DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301 and 1309

[Docket No. DEA–346]

RIN 1117–AB32

Controlled Substances and List I Chemical Registration and Reregistration Fees

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

ACTION: Final rule.

SUMMARY: This rule adjusts the fee schedule for DEA registration and reregistration fees necessary to recover the costs of the 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: *Effective:* April 16, 2012.

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SUPPLEMENTARY INFORMATION:

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 implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801–971), as amended (hereinafter, ''CSA'').[1] DEA 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, is designed to help 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, each controlled substance is classified in one of five schedules based upon its potential for abuse, currently accepted medical use, and the degree of dependence it may cause if abused. 21 U.S.C. 812. Likewise, under the CSA, listed chemicals are separately classified based on their use and importance to the manufacture of controlled substances (List I or List II chemicals). 21 U.S.C. 802(33)–(35). The CSA mandates that DEA register persons and entities who manufacture, distribute, import, or export controlled substances or List I chemicals, and those persons and entities who dispense or conduct research or chemical analysis with controlled substances. These registrants are permitted to handle controlled substances and List I chemicals as authorized by their registration and are required to comply with the applicable requirements associated with their registration. 21 U.S.C. 822, 958. The identification and registration of all individuals and entities authorized to handle controlled substances and List I chemicals establishes a closed system of distribution that DEA is charged to maintain.

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). A Notice of Proposed Rulemaking (NPRM) proposing an adjusted fee schedule for DEA registration and reregistration was published on July 6, 2011, at 76 FR 39318, with a 60 day comment period. The comment period closed on September 6, 2011.

History of Fees

In 1970, Congress consolidated more than 50 laws related to the control 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 the enactment of the CSA, the Bureau of Narcotics and Dangerous Drugs (BNDD) was granted the authority to charge reasonable fees relating to both registration and control [4] of persons and entities engaged in the manufacture, distribution, dispensing, export, and import of controlled substances.[5] To this end, BNDD established a three-

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

[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] 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 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). The term ''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).

[5] 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, Public Law 103–200, 107 Stat. 2333.

tiered fee structure for companies and individuals wishing to participate in the U.S. controlled substance industry.[6]

In 1973, BNDD was abolished, and all of its functions were transferred to the newly-created DEA, including the authority to charge registrants reasonable fees.[7] In 1982, the General Accounting Office (GAO)[8] 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 1983.[9] All fees collected through 1992 were deposited into the general fund of the United States Treasury.

In 1993, Congress determined that the DCP would be fully funded by fees rather than by appropriations,[10] and 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]'' from fees charged by DEA. 21 U.S.C. 886a(1)(C). Congress also specified the general operation of the DCFA. Each fiscal year, the first $15 million of collected fees are transferred to the general fund of the Treasury and are not directly available for use by the DCP. Fees collected in excess of $15 million are used 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).

Shortly after enactment of the 1993 Appropriations Act, DEA published a NPRM proposing to increase the existing fee schedule to comply with Congress's direction to set fees at a level that ensures the recovery of the full costs of operating the DCP.[11] 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.[12] Several registrants impacted by the fee increase challenged it, first in federal district court, where it was upheld, and subsequently on appeal, where it was remanded for additional information to support the fees.[13]

Upon remand, the March 1993 final fee rule was reopened for further comment in 1996.[14] DEA undertook studies and internal reorganizations to enable it to better identify DCP activities and costs, and, in 2002, DEA published for additional public comment more information on the components and activities of the fee-funded DCP.[15] After that publication, the Office of the Inspector General, Department of Justice (OIG) concluded its review of the DCP, and determined that DEA was not adequately supporting the DCP.[16]

In February 2003, DEA published a proposed rule to raise registration and reregistration fees so as to comply with the statutory requirement to charge fees at a level ensuring the recovery of the full costs of operating the various aspects of the DCP.[17] Shortly thereafter, DEA created the Validation Unit to ensure that DCFA-funded expenditures support registration and diversion control-related activities. The Validation Unit reports to the DEA Deputy Administrator and independently reviews specified expenditures attributable to the DCFA. If an expense only partially supports the DCP, such as a field office's rent or utility cost, the Validation Unit determines the amount that may be properly apportioned to the DCFA. On October 10, 2003, a new fee was finalized by publication of a final rule.[18]

Meanwhile, in December 1993, the Domestic Chemical Diversion Control Act of 1993 amended the CSA to require that manufacturers, distributors, importers, and exporters of List I chemicals obtain a registration from DEA. DEA was also authorized to charge ''reasonable fees relating * * * to the registration and control of regulated persons and regulated transactions.'' [19]

In 2004, 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).[20] 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 fees collected in excess of $15 million are deposited into the DCFA, and reimbursements by the Secretary of the Treasury are made without distinction between controlled substance and List I chemical activities.

In 2005, based upon internal organizational changes and the 2005 Appropriations Act, DEA proposed an adjusted fee schedule to appropriately reflect all costs associated with the DCP.[21] 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, including more Special Agent support.[22] The OIG also recommended that DEA increase training for those individuals who support the DCP. 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.[23] Collections associated with that fee adjustment did not begin until FY 2007, on November 1, 2006.

The OIG completed a *Review of DEA's Use of the Diversion Control Fee Account* in 2008 and did not find that any DCFA funds were misused for non-diversion control activities between FY 2004 and FY 2007. To the contrary, the OIG found that DEA did not fully fund

[6] 36 FR 4928 (March 13, 1971); 36 FR 7776 (April 24, 1971).

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

[8] GAO/GGD–83–2, October 29, 1982.

[9] 48 FR 14640 (April 5, 1983); 48 FR 56043 (December 19, 1983).

[10] 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.

[11] 57 FR 60148 (December 18, 1992).

[12] 58 FR 15272 (March 22, 1993).

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

[14] 61 FR 68624 (December 30, 1996).

[15] 67 FR 51988 (August 9, 2002).

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

[17] 68 FR 7728 (February 18, 2003).

[18] 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).

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

[20] 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.

[21] 70 FR 69474 (November 16, 2005).

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

[23] 71 FR 51105 (August 29, 2006).

all diversion control costs with the DCFA, as required by law.[24]

The Proposed Rule

It has been more than five years since the last fee adjustment. DEA proposed a new fee schedule by publication of a NPRM on July 6, 2011. 76 FR 39318–41. DEA outlined the scope of the DCP, the need for a new fee calculation, the four different methodologies or options considered for calculating the fee, the proposed weighted-ratio methodology, and the calculation resulting in the proposed fee increase of approximately 33 percent. The fee increase incorporates additional DCP costs identified in the above-mentioned OIG report, as well as an expanded diversion control program required by Congress, and it accounts for a number of current circumstances related to the diversion of controlled substance pharmaceuticals and listed chemicals.

Methodology for Fee Calculation

Fees must be ''set at a level that ensures the recovery of the full costs of operating the various aspects of [the DCP].'' 21 U.S.C. 886a(1)(C). In addition, any methodology for calculating fees must result in fees that are reasonable. 21 U.S.C. 821 and 958(f). As outlined below in responses to comments, DEA must calculate and collect fees prior to actually expending the funds in order to have funds with which to operate the DCP. Moreover, each year DEA is required to transfer the first $15 million of fee revenues into the general fund of the Treasury, with the remainder deposited into a separate fund of the Treasury called the Diversion Control Fee Account or 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. 21 U.S.C. 886a(1)(B) and (D).

In the NPRM, DEA outlined four alternative methodologies to calculate the registration and reregistration fees. 76 FR 39329–32. These were the Past-Based Option, Future-Based Option, Flat Fee Option, and Weighted-Ratio Option. For each of the options 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 registrant 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 in recovering the full costs of the DCP.

Based on the analysis provided in the NPRM, DEA did not adopt the ''Past-Based Option.'' There are two key reasons for rejecting this methodology. First, the fee increase would be 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 by 10 percent and 32 percent. DEA believes this is unreasonable. Second, the past-based option uses FY 2007–FY 2009 investigation work hour data to set the apportionment of cost to each registrant category. Pre-registration and scheduled investigation costs are assigned to registrant classes and all other costs are recovered on an equal, per-registrant basis. This method is retrospective and assumes that future investigations will be similar to the past. DEA cannot assume that past work hour data accurately reflects future workload because priorities change as the threats change. For example, in order to monitor registrant regulatory compliance and leverage the deterrent effect of scheduled investigations, DEA increased the frequency of all scheduled investigations beginning in 2008. In 2011, DEA began pre-registration investigations of all pharmacies located in the State of Florida in order to address the rampant diversion in south Florida. And in 2010, DEA began conducting nationwide take back events to provide a mechanism for the public to dispose of their unwanted, unused, and expired controlled substance pharmaceutical drugs. The past-based option is vulnerable to short-term fluctuations in priorities which can greatly affect fees among the different categories. As a result, DEA has concluded that past work hour data alone is not the best basis for the calculation of registration fees.

The second option analyzed in the NPRM is the ''Future-Based Option'' which is based on projected work hours for each registrant class using scheduled investigation work plan goals and anticipated/planned resources. Under this option, DEA based its calculations on projected work hour data by registrant group for FY 2012–2014. In other words, 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.

DEA rejects this methodology because it would result in an unreasonable increase in fees for some registrants and a severe disparity of fees among the registrant groups. The large proportional increase in fees for two registrant categories may not pass the reasonable standard required by statute. The vast disparity in the increase, where fees for manufacturers increase by more than 700 percent while fees for dispensers increase by 26 percent, is unreasonable. This method is unfair to the registrant categories because a variety of factors other than scheduled investigations affect cost allocations. Actual operations typically differ from scheduled work plans due to shifting threats and other operational demands. The future-based option is based on projected work hour data of anticipated scheduled investigations, however, only 3.5% of the workload is directly attributable to scheduled investigations. The remaining 96.5% must be apportioned equally across all registrant categories.

The third option analyzed in the NPRM is called the ''Flat Fee Option.'' This methodology would result in equal fees across all registrant groups regardless of the proportion of DCP costs and resources the registrant group may require (e.g., oversight and 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.

DEA did not select this methodology because it would result in disparate changes in fees among registrant groups. Under this option, fees for manufacturers and distributors would decrease by 89 percent and 78 percent respectively, while fees for practitioners would increase by 34 percent. Thus, 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 individual practitioners, such as physicians, physician assistants, dentists, and nurse practitioners. To satisfy the reasonable standard, registration fees should account for differences in regulatory investigations and other DCP costs that vary among the registrant categories.

The fourth methodology evaluated and ultimately selected in the NPRM is the ''Weighted-Ratio Option.'' This option distinguishes among the categories to establish a reasonable fee for each category. To determine the fee, a weighted ratio is assigned based on

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

registrant group, and the amount needed to be collected over the FY 2012–FY 2014 period to cover the costs of the DCP is divided by the weighted number of estimated registrations.

Historically, costs vary and a fee must be set in advance. Since the inception of registration fees, even before DEA was required to recover the full costs of the DCP, DEA has utilized a weighted method of fee allocation. On April 24, 1971, DEA's precursor agency, the Bureau of Narcotics and Dangerous Drugs, published regulations implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970. Those regulations required registration/reregistration fees in the following amounts: $50 for manufacturers; $25 for distributors; and $5 for dispensers and persons conducting research, instructional activities, or chemical analysis. In 1983, DEA published a NPRM which indicated that a 1982 GAO report found that DEA's previous fees did not adequately recover the costs incurred by the Government. The GAO recommended that DEA set a fee schedule of $250 for manufacturers, $125 for distributors, and $25 for practitioners. DEA, however, ultimately set the fee based on its own estimates as follows: $250 for manufacturers; $125 for distributors, importers, and exporters; and $20 for dispensers and persons conducting research, instructional activities, or chemical analysis. DEA indicated that these estimates were based on ''an increase in the number of practitioner registrants since 1980 * * *.'' 48 FR 14640.

The first known published discussion which attempted to capture the specific ratio of fees occurred in the Final Rule; Remanded for Further Notice and Comment, published by DEA in 1996. That Final Rule augmented DEA's first fee-setting rule initiated to recover the full costs of the DCP as defined by Congress. It was published in response to a decision by the United States Court of Appeals which required DEA to identify the components of the DCP and provide a brief explanation of why DEA deemed each component to be part of the program. In that Final Rule, DEA stated that the ratio of fees implemented with the CSA in 1971 was as follows: ''A distributor's fee is 50% of the manufacturer's fee and a dispenser's fee is 16–20% of the distributor's fee. The fee ratios have remained consistent [since 1971] and have not been the subject of any substantive comment or objection by the regulated industry.'' 61 FR 68632. A variation of this ratio has been applied in each fee structure since the implementation of the fee system, usually as expressed above.

The fee structure established by this rule is based on the same ratios that have been utilized since the first amendment to the fee structure, as follows: 1 for researchers, canine handlers, analytical labs, and narcotic treatment programs, who are on a one-year registration cycle; 3 for registrants on three-year registration cycles such as pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners; 6.25 for distributors and importers/exporters; and 12.5 for manufacturers. The ratio of 1 represents a base annual fee by which each ratio is multiplied to determine the total fee per cycle, i.e., one year or three years.

The weighted-ratio methodology, much like the flat fee methodology, is straightforward and easy to understand. Unlike the flat fee, however, this method applies historic weighted ratios to differentiate fees among registrant groups. The fees calculated using this methodology are similar to fees calculated in the past-based option, which allocates three years of historical pre-registration and scheduled investigation costs to registrant groups. This method, however, does not create a disproportionate fee increase in any registrant group. The proposed fee published in the NPRM was calculated using this methodology and resulted in an increase of approximately 33 percent for all registrant groups.

DEA is finalizing the fee schedule using the weighted-ratio methodology as proposed. 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 higher revenues and costs pay higher fees than registrants with lower revenues and costs. Furthermore, the weighted-ratio avoids the disparity that resulted from the past-based methodology. The weighted ratios used by DEA to calculate the fees have proven effective and reasonable over time. Additionally, the selected calculation methodology accurately reflects the differences in registration and other DCP activities by registrant category. For example, these costs are greater for manufacturers. The weighted-ratio methodology results in reasonable fees for all registrant groups at a level sufficient to ensure the recovery of the full costs of operating the DCP.

Discussion of Comments

DEA received 195 comments on the NPRM published on July 6, 2011, at 76 FR 39318. Of these comments, 121 were from mid-level practitioners (e.g. nurse practitioners, nurse mid-wives, nurse anesthetists, clinical nurse specialist, and physician assistants), 4 were from practitioners, 9 were from associations or corporations and 61 commenters did not identify their registration category.

Comments: The majority of commenters opposed the fee increase on principle or as coming at a bad time due to the economic climate. Some commenters believed it was a tax on practitioners and other registrants.

DEA Response: DEA outlined the legal authority, the history of the fees, the need for an increase in fees, the methodology, and the proposed fee calculation in the NPRM in an attempt to make it transparent why there is a fee, why there is a periodic recalculation, and how the proposed new fee schedule was calculated. Rather than a ''tax,'' the registration fee is a statutory requirement for those seeking to participate in the closed system of distribution by handling, or having access to, controlled substances or List I chemicals. The fee funds the DCP under the Controlled Substances Act which includes providing and maintaining services to DEA registrants.

One commenter suggested DEA postpone a fee increase until the economy improves and several suggested imposing incremental increases over a period of time. DEA is sensitive to the economic challenges facing many registrants and has endeavored to set the fee as low as possible consistent with its statutory mandates. DEA continually strives to be fiscally responsible. The last fee increase was set in FY 2006 and was designed to encompass only FYs 2006–2008. Through various efforts and cost-saving measures, the DCP has been able to operate under that fee structure through FY 2011. However, DEA cannot further postpone any increase because without an adjustment in the annual registration fees, the DCP 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 would 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 of

distribution, particularly at this time of increased abuse and diversion outlined in the proposed rule.

It is not feasible for DEA to implement an incremental increase while ensuring the recovery of the full costs of operating the various aspects of the DCP, as required by the CSA, and such an increase would not be fair or equitable to registrants. Under the current fee structure, the vast majority of registrants renew their registration once every three years. If DEA were to implement an incremental increase within the three-year cycle, registrants who must renew their registration in the third year of that cycle would pay a substantially higher amount than those registrants who must renew in the first year of the cycle. Additionally, DEA must have reliable collection estimates for budget formulation and execution activities throughout the three-year collection cycle.

Comments: A number of comments suggested that the calculation recognize that other non-federal licensure and registration fees are also increasing.

DEA Response: DEA recognizes there may be other fee increases by states. However, the CSA requires that DEA fees be based on the full costs of operating the various aspects of the DCP.

Comments: Mid-level practitioners expressed the belief that any fee increase is unfair to certain types of registrants, such as mid-level practitioners, who make less money than other types of practitioners.

DEA Response: The fees are on a graduated scale based on the three categories of registration established by statute. Under current authority, DEA has not created additional fee categories or differentiated within a fee category. As discussed, the fees are based on DCP program costs and individual practitioners, regardless of professional occupation, require similar DCP expenditures related to registration and oversight. Furthermore, as outlined in the economic analysis using estimated 2012 average income based on 2004–2009 data provided by the Bureau of Labor Statistics, the fee as a percentage of average income for physicians and dentists is 0.1% and it is 0.26% for physician assistants. These percentages are essentially the same as in 2006, the year of the previous fee adjustment, where the fee as a percentage of average income was 0.1% for physicians and dentists and 0.25% for physician assistants.

Comments: One comment suggested that the length of registration should be extended at the same time there is an increase in the fee.

DEA Response: The statute clearly sets forth the period of registration:

> ''Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain *annually* a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.'' 21 U.S.C. 822(a)(1) (emphasis added).
>
> ''*Every person who dispenses,* or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. *In no event, however, shall such registrations be issued for less than one year nor for more than three years.* 21 U.S.C. 822(a)(2) (emphasis added).

DEA currently allows for the maximum three-year registrations for dispensers of controlled substances, except certain practitioners who dispense narcotic drugs for narcotic treatment, who are statutorily required to obtain annual registrations. 21 U.S.C. 823(g)(1).

Comments: Some commenters indicated that DEA should not raise registration fees but instead decrease its spending, be more efficient with the fees it currently collects or find another source of funds. One commenter questioned whether increased funding would improve the effectiveness of the DCP.

DEA Response: By statute, DEA cannot use another source of funds for the DCP. By enacting 21 U.S.C. 886a, Congress mandated that the DCP be fully funded through the collection of fees rather than appropriated funds. The CSA specifically states that ''[f]ees charged by the Drug Enforcement Administration under its diversion control program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program.'' 21 U.S.C. 886a(1)(C).

It has been more than five years since the last fee adjustment. DEA last adjusted the fee schedule in August 2006, and that fee schedule was intended to be sufficient to cover the ''full costs'' of the DCP for FY 2006 through FY 2008. The DCP has continued to operate under this fee schedule due to cost savings through reorganization, modernization efforts, and by delays in execution of planned programs. As indicated by the above-referenced 2008 OIG report, additional salary and other costs attributable to diversion control activities needed to be incorporated into the DCP as was done in this fee calculation. In addition, Congress has expanded the scope of the DCP through budgetary and legislative action in order to address an increase in the diversion of controlled substances and listed chemicals that seriously impact public health and safety.

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, the DCP has been evaluated by the OIG and it did not find that DCFA funds were misused. As noted earlier, the OIG found that DEA did not fully fund all diversion control costs with the DCFA as required.[25] The DCP plans to continue cost-saving technology improvements in doing business and to implement such improvements for those that do business with the DCP through its regulatory functions such as registration and reporting systems.

The DCP exercises a variety of management controls, including independent review of certain DCFA expenditures. This is accomplished by the Validation Unit which was established in 2003 to review DCFA expenditures of $500 or more to ensure that each expense is in support of diversion-related activities. DEA continues to evaluate the appropriate mix of management controls. The costs to the DCP associated with additional review of expenditures must be balanced against the risks of error. DEA may adjust the expenditure threshold level for review and validation up to $2,500 to adjust the review process and reduce the associated costs to the DCP. The DCP will continue to provide managerial oversight on expenditures involving DCFA funds to include oversight by agency managers and by the Validation Unit.

The DCP is expanding its use of Tactical Diversion Squads and is conducting more investigations, inspections, and scheduling actions now than ever before due to the increase in prescription drug abuse and the corresponding efforts to divert such substances to illicit use. Similarly, an ever expanding number of synthetic substances, such as synthetic cannabinoids (a large family of chemically unrelated structures functionally similar to [Delta]9-tetrahydrocannabinol (THC), the active principle of marijuana) and synthetic cathinones (drugs of the phenethylamine class which are structurally and pharmacologically similar to amphetamine and other

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

related substances, and are commonly falsely marketed as bath salts or plant food) require the DCP to dedicate resources to analyze and respond to new and emerging threats more often now than at any time in the past to protect the public health and safety.

The DCP also establishes and maintains various IT systems for use by registrants. These systems result in cost savings and help both DEA and the registrants perform day-to-day functions more efficiently.

Comments: One commenter felt DEA appropriations and not DCP funds should be used to pursue illicit entities operating via the internet and ''pill mills'' since they are the major sources of controlled substance abuse and diversion.

DEA Response: DEA must set fees at a level that ensures the recovery of the full costs of operating the various aspects of the DCP. 21 U.S.C. 886a(1)(C). As discussed above under the History of Fees, the fees are for the ''registration and control'' of the manufacture, distribution, and dispensing as well as importing and exporting of controlled substances and listed chemicals. 21 U.S.C. 821 and 958(f). The ''control'' of controlled substances and listed chemicals includes enforcement costs where the DCP carries out the mandates of the Controlled Substances Act. In doing so, the DCP may investigate the diversion of controlled substances regardless of the method or source of diversion, including illicit operations involving the internet and ''pill mills.''

Comments: Several commenters requested more specificity on what the fee increase will support.

DEA Response: A supplemental document titled the Proposed Fee Calculation, located with the NPRM on *www.regulations.gov,* and an updated version of this document titled New Registrant Fee Schedule Calculations, posted with this final rule, also on *www.regulations.gov,* outline specific costs of the DCP used in calculating the fee. As discussed in the NPRM and above, the DCP is defined as ''the controlled substance and chemical diversion control activities of the Drug Enforcement Administration.'' 21 U.S.C. 886a(2)(A). The term ''controlled substance and chemical diversion control activities'' is defined as ''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). Additionally, detailed program costs may be found in the annual President's Budget, as well as supporting budget documents released on the Department of Justice's Web site at *http://www.justice.gov/about/bpp.htm*. See in particular pages 97–101 of the FY 2012 DEA budget.

Comments: One registrant recommended that DCP funds be better used to provide for adequate staffing for the DCP functions involving quota requests, scheduling determinations, and policy and regulatory interpretations in order to be more responsive to the regulated community.

DEA Response: DEA continuously monitors and adjusts the number of employees assigned to various DCP tasks, including those that respond to inquiries from the registrant community. The DCP maintains a robust public Web site that is continually updated with information on topics of interest to registrants such as administrative final orders, significant guidance documents, ''questions and answers'' on common topics, registration tools and resources, and registrant reporting requirements. The Web site is intended to alleviate the burden of responding to multiple inquiries regarding similar or common topics, and to communicate new policies and/or views to registrants. The DCP regulates a registrant population of approximately 1.4 million that continues to grow every year, and each written inquiry requires a thorough review of the pertinent facts in order to provide a fair, measured response. While awaiting a response from the DCP, registrants are encouraged to review the DCP Web site for information and guidance, and to seek assistance from their local DEA offices and state licensing bodies. The DCP also organizes regional conferences designed to provide information and resources to registrants. Finally, all quota requests are scrutinized in detail and the supplemental information provided by quota applicants is verified and cross-checked in order to ensure the DCP is fulfilling all of its statutory obligations. The volume of quota applications and the level of review required for an appropriate assessment is time consuming. Accordingly, DEA is undertaking a comprehensive review of its quota regulations pursuant to Executive Order 13563 with the goal of updating and streamlining the quota application process.

Comments: Several comments stated that any fee increase is unfair to persons who do not prescribe controlled substances but are required by an employer or an insurance company to maintain a DEA registration. Similarly, some allege that many registrants are not reimbursed for their payment of the registration fee by their employer or that fewer reimbursements occur than in the past.

DEA Response: DEA issues registrations to practitioners for the purpose of prescribing or dispensing controlled substances. DEA does not control or otherwise have authority over requirements by outside entities such as insurance companies or employers. Furthermore, DEA expends resources to review applications to determine qualifications, and it expends resources to maintain registrations once they are issued. As such, DEA cannot consider the underlying reasons registrants apply for a registration, other than those related to the handling of controlled substances, nor can DEA consider whether a particular registrant is reimbursed for the fee.

Comments: Other comments stated that any fee increase is detrimental to persons with registrations in multiple states. Another commenter suggested that a DEA number should be assigned to a provider throughout their career, regardless of their practice location.

DEA Response: By statute, ''[a] separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or List I chemicals.'' 21 U.S.C. 822(e). Thus, some registrants, based upon their particular circumstances and business decisions, may have more than one registration within the same state or in multiple states where more than one state has authorized the registrant to conduct the above described activities. Registration is an essential component of the closed system of distribution established under the CSA and is predicated on compliance with all applicable state and local laws, including state licensure in each state the registrant practices.

Comments: A number of commenters focused on situations where one person may be more impacted by the fee increase than another, such as persons working in low-income areas where there is little or no reimbursement for registration fees, persons working in rural areas, and persons in sole practice or in small practices. Several commenters expressed concern that fee increases will affect patient care as some registrants may not renew or seek to register because of the cost.

DEA Response: DEA may only operate within its statutory authority, which requires that the fees be set at a level that ensures the recovery of the full costs of operating the DCP. DEA notes that there are currently 1.4 million active registrants and, as such, even if business model or size of practice could

be objectively measured and accounted for in individualized fee calculations, such individual calculations would be costly. It is likely that any cost savings would be offset by the increased need for personnel to perform the individual fee calculations. It should also be noted that historically, DCP costs are higher for rural areas because of the additional travel costs from DEA office locations. Each applicant for registration must evaluate their need to be able to handle controlled substances or listed chemicals.

Comments: One commenter suggested that those state, federal, and tribal organizations that are exempt from payment of the fee should be required to pay a fee before the current fee is increased.

DEA Response: Registration fee exemptions are set forth in the existing regulations. Generally, hospitals and other institutions operated by an agency of the United States or of any state or any political subdivision or agency thereof, as well as any individual required to obtain a registration in order to carry out his or her duties as an official of an agency of the United States or of any state or any political subdivision or agency thereof may be exempt from payment of a registration or reregistration fee. 21 CFR 1301.21. Such an individual is not exempt if his/her registration is used for appropriate private activities unrelated to the performance of his/her official duties. Tribal governments are also exempt pursuant to the Indian Health Care Improvement Act of 2010.[26] DEA is committed to carefully reviewing all applications for fee exempt status to ascertain that such exemptions are not inappropriately granted. Approximately 96,000 individual and institutional registrants, or 7% of all registrants, are exempt from registration fees.

Comments: Some commenters suggested that persons who over-prescribe or violate the law should be charged additional fees and penalties to help make up any shortfall in collections. Likewise, it was suggested that the end users of controlled substances be charged an additional fee. Others suggested that DEA legalize ''agriculture-based controlled substance production'' to either decrease costs or charge a fee to fund the DCP.

DEA Response: DEA has no authority to implement these suggestions. DEA's statutory authority is to charge reasonable registration fees set at a level that ensures the recovery of the full costs of operating the various aspects of the DCP. In addition, the CSA provides for mechanisms independent of the registration fee by which to exact financial remuneration from registrants who violate the law. Registrants who violate the law with regard to controlled substances may be subject to civil and criminal penalties, as well as forfeitures. 21 U.S.C. 841, 842, 843, 881.

Comments: Some commenters suggested that the fee should be based on the rate of prescribing of controlled substances or pro-rated to the salary of the prescriber or based on the registrant's number of Medicaid and Medicare patients.

DEA Response: DEA does not have access to the controlled substance prescribing rates of practitioners. In fact, many states with prescription drug monitoring programs prohibit law enforcement entities from using prescribing data without specific, independent legal authority to do so, e.g., a subpoena or warrant. Even so, DEA does not have the expertise or resources to calculate the rate of prescribing for each registrant in order to personalize each registrant's registration fee. Additionally, allowing individualized calculations based on prescribing rates, income, or type of patients served would introduce uncertainty and unpredictable fluctuations in the collection cycle, thereby jeopardizing the statutory mandate to recover the full costs of operating the DCP.

Comment: One association felt DEA fails to recognize the unfairness of the ''Weighted-Ratio'' methodology for fee calculation because dispensers or practitioners make no income from writing a prescription whereas manufacturers and distributors more directly benefit from their authorization by registration to handle controlled substances. This commenter believed the difference in annual revenue or income for a practitioner compared to a manufacturer or distributor was more than the 9 times ratio for distributors and the 12 times ratio for manufacturers.

DEA Response: It is important to emphasize that the focus of DEA's fee calculation methodology is to account for DCP program costs among the registrant categories and not to set fees according to a percentage of registrant revenue from use of a DEA registration. DEA provided an analysis of incomes to show the economic impact of the relatively minor proportion of that income that may be expended for payment of a registration fee. Additionally, the analysis showed that the fees as percentages of income/revenue are essentially the same as in 2006, the year of the last fee adjustment.

Need for New Fee Calculation

As discussed in the NPRM, DEA last adjusted the fee schedule in August 2006. This fee schedule was calculated to cover the ''full costs'' of the DCP for FY 2006 through FY 2008 or October 1, 2005 through September 30, 2008. However, collections did not begin until FY 2007.[27] 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 from 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 scope of the DCP has been expanded by Congress and by the need to address the diversion of controlled substances and listed chemicals that seriously impact public health and safety.

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, thereby increasing the deterrent effect of increased regulatory investigations. Tactical Diversion Squads incorporate the criminal investigative skills and statutory authority of Special Agents as well as state and local Task Force Officers in an effort to stop 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 as 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 the need to expand the number and use of Tactical Diversion Squads.

Due to the rise in controlled substance diversion and abuse, as well as the recent emergence of designer drug abuse, the DCP has increased scheduled

[26] 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 officers of the commissioned corps of the Public Health Service and other employees of the Service are exempt from those fees.''

[27] 71 FR 51105 (August 29, 2006).

investigations of registrants and drug scheduling initiatives, as well as other modifications in its diversion 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 help successfully execute the drug trafficking disruption goals of 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 in 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, in FY 2009, the DCP's regulatory activities included more outreach programs to help the registrant population better comply with the CSA. The DCP increased investigation cycles as well as depth of review. In FY 2009, there were 1,065 scheduled investigations; in FY 2012, DEA projected performance targets of 3,906 scheduled investigations—an increase of 2,841. Additionally, DEA coordinates National Prescription Drug Take-Back Day initiatives, providing an opportunity for the safe disposal of unwanted or unused prescription drugs. DEA also projects to increase the number of Diversion Priority Target Organizations not Linked to Consolidated Priority Organization Targets Disrupted or Dismantled to 85 (disrupted)/90 (dismantled), an increase of 32 (disrupted)/66 (dismantled) over FY 2007's 53 (disrupted)/24 (dismantled), and is authorized and plans to establish an additional 12 Tactical Diversion Squads, which conduct criminal enforcement activities, across the United States. The new fee schedule will allow DEA to sustain current, planned, and future operations and employ additional personnel in support of important program initiatives during Fiscal Years 2012–2014.

Fee Calculation

DEA must ensure the recovery of the full costs of operating the DCP while charging registrants reasonable fees relating to the registration and control of the manufacture, distribution, import, and export of controlled substances and listed chemicals, as well as the dispensing of controlled substances. 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 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. 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); therefore, there must always be more collected than is actually spent to avoid running a deficit in violation of federal fiscal law.[28] In operating the DCP, DEA must be prepared for changes in investigative priorities, diversion trends, and emerging drugs and chemicals posing new threats to the public health and safety.

Current options to calculate fees are also limited by the ability and practicability of tracking and allocating detailed costs, although the agency continues to improve its capabilities on this front. Part of the difficulty stems from the fact that the mission of DEA involves investigations and actions that often involve poly-drug organizations (drug trafficking organizations that traffic multiple drugs), various types of registrants, or investigations that may start out as one type of investigation and result in another, based upon the way the facts develop. It is apparent that 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 Congress differentiated among the categories of registrants for purposes of calculating a reasonable fee, i.e., manufacturers, distributors, importers, exporters, and dispensers. The weighted ratio of 12.5 for manufacturers, 6.25 for distributors (including importers and exporters), and 1 for dispensers is consistent with Congress's differentiation between the categories of registrants.

Because of the complexity of many diversion investigations, tracking costs within the DCP according to registrant categories or within a given registrant category has not been possible or cost-efficient. Such detailed cost attribution may or may not be feasible in the future. 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. DEA has also made progress through reorganization and there is recognition throughout the agency of the need to identify and separate DCP costs from other agency costs.

Thus, the fee is calculated by assigning registrants to a business activity or category (*e.g.,* researcher, practitioner, distributor, manufacturer) 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 business activity or category. 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. Historically, registration and other DCP activities are greatest for manufacturers. This is because there is great risk and grave consequences associated with the quantity and purity of controlled substances and/or chemicals with each manufacturer 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.

In calculating fees to recover the full costs of operating the DCP, DEA estimates the costs of operating the DCP

[28] 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.

for the next three fiscal years.[29] To develop the DCFA budget estimates for Fiscal Year (FY) 2012, FY 2013 and FY 2014, DEA compiles: (1) The actual DCFA financial data for FY 2011; (2) the FY 2012 President's Budget Request; (3) the estimated budgets for FY 2013 and FY 2014; and (4) 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. These additional costs have not been reflected in the fees until now because the fees were last adjusted for 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.[30]

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 investigative costs, travel, and purchases of goods and services. 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 *percentage* of costs; however, totals for each of these major cost categories do increase to reflect additional costs in each of these categories.

In addition to the budget estimates 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 purchase 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, *e.g.,* 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 $13.5 million per year.

Transfer to Treasury

As discussed, in 1993, Congress determined that the DCP would be fully funded by registration fees rather than by appropriations.[31] 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]'' from fees charged by DEA. 21 U.S.C. 886a(1)(C). Collected fees are deposited into the DCFA. 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 transfer to the Treasury.

Operational Continuity Fund (OCF)

DEA maintains an operational continuity fund (OCF) based on the need to maintain DCP operations when monthly collections and obligations fluctuate. Historically, current obligations sometimes exceed current collections 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. Using statistical analysis of the historical fluctuations between amounts collected and amounts obligated, DEA has determined that seven percent of the projected obligations is adequate to avoid operational disruptions. The amount required to bring the operational continuity fund balance to the $15 million plus seven percent level is added to projected costs.

The FY 2012–FY 2014 OCF balance projections have been changed from those shown in the NPRM to reflect actual FY 2011 financial data. The FY 2012 beginning OCF balance of $41,726,554 is higher than the FY 2014 end of year target OCF balance of $40,943,670 by $782,884. The higher beginning OCF balance allows lower required collections from registration fees. The incremental changes in OCF balance for FY 2012, FY 2013, and FY 2014 are −$2,047,144, $863,240, and $401,020 respectively (or a cumulative decrease of $782,884). The cumulative decrease of $782,884 is a change from the cumulative increase of $8,320,115 estimated in the NPRM. The two main factors that contributed to the change from the NPRM calculation estimated in early 2011 to the final rule calculation performed after the end of FY 2011 (September 30, 2011) are: (1) Lower than estimated actual FY 2011 spending which led to a higher beginning FY 2012 OCF balance; and (2) lower estimated budgets for FY 2013 and FY 2014, which lowered the target OCF balance.

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

	FY2012	FY2013	FY2014
Budget	$322,000,000	$352,563,000	$364,895,000
Target OCF ($15M + 7%)	39,679,410	40,542,650	40,943,670
Beginning OCF balance	41,726,554	.....	.....

[29] See ''New Registrant Fee Schedule Calculations'' in this rulemaking docket found at www.regulations.gov.

[30] See ''U.S. Department of Justice, Drug Enforcement Administration, FY 2012 Performance Budget Congressional Submission'' for details on the FY 2012 budget. The budget document is available online at *http://www.justice.gov/jmd/2012justification/pdf/fy12-dea-justification.pdf.*

[31] 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.

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

	FY2012	FY2013	FY2014
Needed Change to Achieve Target OCF	(2,047,144)	863,240	401,020
3-year cumulative change			(782,884)

Combat Methamphetamine Act of 2005 (CMEA) Collections

Under the 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 in good standing and holding a current DEA registration to dispense controlled substances, such as a pharmacy. DEA has observed an approximately 26 percent decline in self-certifications from FY 2008 to FY 2011 and anticipates that the decline will stabilize at approximately 5,000 per year from FY 2012 to 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 $105,000 annually.

TABLE 2—CMEA COLLECTIONS FY 2012–2014

	FY2012	FY2013	FY2014
Number of paying self-cert	5,000	5,000	5,000
Fee	$21	$21	$21
CMEA collection estimate	$105,000	$105,000	$105,000

Other Collections

DEA also derives revenue from the sale/salvage of official government vehicles dedicated to DCP use. DEA's estimate for all other collections is $533,766 per year. This is the actual amount for FY 2011.

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 $320,814,090. This figure includes the budget of $322,000,000, plus $15 million for transfer to the Treasury, minus $13.5 million in recoveries, $2,047,144 for the decrease in the OCF balance, $105,000 in CMEA self-certification collections, and $533,766 in other collections.

Required registration fee collections for FY 2013 are $354,287,474. This figure includes the estimated budget of $352,563,000, plus $15 million for transfer to the Treasury and $863,240 for the increase in the OCF balance, minus $13.5 million in recoveries, $105,000 in CMEA self-certification collections, and $533,766 in other collections.

Required registration fee collections for FY 2014 are $366,157,254. This figure includes the estimated budget of $364,895,000, plus $15 million for transfer to the Treasury and $401,020 for the increase in the OCF balance, minus $13.5 million in recoveries, $105,000 in CMEA self-certification collections, and $533,766 in other collections.

TABLE 3—NEEDED FEE COLLECTIONS FY 2012–2014

	FY2012	FY2013	FY2014	3-yr total
Budget/Estimated Budget	$322,000,000	$352,563,000	$364,895,000	$1,039,458,000
Recoveries	(13,500,000)	(13,500,000)	(13,500,000)	(40,500,000)
Net Budget	308,500,000	339,063,000	351,395,000	998,958,000
Transfer to the Treasury	15,000,000	15,000,000	15,000,000	45,000,000
Change to Achieve Target OCF	(2,047,144)	863,240	401,020	(782,884)
CMEA Self-cert collections	(105,000)	(105,000)	(105,000)	(315,000)
Other collections	(533,766)	(533,766)	(533,766)	(1,601,297)
Required collections from Registration Fees	320,814,090	354,287,474	366,157,254	1,041,258,818

Numbers are rounded.

In total, DEA needs to collect $1,041,258,818 in registration fees over the three year period, FY 2012–FY 2014, to fully fund the DCP.

As in the past, DEA is calculating 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. For purposes of calculating the new fee schedule, DEA used a new fee collection start date of March 1, 2012, and used the current fee schedule for calculating the first five months of FY 2012 registration fee collections.

In calculating the new fees through FY 2014 using the selected weighted-ratio methodology, DEA has updated the data used in the calculation set forth in the proposed rule. Instead of budget estimates for FY 2012, 2013, and 2014, the final fee calculation uses the actual FY 2012 budget, revised budget estimates for FY 2013 and FY 2014, and revised estimates for recoveries from deobligations and for the Operational Continuity Fund. These revisions are

outlined in the overview of the Diversion Control Fee Account below:

	FY2012	FY2013	FY2014
Congressional Budget/Cost Estimates	$322,000,000	$352,563,000	$364,895,000
Operational Continuity Fund (OCF) Brought Forward From Prior Year	41,726,554	39,701,112	36,496,165
Collections: Registration Fees	320,835,793	350,219,287	369,879,300
Collections: CMEA	105,000	105,000	105,000
Treasury	(15,000,000)	(15,000,000)	(15,000,000)
Net Collections	305,940,793	335,324,287	354,984,300
Recoveries from Deobligations	13,500,000	13,500,000	13,500,000
Other Collections	533,766	533,766	533,766
Subtotal Availability	361,701,112	389,059,165	405,514,231
Obligations	322,000,000	352,563,000	364,895,000
EOY OCF Balance	39,701,112	36,496,165	40,619,231
Target OCF ($15M+7% of Budget)	39,679,410	40,542,650	40,943,670

Numbers are rounded.

Note: Due to rounding of the fees to the whole dollar, the total 3-year registration fee collection estimate of $1,040,934,380 does not equal the target collection amount of $1,041,258,818 used to calculate the fees.

Based upon careful consideration of all of the comments and applying the above, a new fee schedule is set forth below. This new fee schedule is *slightly less* than the fee schedule proposed in the NPRM on July 6, 2011, due to the completion of FY 2011 and the availability of actual financial data for the fiscal year as well as progression in the budget process due to the passage of time since the NPRM was prepared.

REGISTRANTS ON THREE-YEAR REGISTRATION CYCLE

Registrant class/business	Fee
Pharmacy	$731
Hospital/Clinic	731
Practitioner	731
Teaching Institution	731
Mid-Level Practitioner	731

* Pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners currently pay a fee for a three-year period. Fee of $731 is equivalent to approximately $244 annually.

REGISTRANTS ON ANNUAL REGISTRATION CYCLE

Registrants class/business	Fee
Researcher/Canine Handler	$244
Analytical Lab	244
Maintenance	244
Detoxification	244
Maintenance and Detoxification	244
Compounder/Maintenance	244
Compounder/Detoxification	244
Compounder/Maintenance/Detoxification	244
Distributor (chemical and controlled substances)	1,523
Reverse distributor	1,523
Importer (chemical and controlled substances)	1,523
Exporter (chemical and controlled substances)	1,523
Manufacturer (chemical and controlled substances)	3,047

This fee schedule replaces 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. Particularly in light of increased needs for diversion control and demands upon the DCP outlined in the NPRM, the following fees for the FY 2012–2014 period will be effective April 16, 2012.

DEA continues to review possible methodologies as technology continues to afford increased tracking and 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, the 12.5 ratio is applied to the manufacturing registrant group. The 6.25 ratio applies to the ''distribution'' of controlled substances and listed chemicals, or the distributor registrant group. The ''dispensing'' registrant group has the largest number of registrants and each registrant has a relatively low registration and control cost, and a relatively smaller quantity and lower purity of controlled substances within their physical possession. Thus, the base fee, or the 1 ratio, is applied to the dispensing registrant group. The practitioner fee is the base fee on an annual basis but is collected every three years for administrative convenience.

Thus, the new fees, some of which are paid annually and some of which are paid every three years, range from $244 for ratio 1 to $3,047 for ratio 12.5, depending upon the particular registrant category. Specifically, the annual registration fee for practitioners, mid-level practitioners, dispensers, researchers, and narcotic treatment programs is $244. For administrative convenience for both the collection and the payment, practitioners will pay a combined registration fee of $731 every three years. The annual registration fee for distributors, importers, and exporters is $1,523, and for manufacturers the annual fee is $3,047. 21 CFR 1301.13 and 1309.11.

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 complying with laws and regulations 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. DEA cannot foresee Congressionally-mandated changes to the DCP, emerging trends, or how such trends may impact the DCP, 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.

Summary of Impact of New Fee Relative to Current Fee

Affected Entities

In updating the number of registrants since the NPRM and the proposed fee calculation, there is a slight increase, with a total of 1,407,119 controlled substances and listed chemical registrants as of August 2011 (1,406,021 controlled substances registrants and 1,098 chemical registrants), as shown in Table 10.

TABLE 10—NUMBER OF REGISTRANTS BY BUSINESS ACTIVITY

Registrant class/business	Controlled substances	Chemicals
Pharmacy	66,934	
Hospital/Clinic	15,737	
Practitioner	1,115,398	
Teaching Institution	336	
Mid-Level Practitioner	193,877	
Researcher/Canine Handler	9,120	
Analytical Lab	1,500	
Narcotic Treatment Program	1,267	
Distributor	828	550
Reverse Distributor	60	
Importer	209	182
Exporter	233	159
Manufacturer	522	207
Total	1,406,021	1,098
Total (all registrants)	1,407,119	

* Data as of August 2011.

Not all registrants listed in Table 10 are subject to the fees. Publicly owned institutions, law enforcement agencies, the Indian Health Service, 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 prescribe controlled substances.

Characteristics of Entities

This 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 August 2011, there was an increase of registrants from December 2010, with 1,407,119 controlled substances and List I chemical registrants (1,406,021 controlled substances registrants and 1,098 List I chemical registrants), as shown above in Table 10.

Pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners comprise 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 described in more detail in the sections below.

The fees affect a wide variety of entities. Table 11 indicates the sectors affected by this rule and their average annual revenue/income. Most DEA registrants are considered small entities under Small Business Administration (SBA) standards. There are 1,309,275 registered practitioners and mid-level practitioners as of August 2011, and almost all practitioners are considered small (annual revenues of less than $6 million to $8.5 million, depending on specialty).

TABLE 11—INDUSTRIAL SECTORS OF DEA REGISTRANTS

Sector	NAICS code	Average annual revenue *
Manufacturers:		

TABLE 11—INDUSTRIAL SECTORS OF DEA REGISTRANTS—Continued

Sector	NAICS code	Average annual revenue *
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:		
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 that operate their own distribution centers.

Economic Impact Analysis of Fee

This fee is expected to have two levels of impact. Initially, the fee adjustment will impact the registrants. Then the fee or portion of the fee increase may be passed on to the general public. The analysis below assumes that the impact of the fee adjustment is absorbed entirely by the registrants. Some commenters have confirmed this statement and have indicated some registrants may decide not to renew their registration as a result of the higher fees.

The registration fee may be a deductible business expense for some registrants. As a result, the increase in the fee may 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.[32]

DEA examined the new 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 adjustment is expected to have the greatest effect on small businesses in the practitioner registrant group. The majority of practitioners work in small businesses. Physicians, dentists, and physician's assistants reflect a representative sub-group of the practitioner registrant group. 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, and reflects the impact of the fee as a percentage of average income. This analysis assumes that the fee is absorbed personally by each practitioner and is not passed on to customers in such forms as higher prices for medical services or products. The analysis also ignores the dampening effect of registration fees as a potentially deductible business expense.

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

Year	Average income [33]			Fee	Fee as percent 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

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

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

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

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

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 new 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 the new fee is approximately 33 percent above the current fees implemented at the end of 2006, average incomes for physicians, dentists, and physician's assistants have increased 26 percent, 19 percent, and 22 percent respectively over the same period. This estimated increase in average income dampens the effect of the fee increase as a percentage of average income. 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 is any hospital or other institution that is operated by an agency of the United States, of any state, or of any political subdivision or 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.[34] Fee exempt registrants are not affected by the new fees.

Conclusion

DEA concludes that this new fee schedule is not an economically 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.[35] The new fee will initially affect all fee paying registrants. The fees may eventually be passed on to the general public, diminishing the impact of the fee adjustment on individual registrants. The impact of the fee on registrants may also be 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.[36] Moreover, DEA believes that this final rule will enhance the public health and safety.

Regulatory Analyses

This final 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 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 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 $76,226,568.

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

This 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 final 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 rulemaking has been drafted consistent with the Act and that a regulatory analysis on the effects or impact of this rulemaking on small entities has been done and summarized above.[37] While DEA recognizes that this 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 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

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

[35] 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.

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

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

costs of activities constituting the DCP through registrant fees (21 U.S.C. 821, 886a, and 958(f)). As discussed above and in the Economic Impact Analysis of the Final Rule found in the rulemaking docket at 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 new fee structure. This approach has been used since Congress established registrant fees and continues to be a reasonable reflection of differing costs. Furthermore, the weighted-ratio does not create a disparity in the relative increase in fees from the current to the new fees. The weighted-ratios used by DEA to calculate the 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 represent 93 percent of all registrants, and nearly all practitioners are employed by small businesses pursuant to SBA standards. Practitioners will pay a three-year registration fee of $731 or the equivalent of $244 per year.

For consideration of the impact of the fee on small businesses, DEA analyzed the new 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 registrant group. For practitioners, the 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 Final Rule,* the impacts of the new fees, $60 per year increase from current fees, were found to be 0.007 percent, 0.014 percent, and 0.022 percent (rounded to the third decimal) 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 Final Rule,* DEA concludes that the final rule will not have a significant economic impact on a substantial number of small entities.

Executive Orders 13563 and 12866

This final rule increasing registrant fees has been developed in accordance with the principles of Executive Orders 13563 and 12866. Supporting information may be found at www.regulations.gov. The difference between the current fee and the 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 new fee rates for the three years of FY 2012–FY 2014 is $228,679,704. Thus, the annual increase is $76,226,568. This rule has been reviewed by the Office of Management and Budget.

The primary cost of this final rule is the increase in the registration fees paid by registrants. Benefits of the 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 final 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, impose enforcement responsibilities on any state or 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 $136,000,000 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 this fee adjustment on individual entities and practitioners is minimal. The majority of the affected entities will pay a fee of $731 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 rule is required by statute, will not have tribal implications and will not impose substantial direct compliance costs on Indian tribal governments.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (5 U.S.C. 804). This rule will not result in an annual effect on the economy of $100,000,000 or more, a major increase in costs or prices, or have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

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 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.	$3,047	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.	1,523	1	
(iii) Reverse distributing.	Schedules I–V ...	New–225 Renewal–225a.	1,523	1	
(iv) Dispensing or instructing (includes Practitioner, Hospital/Clinic, Retail Pharmacy, Central fill pharmacy, Teaching Institution).	Schedules II–V ..	New–224 Renewal–224a.	731	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.
(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.	1,523	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.	1,523	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 revised 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 $3,047.

(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 $1,523.

■ 5. In § 1309.21, revise paragraph (c) 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	New–510	$3,047	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
	Drug products containing ephedrine, pseudoephedrine, phenylpropanolamine.	Renewal–510a.	3,047		
Distributing	List I	New–510	1,523	1	
	Scheduled listed chemical products.	Renewal–510a.	1,523		
Importing	List I	New–510	1,523	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
	Drug Products containing ephedrine, pseudoephedrine, phenylpropanolamine.	Renewal–510a.	1,523		
Exporting	List I	New–510	1,523	1	
	Scheduled listed chemical products.	Renewal–510a.	1,523		

Dated: March 12, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 627

[FHWA Docket No. FHWA–2011–0046]

RIN 2125–AF40

Value Engineering

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: This rule updates regulations to enhance the integration of value engineering (VE) analysis in the planning and development of highway improvement projects. In issuing the final rule, FHWA revises the VE regulations to make them consistent with prior changes in legislation and regulations. This rulemaking does not otherwise impose any new burdens on States, revise the threshold of projects for which a VE analysis is required, or change the reporting structure now in place.