ''Follow-Up Review of the Drug Enforcement Administration's Efforts to Control the Diversion of Controlled Pharmaceuticals,'' I–2006–004, July 2006, *http://www.usdoj.gov/oig/reports/DEA/e0604/final.pdf.*

[26] 71 FR 51105, August 29, 2006.

[27] ''Review of the Drug Enforcement Administration's Use of the Diversion Control Fee Account,'' I–2008–002, February 2008, *http://www.usdoj.gov/oig/reports/DEA/e0802/final.pdf.*

[28] Reorganization Plan No. 2 of 1973, 38 FR 18380 (July 2, 1973).

[29] 21 U.S.C. 823(a)–(e).

controls. This disparity in regulatory authority generated more regulatory oversight and, hence, compliance, at the manufacturer and distributor level than at the retail level. The limitations on DEA's statutory authority severely restricted its ability to regulate practitioners.

By 1977, all 197 DEA compliance investigators (now diversion investigators) were fully occupied monitoring approximately 3,300 controlled substance manufacturers, distributors, importers, exporters, and narcotic treatment programs, where large stocks of controlled substances and the potential for large-scale diversion were present.[30] At that time, 98 percent of DEA registrants were in the dispensing category, *i.e.,* physicians, dentists, veterinarians, retail pharmacies, hospitals, and teaching institutions.[31] In 1978, the Comptroller General issued a report to Congress that examined DEA's efforts to prevent diversion of controlled substances at the retail level, *i.e.,* by doctors and pharmacists.[32] The report explored the barriers to DEA's efforts to control retail diversion: inadequate statutory authority, weak regulatory requirements, and inadequate resources. One of the Comptroller General's recommendations to Congress was that Congress change DEA's role by authorizing DEA to exercise direct regulatory authority over retail level practitioners. This would have been a deviation from DEA's traditional enforcement role and would require significant legislative changes and manpower increases.

Shortly thereafter, many amendments to the CSA between 1984 and 1990 strengthened and expanded DEA's statutory authority. The Dangerous Drug Diversion Control Act of 1984 [33] provided DEA with new authority to deny or revoke a practitioner's DEA registration on the basis of specifically defined public interest grounds [34] and also provided DEA with emergency scheduling authority.[35] The Anti-Drug Abuse Act of 1986 established penalties for the manufacture and distribution of ''designer drugs.'' [36] The Anti-Drug Abuse Act of 1988 for the first time required recordkeeping and reporting by chemical distributors, importers, and exporters, and established penalties for illegal activities related to precursor and essential chemicals.[37] The Anabolic Steroids Control Act of 1990 brought steroids under the regulatory oversight and control of the DEA by placing certain anabolic steroids in schedule III of the CSA.[38] This Act required certain steroid manufacturers and distributors to register with DEA and brought anabolic steroids under the recordkeeping, reporting, security, prescribing, import, and export controls of the CSA.

As discussed above, the Domestic Chemical Diversion Control Act of 1993 amended the CSA to require manufacturers, distributors, importers, and exporters of List I chemicals obtain a registration from the DEA, thus greatly expanding the authority and activities of the DCP.

On October 17, 2000, Congress passed the Drug Addiction Treatment Act, permitting qualified physicians to treat narcotic dependence with certain schedule III through V narcotic controlled substances.[39] The Act waived the requirement for certain qualified physicians to obtain a separate DEA registration as a Narcotic Treatment Program. However, upon application, the DCP must issue such qualifying physicians an identification number for inclusion with the physician's DEA Certificate of Registration.[40] As a result, when a qualifying physician submits notice of his waiver pursuant to the Act, the DCP issues the physician a new DEA Certificate of Registration with the appropriate identification number.

Renamed from the Office of Compliance and Regulatory Affairs and then the Diversion Control Program, today, the DEA Office of Diversion Control administers the DCP.[41] As such, it is responsible for ensuring the availability of controlled substances and listed chemicals for legitimate uses in the United States while exercising controls to prevent the diversion of these substances and chemicals for illegal uses. The Office of Diversion Control maintains an overall geographic picture of the drug and chemical diversion and abuse problems to identify new trends or patterns in diversion and abuse. This enables the Office of Diversion Control to appropriately direct resources.

The DCP is executed by maintaining the closed system of distribution, regulating and controlling nearly 1.4 million DEA registrants,[42] and investigating activity related to the diversion of controlled substances and listed chemicals. The DCP's regulatory function is accomplished through routine regulatory inspections, by providing information and assistance to registrants, and by controlling and monitoring the manufacture, distribution, dispensing, import, and export of controlled substances and listed chemicals. The DCP's enforcement function is accomplished by identifying and investigating those persons or entities responsible for diverting controlled substances and listed chemicals from legitimate commerce. Violators are subject to administrative sanction, and civil and criminal prosecution.

To ensure accountability within the closed system of distribution, the DCP administers, maintains, controls, and oversees the DEA registration system.[43] This entails processing, reviewing, and, if necessary, investigating all applications for registration and reregistration, collecting fees, and, when appropriate, proposing to take administrative action on registrations or applications for registration, such as restriction, revocation, suspension, or denial of an application. Maintaining the DEA registration system requires coordination with state regulatory agencies and other federal agencies such as the Center for Substance Abuse Treatment.[44]

In addition, the DCP exercises statutory authority to determine the appropriate procedures necessary to the ordering and distribution of schedule I and II controlled substances.[45] This enables the DCP to monitor the flow of certain controlled substances from their point of manufacture through commercial distribution. It also monitors registrant compliance with

[30] GAO/GGD–78–22, March 10, 1978 at 3, 18.

[31] GAO/GGD–78–22 at 3.

[32] GAO/GGD–78–22.

[33] Part B—Diversion Control Amendments, Public Law 98–473, 98 Stat. 2070 (Oct. 12,1984).

[34] 21 U.S.C. 823(f), 824(a)(4).

[35] 21 U.S.C. 811(h) (The amendment provided for one-year emergency scheduling of a drug, the abuse of which constituted an ''imminent hazard to the public safety.'' The drug would remain in schedule I for up to one year, during which the normal scheduling procedures would proceed).

[36] Subtitle E—Controlled Substances Analogue Enforcement Act, Public Law 99–570, 100 Stat. 3207 (Oct. 27, 1986).

[37] Title VI, Subtitle A—Chemical Diversion and Chemical Trafficking Act of 1988, Public Law 100–690, 102 Stat. 4181 (Nov. 18, 1988).

[38] Public Law 101–647, 104 Stat. 4851 (Nov. 29, 1990).

[39] Public Law 106–310, 114 Stat. 1222 (Oct. 17, 2000).

[40] 21 U.S.C. 823(g)(2)(D)(ii).

[41] 28 CFR Part 0, Appendix to Subpart R.

[42] This represents the total registrant population. Approximately seven percent of the total registrant population consists of fee exempt registrants who are not included in the fee calculations presented herein. The registrant population grew at a rate of approximately 2.6 percent per year from 2007 to 2010.

[43] See 21 U.S.C. 822–25, 827–29, 831, 952–54, 956–58, 971.

[44] See 21 U.S.C. 823(g).

[45] 21 U.S.C. 828.

electronic reporting systems such as the Automation of Reports and Consolidated Orders System (ARCOS), and manages the cataloging of controlled substances based on the National Drug Code (NDC) system, the Drug/Ingredient file, Trade Name file, DEA Generic Name file and U.N. Code/Name file. Other oversight activities include maintaining the Controlled Substance Ordering System (CSOS), monitoring CSOS activities through the initial certification process, and periodic auditing of registrant systems. CSOS provides registrants with an electronic platform that reduces costs to registrants while ensuring a more efficient and effective ordering process.

One of the primary functions of the DCP is to ensure that registrants are in compliance with the safeguards inherent in the CSA. This proactive approach is designed to identify and prevent the large scale diversion of controlled substances and listed chemicals into the illicit market.

Registrant compliance is determined primarily through the conduct of pre-registration, scheduled, and complaint investigations. DCP regulatory activities have an inherent deterrent function, and they are designed to ensure that those businesses and individuals registered with DEA to handle controlled substances or listed chemicals have sufficient measures in place to prevent the diversion of these substances. These investigations also help registrants understand and comply with the CSA [46] and identify those registrants who violate the CSA and implementing regulations. Preregistration investigations reduce the possibility of registering unauthorized subjects, ensure that the means to prevent diversion are in place, and determine whether registration is consistent with the public interest.

Manufacturers, distributors, reverse distributors, importers, exporters, and narcotic treatment programs pose the greatest potential for large-scale diversion. Accordingly, scheduled investigations of these non-practitioner registrants are a major priority of the DCP. These investigations serve as a deterrent to diversion through the continuous evaluation of registrants' recordkeeping procedures, security, and overall adherence to the CSA. Emphasis during these investigations is given to verifying inventory, records and recordkeeping procedures, a review of customers and their ordering patterns, and security protocols.

The DCP is constantly evaluating diversion trends, patterns, routes, and techniques in order to appropriately focus its regulatory, civil and criminal enforcement activities. This is accomplished in many ways, including collecting and analyzing targeting and analysis data, conducting diversion threat assessments, working with state and local medical and pharmacy boards and state and local law enforcement agencies, and developing intelligence.

The DCP conducts criminal enforcement activities primarily through Tactical Diversion Squads (TDSs). TDSs are comprised of many DEA specialties, including DEA Special Agents and Diversion Investigators, and state and local counterparts such as state law enforcement and regulatory personnel. These groups combine varied resources and expertise in order to investigate, disrupt, and dismantle those individuals or organizations involved in diversion schemes (*e.g.,* doctor shoppers, prescription forgers, and prevalent retail-level violators).

In fulfillment of its function to control the import and export of controlled substances and listed chemicals, the DCP issues import and export registrations and permits, and monitors declared imports, exports, and transshipments of these substances. The DCP must ensure that all imports and exports of controlled substances and listed chemicals meet the requirements of the CSA. As such, the DCP maintains and monitors many electronic reporting systems, such as the Chemical Handlers Enforcement Management System (CHEMS), which provides information on entities manufacturing, distributing, and exporting and importing regulated chemicals, and encapsulating and tableting machines.[47]

The DCP's authority over controlled substances and listed chemicals requires its support of domestic and foreign investigations of these substances. As such, the DCP serves as the Competent National Authority (CNA) for the United States vis-à-vis precursor chemicals and international treaties. The DCP works with the international community to identify and seize international shipments of precursor and essential chemicals destined for clandestine laboratories for use in manufacturing controlled substances. The DCP also works on a bilateral basis to urge international partners to take effective action, in cooperation with chemical companies, to prevent the diversion of precursor chemicals from legitimate trade. In addition to its other oversight and regulatory responsibilities in this area,[48] the DCP reviews and approves importation requests for List I chemicals and reviews chemical registrant submissions.

Not only does the DCP exercise authority and control over the registrant population, the DCP exercises authority over the classification of substances.[49] This is accomplished by evaluating drugs and chemicals to determine whether these substances are being abused or potentially involved in illicit traffic, and to evaluate whether any substances should be scheduled as a controlled substance. This requires the collection and analysis of data from various sources across the United States. These evaluations are used by DEA as a basis for developing appropriate drug control policies, determining the status of controlled, excluded, or exempted drugs and drug products, and supporting United States initiatives in international forums.

Another crucial function of the DCP is the annual establishment of quotas for all schedule I and II controlled substances and the List I chemicals pseudoephedrine, ephedrine, and phenylpropanolimine.[50] Along with this responsibility, the DCP also provides scientific support for policy guidance and training, expert witness testimony and conference presentations. The DCP fulfills U.S. treaty obligations pertaining to the CSA, including the preparation of periodic reports for submission to the United Nations as mandated by U.S. international drug control treaty obligations on the manufacture and distribution of narcotic and psychotropic substances as well as determining the anticipated future needs for narcotic and psychotropic substances.

In the execution of its regulatory functions, the DCP reviews proposed legislation pertinent to the availability of controlled substances and listed chemicals for legitimate uses in the United States and controls to prevent the diversion of these substances and chemicals. The DCP constantly reviews its own regulations and develops and implements regulations designed to enhance DEA's diversion control efforts and to implement newly enacted legislation.

All DCP regulatory activities require education and outreach to ensure appreciation of and compliance with the CSA and applicable policies and regulations. Providing such guidance is also necessary to reduce the likelihood of diversion from legitimate commerce

[46] See 21 U.S.C. 827 (records and reports of registrants).

[47] See 21 U.S.C. 830, 957–58.

[48] 21 U.S.C. 830; 21 CFR Parts 1310, 1313, 1314.

[49] 21 U.S.C. 811–814.

[50] 21 U.S.C. 826.

to illegitimate purposes. One aspect of the DCP's outreach efforts is establishing and maintaining liaison and working relationships with other federal agencies, as well as foreign, state and local governments, and the regulated community. Other efforts include developing and maintaining manuals and other publications; organizing and conducting national conferences on current issues, policies, and initiatives; and providing guidance to the general public.

Changes in the Controlled Substances Act Since the Last Fee Rule in 2006

Since implementation of the last fee rule in 2006, Congress has made several changes to the CSA that impact how the DCP operates to control controlled substances and listed chemicals and register those individuals who wish to handle these substances. Additionally, the nature of the diversion control problem has increased in size and complexity. These statutory changes, in addition to the changing scope of diversion, required the DCP to implement program and organizational changes. These changes impact DEA beyond its DCP and thus are not necessarily funded through the DCFA.

Methamphetamine Abuse

Congress has enacted a series of legislative initiatives to combat the rise in methamphetamine abuse. Methamphetamine is a highly addictive drug with potent central nervous system stimulant properties. Control as a schedule II substance and the removal of methamphetamine injectable formulations from the United States market, combined with a better appreciation for its high abuse potential, led to a drastic reduction in the abuse of this drug in 1971. However, a resurgence of methamphetamine abuse occurred in the 1980s and it is currently considered a major drug of abuse. The widespread availability of methamphetamine today is largely fueled by illicit production in large and small clandestine laboratories throughout the United States and illegal production and importation from Mexico.

Methamphetamine is abused for its stimulant and euphoric effects. High-dose chronic abuse has been associated with irritability, tremors, convulsions, anxiety, paranoia, and neurotoxic effects that cause damage to neurons and blood vessels. Aggressive and violent behavior by users, often directed at spouses and children, pose a significant risk to those individuals in contact with methamphetamine addicts. Death has resulted from extreme anorexia, hyperthermia, convulsions, and cardiovascular collapse (including stroke and heart attacks).

The methods used to manufacture methamphetamine are directly impacted by the availability of precursor chemicals and ease of synthesis. Currently, methamphetamine is primarily produced domestically by utilizing diverted pseudoephedrine combination products that are sold at retail and, to a lesser extent, ephedrine products. The manufacture of this drug poses a significant threat to the public health and safety due to the toxic waste and the risk of fire and explosion associated with the clandestine laboratories that manufacture the drug, and the fact that many individuals, including children, are at risk of exposure to toxic chemicals and waste generated during the manufacturing process.

A Rand Corporation study reported that the 2005 cost to the U.S. for overall methamphetamine-related activities including crime and criminal justice costs, health care costs, endangered children put in foster care, the loss of productivity, drug treatment, and injuries and death at methamphetamine laboratories was estimated at $23.4 billion.[51] Similarly, the Vanderbilt University Medical Center in Tennessee reported spending $325 million between July 2009 and June 2010 for uncompensated medical care at its Burn Center.[52] One-third of its patients were burned from exploding methamphetamine laboratories.[53]

In 2010, there were in excess of 10,000 clandestine laboratory incidents in the United States related to the manufacture of methamphetamine.[54] Coinciding with the upward trend in methamphetamine laboratory seizures is an alarming upward trend in methamphetamine abusers. According to the 2009 National Survey on Drug Use and Health, between 2008 and 2009 there was a 60 percent increase in the number of past month users of methamphetamine.[55] This comes after a significant reduction of past month users between 2006 and 2008, a period when the U.S. was experiencing decreases in the number of methamphetamine laboratory seizures.

The Combat Methamphetamine Epidemic Act of 2005 (CMEA) was enacted on March 9, 2006. 21 U.S.C. 971. It requires retailers of non-prescription products containing pseudoephedrine, ephedrine and phenylpropanolamine to place these products behind the counter or in a locked cabinet. Consumers must show identification and sign a logbook for each purchase. An interim final rule was published to implement section 716 of the Act and require additional reporting for import, export, and international transactions involving all List I and List II chemicals.[56] On October 14, 2008, Congress enacted the Methamphetamine Production Prevention Act of 2008, which amended the CSA to require the sellers of methamphetamine precursor chemicals to record information about sales and purchasers in electronic logbooks or bound paper books. 21 U.S.C. 830(e)(1)(A)(iv)–(vi). Further, on October 12, 2010, the Combat Methamphetamine Enhancement Act of 2010 (MEA) was enacted, establishing new requirements for mail-order distributors of scheduled listed chemical products (Pub. L. 111–268).

Internet Diversion

On October 15, 2008, Congress amended the CSA with enactment of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. DEA amended its regulations accordingly by interim final rule to prevent the illegal distribution and dispensing of controlled substances by means of the Internet.[57]

Disposal of Controlled Substances

Lastly, on October 12, 2010, Congress amended the CSA with the enactment of the Secure and Responsible Drug Disposal Act of 2010 (Pub. L. 111–273). Pursuant to this amendment, DEA must promulgate new regulations that allow ultimate users and long-term care facilities to dispose of controlled substances through a variety of methods of collection and disposal. DEA is in the process of drafting these regulations.

[51] Nancy Nicosia et al., ''The Economic Cost of Methamphetamine Use in the United States, 2005,'' RAND Corporation, 2009.

[52] John Brannon, ''Meth-related Burns a Growing Part of Uncompensated Care at Vanderbilt,'' *Messenger,* August 12, 2010, *http://www.nwtntoday.com/news.php?viewstory=44736.*

[53] *Id.*

[54] The El Paso Intelligence Center (EPIC) has not validated this data as of the date of this Notice of Proposed Rulemaking, however, all indications are that there were approximately 12,000 such clandestine laboratory incidents in 2010.

[55] Substance Abuse and Mental Health Services Administration (SAMHSA), ''Results from the 2009 National Survey on Drug Use and Health: Volume I, Summary of National Findings,'' Office of Applied Studies, 2010 (NSDUH Series H–38A, HHS Publication No. SMA 10–4856), *http://www.oas.samhsa.gov/nsduh/2k9NSDUH/2k9Results.pdf.*

[56] 72 FR 17401, April 9, 2007. Implementation was delayed an additional 30 days until June 8, 2007, to allow industry more time to fully comply with the new provisions. 72 FR 28601, May 22, 2007.

[57] 74 FR 15596, April 6, 2009.

Increased Need for Diversion Control

Coincident with the above statutory changes, the increased misuse of controlled substances and listed chemicals highlights the urgency of and need for diversion control. The National Survey on Drug Use and Health (NSDUH) (formerly the National Household Survey on Drug Abuse) is an annual survey of the civilian, non-institutionalized, population of the United States aged 12 or older. The survey is conducted by the Department of Health and Human Services Office of Applied Studies, Substance Abuse and Mental Health Services Administration. Findings from the 2009 NSDUH [58] estimate that 7.0 million persons used prescription-type psychotherapeutic drugs—pain relievers, anti-anxiety medications, stimulants, and sedatives—non-medically in the previous month. This represents 2.8 percent of the population aged 12 or older. These estimates were 13 percent higher than those from the 2008 Survey. From 2002 to 2009, there was an increase in the rate of current non-medical use of prescription-type drugs (from 5.5 to 6.3 percent) among young adults aged 18 to 25, driven primarily by an increase in pain reliever misuse. In 2009, an estimated 3.1 million persons aged 12 or older used an illicit drug for the first time within the past twelve months. Of those, an estimated 28.7 percent initiated with psychotherapeutics, including 17.1 percent with pain relievers, 8.6 percent with tranquilizers, 2.0 percent with stimulants, and 1.0 percent with sedatives.

Abuse of prescription controlled substances among teenagers is second only to abuse of illegal marijuana. The 2010 ''Monitoring the Future'' survey of teenagers found that 8 percent of high school seniors reported non-medical use of Vicodin, and 5.1 percent reported non-medical use of OxyContin, both scheduled controlled substances (painkillers).[59] This reported abuse is consistent with reports by high-school students of increased non-medical use of painkillers in the past five years.[60] As reported by The Partnership at Drugfree.org (formerly the Partnership for a Drug-Free America) from its 2009 survey, more than 50 percent of teenagers (grades 9–12) believe that prescription drugs are easier to obtain than illegal drugs. There is a concern that young people may perceive prescription and/or over-the-counter drugs as ''safer'' than illegal drugs because of their intended, legitimate medical use.[61]

The consequences of prescription drug abuse are seen in the data collected by the Substance Abuse and Mental Health Services Administration (SAMHSA) on emergency room visits. According to their latest data, ''Drug Abuse Warning Network (DAWN), 2009: National Estimates of Drug-Related Emergency Department Visits,'' SAMHSA estimates that of the 4.6 million emergency department visits in 2009 associated with drug use, about 1.2 million visits involved the non-medical use of pharmaceuticals.[62] Emergency department visits involving non-medical use of pharmaceuticals (misuse or abuse) almost doubled between 2004 and 2009 from 627,291 in 2004 to 1,244,679 visits in 2009 (98.4 percent increase).[63] About half of the 2009 emergency department visits related to abuse or misuse of pharmaceuticals involved painkillers and more than one-third involved drugs to treat insomnia and anxiety.[64]

According to the Centers for Disease Control, overdose deaths caused by prescription drugs is the second leading cause of accidental death in the United States among young people.[65] The Florida Medical Examiner's Commission reported that between 2005 and 2009 the number of deaths in Florida associated with oxycodone rose 248.5 percent.[66]

Operational Changes of the DCP Since 2006

As discussed above, the OIG reviewed DEA's efforts to control the diversion of controlled pharmaceuticals and in 2006 recommended that DEA incorporate law enforcement support and law enforcement authority to assist the DCP in performing criminal investigations that inherently require law enforcement authority, *e.g.,* the authority to arrest, execute search warrants, and conduct surveillance and undercover activities. As discussed above, DEA expanded the use of Tactical Diversion Squads comprised of many DEA specialized resources such as Special Agents, Diversion Investigators and state and local law enforcement and regulatory personnel to more effectively investigate, disrupt, and dismantle those individuals or organizations involved in diversion schemes. Since the last fee calculation, DEA added 161 Special Agent positions to the DCP. The majority of these positions were allocated to the DCP Tactical Diversion Squads. By 2009, there were 37 operational Tactical Diversion Squads across the United States and DEA is committed to increasing this number within this fee cycle. These squads are designed to address controlled substance diversion in consonance with the traditional Diversion Investigator regulatory efforts.

DEA made other organizational changes to incorporate in the DCP those units responsible for diversion control operations. To ensure the proper utilization of DCFA resources, DEA created a Diversion Value and Analysis Unit in the Diversion Planning and Resources Section to identify and prevent duplication of effort, conduct cost benefit analyses, and develop, oversee, and review acquisitions.

In 2009, the DCP intensified its regulatory activities to help the registrant population better comply with the CSA and to identify those registrants who violated the CSA and implementing regulations. The modifications included increasing investigation cycles as well as depth of review. Scheduled investigations were increased from every five years to every three years for controlled substance manufacturers, bulk manufacturers, distributors, reverse distributors, importers, exporters, bulk importers, and Narcotic Treatment Programs; scheduled investigations for chemical manufacturers, bulk manufacturers, distributors, importers, exporters, and bulk importers were increased from two

[58] SAMHSA, ''Results from the 2009 National Survey on Drug Use and Health: Volume I, Summary of National Findings,'' Office of Applied Studies, 2010 (NSDUH Series H–38A, HHS Publication No. SMA 10–4856), *http://www.oas.samhsa.gov/nsduh/2k9NSDUH/2k9Results.pdf.*

[59] Lloyd D. Johnson, PhD, *et al,* ''Monitoring the Future National Results on Adolescent Drug Use: Overview of Key Findings, 2010,'' Institute for Social Research, The University of Michigan, 2011.

[60] Lloyd D. Johnston, PhD, *et al,* ''Monitoring the Future National Results on Adolescent Drug Use: Overview of Key Findings, 2009,'' National Institute of Drug Abuse, 2010 (NIH Publication No. 10–7583).

[61] Partnership for a Drug-Free America and MetLife Foundation, ''2009 Parents and Teens Attitude Tracking Report,'' March 2, 2010.

[62] SAMHSA, Highlights of the 2009 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits, Center for Behavioral Health Statistics and Quality, The DAWN Report, December 28, 2010.

[63] *Id.* at 4.

[64] *Id.* at 3.

[65] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, Web-based Injury Statistics Query and Reporting System (WISQARS), ''20 Leading Causes of Death, United States, 2007, All Races, Both Sexes.''

[66] Florida Dep't of Law Enforcement, Medical Examiners Commission, ''Drugs Identified in Deceased Persons by Florida Medical Examiners 2005 Report,'' at 15 (May 2006) and Florida Dep't of Law Enforcement, Medical Examiners Commission, ''Drugs Identified in Deceased Persons by Florida Medical Examiners 2009 Report,'' at 17 (June 2010).

per Diversion Investigator per year to all such registrants every three years. Investigations of Office Based Opioid Treatment/Buprenorphine Physicians, currently referred to as DATA–Waived Practitioners, were increased from one such registrant per Diversion Group per year to all such registrants per Diversion Group every five years. Researchers were increased from only being investigated on a complaint basis to two schedule I researchers plus two schedule II–V researchers per Diversion Group per year. Finally, analytical laboratories, previously not subject to scheduled investigations, were increased to include analytical laboratories affiliated with manufacturers being investigated every three years in tandem with the affiliated manufacturer's scheduled investigation.

In an effort to enhance the DCP's enforcement capabilities, to reduce costs, to streamline the regulatory compliance process for registrants, and to keep the public informed, the DCP made several improvements to its information technology capabilities. Underperforming contracts were terminated and a new unit was created within the DCP to manage all information technology projects exclusively for the DCP. This resulted in significant cost reductions and improved program efficiency and responsiveness to both registrants and the public.

The new unit successfully made cost-saving improvements to the technology infrastructure of the Controlled Substances Ordering System (CSOS) and streamlined the application process for registrants by implementing an online system for new applications and renewal applications for registrations. The DCP is also enhancing the communications system to allow interconnectivity between many different systems. The DCP is continually working to improve the quality and accessibility of its reporting systems, such as the Automated Reports and Consolidated Orders System (ARCOS) and Drug Theft/Loss (DTL). These two programs generate timely, accurate, and actionable data that improve the DCP's enforcement and control efforts as well as providing for a more efficient means by which registrants may submit such reports.

DEA's Interim Final Rule on Electronic Prescriptions for Controlled Substances (EPCS), effective June 1, 2010, will enhance diversion control as a means to protect against fraudulent prescriptions and will streamline the recordkeeping process for pharmacies (75 FR 16236, March 31, 2010). This rule provides practitioners with the option to electronically sign and transmit prescriptions for controlled substances. Likewise, with this new rule, pharmacies are permitted to receive and archive electronic prescriptions. The DCP is working to develop and implement EPCS.

As part of the requirements of the Combat Methamphetamine Epidemic Act of 2005 (CMEA), regulated sellers of scheduled listed chemical products are required to self-certify annually. Regulated sellers can self-certify and find training manuals on the Diversion Control Program Web site.

Need for a New Fee Calculation

DEA last adjusted the fee schedule in August 2006, however, collections did not begin until FY 2007.[67] This fee schedule was intended to be sufficient to cover the ''full costs'' of the DCP for FY 2006 through FY 2008 or October 1, 2005 through September 30, 2008. The DCP program has continued to operate under this fee schedule due to cost savings through reorganization and modernization efforts and by inadvertently excluding certain costs to the DCP. As indicated by the above-referenced 2008 OIG report, additional salary and other costs attributable to diversion control activities need to be incorporated into the DCP. In addition, the mission of the DCP has been expanded by Congress and by the need to address an explosion in the abuse of prescription drugs that seriously impact public health and safety. The National Drug Control Strategy is focused on all aspects of the problem—supply, demand, and treatment.

The Office of Diversion Control at DEA is focused on the supply side of this serious threat to the public health and safety. At the end of FY 2008, a reorganization within DEA expanded the use of Tactical Diversion Squads across the country to allow Diversion Investigators to focus their expertise on regulatory oversight and the deterrent effect of increased regulatory investigations. Tactical Diversion Squads incorporate the criminal investigative skills and statutory authority of Special Agents and state and local Task Force Officers to bring to the criminal justice system those organizations and individuals who violate the CSA by diverting controlled substances and listed chemicals into the illicit market. Diversion Investigators are a key asset to Tactical Diversion Squads because they lend their keen knowledge of the closed system of distribution to the Tactical Diversion Squads. Diversion Investigators' familiarity and detailed understanding of the closed system of distribution require, however, that they continue to lead the regulatory oversight of DEA registrants. DCP costs increase with an expanded number and use of Tactical Diversion Squads.

Due to the alarming rise in prescription drug abuse, as well as an increase in the production and use of chemicals that are harmful if abused, the DCP has increased scheduled investigations of registrants and drug and chemical scheduling initiatives, as well as other modifications in its control efforts. The DCP continues to draw technical expertise from Diversion Investigators, and the DCP has incorporated greater numbers of Special Agents, Chemists, Information Technology Specialists, Attorneys, Intelligence Research Specialists, and State and Local personnel. It is essential to utilize a diverse skilled workforce and constantly review and modify all aspects of the DCP to successfully execute the National Drug Control Strategy and effectively prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of these substances for legitimate medical, scientific, research, and industrial purposes.

DEA has been and will continue to be fiscally responsible and will remain vigilant towards identifying methods to improve efficiencies or identifying other cost saving measures. As discussed above, however, a new fee calculation is needed. Without an adjustment in the annual registration fees, DEA will be unable to continue current operations and will be in violation of the statutory mandate that fees charged ''shall be set at a level that ensures the recovery of the full costs of operating the various aspects of [the diversion control program].'' 21 U.S.C. 886a(1)(C). For example, collections under the current fee schedule will require the DCP to significantly cut existing and planned DCP operations vital to its mission. DEA relies on the DCP to maintain the integrity of the closed system for controlled substances and listed chemicals, particularly at this time of dramatic increases in abuse and diversion.

DEA must determine the proper scope of the DCP, the projected costs for the program, a fee calculation methodology, and a new fee schedule that recovers the costs of the DCP and sets reasonable fees for the registration and control of manufacturers, distributors, importers, exporters and dispensers of controlled substances and listed chemicals.

[67] 71 FR 50115, August 29, 2006.

Fee Calculation

DEA is delegated the task of determining the details of fulfilling the statutory requirements of ensuring the recovery of the full costs of operating the diversion control program (DCP) as described above, while charging registrants participating in the closed system of distribution reasonable fees relating to the registration and control ''of the manufacture, distribution, dispensing'' and ''of importers and exporters'' of controlled substances and listed chemicals. For the DCP to have funds to function, DEA must determine, in advance of actual expenditures, a reasonable fee to be charged. As a result, historical data and projections must be used rather than actual, current costs to project the annual costs of the DCP. Additionally, a reasonable fee must be calculated that will fully recover the costs of the DCP based on the variability over time of the number of registrants in the different categories of registration, *e.g.,* manufacturers, distributors, importers, exporters, reverse distributors, practitioners, and individual researchers. Since the fees collected must be available to fully fund the DCFA and to reimburse DEA for expenses incurred in the operation of the DCP (21 U.S.C. 886a), there must always be more collected than is actually spent to avoid running a deficit and being in violation of federal fiscal law.[68] In operating the DCP, DEA must be prepared for changes in investigative priorities, diversion trends, and emerging drugs or chemicals posing new threats to the public health and safety. By definition, it is an inexact effort. Given that fact, the agency must select a single methodology that it consistently follows throughout any given fee cycle.

Current options to calculate fees are also limited by the feasibility and practicability of tracking and allocating detailed costs, although the agency continues to improve its capabilities on this front. DEA has made progress through reorganization and there is recognition throughout the agency of the need to separate DCP costs from other agency costs. DEA is in the process of testing a system where personnel would account for their daily hours according to whether their time is spent on DCP or other DEA mission activities. Part of the difficulty stems from the fact that the mission of DEA involves investigations and actions that may involve poly-drug organizations or that may start out as one type of investigation and result in another, based upon the way the facts develop.

To date, tracking costs within the DCP according to registrant categories or within a given registrant category has not been feasible or cost-efficient. Such detailed cost attribution may or may not be feasible in the future. However, Congress recognized that the costs of the registration and control of controlled substances and listed chemicals are not properly attributed on a per registrant basis when it differentiated among the categories of registrants for purposes of calculating a reasonable fee, e.g., manufacturers, distributors, importers, exporters, and dispensers.[69] Thus, the methodology used to calculate fees needs to distinguish among these categories. The historical fee calculation based on a weighted ratio of 12.5 for manufacturers, 6.25 for distributors (including importers and exporters), and 1 for dispensers was used for many years prior to and when Congress established the DCFA and has been the method used to date.

As discussed in more detail below, DEA considered several methodologies to calculate the new fee. One methodology considered was a flat fee that takes projected DCP costs and divides it among all registrants regardless of their business activity/registrant group. On its face, this would not result in a ''reasonable'' fee for a large portion of registrants given the disparity in economic size among registrants and the different levels of control needed among the registrant categories. Registrants range from multi-billion dollar manufacturers in possession of large quantities of controlled substances or listed chemicals to canine handlers in possession of small amounts of controlled substances. Thus, the inspection, investigation and oversight costs associated with a manufacturer are much greater than for a canine handler. A flat fee methodology has been rejected since the inception of a fee.

DEA considered another fee calculation methodology called the Past-Based Option. This method is based on the principle that the cost of the DCP should be shared equally among all paying registrants, except for the cost of scheduled or regularly planned investigations and the preregistration investigation costs to determine eligibility of registrant applicants, as these additional costs vary by registrant category. Rather, these historical costs should be allocated to the registrant group receiving the scheduled and preregistration investigations. Since the direct labor costs of scheduled and preregistration investigations are historically around three percent of total DCP costs, this methodology results in concerns similar to the flat fee as the base amount is nearly as great as the flat fee amount.

DEA considered another methodology called the Future-Based Option, which takes the same approach described in the preceding paragraph, but the costs of scheduled investigations are derived from planned work, not historical work hours. This methodology results in large differences in fees among registrant groups and has been rejected by DEA as not a ''reasonable'' charge.

Since the inception of the fee, the agency has selected a weighted-ratio method to determine a reasonable fee for each category of registrants. Under this method, registrants are assigned to a business activity or category (*e.g.,* researcher, practitioner, distributor, manufacturer, *etc.*) based on the statutory fee categories. Then a base fee rate is established according to the annual estimated costs of the DCP. A projected population is calculated for each category or business activity. That figure is then multiplied by a ratio of 1.0 for researchers, 3.0 for practitioners (for administrative convenience the fee is collected every three years for practitioners), 6.25 for distributors and 12.5 for manufacturers. By utilizing these different ratios, the agency recognizes the statutory need to charge reasonable fees relating to the registration and control of the manufacture, distribution, dispensing, importation and exportation of controlled substances and listed chemicals. As historical costs support, inspections, scheduled investigations and other control and monitoring costs are greatest for manufacturers. This is because there is an increased risk associated with the quantity of controlled substances and/or chemicals located at this point in the closed system. All of the individual business activity figures are then added together to form a weighted sum for one projected year. This process is performed for two more years using future projected registrant populations for those years multiplied by the ratio. The annual figures for these three years are then added together and divided into the total budget requirements for that three-year period to arrive at the base rate fee to be charged to each category of registrant.

DEA continues to review possible methodologies as technology continues to afford increased tracking and

[68] In general, no officer or employee of the United States Government may make or authorize an expenditure or obligation in excess of an amount available in an appropriation or fund. 31 U.S.C. 1341.

[69] 21 U.S.C. 886a(2)(B).

allocation of specific costs. However, at this time, DEA has determined that it is both practicable and reasonable to continue to apply the weighted-ratio methodology. Consistent with the statutory direction to charge reasonable fees relating to the registration and control of the manufacture of controlled substances and listed chemicals and the associated oversight costs, the 12.5 ratio is applied to the manufacturing registrant group. At 50 percent of that ratio is the 6.25 ratio which applies to the ''distribution'' of controlled substances or the distributor registrant group. Likewise, ''dispensing'' has the largest number of registrants, but with relatively low oversight costs and a relatively small quantity of controlled substances or listed chemicals within their physical possession. The base fee or the 1 ratio is charged for those dispensing or individuals registered to do research or other such activities that use the substance and create limited vulnerability to the closed system, and thus require less control in protecting the closed system. The practitioner fee is the base fee on an annual basis but is collected every three years for administrative convenience.

Thus, the current fees, some of which are paid annually and some of which are paid every three years, range from $184 for ratio 1 to $2,293 for ratio 12.5 depending upon the particular registrant category. Specifically, practitioners, mid-level practitioners, dispensers, researchers, and narcotic treatment programs pay an annual registration fee of $184. For administrative convenience for both the collection and the payment, practitioners pay a combined registration fee of $551 every three years. Distributors, importers and exporters pay an annual fee of $1,147 and manufacturers pay an annual fee of $2,293. 21 CFR 1301.13 and 1309.11.

Projected Costs for the Diversion Control Program

In calculating fees to recover the mandated full costs of operating the DCP, DEA estimates the costs of operating the DCP for the next three fiscal years.[70] To develop the DCFA budget request estimates for FY 2012, FY 2013 and FY 2014, DEA compiles: (1) The DCFA Budget Request for Fiscal Year (FY) 2011, which forms a base spending level for the current level of service, (2) the estimated additional required funds for FY 2012, FY 2013 and FY 2014, and (3) the required annual $15 million transfer to the United States Treasury as mandated by the CSA (21 U.S.C. 886a). The following paragraphs explain the annual revenue calculations and how the total amount to be collected for the FY 2012–2014 period was calculated. In developing this figure, DEA begins with annual projected DCP obligations, including payroll, operational expenses and necessary equipment. The DCP budget has increased due to inflationary adjustments for rent and payroll and to increase staffing resources that support the regulatory and law enforcement activities of the program. The fees have not been adjusted to reflect these factors as they last covered the time period of FY 2006–2008. Specific details on the DCP budget are available in the annual President's Budget Submission and supplemental budget justification documents provided to Congress.[71]

Total obligations for the DCP have increased from FY 2007 to FY 2010 by approximately 49 percent. For the FY 2006–2008 period, payroll expenses (staff compensation and benefits) composed the largest component of DCP costs at 55.7 to 57.6 percent per year. Between the period of FY 2006 and FY 2010, payroll constituted an average of 56.7 percent of DCP expenses. Operating expenses and capital expenditures made up the remainder of DCP costs. Operating expenses (an average of 39.3 percent for the FY 2006–2010 period) include daily operation costs such as purchase of evidence or payment for information as part of investigations, travel, and non-equipment purchases. Capital expenditures, including equipment and furniture purchases, capital leases, and land/structure improvements and purchases, averaged 4.0 percent during this same period.

For the FY 2012–2014 period covered by this rulemaking, the overall breakdown of DCP major cost categories does not depart significantly from previous years in terms of *percent* of budget; however, total budgets for each of these major cost categories do increase to reflect additional costs in each of these categories.

In addition to the budget for each of the fiscal years, the cost components outlined below are also considered in determining required registration fee collections.

Recoveries From Money Not Spent as Planned (Deobligation of Prior Year Obligations)

At times, DEA enters into an obligation to make a purchase of a product or service that is not delivered immediately, such as in a multi-year contract. Changes in obligations can occur for a variety of reasons, *i.e.,* changes in planned operations, delays in staffing, implementation of cost savings, changes in vendor capabilities, etc. When DEA does not expend its obligation, the ''deobligated'' funds are ''recovered'' and the funds become available for DCP use. Based on historical trends and for purposes of calculating the fee levels, the recovery from deobligation of prior year obligations is estimated at $10 million per year.

Payment to Treasury

In the 1993 appropriations for DEA, Congress determined that the DCP would be fully funded by registration fees and no longer by appropriations.[72] Congress established the DCFA as a separate account of the Treasury to ''ensure the recovery of the full costs of operating the various aspects of [the Diversion Control Program]'' by those participating in the closed system established by the CSA. 21 U.S.C. 886a(1)(C). Fees collected are deposited into a separate Treasury account. Each fiscal year, the first $15 million is transferred to the Treasury and is not available for use by the DCP. Therefore, DEA needs to collect an additional $15 million per year beyond estimated costs for payment to the Treasury.

Operational Continuity Fund (OCF)

DEA maintains an operational continuity fund (OCF) based on the need to maintain DCP operations during historically low (or negative) collection periods (*e.g.,* the first quarter of a new fiscal year when the first $15 million collected is transferred to Treasury). Monthly collections and obligations fluctuate throughout the year. There are times when obligations (spending) exceed collections. This can happen consecutively for several months. Therefore, an operational continuity fund is maintained in order to avoid operational disruptions due to these fluctuations and monthly differences in collections and obligations (spending). Using statistical analysis of the historical fluctuations between amounts collected and amounts obligated, DEA has determined that seven percent of the projected obligations is normally adequate to avoid operational disruptions. The amount required to bring the operational continuity fund

[70] See ''Proposed New Registrant Fee Schedule Calculations'' in this rulemaking docket found at *http://www.regulations.gov.*

[71] See this rulemaking docket found at *http://www.regulations.gov.*

[72] Departments of Commerce, Justice, and State, the Judiciary and Related Agencies Appropriations Act of 1993, Public Law 102–395, codified in relevant part at 21 U.S.C. 886a.

balance to the $15 million plus seven percent level is added to projected costs.

The increase in OCF balance for FY 2012, FY 2013, and FY 2014 are $6,452,395, $1,067,428, and $800,291 respectively.

TABLE 1—INCREASE IN OPERATIONAL CONTINUITY FUND BALANCE FY 2012–2014

	FY 2012	FY 2013	FY 2014
Budget	$321,990,000	$356,582,322	$371,831,295
Target OCF ($15M + 7%)	39,960,763	41,028,191	41,828,482
Beginning OCF balance	*33,508,367*	*39,960,763*	*41,028,191*
Increase in OCF balance	6,452,395	1,067,428	800,291

Combat Methamphetamine Act of 2005 (CMEA) Collections

Under CMEA, DEA collects a self-certification fee for regulated sellers of scheduled listed chemical products, which is included as part of the total collections. The fee is waived for any person holding a current DEA registration in good standing such as a pharmacy to dispense controlled substances. DEA has observed an approximately 15 percent decline in self-certifications from FY 2008 to FY 2010 and anticipates that the decline will continue through FY 2014. The self-certification fee is $21. CMEA self-certification fee collection estimates for FY 2012, FY 2013, and FY 2014 for purposes of calculating the fee levels are $173,040, $146,853, and $124,635, respectively.

TABLE 2—CMEA COLLECTIONS FY 2012–2014

	FY 2012	FY 2013	FY 2014
Number of paying self-certifications	8,240	6,993	5,935
Fee	$21	$21	$21
CMEA collection estimate	$173,040	$146,853	$124,635

Other Collections

DEA also derives revenue from the sale/salvage of official government vehicles dedicated to DCP use. DEA's estimate for other collections is $307,153 per year. This is the actual amount for FY 2010.

Estimated Total Required Collections

Based on these figures, DEA calculated the total amount required to be collected for the FY 2012–2014 period for purposes of calculating the fee levels as follows:

Required registration fee collections for FY 2012 are $332,962,203. This figure includes the budget of $321,990,000, net of $10 million in recoveries, plus $15 million for transfer to Treasury, plus $6,452,395 for increase in OCF balance, net of $173,040 in CMEA self-certification collections, and net of $307,153 in other collections.

Required registration fee collections for FY 2013 are $362,195,745. This figure includes the budget of $356,582,322, net of $10 million in recoveries, plus $15 million for transfer to Treasury, plus $1,067,428 for increase in OCF balance, net of $146,853 in CMEA self-certification collections, and net of $307,153 in other collections.

Required registration fee collections for FY 2014 are $377,199,798. This figure includes the budget of $371,831,295, net of $10 million in recoveries, plus $15 million for transfer to Treasury, plus $800,291 for increase in OCF balance, net of $124,635 in CMEA self-certification collections, and net of $307,153 in other collections.

TABLE 3—NEEDED FEE COLLECTIONS FY 2012–2014

	FY 2012	FY 2013	FY 2014	3-yr total
Budget	$321,990,000	$356,582,322	$371,831,295	$1,050,403,617
Recoveries	*(10,000,000)*	*(10,000,000)*	*(10,000,000)*	*(30,000,000)*
Net Budget	311,990,000	346,582,322	361,831,295	1,020,403,617
Payment to Treasury	15,000,000	15,000,000	15,000,000	45,000,000
Increase in OCF balance	6,452,395	1,067,428	800,291	8,320,115
CMEA Self-cert collections	(173,040)	(146,853)	(124,635)	(444,528)
Other collections	*(307,153)*	*(307,153)*	*(307,153)*	*(921,458)*
Required collections from Registration Fees	332,962,203	362,195,745	377,199,798	1,072,357,746

Numbers are rounded.

In total, DEA needs to collect $1,072,357,746 in registration fees over the three year period, FY 2012–FY 2014 to fully fund the DCP.

As in the past, DEA proposes to set the fee for each registrant category for a three-year period (FY 2012–2014). The vast majority of registrants are practitioners who pay a three-year registration fee. These registrants are divided into three separate groups who pay their three-year registration fees on alternate year cycles. Because registration cycles may differ from year to year, the total amount collected through fees in a given year may not exactly match the projected amount.

DEA Efforts To Control DCP Costs

DEA continually reviews the DCP and its methods of operation to ensure that it is fiscally responsible. The DCP works diligently to provide the registrants with cost effective and state-of-the-art means for conducting their businesses related to manufacturing, distributing, dispensing, importing, and exporting controlled substances and listed chemicals. Some examples of this include online registration, the Controlled Substance Ordering System (CSOS) for electronic controlled substance ordering between registrants, and electronic reporting of thefts and significant losses of controlled substances.

DEA takes seriously its responsibilities to manage the DCP in an efficient and effective manner, particularly in light of the current economy. The Office of Diversion Control acknowledges the important role that the Validation Unit provides in the appropriate expenditure of the DCFA. DEA cannot foresee Congressionally-mandated changes to the DCP or diversion trends, but it is committed to managing in a fiscally responsible manner. The Office of Diversion Control is committed to reviewing the registration process to ensure efficiency and accountability as well as reviewing current regulations related to fee exempt registrants. In addition, to ensure careful decision-making at all levels of the DCP, the Office of Diversion Control is considering several measures to ensure accountability for the effective utilization of resources.

Proposed Methodology for New Fee Calculation

In developing this proposed rule, DEA examined alternative methodologies to calculate the registration and registration fees. DEA analyzed alternative methodology approaches keeping in mind its statutory obligations under the CSA. First, pursuant to statute, DEA is authorized to charge reasonable fees relating to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and listed chemicals. 21 U.S.C. 821 and 958(f). Second, DEA must set fees at a level that ensures the recovery of the full costs of operating the various aspects of its diversion control program (DCP). 21 U.S.C. 886a. Accordingly, in examining each alternative methodology DEA considered whether the fee calculation (1) was reasonable and (2) could fully fund the costs of operating the various aspects of the DCP.

Moreover, the CSA establishes a specific regulatory requirement that DEA charge fees to fully fund the DCP, but that the fees collected by DEA are to be expended through the budget process only. Specifically, each year DEA is required by statute to transfer the first $15 million of fee revenues into the general fund of the Treasury and the remainder of the fee revenues is deposited into a separate fund of the Treasury called the Diversion Control Fee Account (DCFA). 21 U.S.C. 886a(1). On at least a quarterly basis, the Secretary of the Treasury is required to refund DEA an amount from the DCFA ''in accordance with estimates made in the budget request of the Attorney General for those fiscal years'' for the operation of the DCP. 21 U.S.C. 886a(1)(B) and (D). For that reason, DEA is only considering alternative methodologies to calculate the registration and reregistration fees, not alternative approaches to expend fees collected because those decisions are governed by the CSA and the budget process.

In developing this rule, DEA considered four methodologies to calculate registration and reregistration fees: Past-Based Option, Future-Based Option, Flat Fee Option, and Weighted-Ratio Option. Although the increase in the fees may be passed down to the registrants' customers, the alternatives are analyzed on the worst-case scenario where the increase in the fee is absorbed fully by the registrants.

For each of the alternatives considered, the calculated fees are analyzed for reasonableness by examining: (1) The absolute amount of the fee increase, (2) the change in fee as a percentage of revenue from 2007 to 2012, and (3) the relative fee increase across registrant groups. Additionally, each calculation methodology is re-evaluated for its overall strengths and weaknesses.

Past-Based Option

Option 1 is called the Past-Based Option, and is based on historic investigation work hour data to set the apportionment of cost to each registrant category. In considering Option 1, DEA used historic investigation work hour data from the Fiscal Year 2007–2009. DEA's records permit an accurate apportionment of work hours for certain types of diversion control activities (*e.g.,* investigations) among classes of registrants. DEA estimates that approximately three to five percent of costs can be directly linked to pre-registration and scheduled investigations. Although some criminal investigations can be attributed to registrant groups, DEA did not include the cost of criminal investigations for the fee calculation under the Past-Based Option. While DEA develops annual work plans for the number of scheduled investigations by registrant type, DEA does not develop such plans for criminal investigations. Therefore, the cost of criminal investigations is allocated equally across all registrant groups, regardless of business activity. The remaining costs associated with DCP activities and components benefit all registrants (*e.g.,* policy, registration, and legal activities); however, DEA records cannot attribute these costs by registrant class. Under Option 1, pre-registration and scheduled investigation costs are assigned to registrant classes and all other costs are recovered on an equal, per-registrant basis.

DEA calculated the annual registrant fee for key registrant groups under Option 1 and compared this fee to the current fee. Although distributors and importers/exporters are in the same fee class in the current fee structure (Weighted-Ratio Option), in this analysis, distributors are separated from importers and exporters based on the available historic work hour data and reported work hours by type of registrant.

In the past-based option, the calculated fees increase by a factor of 1.16, 3.19, 1.10, and 1.32 for manufacturers, distributors, importers/exporters, and practitioners, respectively.

The proposed fees as a percentage of revenue is very low as indicated in Table 4 below, 0.000 to 0.019 percent, 0.005 to 0.134 percent, 0.000 to 0.005 percent, and 0.125 to 0.257 percent for manufacturers, distributors, pharmacies, and practitioners, respectively. The impact of the incremental increase in the fee from current fees as a percentage of revenue is even lower.

Finally, the largest increase, by a factor of 3.19, is incurred by distributors, largely as a consequence of their separation from exporters and importers, while the increases for other groups range from a factor of 1.10 to 1.32.

TABLE 4—ANNUAL REGISTRANT FEES UNDER PAST-BASED OPTION

	Current fee (annual)	Past-based fee (annual)	Increase from current fee	Ratio: past-based fee to current fee	Percent of annual revenue current fee **	Percent of annual revenue past based fee ***
Manufacturers	$2,293	$2,668	$375	1.16	0.000%–0.017%	0.000%–0.019%
Distributors	1,147	3,361	2,214	2.93	0.002%–0.042%	0.005%–0.123%
Importers/exporter	1,147	1,258	111	1.10	*	*
Pharmacies	184	243	59	1.32	0.000%–0.004%	0.000%–0.005%
Practitioners	184	243	59	1.32	0.119%–0.237%	0.125%–0.257%

Source: 2007 Economic Census; Bureau of Labor Statistics.
* No NAICS code for Importer/Exporter of controlled substances and/or List I chemicals.
** Current Fee divided by average revenue/income in 2007, first full year of the current fee.
*** Past-Based Fee divided by average revenue in 2007 for manufacturers, distributors and pharmacies. Past-Based Fee divided by projected average income in 2012 for practitioners. Only 2002 and 2007 data are available for manufacturers, distributors, and pharmacies, while practitioner income projection is based on five years of income data, 2004–2009.

While Option 1 is based on accurate historical data, it does not allow for future needs, demands and shifting responsibilities of the DCP, such as Agency priorities, new legislation, control of substances, new investigative requirements, and other program needs.

Conclusion

DEA does not propose the past-based option for two key reasons. First, the fee increase is disproportionately burdensome to a small number of registrants. Distributors' fees would increase by over three fold, while the fees for the remaining registrant groups would increase from 10 percent to 32 percent. DEA deemed this option unreasonable. Second, the past-based option is backward looking and implicitly assumes that the future will be similar to the past. DEA cannot assume that future workload will reflect past DEA work hour data. For example, DEA plans to conduct more scheduled investigations in accordance with the new scheduled investigation work plan. As a result, DEA has concluded that past data is not the best basis for the calculation of proposed fees.

Future-Based Option

Option 2 is called the Future-Based Option, and is based on projected work hours for each registrant class using scheduled investigation work plan goals and anticipated/planned resources. In considering Option 2, DEA based its calculations on projected work hour data by registrant group for FY 2012–2014. The future-based option is based on DEA's projection of work plan goals and the resources required for these years—specifically, examining the direct cost of anticipated scheduled investigations.[73] Based on the data used to develop the projections, the future-based option divides registrants into six classes and examines the projected work hour data within these categories. In contrast to Option 1 above, which is calculated using actual data, Option 2 is calculated using projected data relative to work plan goals and resources. This type of calculation results in a more finely tuned analysis of anticipated work hours. DEA calculated the projected annual fees under Option 2 and compared these fees to the current fees. Table 5 presents these results:

TABLE 5—ANNUAL REGISTRANT FEES UNDER FUTURE-BASED OPTION

	Current fee (annual)	Future-based fee (annual)	Amount of increase from current fee	Ratio: future-based fee to current fee	Percent of Annual revenue current fee **	Percent of Annual revenue future-based fee ***
Manufacturers 1: controlled substance manufacturers.	$2.293	$17,595	$15,302	$7.67	0.000%–0.017%	0.001%–0.128%
Manufacturers 2: List I chemical manufacturers	2,293	8,124	5,831	3.54	0.000%–0.017%	0.001%–0.059%
Distributors 1: controlled substance distributors and List I chemical distributors.	1,147	6,546	5,399	5.71	0.002–0.042%	0.009%–0.239%
Distributors 2: exporters and importers of controlled substances.	1,147	4,968	3,821	4.33	*	*
Distributors 3: List I chemical exporters and importers.	1,147	4,021	2,874	3.51	*	*
Pharmacies	184	232	48	1.26	0.000%–0.004%	0.000%–0.005%
Practitioners	184	232	48	1.26	0.119%–0.237%	0.119%–0.245%

Source: 2007 Economic Census; Bureau of Labor Statistics.
* No NAICS code for Importer/Exporter of controlled substances and/or List I chemicals.
** Current Fee divided by average revenue/income in 2007, first full year of the current fee.
*** Future-Based Fee divided by average revenue in 2007 for manufacturers, distributors and pharmacies. Future-Based Fee divided by projected average income in 2012 for practitioners. Only 2002 and 2007 data is available for manufacturers, distributors, and pharmacies, while practitioner income projection is based on five years of income data, 2004–2009.

In the future-based option, as shown in the table above, the fee increase ranges from a factor of 1.26 for practitioners to 7.67 for manufacturers of controlled substances.

[73] Many criminal investigations are attributable to the type of registrant(s) being investigated. However, because DEA cannot anticipate the volume of criminal cases initiated, either historically or in future years, these costs were not attributed directly to the registrant types affected. Rather, criminal investigative costs are spread across all registrants equally in both Option 1 and Option 2.

The proposed fees as a percentage of revenue is very low as indicated in Table 5: 0.001 to 0.128 percent for controlled substances manufacturers, 0.001 to 0.059 percent for manufacturers of List I chemical manufacturers, 0.009 to 0.239 percent for distributors, 0.000 to 0.005 percent for pharmacies, and 0.119 to 0.245 percent for practitioners. The impact of the incremental increase in the fee from current fees as a percentage of revenue is even lower. As expected, registrant groups with a larger fee increase under this option would experience a larger increase as a percentage of revenue.

Under this option, the increases in fees vary greatly across registrant groups. For example, controlled substances manufacturers incur the largest proportional increase by a factor of 7.67 or $15,302 annually, while practitioner fees increase by a factor of 1.26 or $48 annually.

Option 2 is calculated using projected data relative to work plan goals and resources. This results in a more finely tuned analysis of anticipated work hours. The disadvantage of Option 2 is that, because the calculation is based on projected work hour data, it may not be able to adapt to the shifting priorities and demands of DCP operations. Additionally, a change in work plan can cause actual cost to be much different for some registrant groups, causing a contradiction between the rationales used to calculate the fees and actual operations.

Conclusion

In reviewing Option 2, DEA concluded that for most registrant categories, the large proportional increase in fees would not pass the ''reasonable fee'' standard required by statute and could represent a significant burden on some registrants. Additionally, DEA believes that the vast disparity in the increase, where fees for manufacturers increase by more than seven fold, while fees for registrants increase by 26 percent, is unreasonable. Although there is concern regarding a potential difference between the scheduled investigation work plan and actual operations, DEA recognizes that no plan is perfect and operations may be adjusted as the environment changes. This potential exists for all four options. Therefore, the potential change in work plan did not weigh into the DEA's decision to not select Option 2. DEA's decision to not select Option 2 is based on the unreasonable increase in fees for some registrants and the severe disparity in increase among the registrant groups.

Flat Fee Option

Option 3 is called the Flat Fee Option. The flat fee option would provide equal fees across all registrant groups regardless of the proportion of DCP costs and resources the registrant group may require (*e.g.,* investigation resources). The fee calculation is straightforward: the total amount needed to be collected over the three year period is divided by the total number of registration fee transactions over the three year period, adjusting for registrants on the three year registration cycle (so that the fees for a three year period are three times the annual fee).

DEA calculated the annual registrant fee for key registrant groups under Option 3 and compared this fee to the current fee:

TABLE 6—ANNUAL REGISTRANT FEES UNDER FLAT-FEE OPTION

	Current fee (annual)	Flat fee (annual)	Amount of increase from current fee	Ratio: flat fee to current fee	Percent of annual revenue current fee*	Percent of annual revenue flat fee**
Manufacturers	$2,293	$247	$(2,046)	0.11	0.000%–0.017%	0.000%–0.002%
Distributors	1,147	247	(900)	0.22	0.002%–0.042%	0.000%–0.009%
Practitioners	184	247	63	1.34	0.119%–0.237%	0.127%–0.261%

Source: 2007 Economic Census; Bureau of Labor Statistics.

* Current Fee divided by average revenue/income in 2007, first full year of the current fee.

** Flat Fee divided by average revenue in 2007 for manufacturers, distributors and pharmacies. Flat Fee divided by projected average income in 2012 for practitioners. Only 2002 and 2007 data is available for manufacturers, distributors, and pharmacies, while practitioner income projection is based on five years of income data, 2004–2009.

In the flat-fee option, the registration fees for manufacturers and distributors are reduced significantly, from $2,293 for manufacturers and $1,147 for distributors to $247 for both. This reduction represents an 89 percent and 78 percent reduction for manufacturers and distributors respectively. The registration fee for practitioners increases by 34 percent to $247 on an annual basis.

The proposed fees as a percentage of revenue is very low as indicated in Table 6 above: 0.000 to 0.002 percent for manufacturers, 0.000 to 0.009 percent for distributors, and 0.127 to 0.261 percent for practitioners. The impact of the incremental increase in the fee from current fees as a percentage of revenue is even lower. Registrant groups with a decrease in fee under this option would experience a decrease as a percentage of revenue.

As with the other options, the calculation considered in Option 3 results in a dramatic fee disparity among registrant groups. The fees for manufacturers and distributors decrease, while the fees for practitioners increase.

The flat fee option has positive and negative aspects. The fee that DEA is required to charge registrants is based on a statutory requirement—it is not a user fee. A user fee calculation would require a calculation of the direct and indirect costs associated with each of the registrant groups and set fees to recover the costs associated with each of these groups. Since the registration fee is not a user fee, DEA is not required to calculate fees according to its costs by registrant groups. General historical costs of scheduled investigations support different fees among the categories. However, setting the same fees for all registrants, from multi-national corporations to mid-level practitioners is unreasonable.

Conclusion

After consideration of the flat fee option, DEA did not select this option to calculate the proposed new fees. The fee disparity among registrant groups caused by this calculation alternative is too great. Under this option, the calculation would result in reduced fees for manufacturers and distributors by 89 percent and 78 percent respectively, while practitioner fees would increase by 34 percent. Setting the fees at the same level across all registrant groups is not ''reasonable.'' DEA registrants include some of the largest corporations

in the world although the vast majority of registrants are practitioners, such as physicians and nurses. To satisfy the ''reasonable'' standard, registration fees should be different among the categories to account for cost and economic differences among the registrant categories. Option 3 did not satisfy this requirement.

Weighted-Ratio Option (Selected Methodology)

Option 4 is called the Weighted-Ratio Option. In this option, fees are assigned to different registrant categories based on DEA's general historical cost data. This option distinguishes among the categories to establish a ''reasonable'' fee for each category. The different fees are expressed in ratios: 1 for researchers, canine handlers, analytical labs, and narcotics treatment programs; 3 for registrants on three year registration cycles, pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners; 6.25 for distributors and importers/exporters; and 12.5 for manufacturers. The adopted ratios are applied for administrative convenience since historically costs vary and a fee must be set in advance. To determine the fee, a weighted ratio is assigned based on registrant group, and the amount needed to be collected over the FY 2012–FY 2014 period is divided by the weighted number of estimated registrations to determine the fees.

TABLE 7—ANNUAL REGISTRANT FEES UNDER WEIGHTED-RATIO OPTION

[Registrants on three year registration cycle]

Registrant class/business	Current three year fee*	Proposed three year fee*	Difference per year
Pharmacy	$551	$732	$60
Hospital/Clinic	551	732	60
Practitioner	551	732	60
Teaching Institution	551	732	60
Mid-Level Practitioner	551	732	60

* Pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners currently pay a fee for a three-year period. This current three-year fee is $551. The proposed new fee for the three year registration period would be $732. The three year difference is $181 or an annual difference of $60.

[Registrants on annual registration cycle]

Registrant class/business	Current annual fee	Proposed annual fee	Difference
Researcher/Canine Handler	$184	$244	$60
Analytical Lab	184	244	60
Maintenance	184	244	60
Detoxification	184	244	60
Maintenance and Detoxification	184	244	60
Compounder/Maintenance	184	244	60
Compounder/Detoxification	184	244	60
Compounder/Maintenance/Detoxification	184	244	60
Distributor (chemical and controlled substances)	1,147	1,526	379
Reverse distributor	1,147	1,526	379
Importer (chemical and controlled substances)	1,147	1,526	379
Exporter (chemical and controlled substances)	1,147	1,526	379
Manufacturer (chemical and controlled substances)	2,293	3,052	759

In the weighted-ratio option, the registration fees for all registrant groups increase by 33 percent from current fees, although the absolute dollar amount may differ. The proposed new registration fees range from $244 annually (or annual equivalent) to $3,052. Registration fees are collected by location and by registered business activity. Most small registrants are expected to pay a single registration fee of $244 ($60 annual increase), $1,526 ($379 annual increase) or $3,052 ($759 annual increase). Registration fees for all registrant groups increase by 33 percent and as a result, there is no disparity in the fee increase among registrant groups.

The weighted-ratio methodology, much like the flat fee, is straightforward and easy to understand, but unlike the flat fee, this method applies historic weighted ratios to differentiate fees among registrant groups. Additionally, the fees calculated using this methodology are similar to fees calculated in the past-based option, which allocates historical pre-registration and scheduled investigations costs to registrant groups. Finally, this method does not create a disproportionate fee increase in any registrant group.

Conclusion

DEA selected Option 4 to calculate the proposed new fee structure. This approach has been used since Congress established registrant fees and continues to be a reasonable reflection of differing costs. The registration fees under the weighted-ratio option result in differentiated fees among registrant groups, where registrants with larger revenues and costs pay higher fees than registrants with lower revenues and costs. Furthermore, the weighted-ratio does not create a disparity in the relative increase in fees from the current to the proposed fees. The weighted ratios used by DEA to calculate the proposed fee have proven effective and reasonable over time. Additionally, the selected calculation methodology accurately reflects the differences in activity level, notably in inspections, scheduled investigations and other control and monitoring, by registrant category; for example, these costs are greatest for manufacturers. DEA selected this option because it is the only option that resulted in ''reasonable'' fees for all registrant groups.

Proposed New Fees

Based on thorough analysis of the identified fee calculation options—including the anticipated economic impact on registrants—DEA has determined that the current weighted-ratio option represents the most reasonable approach to calculate registrant fees sufficient to fully fund the DCP.

The proposed fee schedule would replace the current fee schedule for controlled substance and chemical registrants in order to recover the full costs of the DCP so that it may continue to meet the programmatic responsibilities set forth by statute, Congress, and the President. As discussed, without an adjustment to fees, the DCP will be unable to continue current operations, necessitating dramatic program reductions, and possibly weakening the closed system of distribution. Accordingly, DEA proposes the following new fees for the FY 2012–2014 period.

TABLE 8—PROPOSED REGISTRATION AND REREGISTRATION FEES BY CLASS/BUSINESS

[Registrants on three year registration cycle]

Registrant class/business	Current three year fee*	Proposed three year fee*	Difference per year
Pharmacy	$551	$732	$60
Hospital/Clinic	551	732	60
Practitioner	551	732	60
Teaching Institution	551	732	60
Mid-Level Practitioner	551	732	60

* Pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners currently pay a fee for a three-year period. This current three-year fee is $551. The proposed new fee for the three year registration period would be $732. The three year difference is $181 or an annual difference of $60.

[Registrants on annual registration cycle]

Registrant class/business	Current annual fee	Proposed annual fee	Annual difference
Researcher/Canine Handler	$184	$244	$60
Analytical Lab	184	244	60
Maintenance	184	244	60
Detoxification	184	244	60
Maintenance and Detoxification	184	244	60
Compounder/Maintenance	184	244	60
Compounder/Detoxification	184	244	60
Compounder/Maintenance/Detoxification	184	244	60
Distributor (chemical and controlled substances)	1,147	1,526	379
Reverse distributor	1,147	1,526	379
Importer (chemical and controlled substances)	1,147	1,526	379
Exporter (chemical and controlled substances)	1,147	1,526	379
Manufacturer (chemical and controlled substances)	2,293	3,052	759

TABLE 9—OVERVIEW OF PROPOSED DIVERSION CONTROL FEE ACCOUNT (DCFA)

	FY2011	FY2012	FY2013	FY2014
Congressional Budget	290,304,000	321,990,000	356,582,322	371,831,295
Operational Continuity Fund (OCF) Brought Forward From Prior Year	68,089,927	33,508,367	63,225,476	50,588,959
Collections: Registration Fees*	257,254,274	356,226,916	348,491,800	366,937,230
Collections:				
CMEA	203,889	173,040	146,853	124,635
Treasury	*(15,000,000)*	*(15,000,000)*	*(15,000,000)*	*(15,000,000)*
Net Collections	242,458,163	341,399,956	333,638,653	352,061,865
Recoveries from Deobligations	12,957,124	10,000,000	10,000,000	10,000,000
Other Collections	*307,153*	*307,153*	*307,153*	*307,153*
Subtotal Availability	323,812,367	385,215,476	407,171,281	412,957,977
Obligations**	290,304,000	321,990,000	356,582,322	371,831,295
End of Year OCF Balance	33,508,367	63,225,476	50,588,959	41,126,682
Target OCF ($15M + 7% of Budget)	*37,539,300*	*39,960,763*	*41,028,191*	*41,828,482*

Numbers are rounded.

* NOTE: Total FY 2012–2014 collections from registration fees is $1,071,655,946. This amount is different from the total required collections of $1,072,357,746 described in Table 3: Needed Fee Collections FY 2012–2014. Initially, the required collection of $1,072,357,746 resulted in a calculated base (ratio: 1) annual fee of $244.16. The weighted ratios were applied and rounded to the whole dollar to determine the proposed fees. Due to rounding of the fees to the whole dollar, the proposed fees generate $1,071,655,946 rather than $1,072,357,746.

** For purposes of the proposed fee calculation, the Congressional Budget and Obligations are treated as the same.

Summary of Impact of Proposed New Fee Relative to Current Fee

Affected Entities

As of December 2010 there were a total of 1,378,609 controlled substances and chemical registrants (1,377,466 controlled substances registrants and 1,143 chemical registrants), as shown in Table 10.

TABLE 10—NUMBER OF REGISTRANTS BY BUSINESS ACTIVITY

Registrant class/business	Controlled substances	Chemicals
Pharmacy	66,766	
Hospital/Clinic	15,774	
Practitioner	1,097,454	
Teaching Institution	351	
Mid-Level Practitioner	183,538	
Researcher/Canine Handler	8,997	
Analytical Lab	1,496	
Narcotic Treatment Program	1,272	
Distributor	795	584
Reverse Distributor	56	
Importer	203	180
Exporter	236	166
Manufacturer	528	213
Total	1,377,466	1,143
Total (all registrants)	1,378,609	

* Data as of December 2010.

Not all registrants listed in Table 10 are subject to the fees. Publicly owned institutions, law enforcement agencies, Indian Health Services, the Department of Veterans Affairs, Federal Bureau of Prisons, and military personnel are exempt from fees.

The number of registrations exceeds the number of individual registrants because some registrants are required to hold more than one registration. The CSA requires a separate registration for each location where controlled substances are handled and a separate registration for each business activity; that is, a registration for activities related to the handling of controlled substances and a registration for activities related to the handling of List I chemicals. Some registrants may conduct multiple activities under a single registration (*e.g.,* manufacturers may distribute substances they have manufactured without being registered as a distributor), but firms may hold multiple registrations for a single location. Individual practitioners who prescribe, but do not store controlled substances, may use a single registration at multiple locations within a state, but need separate registrations for each state in which they practice and are authorized to dispense controlled substances. Firms with multiple locations must have separate registrations for each location.

Characteristics of Entities

This proposed rule affects those manufacturers, distributors, dispensers, importers, and exporters of controlled substances and List I chemicals that are required to obtain and pay a registration fee with DEA pursuant to the CSA (21 U.S.C. 822 and 958(f)). As of December 2010, there were 1,378,609 controlled substances and chemical registrants (1,377,466 controlled substances registrants and 1,143 chemical registrants), as shown above in Table 10.

Pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners make up 98.9 percent of all registrants. These registrants register every three years. Other registrants maintain an annual registration. Registration and reregistration costs vary by registrant category as is described in more detail in the sections below.

The proposed fees would affect a wide variety of entities. Table 11 indicates the sectors affected by the proposed rule and their average annual revenue/income. Most DEA registrants are small entities under Small Business Administration (SBA) standards. Almost all practitioners, which are the largest category of registrants, would be considered small (annual revenues of less than $6 million to $8.5 million, depending on specialty), and practitioners and mid-level practitioners total 1,280,992 (as of December 2010).

TABLE 11—INDUSTRIAL SECTORS OF DEA REGISTRANTS

Sector	NAICS Code	Average annual revenue *
Manufacturers:		
Petro-chemical Manufacturing (organic, inorganic)	32511	$1,390,485,971
Medicinal and Botanical Manufacturing	325411	27,601,834
Pharmaceutical Manufacturing	325412	144,173,821
Adhesive Manufacturing	325520	17,482,468
Toilet Preparation Manufacturing	325620	50,322,290
Other Chemical Manufacturing	325998	13,720,807
Distributors:		

TABLE 11—INDUSTRIAL SECTORS OF DEA REGISTRANTS—Continued

Sector	NAICS Code	Average annual revenue *
Drugs and Druggist Sundries Wholesalers	424210	64,793,480
General Line Grocery Wholesalers	424410	45,518,407
Confectionary Merchant Wholesalers	414450	17,175,982
Chemical Wholesalers	424690	12,856,993
Tobacco Wholesalers	424940	71,437,205
Miscellaneous Wholesalers	424990	2,741,857
Pharmacies:		
Supermarkets	445110	7,247,540
Drug Stores	446110	4,829,487
Discount Stores	452112	26,535,201
Warehouse Clubs and Superstores	452910	76,300,280
Other:		
Testing Labs	541380	1,907,414
Packaging and Labeling Services	561910	2,696,904
Other Practitioners:		
Professional Schools	611310	1,373,855
Ambulatory Health Care Services	621	1,236,852
Hospitals	622	108,286,641

Source: 2007 Economic Census. *http://www.census.gov/econ/census07.*

Supermarkets, discount stores, warehouse clubs, and superstores handle controlled substances through their distribution centers and pharmacies. Drug products containing List I chemicals are primarily distributed as over-the-counter medicines. These are distributed by drug wholesalers who specialize in non-prescription drugs, wholesalers who supply convenience stores, and grocery, pharmacy, and discount stores (*e.g.,* superstores) that operate their own distribution centers.

Economic Impact Analysis of Proposed Fee

The proposed fee, if implemented, is expected to have two levels of impact. Initially, the increase in the fee will impact the registrants. Then the fee increase or portion of the fee increase is expected to be eventually passed on to the general public. To be analytically conservative, the analysis below assumes that the impact of the fee increase is absorbed entirely by the registrants.

DEA assumes that the registration fees are business expenses for all registrants. As a result, the increase in the fee will be dampened by reduced tax liability, as a result of the increase in registration fee expense. For example, if a practitioner pays an additional $60 per year in registration fees and the combined federal and state income tax is 35 percent, the net cash impact is $39, not $60. The additional $60 causes income/profit to decrease by $60, decreasing the tax liability by $21. The net cash outlay is $39.[74]

DEA examined the proposed fees as a percentage of income for physicians, dentists, and physician's assistants in the practitioner registrant group and as a percentage of revenue for pharmacies, manufacturers and distributors. This analysis indicates the fee increase is expected to have the greatest affect on small businesses in the practitioner registrant group. The majority of practitioners and mid-level practitioners work in small businesses. Physicians, dentists, and physician's assistants reflect a representative sub-group of the practitioner and mid-level practitioner registrant groups. The effect of the fee increase is diminished by any increase in registrant income.

The table below describes the average income for physicians, dentists, and physician's assistants from 2004 to 2012. The table below also reflects the impact of the proposed fee increase as a percentage of average income. This analysis assumes that the fee increase is absorbed personally by each practitioner/mid-level practitioner. The analysis ignores the dampening effect of registration fees as a business expense and the potential that the fee increase might be passed on to customers.

TABLE 12—FEE AS PERCENTAGE OF INCOME FY 2004–2012

Year	Average income [75]			Fee	Fee as % of average income		
	Physicians	Dentists	Physician assistants	(Annual basis)	Physicians	Dentists	Physician assistants
2004	137,610	130,300	68,780				
2005	138,910	133,680	71,070				
2006	142,220	140,950	74,270	184	0.129%	0.131%	0.248%
2007	155,150	147,010	77,800	184	0.119%	0.125%	0.237%
2008	165,000	154,270	81,610	184	0.112%	0.119%	0.225%
2009	173,860	156,850	84,830	184	0.106%	0.117%	0.217%
2010	179,370	163,901	87,933	184	0.103%	0.112%	0.209%
2011	187,154	169,632	91,230	184	0.098%	0.108%	0.202%
2012	194,939	175,363	94,528	244	0.125%	0.139%	0.258%

[74] This example is for illustration purposes only. Each entity should seek competent tax advice for tax consequences of the proposed rule.

[75] Source: Bureau of Labor Statistics, *http://www.bls.gov.*

TABLE 12—FEE AS PERCENTAGE OF INCOME FY 2004–2012—Continued

Year	Average income [75]			Fee	Fee as % of average income		
	Physicians	Dentists	Physician assistants	(Annual basis)	Physicians	Dentists	Physician assistants
Increase from 2007 to 2012	26%	19%	22%	33%	6%	11%	9%
Increase from 2006 to 2012	37%	24%	27%	33%	−7%	3%	4%

* Average income data for 2004 to 2009 is provided by the Bureau of Labor Statistics. 2010 to 2012 are estimated figures based on linear regression, where a straight-line increase is calculated from years 2004 to 2009, then using the line to estimate average income for 2010 to 2012.

In 2007, the current fee of $184 on an annual basis represents 0.119 percent, 0.125 percent, and 0.237 percent of annual income for physicians, dentists, and physician's assistants respectively. In 2012, the proposed fee of $244 (on an annual basis) would represent approximately 0.125 percent, 0.139 percent, and 0.258 percent of annual income for physicians, dentists, and physician's assistants respectively. While proposed fees are 33 percent above the current fees implemented at the end of 2006, average incomes for physicians, dentists, and physician's assistants increased 26 percent, 19 percent, and 22 percent respectively. This estimated increase in average income dampens the effect of the fee increase as a percentage of average income. The 33 percent fee increase as a percentage of average income is 6 percent for physicians, 11 percent for dentists, and 9 percent for physician's assistants from 2007 to 2012. The diminishing effect is more apparent when comparing 2012 to 2006, the year for which the current fee was calculated and implemented. Additionally, as the average income grows in 2013 and 2014, the income adjusted fees are not any higher than in recent history.

Exempt from the payment of registration fees are any hospital or other institution that is operated by an agency of the United States, of any State, or any political subdivision of an agency thereof. Likewise, an individual who is required to obtain a registration in order to carry out his/her duties as an official of a federal or State agency is also exempt from registration fees.[76] Fee exempt registrants are not affected by the proposed fees.

Conclusion

DEA concludes that this proposed rule is not a significant regulatory action because it does not result in a materially adverse effect on the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.[77] The proposed fee, if implemented, would initially affect all fee paying registrants. The fees may eventually be passed on to the general public, diminishing the impact of the proposed fee increase on individual registrants. The impact of the proposed fee on registrants is also diminished by a reduction in tax liabilities and an increase in average income. Additionally, hospitals and institutions operated by federal, State, or local governments and their employees are exempt from registration fees.[78] Moreover, DEA believes that this proposed rule will enhance the public health and safety.

Regulatory Analyses

This proposed rule is necessary to ensure the full funding of the DCP through registrant fees as required by 21 U.S.C. 886a. It has been five years since the last fee change. As discussed above, statutory and operational changes to the DCP cannot be fully offset by improved operational efficiencies and require a recalculation of registrant fees. This proposed rule does not change the requirement to register to handle controlled substances and/or List I chemicals but rather changes the annual fee associated with registration and reregistration that will allow DEA to meet its statutory obligations. DEA recognizes that the proposed fee changes affect small businesses, but does not believe the relative individual impact is significant. The average annual increase in estimated registration fee collections is less than $100 million at an estimated annual increase of $88,333,030.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3511)

This proposed rule will not impose additional information collection requirements on the public.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612) (RFA), federal agencies must evaluate the impact of rules on small entities and consider less burdensome alternatives. DEA has evaluated the impact of this proposed rule on small entities as summarized above and concluded that although the rule will affect a substantial number of small entities, it will not impose a significant economic impact on any regulated entities.

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Deputy Assistant Administrator hereby certifies that this proposed rulemaking has been drafted consistent with the Act and that a regulatory analysis on the effects or impact of this proposed rulemaking on small entities has been done and summarized above.[79] While DEA recognizes that this proposed increase in fees will have a financial effect on registrants, the change in fees will not have a significant economic impact. A change in fees is necessary to fully comply with 21 U.S.C. 886a and related statutes governing the Diversion Control Program (DCP) and the Diversion Control Fee Account by which DEA is legally mandated to collect fees to cover the full costs of the DCP as defined by all activities relating to the registration and control of the manufacture, distribution, import, export, and dispensing of controlled substances and listed chemicals.

This rule is not a discretionary action but implements statutory direction to charge reasonable fees to recover the full costs of activities constituting the DCP

[76] See 21 CFR 1301.21 for complete fee exemption requirements.

[77] In accordance with 25 U.S.C. 1616q, employees of a tribal health or urban Indian organization are exempt from ''payment of licensing, registration, and any other fees imposed by a Federal agency to the same extent that officer of the commissioned corps of the Public Health Service and other employees of the Service are exempt from those fees.'' To the extent that any hospital or other institution operated by or any individual practitioner associated with an Indian Tribal Government must pay fees, the economic impact is not substantial.

[78] See 21 CFR 1301.21 for complete requirements for exemption of registration fees.

[79] See ''Economic Impact Analysis of Proposed Rule on Controlled Substances and List I Chemical Registration and Reregistration Fees, DEA–346'' in this rulemaking docket found at *http://www.regulations.gov.*

through registrant fees (21 U.S.C. 821, 886a, and 958(f)). As discussed above and in the Economic Impact Analysis of the Proposed Rule found in the rulemaking docket at *http://www.regulations.gov,* DEA analyzed four fee calculation methodologies—Past-Based, Future-Based, Flat Fee, and Weighted-Ratio. DEA selected the weighted-ratio methodology to calculate the proposed new fee structure. This approach has been used since Congress established registrant fees and continues to be a reasonable reflection of differing costs. The registration fees under the weighted-ratio option result in differentiated fees among registrant groups, where registrants with larger revenues pay higher fees than registrants with lower revenues. Furthermore, the weighted-ratio does not create a disparity in the relative increase in fees from the current to the proposed fees. The weighted-ratios used by DEA to calculate the proposed fee have proven effective and reasonable over time. Additionally, the selected calculation methodology accurately reflects the differences in activity level, notably in pre-registration and scheduled investigations, by registrant category: for example, these costs are greatest for manufacturers. DEA selected this option because it is the only option that resulted in reasonable fees for all registrant groups.

Under the weighted-ratio methodology, the individual effect on small business registrants is minimal. Practitioners and mid-level practitioners represent 92.9 percent of all registrants and nearly all practitioners and mid-level practitioners are employed by small businesses pursuant to SBA standards. Practitioners and mid-level practitioners would pay a three-year registration fee of $732 or the equivalent of $244 per year.

For consideration of the impact of the proposed fee increase on small businesses, DEA analyzed the proposed registration fee as a percentage of annual income for a representative practitioner group: physicians, dentists, and physician's assistants. While there are many specialists listed in the Bureau of Labor Statistics income data, incomes for physicians, dentists, and physician's assistants are representative of the practitioner and mid-level practitioner registrant groups. For practitioners and mid-level practitioners, the proposed new fee, on an annual basis, would be $244; the annual increase would be $60 from the current fee. From the calculation performed in the preceding section, *Economic Impact Analysis of Proposed Rule,* the impacts of the proposed fees, $60 per year increase from current fees, were found to be 0.007 percent, 0.014 percent, and 0.022 percent of annual income for physicians, dentists, and physician's assistants respectively, when normalized for income increases. In consideration of the calculated impact and potentially further mitigating factors discussed in the *Economic Impact Analysis of Proposed Rule,* DEA concludes that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Executive Orders 13563 and 12866

This proposed rule to increase registrant fees has been developed in accordance with the principles of Executive Orders 13563 and 12866. Public comment is encouraged through the Internet with easy Internet access to supporting information found at *http://www. regulations.gov.* The difference between the current fees and the proposed new fee—the fee increase—is less than $100 million annually. Specifically, the difference in the fees projected to be collected under the current fee rates and in the fees projected to be collected under the proposed new fee rates for the three years of FY 2012–FY 2014 is $264,999,092. Thus, the annual increase is $88,333,030. This proposed rule has been reviewed by the Office of Management and Budget.

The primary cost of the proposed rule is the incremental increase in the combined registration fees paid by registrants. Benefits of the proposed rule are an extension of the benefits of the DCP. The DCP is a strategic component of United States law and policy aimed at preventing, detecting, and eliminating the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research and industrial purposes. The absence of or significant reduction in this program would result in enormous costs for the citizens and residents of the United States due to the diversion of controlled substances and listed chemicals into the illicit market as outlined in the Economic Impact Assessment found in the rulemaking docket.

Executive Order 12988

This proposed regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards and reduce burden.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule does not contain a federal mandate and will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $126,400,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. DEA notes that many governmental entities operate DEA-registered facilities and that they are currently fee exempt. Moreover, the effect of the proposed increase on individual entities and practitioners is minimal. The majority of the affected entities will pay a fee of $732 for a three year registration period ($244 per year or an increase of $60 per year). This rule is promulgated in compliance with 21 U.S.C. 886a that the full costs of operating the DCP be collected through registrant fees.

Executive Order 13175

This proposed rule is required by statute, will not have tribal implications and will not impose substantial direct compliance costs on Indian tribal governments.

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

For the reasons set out above, 21 CFR Parts 1301 and 1309 are proposed to be amended as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS AND DISPENSERS OF CONTROLLED SUBSTANCES

1. The authority citation for Part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 953, 956, 957, 958.

2. Amend § 1301.13 by revising paragraph (e)(1) to read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(e) * * *

(1)

Business activity	Controlled substances	DEA Application forms	Application fee ($)	Registration period (years)	Coincident activities allowed
(i) Manufacturing	Schedules I–V	New–225, Renewal—225a.	$3,052	1	Schedules I–V: May distribute that substance or class for which registration was issued; may not distribute or dispose of any substance or class for which not registered. Schedules II–V: except a person registered to dispose of any controlled substance may conduct chemical analysis and preclinical research (including quality control analysis) with substances listed in those schedules for which authorization as a mfg. was issued.
(ii) Distributing	Schedules I–V	New—225, Renewal—225a.	1,526	1	
(iii) Reverse distributing	Schedules I–V	New—225, Renewal—225a.	1,526	1	
(iv) Dispensing or instructing (includes Practitioner, Hospital/Clinic, Retail Pharmacy, Central fill pharmacy, Teaching Institution).	Schedules II–V	New—224, Renewal—224a.	732	3	May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under State statute. A pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in Schedule II–V in a proportion not exceeding 20% of the complete solution, compound or mixture. A retail pharmacy may perform central fill pharmacy activities.

Business activity	Controlled substances	DEA Application forms	Application fee ($)	Registration period (years)	Coincident activities allowed
(v) Research	Schedule I	New—225, Renewal—225a.	244	1	A researcher may manufacture or import the basic class of substance or substances for which registration was issued, provided that such manufacture or import is set forth in the protocol required in § 1301.18 and to distribute such class to persons registered or authorized to conduct research with such class of substance or registered or authorized to conduct chemical analysis with controlled substances.
(vi) Research	Schedules II–V	New—225, Renewal—225a.	244	1	May conduct chemical analysis with controlled substances in those schedules for which registration was issued; manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration or reregistration and provided that the manufacture is not for the purposes of dosage form development; import such substances for research purposes; distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities or research with such substances, and to persons exempted from registration pursuant to § 1301.24; and conduct instructional activities with controlled substances.
(vii) Narcotic Treatment Program (including compounder).	Narcotic Drugs in Schedules II–V.	New—363, Renewal—363a.	244	1	
(viii) Importing	Schedules I–V	New—225, Renewal—225a.	1,526	1	May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered.
(ix) Exporting	Schedules I–V	New—225, Renewal—225a.	1,526	1	

Business activity	Controlled substances	DEA Application forms	Application fee ($)	Registration period (years)	Coincident activities allowed
(x) Chemical Analysis	Schedules I–V	New—225, Renewal—225a.	244	1	May manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to § 1301.24; may export such substances to persons in other countries performing chemical analysis or enforcing laws related to controlled substances or drugs in those countries; and may conduct instructional activities with controlled substances.

* * * * *

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS, AND EXPORTERS OF LIST I CHEMICALS

3. The authority citation for Part 1309 is corrected to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 952, 953, 957, 958.

4. Revise § 1309.11 to read as follows:

§ 1309.11 Fee amounts.

(a) For each application for registration or reregistration to manufacture the applicant shall pay an annual fee of $3,052.

(b) For each application for registration or reregistration to distribute, import, or export a List I chemical, the applicant shall pay an annual fee of $1,526.

5. In § 1309.21, paragraph (c) is revised to read as follows:

§ 1309.21 Persons required to register.

* * * * *

(c) * * *

SUMMARY OF REGISTRATION REQUIREMENTS AND LIMITATIONS

Business activity	Chemicals	DEA Forms	Application fee	Registration period (years)	Coincident activities allowed
Manufacturing	List I, Drug products containing ephedrine, pseudoephedrine, phenylpropanolamine.	New—510	$3,052	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
		Renewal—510a	3,052		
Distributing	List I, Scheduled listed chemical products.	New—510	1,526	1	
		Renewal—510a	1,526		
Importing	List I, Drug Products containing ephedrine, pseudoephedrine, phenylpropanolamine.	New—510	1,526	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
		Renewal—510a	1,526		
Exporting	List I, Scheduled listed chemical products.	New—510	1,526	1	
		Renewal—510a	1,526		

Dated: June 30, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2011–16847 Filed 7–5–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–114206–11]

RIN 1545–BK21

Encouraging New Markets Tax Credit Non-Real Estate Investments; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to advance notice of proposed rulemaking.

SUMMARY: This document contains a correction to advance notice of proposed rulemaking (REG–114206–11) that was published in the **Federal Register** on Tuesday, June 7, 2011 (76 FR 32880). This document invites comments from the public on how the new markets tax credit program may be amended to encourage non-real estate investments.

FOR FURTHER INFORMATION CONTACT: Julie Hanlon-Bolton, (202) 622–3040 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The correction notice that is the subject of this document is under section 45D of the Internal Revenue Code.

Need for Correction

As published, the advance notice of proposed rulemaking (REG–114206–11) contains an error that may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication of advance notice of proposed rulemaking (REG–114206–11), which was the subject of FR Doc. 2011–13981, is corrected as follows:

On page 32881, column 2, in the preamble, under the paragraph heading ''Background'', second paragraph of the column, fourth line, the language ''nonprofit corporation) or partnership if'' is corrected to read ''nonprofit corporation) or partnership, if''.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2011–16824 Filed 7–5–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–118809–11]

RIN 1545–BK27

Modification of Treasury Regulations Pursuant to Section 939A of the Dodd-Frank Wall Street Reform and Consumer Protection Act

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing final and temporary regulations that remove any reference to, or requirement of reliance on, credit ratings in regulations under the Internal Revenue Code (Code) and provide substitute standards of credit-worthiness where appropriate. The Dodd-Frank Wall Street Reform and Consumer Protection Act requires each Federal agency to take such actions regarding its regulations. These regulations affect persons subject to various provisions of the Code. The text of the temporary regulations published in the Rules and Regulations section of the **Federal Register** also serves as the text of the proposed regulations.

DATES: Written and electronic comments and requests for a public hearing must be received by August 30, 2011.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–118809–11), Room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered to: CC:PA:LPD:PR Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–118809–11), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–118809–11).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Arturo Estrada, (202) 622–3900; concerning submissions of comments and requests for a public hearing, Oluwafunmilayo Taylor, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Section 939A(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203 (124 Stat. 1376 (2010)), (the ''Dodd-Frank Act''), requires each Federal agency to review its regulations that require the use of an assessment of credit-worthiness of a security or money market instrument, and to review any references or requirements in those regulations regarding credit ratings. Section 939A(b) directs each agency to modify any regulation identified in the review required under section 939A(a) by removing any reference to, or requirement of reliance on, credit ratings and substituting a standard of credit-worthiness that the agency deems appropriate. Numerous provisions under the Code are affected.

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend the Income Tax Regulations (26 CFR part 1) under sections 150, 171, 197, 249, 475, 860G, and 1001 of the Code. The temporary regulations also amend the Manufacturers and Retailers Excise Tax Regulations (26 CFR part 48) under section 4101 of the Code. The text of the temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and the proposed regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.