Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301 and 1309

[Docket No. DEA-501]

RIN 1117-AB51

Registration and Reregistration Fees for Controlled Substance and List I Chemical Registrants

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is adjusting the fee schedule for registration and reregistration fees necessary to recover the costs of its Diversion Control Program relating to the registration and control of the manufacture, distribution, dispensing, importation and exportation of controlled substances and list I chemicals as mandated by the Controlled Substances Act (CSA). This final rule adopts the notice of proposed rulemaking published on March 16, 2020, to change the fee schedule and codify existing practices of the issuance of refunds by DEA for applicant registration fees, without change.

DATES: This final rule is effective October 1, 2020. The new fee schedule will be in effect for all new applications submitted on or after October 1, 2020, and for all renewal applications submitted on or after October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting & Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration;

Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

I. Executive Summary

The Diversion Control Program

DEA's Diversion Control Program (DCP) is administered by the Diversion Control Division (DC). DC ensures the availability of controlled substances and listed chemicals for legitimate use in the United States. The DCP is responsible for maintaining a closed system of distribution by preventing diversion of controlled substances and listed chemicals in the United States and enforcing the provisions of the CSA for DEA. The DCP regulates over 1.8 million registrants, ensuring their compliance with the CSA.

Legal Authority

The DCP is a strategic component of DEA's law enforcement mission, which regulates the registration and control of the manufacture, distribution, dispensing, importation, and exportation of pharmaceutical controlled substances and listed chemicals. The DCP implements and enforces the CSA 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.[1]

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

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

year, DEA is required by statute to transfer the first $15 million of fee revenues into the general fund of the Treasury and the remainder of the fee revenues is deposited into a separate fund of the Treasury called the Diversion Control Fee Account (DCFA). 21 U.S.C. 886a(1). On at least a quarterly basis, the Secretary of the Treasury is required to reimburse DEA an amount from the DCFA "in accordance with estimates made in the budget request of the Attorney General for those fiscal years" for the operation of the DCP.[2] 21 U.S.C. 886a(1)(B) and (D). The first $15 million of fee revenues that are transferred to the Treasury do not support any DCP activities.

The Proposed Rule

DEA published a notice of proposed rulemaking (NPRM) on March 16, 2020, in the *Federal Register*, proposing new registration and reregistration fees for registrants, as well as proposing to codify existing practices of issuing refunds for these fees in limited circumstances. 85 FR 14810. In the NPRM, DEA proposed to amend 21 CFR 1301.13, 1309.11, 1309.12, and 1309.21 within the Code of Federal Regulations.

In the NPRM, DEA proposed a new fee of $3,699 per year for manufacturers of controlled substances. For distributors, reverse distributors, importers, and exporters of controlled substances, DEA proposed a new fee of $1,850 per year. For controlled substance business activities involving dispensing, a new fee of $888 per three year cycle was proposed. For all other business activities of controlled substances (research, narcotic treatment programs (NTPs), and chemical analysis), the proposed new fee was $296 per year. For manufacturers of list I chemicals, DEA proposed a new fee of $3,699 per year. For distributors, importers, and exporters of list I chemicals, DEA proposed a new fee of $1,850 per year.

[2] The DCP consists of the pharmaceutical controlled substance and listed 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)).

This final rule adopts the March 16, 2020, NPRM proposal to change the fee schedule and codify existing practices of the issuance of refunds by DEA for applicant registration fees, without change.

II. Background

History of Fees

In October 1992, Congress passed the Departments of Commerce, Justice, and State, the Judiciary and Related Agencies Appropriations Act of 1993 (Pub. L. 102-395), which changed the source of funding for DEA's DCP from being part of DEA's annual Congressional appropriation to full funding by registration and reregistration fees through the establishment of the DCFA.[3] The Appropriations Act of 1993 required 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." The legislation did not, however, provide clarification on what constituted the "Diversion Control Program," thus leaving open the issue as to what fee-setting criteria should be used to determine which costs could be reimbursed from the DCFA.

In response to the Appropriations Act of 1993, DEA published an NPRM in December 1992 to adjust the registration and reregistration fees for controlled substance registrants (57 FR 60148, December 18, 1992). In the absence of guidelines from Congress regarding the specific criteria to be followed in identifying costs and setting the fees, DEA relied on the plain language of the Appropriations Act of 1993 and proposed fees necessary to cover the costs of the activities that were identified within the budget decision unit known as the "Diversion Control Program."

[3] 21 U.S.C. 886a(1)(C).

At the time that the Appropriations Act of 1993 was passed, 21 U.S.C. 821 did not extend to chemical control activities; accordingly, there were no registration or fee requirements for handlers of list I chemicals. DEA therefore excluded chemical control costs from its Final Rule implementing the requirements of the Appropriations Act of 1993 (58 FR 15272, March 22, 1993). Congress amended 21 U.S.C. 821 on December 17, 1993, to require reasonable fees relating to "the registration and control of regulated persons and of regulated transactions" (Domestic Chemical Diversion Control Act of 1993, 3(a), Pub. L. 103-200, 107 Stat. 2333); however, despite this amendment, DEA continued to endeavor to maintain separate funding for its controlled substances diversion control and its chemical diversion control activities.

Following publication of DEA's Final Rule, the American Medical Association (AMA) and others filed a lawsuit objecting to the increase in registration and reregistration fees on the grounds that DEA had failed to provide adequate information as to what activities were covered by the fees and how they were justified. The district court issued its final order granting DEA's motion for summary judgment and disposing of all claims on July 5, 1994.[4] Upon AMA's appeal, the U.S. Court of Appeals for the District of Columbia Circuit remanded, without vacating, the rule to DEA, requiring the agency to provide an opportunity for meaningful notice and comment on the fee-funded components of the DCP. In doing so, the court confirmed the boundaries of the DCP that DEA can fund by registration fees, finding that the current statutory scheme (21 U.S.C. 821 and 958) required DEA to set reasonable registration fees to recover the full costs of the DCP. *See AMA* v. *Reno,* 57 F.3d 1129, 1135 (D.C. Cir. 1995). DEA responded to the remand requirement through a notice and comment in the *Federal Register* on December 30, 1996, describing the fee-funded components and activities of the DCP with an explanation of

[4] *AMA v. Reno*, 857 F. Supp. 80 (D.D.C. 1994).

how each satisfies the statutory requirements for fee-funding (61 FR 68624-32, December 30, 1996).

Thus, in the absence of a simple, objective measure by which DCP costs could be identified and the appropriate fees calculated, both DEA and the courts have looked to 21 U.S.C. 821 and 958 to define the guidelines for determining what costs should be included in the calculation of the fees and from whom the fees might be collected.

The Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 2005 was signed into law on December 8, 2004, as Division B of the Consolidated Appropriations Act of 2005 (Pub. L. 108-447). Title IV, Section 634 of the Appropriations Act of 2005 provided clarification as to the activities constituting the DCP. The Appropriations Act of 2005 amended 21 U.S.C. 886a(2)(A) to define the Diversion Control Program as "the controlled substance and chemical diversion control activities of the Drug Enforcement Administration," which are further defined as the "activities related to the registration and control of the manufacture, distribution and dispensing, importation and exportation of controlled substances and listed chemicals." It also amended 21 U.S.C. 886a(1)(B) to provide that reimbursements from the DCFA "shall be made without distinguishing between expenses related to controlled substances activities and expenses related to chemical activities." Finally, the Appropriations Act of 2005 amended 21 U.S.C. 821 and 958(f) to make the language of those sections consistent with the definition of the DCP (Pub. L. 108-447). The net effect of the amendments was to allow DEA to deposit all registration and reregistration fees (controlled substance and chemical) into the DFCA and fund all controlled substance and chemical diversion control activities from the account without distinguishing as to the type of activity (controlled substance or chemical) being funded.

Independent of the passage of the Appropriations Act of 2005, DEA undertook an internal reorganization to increase operational efficiencies and overall effectiveness. As discussed in detail in DEA's Final Rule published on August 29, 2006 (71 FR 51105), the resulting internal reorganization removed the focus from the single business decision unit of the DCP to a focus on diversion control activities irrespective of the business decision unit. That is, the diversion control activities of DEA are no longer contained in a single business decision unit identified as the DCP. Thus, in identifying the activities that constitute the DCP, DEA looks across the agency at all functions related to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and listed chemicals. This approach adheres both to the language contained in 21 U.S.C. 821 and 958 and to the court's requirement that there must be a nexus between the DCP's activities funded through fees, and the registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals of regulated persons and regulated transactions.

In keeping with this organizational and functional change, DEA continues to identify the diversion control activities to be funded by the DCFA. Accordingly, this NPRM describes the activities that constitute the DCP, irrespective of organizational structure within the agency and in compliance with 21 U.S.C. 821 and 958, and 21 U.S.C. 886a, which require that DEA charge reasonable fees relating to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and listed chemicals and that DEA collect fees adequate to fully fund the controlled substances and listed chemical diversion control activities that constitute the DCP, as defined by DEA.

The Department of Justice's (DOJ) Office of the Inspector General (OIG) completed a review of DEA's use of the DCFA in 2008 and did not find any misused DCFA funds for non-

diversion control activities between Fiscal Year (FY) 2004 and FY 2007. To the contrary, the OIG found that DEA did not fully fund all diversion control costs with the DCFA as required by law.[5] Therefore, in 2011 DEA published a NPRM to continue efforts to fully fund the DCP. The 2011 NPRM included additional DCP costs which were identified in the OIG report and resulted in an approximately 33 percent fee increase across all registrant groups. The 2011 NPRM was finalized in 2012, and this was the last time DEA adjusted the fees prior to the current fee increase.

III. Diversion Control Program

Scope of the Diversion Control Program

The mission of DEA's DC is to prevent, detect and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels while ensuring an adequate and uninterrupted supply of pharmaceutical controlled substances and listed chemicals to meet legitimate medical, commercial, and scientific needs. This Division administers the DCP, which is responsible for enforcing the provisions of the CSA, as they pertain to ensuring the availability of controlled substances and listed chemicals for legitimate uses in the U.S., while exercising controls to prevent the diversion of these substances and chemicals for illegal uses. This Division maintains an overall geographic picture of drug and chemical diversion and abuse problems to identify new trends or patterns in diversion and abuse, which enables it to appropriately direct resources.

The DCP is executed by maintaining a closed system of distribution by regulating and managing over 1.8 million DEA registrants and investigating activity related to the diversion of

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

pharmaceutical controlled substances and listed chemicals. To ensure accountability within the closed system of distribution, the DCP administers, maintains, and oversees DEA's registration system. This entails processing, reviewing, and, if necessary, investigating all applications for registration and reregistration, collecting fees, and, when appropriate, proposing to take administrative action on registrations or applications for registration, such as restriction, revocation, suspension, or denial of an application.

The DCP's regulatory function is accomplished by registering those entities that handle controlled substances or listed chemicals, conducting regulatory inspections, providing information and guidance to registrants, and controlling and monitoring the manufacture, distribution, dispensing, import, and export of controlled substances and listed chemicals. The DCP determines the appropriate procedures necessary for ordering and distributing schedule I and II controlled substances, using DEA Form 222 or its electronic equivalent.[6] This enables the DCP to monitor the flow of certain controlled substances from their point of manufacture through commercial distribution. The DCP also executes its regulatory functions by fulfilling its U.S. treaty obligations pertaining to the CSA, such as the preparation of periodic reports for submission to the United Nations (UN) as mandated by U.S. international drug control treaty obligations on the manufacture and distribution of narcotic and psychotropic substances, as well as determining the anticipated future needs for narcotic and psychotropic substances.

The DCP ensures that registrants are in compliance with the safeguards of the CSA. This allows for the identification and the prevention of diversion of pharmaceutical controlled substances and listed chemicals into illicit markets. Registrant compliance is determined primarily through pre-registration, scheduled, and complaint investigations. DCP regulatory

[6] 21 U.S.C. 828, 21 CFR part 1305.

activities have an inherent deterrent function, and they are designed to ensure that those businesses and individuals registered with DEA to handle controlled substances or listed chemicals have sufficient measures in place to prevent the diversion of these substances. These investigations also help registrants understand and comply with the CSA, identify those registrants who violate the CSA, and implement regulations. Pre-registration investigations reduce the possibility of registering unauthorized entities, ensure that the means to prevent diversion are in place, and determine whether registration is consistent with the public interest.

Not only does the DCP exercise authority and control over the registrant population, the DCP exercises authority over the classification of substances.[7] This is accomplished by evaluating drugs and chemicals to determine whether these substances are being abused or potentially involved in illicit traffic, and to evaluate whether any substances should be scheduled as a controlled substance or regulated as a listed chemical. This requires the collection and analysis of a large amount of data from various sources. These evaluations are used by DEA as a basis for developing appropriate drug control policies; determining the status of controlled, excluded, or exempted drugs and drug products; and supporting U.S. initiatives in international forums.

The DCP's authority over controlled substances and listed chemicals requires its support of domestic and foreign investigations of these substances. As such, the DCP serves as the competent national authority for the U.S. regarding listed chemicals and international treaties. The DCP works with the international community to identify and seize international shipments of listed chemicals destined for the U.S. The DCP also works on a bilateral basis to urge international partners to take effective action, in cooperation with chemical companies, to establish controls and prevent the diversion of listed chemicals from legitimate trade. In addition

[7] 21 U.S.C. 811-814.

to its other oversight and regulatory responsibilities in this area, the DCP reviews the importation and exportation notifications of listed chemicals.

The DCP also controls the manufacture of controlled substances by setting the aggregate production quotas, individual manufacturing quotas, and procurement quotas for basic classes of schedule I and II controlled substances. Similarly, the DCP controls the manufacture of list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine by setting the assessment of annual needs, individual manufacturing quotas, procurement quotas and import quotas for these three list I chemicals. As such, the DCP maintains and monitors the Year-End Reporting System/Quota Management System (YERS/QMS), which provides information on entities manufacturing schedule I and II controlled substances and list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Furthermore, the DCP issues import and export registrations and permits, and monitors declared imports, exports, and transshipments of these substances. The DCP must ensure that all imports and exports of controlled substances and listed chemicals meet the requirements of the CSA. As such, the DCP maintains and monitors many electronic reporting systems, such as the Chemical Handlers Enforcement Management System, which provides information on entities manufacturing, distributing, and exporting and importing regulated chemicals, and encapsulating and tableting machines.[8]

To effectively execute its regulatory functions, the DCP reviews legislation pertinent to the availability of controlled substances and listed chemicals for legitimate uses in the U.S. and controls to prevent the diversion of these substances and chemicals. The DCP drafts and implements regulations to keep DEA in compliance with legislation enacted by Congress. The DCP constantly reviews its own regulations and develops and implements regulations designed

[8] *See* 21 U.S.C. 830, 957-58.

to enhance DEA's diversion control efforts. The DCP's regulatory activities also require education and outreach to ensure understanding of and compliance with the CSA and applicable regulations, and to ensure registrants have sufficient measures in place to prevent diversion. The DCP's outreach efforts include establishing and maintaining liaison and working relationships with other Federal agencies, the regulated community, and foreign, state, and local governments. Other efforts include developing and maintaining manuals and other publications; organizing and conducting national conferences on current issues, policies, and initiatives; and providing scientific support for policy guidance, expert witness testimony, and conference presentations.

The DCP continues to address the growing threat of synthetic substances through the collection and evaluation of pharmacological, medical, epidemiological and other scientific data for new drugs of abuse and when appropriate, initiate the necessary administrative procedures to place these substances under regulatory control.

Since the last fee increase in 2012, the nature of the diversion control problem has increased in size and complexity. The increased diversion threats and changing diversion schemes such as the opioid epidemic, as well as amendments to the CSA, have necessitated the need to increase DEA registration fees in order to fully fund all aspects of the DCP.

Although DEA has been fiscally responsible and has not increased registration fees since 2012, a registration fee increase is needed. This increase will fund personnel and operations supporting the DCP's mission to prevent and detect diversion, protect the closed system of distribution in the U.S., and combat the nation's opioid crisis. Without an increase in 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).

IV. Discussion of Comments

Following publication of the NPRM on March 16, 2020, 85 FR 14810-14837, DEA received twelve comments in response to the rule. Of these comments, five comments are out of scope in their entirety, and did not address the fee calculation or the issuance of refunds by DEA for applicant registration fees. Two comments supported the proposed rule in part. The remainder of the comments expressed concern about the fee increase, as further described below.

Support for the Fee Increase and Proposal to Grant Registration Refunds

Issue: An association agreed with DEA's proposed methodology for the new fee calculation and the proposal to grant registration fee refunds under certain circumstances. The commenter expressed its appreciation for DEA's acknowledgement that there will be a certain amount of honest errors either on the part of the registrant or on DEA's part. This commenter wrote that the proposed rule provides a useful explanation of the three alternative methodologies to calculate the new registration fees and agreed with DEA's selection of the weighted-ratio method. The commenter wrote that because all supply chain trading partners share a responsibility for helping to avoid the misuse/abuse of the controlled substances and other products that DEA regulates, adopting a method that applies an equivalent increase to all registrants is reasonable.

Another association also supported the proposal to allow the Administrator to refund registration fees under certain circumstances. They requested that information regarding the refund process be easily accessible, and that an efficient process be established to issue the refunds.

DEA Response: DEA appreciates the support for the selected fee calculation methodology, and the codification of DEA policy regarding refunding of registration fees in certain

circumstances. In developing the fee schedule, DEA conducted a thorough analysis of the identified fee calculation options – including the anticipated economic impact on registrants – and determined that the weighted-ratio option represents the most reasonable approach to calculate registrant fees sufficient to fully fund the DCP.

Based on the Administrator's discretionary authority, the refunds for fees will be issued under limited circumstances, to include applicant error, DEA error, and death of a registrant within the first year of the three-year registration cycle. The process for obtaining a refund will be made available on DEA Diversion Control's website (www.deadiversion.usdoj.gov).

Objection to the Fee Increase

Auditing Mechanisms

Issue: Two commenters, one of whom is a physician, the other of whom is anonymous, raised concern about tracking DEA's accountability with respect to the DCFA. These commenters wrote that an audit should be done on the DCFA to avoid waste and to ensure that the DCFA does not become a blank check for DEA to do whatever they want with it. In particular, the commenters were concerned with how the fees are being spent. The physician commenter objected to the fee increase and proposed that an independent, non-governmental audit be performed on an annual basis to ensure that there is no fraud or waste of the fees.

DEA Response: As required by the Chief Financial Officers (CFO) Act, DOJ OIG annually audits DEA's financial statements, using a third party auditor (currently KPMG). These audits cover all of DEA's funding sources and lines of business, including the DCFA. DEA has received an unqualified audit opinion for approximately twenty years.

Additionally, DEA has established a robust system of internal controls to ensure that DEA recovers the full cost of the DCP, and that the DCFA is used only for all of that program's costs,

as directed by law. These internal controls over non-personnel expenses are managed by the Cost Diversion Validation Unit. This unit is independent of the DCP and resides within the Financial Management Division, which is responsible for all of DEA's financial management, including that of the DCFA. The unit reviews every DCFA expenditure over $500 for a justification for how it relates to the DCP and ensures that DCFA funding is in compliance with established methodologies. The Cost Diversion Validation Unit recommends methodologies for the appropriate and consistent use of DCFA funding across commodities and cost areas, to ensure the funding is used to pay for only costs attributable to the DCP.

Along with the oversight of the Cost Diversion Validation Unit over non-personnel expenses, DEA's Office of Resource Management reviews the investigative work performed by DEA's workforce, including Special Agents, on a quarterly basis. These reviews enable DEA to ensure that the DCFA pays for all payroll costs associated with DCP casework and does not pay for the payroll or employees working on non-DCP casework. In instances where DCFA funded employees work on non-DCP cases, DEA's salaries and expenses (non-DCFA) account reimburses the DCFA for those payroll expenses. These internal controls ensure that DCFA funding is used only for the requirements of the DCP and not made available for non-diversion related expenses within DEA.

DC, as part of DEA, must adhere to Office of Management and Budget (OMB) Circular A-123, Management's Responsibility for Enterprise Risk Management,[9] and Internal Control and Federal Managers' and Financial Integrity Act[10] which have been at the center of Federal requirements to improve accountability in Federal programs and operations since 1981. Under

[9] Office of Management and Budget (OMB) Circular No. A-123, *Management's Responsibility for Internal Control*.
[10] 31 U.S.C. 3512.

OMB Circular A-123, DEA must maintain internal controls that reduce the risk of fraud, waste, and error. DEA is also responsible for establishing and maintaining internal controls to achieve specific internal control objectives related to operations, reporting, and compliance.

In addition to DEA's internal inspection and evaluation practices, DEA's programs are subject to external audits and reviews, as part of maintaining the public's trust in DEA's ability to manage resources in fulfillment of its mission. DOJ, OIG, and the Government Accountability Office (GAO) are the primary auditing agencies that review DEA's programs on an ad hoc basis. The outcome of external audits, whether positive or negative, has a significant impact on DEA's programs.

Moreover, all budget submissions for the DCP are subject to multiple levels of scrutiny and review within DEA, the DOJ, and OMB. Each of DEA's annual budget requests to Congress, which includes the DCP, is available for public view. Each budget request is examined and approved by both DOJ and OMB.

The DCP's implementation of internal inspection and evaluation practices coupled with federal mandates established by OMB, OIG, and GAO are sufficient to maintain DC's program integrity, efficiency, and transparency. All aspects of the DCP are inspected to detect any waste, fraud, or abuse. An external, non-governmental audit, as suggested by the physician commenter, would require a large expenditure of registrant fees, and would be excessive, given the other safeguards that are already in effect.

Hiring of Additional Personnel to Address DCP's Mission; Finalizing Rules and Updates to DEA Publications

Issue: The anonymous commenter raised concern about the increase in fees as it relates to the hiring of additional personnel, and the physician questioned what is being funded by

registrant fees. The anonymous commenter stated that hiring personnel did not seem to be the answer because enforcement was not working on the opioid epidemic. The anonymous commenter further suggested that hiring additional people would not solve the problems of the opioid epidemic, and opined that DEA believes that additional people will magically solve the opioid epidemic. Both commenters stated that DEA has failed to meet many Congressional deadlines that were imposed by the enactment of various legislation. The physician also added that DEA has been slow to draft implementing regulations for statutory amendments to the CSA, and to draft other rules, schedule substances, or update manuals and publications that help registrants.

DEA Response: As a part of executing the DCP's mission, DEA is focused on combatting the opioid epidemic, as well as addressing the diversion of other controlled substances and listed chemicals. While DEA knows that the hiring of additional people will not automatically solve the epidemic, hiring more people will improve DEA's ability to successfully investigate diversion. By increasing personnel and devoting more resources towards prioritizing and drafting rules, DEA will be able to more efficiently and effectively meet deadlines and address diversion.

While DEA aims to meet every deadline Congress puts in place when creating new legislation, DEA's rulemaking process involves many steps. Where Congress has enacted statutory amendments to the CSA, such as the SUPPORT Act, DEA complies with these laws while finalizing implementing regulations for these amendments. Moreover, finalizing and implementing rules require the publication of proposed rules or interim final rules and final rules. These documents require significant drafting and analysis, as well as a lengthy review process to ensure that the rule is legal, fair, and will be effective in meeting the goal of the particular rule.

In the proposed rule to increase fees, DEA chose not to discuss any other proposed rules or their status, due to the sensitive nature of rule drafting, as well as the fact that proposed rules can change prior to finalization. However, DEA received comments questioning the necessity of the fee increase due to the fact that implementing regulations for statutory amendments to the CSA, as well as a regulation related to marijuana growers, have yet to be published. As stated above, the rulemaking process is lengthy and involves multiple phases. In 2019, DEA published two NPRMs, three Final Rules, and two Notices (regarding the setting of the aggregate production quota and assessment of annual needs). So far, in 2020, DEA has published three NPRMs and one Notice (to adjust the established aggregate production quotas and assessment of annual needs).

The physician commenter also noted that DEA's Diversion Control website Manuals and Publications section contains older manuals. However, this is not indicative of DEA's continuous efforts to keep policies and procedures current with regulations, technology, and industry best practices. DEA is in the process of updating the entire Manuals and Publications section on its website and several manuals are being drafted. DCFA funds will be used to provide the DCP with additional resources to update the manuals and outdated documents. The physician also contended that DEA publishes an average of only three scheduling actions per year. This is inaccurate. Since FY 2019 alone, DEA has published in the *Federal Register* over twenty final rules placing dangerous substances in schedules I and II of the CSA.

Quotas

Issue: The physician commenter raised a concern about DEA's process for setting quotas. In particular, the commenter did not understand how proposing new use-specific quotas would

expedite the process or provide clarity. The commenter wrote that it is unsettling to pay for leadership that is unsure about how certain processes under their purview work.

DEA Response: DC's leadership fully understands the quota setting process and plays an active role in the rule-making process.

In addition, DEA is committed to ensuring that quotas are set in such a way as to grant manufacturers the ability to provide controlled substances to meet the demand of the legitimate medical, scientific, industrial, and research needs of the U.S. DEA is required to understand what is available for legitimate patient need versus what is available for product development to properly calculate the Aggregate Production Quota (APQ) and individual quotas. Additionally, as the number of manufacturers continues to increase and industry practices and specializations change, the ability to methodically track movements of material between registrants at all stages of manufacturing becomes more critical. Use-specific subcategories improve the efficiency of the application and reporting process for DEA-registered manufacturers. The specification of quota subcategories reflects the manufacturing activity of the applying DEA registrant, has facilitated the issuance of manufacturing and procurement quotas, and has provided a more accurate calculation of the APQs for the U.S. by preventing double counting of quotas. Use-specific quotas have been informally in place for well over a decade with no complaints from the registrants who have found the system beneficial in separating their product development and packaging efforts from their commercial manufacturing efforts when requesting adjustments to their quotas.

Education and Outreach Programs

Issue: The physician commenter suggested that DEA could save money and manpower by eliminating programs such as DEA 360 Strategy, National Take-Back Initiative (NTBI), and

Tactical Diversion Squads (TDS). This commenter believes that DEA has not been proactive enough in its mission to address or prevent the opioid problem.

DEA Response: DEA works diligently to achieve operational efficiencies in all of its programs, including the DCP, while keeping costs as low as possible. Due to increased diversion and prescription drug abuse, as well as an increase in the production and use of chemicals that contribute to the health emergency, DEA's 360 Strategy, NTBI, and TDS groups are necessary tools to aid ending the deadly cycle of prescription opioid misuse.

Through DEA's 360 program, prescription opioid misuse is targeted using a holistic approach while leveraging enforcement resources. Given the number of opioid-related deaths, the coordinated and targeted enforcement efforts of federal, state, and local law enforcement are needed resources to help fight the epidemic. This epidemic is too massive for state and local governments to handle alone. The opioid epidemic is a national matter, which requires coordinated law enforcement, diversion control, and community outreach efforts, and which is aided by DEA's 360 Strategy initiative.

Before DEA began NTBI, most U.S. communities did not routinely offer opportunities to properly dispose of expired, unused, or unwanted pharmaceutical controlled substances. As a result, many people kept these drugs because they did not know how to dispose of them. In many cases, dispensed controlled pharmaceutical drugs remain in household medicine cabinets well after medication therapy has been completed, thus providing easy access to non-medical users for abuse or accidental ingestion. NTBI events have been overwhelmingly successful for over a decade, and have resulted in the collection and disposal of over 6,349 tons of pharmaceuticals. The huge volume of drugs must be transported for proper disposal. The assistance from local points of contact is necessary to pick up collected drugs for disposal in

accordance with Federal and State environmental standards. The NTBI program is an example of the DCP's commitment to community outreach efforts and the need to properly dispose of unused and unwanted controlled substances. This collaborative effort between DEA and State and local law enforcement agencies is focused on removing potentially dangerous controlled pharmaceutical substances from our nation's medicine cabinets to reduce opportunities for diversion.

The TDS program has been a successful tool employed by the DCP to combat the illegal diversion of controlled substances. Combining the criminal drug investigative experience of DEA Special Agents, the subject matter expertise of Diversion Investigators (DIs), and the local knowledge and capabilities of deputized Task Force Officers, the TDSs can effectively confront the diversion problem on multiple levels. Since the initial deployment, TDSs have initiated an average of more than 1,500 cases and made more than 2,100 arrests per year.

The opioid epidemic is a national matter, which requires consistent coordinated law enforcement, diversion control, and community outreach efforts through DEA's 360, NTBI, and TDSs to represent the interests of the nation as a whole. Elimination of these programs would reduce the awareness of the opioid crisis, increase opportunities for diversion, and possibly result ina rise in opioid-related deaths.

Fee Calculation Methodology

Issue: The physician commenter believes that the methods described by the Agency that were used to come up with the fee increase seem arbitrary.

DEA Response: In developing this rule, DEA considered three methodologies to calculate registration and reregistration fees. DEA selected the current weighted-ratio option to calculate the new fees. 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 generally larger revenues and costs pay higher fees than registrants with lower revenues and costs. Furthermore, the weighted-ratio does not create a disparity in the relative increase in fees from the current to the new fees. The weighted-ratios used by DEA to calculate the current fee have proven effective and reasonable over time, and generally reflect the differences in activity level, notably in inspections, scheduled investigations, and other control and monitoring, by registrant category (i.e., these costs are higher for manufacturers). DEA selected this option because it is the only option that resulted in "reasonable" fees for all registrant groups.

Fees for Registrant Categories

Issue: The pharmaceutical company objected to the increased registration fees, especially for small businesses. This commenter proposed two alternatives for assessing registration fees: assessing fees based on the size of the business, or having registrants with a significant history of CSA violations pay higher registration fees. The commenter stated that in the first proposal, registration fees would be assessed based on the size of the business (e.g., the number of employees, annual earnings, etc.). The commenter's second proposal requires registrants with a significant history of CSA violations to pay dramatically increased registration fees. The commenter believes that specific manufacturers and wholesale distributors contributed to the opioid epidemic by turning a blind eye to CSA laws and implementing regulations, and were lured by sales of opioid medications and profits over their responsibilities as DEA registrants.

DEA also received a comment from an association agreeing with the concern for imposing disproportionately higher fees on NTPs, but objecting because they believe distributors will not be paying their fair share under the proposed "weighted ratio option." The comment states that

the "past-based option" would lead to a 117 percent increase for distributors, as opposed to the lower 21 percent that is being proposed. In their view, practitioners under the current and proposed "weighted ration option" would be paying too much as compared to manufacturers and distributors. The association also included a suggestion to lower fees for physicians who comply with DEA regulations that impose an extra cost upon the registrants, such as the electronic prescribing of controlled substances (EPCS) or a waiver to prescribe buprenorphine. The association takes the position that if EPCS is supposed to reduce diversion, then DCP must be incurring lower costs for those who adopt EPCS. Similarly, they state that physicians trained to prescribe buprenorphine to treat opioid use disorder are lowering DCP costs by lowering the costs associated with drug addiction.

A company in support of the fee increase suggested that DEA eliminate the duplicative registration requirement. This company previously sent a letter to the Office of Legal Policy, U.S. Department of Justice, dated August 14, 2017, requesting that DEA amend the regulations to waive the chemical registration requirement for wholesale distributors who are also registered as controlled substance handlers. The company further stated that it is redundant, unnecessary, and unfair to make a single facility pay two registration fees. The company was specifically concerned that wholesale distributors that possess and distribute both controlled substances and certain iodine products must apply and pay registration fees for two separate registrations, even though they are storing and distributing these products at a single warehouse.

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 business size or quantities of controlled substances handled. DEA provided economic impact analysis demonstrating the relatively minor proportion of registrant's total

income needed to pay a registration fee. Additionally, the analysis showed that the percentage fee increase is comparable to inflation.

DEA continues to review possible methodologies for differentiating fees between various registrant groups. However, at this time, DEA has determined that it is both practicable and reasonable to continue to apply the weighted-ratio methodology without distinction between small and large businesses.

Regarding using CSA violations as a factor in setting registration fees, 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. As a practical matter, the vast majority of DEA registrants are in compliance with the CSA, and DEA works with any registrant who is not in full compliance with the CSA to bring that registrant into compliance. The CSA provides for mechanisms independent of the registration fee by which to exact financial penalties from registrants who violate the law. Registrants who violate the CSA may be subject to civil and criminal penalties, as well as forfeitures. 21 U.S.C. 841, 842, 843, 881. Additionally, DEA would move to suspend the registration of a person whose registration is inconsistent with the public interest.

As discussed in the NPRM and in the final rule, DEA examined three alternative methodologies to calculate registration and reregistration fees. DEA did not select the past-based option for two key reasons. First, the fee increase is disproportionately burdensome to a small number of registrants. Narcotic treatment program fees would increase by 856 percent, while the change for the remaining registrant groups would range from a decrease of 44 percent to an increase of 131 percent. DEA deemed this option unreasonable. Second, the past-based option is backward looking and implicitly assumes that the future will be similar to the past. DEA

cannot assume that future workload will reflect past DEA work hour data. For example, DEA plans to conduct more scheduled investigations in accordance with the new scheduled investigation work plan. As a result, DEA has concluded that past data is not the best basis for the calculation of new fees. The selected methodology must be applied to all registrants. For example, DEA cannot only apply the past-based option to distributors.

DEA does not have access to practitioners' rates of EPCS use or buprenorphine prescribing rates. 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 resources to calculate the rate of prescribing for each registrant or to personalize each registrant's registration fee. Additionally, allowing individualized calculations based on EPCS use, prescribing rates, business size, 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.

Purchasers and suppliers of controlled substances and listed chemicals are regulated under the CSA and are therefore subject to the registration and reregistration requirement and fees.[11] The CSA is Federal law and cannot be changed by DEA. DEA carries out the mandates of the CSA by preventing the diversion of controlled substances and listed chemicals into the illicit market, but does not have the authority to change Federal provisions. The commenter suggested that DEA eliminate the duplicative registration requirement for certain chemicals (e.g., iodine). The CSA requires a separate registration for certain chemicals to prevent its diversion into the illicit market. Iodine is not identified as a listed chemical that is contained in a drug marketed or

[11] 21 U.S.C. 822(a)(1); 21 U.S.C. 833(b).

distributed lawfully in the U.S. under the Federal Food, Drug, and Cosmetic Act.[12] Furthermore, iodine may be used for non-research, illegitimate purposes, and is also used in the illicit manufacture of methamphetamine. DEA requires a separate registration for this chemical due to the high probability that it may be diverted to the clandestine manufacture of methamphetamine.

Extension of Implementation Due to Coronavirus Disease 2019 Public Health Emergency

Issue: Three commenters recommended deferring the proposed fee increase and one objected to its implementation due to the Coronavirus Disease (COVID-19) pandemic and the economic uncertainty that it has engendered. A pharmaceutical company suggested that DEA postpone the fee increases and the comment period at least until January 2021, and noted that publishing a proposed fee increase during a worldwide health pandemic with looming economic uncertainties was poorly timed, as the nation's current priority is to focus public health and safety measures on the COVID-19 pandemic. An association recommended that the fee increases be postponed until the conclusion of the public health emergency, stating that implementing the proposed 21 percent increase would be a heavy burden to pharmacists who are already struggling during this time, as the pandemic has led to a decrease in patient services and revenues. A third commenter, also an association, urged that DEA defer the registration fee increases for at least 12 months due to the COVID-19 pandemic and resulting economic recession, or until the business community has recovered.

A fourth commenter objected to the increase in practitioners' registration fees because physicians cannot afford to pay higher DEA registration and reregistration fees. It stated that Medicare payment rates are in the midst of a six-year freeze, and COVID-19 has led to steep

[12] 21 CFR 1300.02(1)(iv).

declines in patient services and associated revenues, even for frontline physicians caring for patients with COVID-19, who may face a reduction in revenues from elective procedures and increased expenses due to new infection control processes and supplies.

DEA Response: DEA recognizes that industry is experiencing unique challenges, including financial challenges, during the current coronavirus pandemic. Protecting the health and safety of our communities is DEA's top priority, and that commitment has continued during the unprecedented public health emergency caused by the ongoing COVID-19 pandemic. During this emergency, DC is responding quickly and appropriately to ensure continued access to necessary controlled substances. DC's efforts include supporting prescribing practices that limit exposure, enabling uninterrupted access to practitioners, and safeguarding a consistent and reliable drug supply. Some of the ways DC continues to fulfill its mission and serve the American people during this challenging time include:

- Working with registrants to facilitate satellite hospitals and clinic locations;
- Temporarily lifting restrictions on DEA's "five percent rule";
- Temporarily raising aggregate production quotas for certain medications;
- Providing clear guidance on electronic prescribing of controlled substances;
- Allowing Narcotic Treatment Programs to sign invoices post delivery;
- Ensuring Narcotic Treatment Programs can get medication to their patients; and
- Supporting responsible use of telemedicine while providing medication assisted treatment.

These additional COVID-19-related responsibilities have put additional pressure on the DCP and its resource needs.

Moreover, DEA's scope of responsibilities has expanded due to Congressional mandates since the last fee schedule revision in 2012. 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 to explain why there is a fee, why there is a periodic recalculation, and how the proposed new fee schedule was calculated. 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. These fees fund the DCP, which includes providing and maintaining services to DEA registrants.

DEA is sensitive to the challenges facing many registrants and has endeavored to set the fee as low as possible, consistent with its statutory mandates, and has provided a 60-day comment period to solicit input from interested parties. DEA continuously strives to be fiscally responsible. The last fee increase was set in FY 2012, and was intended to encompass only FYs 2012-2014. Through various efforts and cost-saving measures, the DCP has been able to operate under that fee structure through FY 2020. While DEA is publishing this final rule at this current time, the increase will not immediately go into effect on the date of publication of this rule. The new fee schedule will be implemented for all new applications submitted on or after October 1, 2020, and for all renewal applications submitted on or after October 1, 2020. Thus, not all registrants will be paying registration and reregistration fees on October 1, 2020. Those whose reregistration fees are due between now and September 30, 2020, will continue to pay the current fees until their next date of renewal. As such, only a small subset of registrants will be affected when the rule is first implemented.

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 "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). Continued 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 as outlined in the proposed rule, particularly at this time of increased abuse and diversion.

V. Provisions of the Final Rule

After careful consideration of all the comments, DEA is finalizing, without change, the fee schedule, and codifying existing practices of the issuance of refunds by DEA for applicant registration fees as proposed in the NPRM published on March 16, 2020. 85 FR 14810-14837.

Revised Fees

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

The fee schedule replaces the current fee schedule for controlled substance and chemical registrants to recover the full costs of the DCP so it can continue to meet the programmatic responsibilities set forth by statute, Congress, and the President. As discussed, without an adjustment to fees, the DCP will be unable to continue current operations, necessitating dramatic program reductions, and possibly weakening the closed system of distribution. Accordingly, DEA finalizes the following new fees for the FY 2021 to FY 2023 period.

Table 1: Registration and Reregistration Fees by Business Activity

Business Activity	Current Fees ($)	New Fees ($)	Difference ($)
*Registrants on Three Year Registration Cycle**			
Pharmacy	731	888	157
Hospital/Clinic	731	888	157
Practitioner	731	888	157
Teaching Institution	731	888	157
Mid-level Practitioner (MLP)	731	888	157
Registrants on Annual Registration Cycle			
Manufacturer	3,047	3,699	652
Distributor	1,523	1,850	327
Researcher/Canine Handler	244	296	52

Analytical Lab	244	296	52
Importer	1,523	1,850	327
Exporter	1,523	1,850	327
Reverse Distributor	1,523	1,850	327
Narcotic Treatment Program	244	296	52
Chemical Manufacturer	3,047	3,699	652
Chemical Importer	1,523	1,850	327
Chemical Distributor	1,523	1,850	327
Chemical Exporter	1,523	1,850	327

*Pharmacy, hospital/clinic, practitioner, teaching institution, and mid-level practitioner registration fees are for a three-year period. This current three-year fee is $731. The revised fee for the three-year registration period is $888. The three-year difference is $157 or an annual difference of $52.

The fees are estimated to fund the full cost of the DCP – to include the increased programmatic and personnel requirements currently, or expected to be in place from FY 2021 to FY 2023, and have a FY 2023 end-of-year balance of at least $50 million.

Table 2: Overview of Diversion Control Fee Account

	FY 2021 ($M)	FY 2022 ($M)	FY 2023 ($M)	3-Years Combined ($M)
DCFA Balance Carried Forward From Prior Year	69	96	86	69
Total Collections	576	596	625	1,797
Treasury Amount	(15)	(15)	(15)	(45)
Other Collections (OGV, CMEA)	1	1	1	3
Net Collections	562	582	611	1,755
Total Obligations	555	613	670	1,838
Recoveries from Deobligations	(20)	(22)	(24)	(65)
Net Obligations	535	591	647	1,773
End of Year DCFA Balance	96	86	50	50

Refund of Registration Fees

DEA is amending 21 CFR 1301.13(e) and 1309.12(b) to codify existing practices of the issuance of refunds by DEA for applicant registration fees. Generally, registration fees are not

refundable. This regulation was implemented when registration fees were nominal. With increased registration fees, DEA recognizes the need to issue refunds in limited circumstances. These provisions of the rule will give the DEA Administrator discretionary authority to refund registration fees in limited circumstances, such as: applicant error, DEA error, and death of a registrant within the first year of the three-year registration cycle. Refunds will be issued for applicant error when there has been a duplicate payment for the same renewal, incorrect billing or incorrect transposing of credit card digits, payment for incorrect business activity, or when an applicant is fee-exempt. Refunds will be issued based on DEA error when DEA caused the error; for example, when DEA incorrectly advised that a new application was needed, or advised a registrant to submit payment for a wrong business activity. While these provisions will have no economic costs or benefits, DEA believes it is important to accurately codify existing practices.

VI. Need for a New Fee Calculation

As discussed in the NPRM, DEA last adjusted the fee schedule in March 2012, with collections beginning in April 2012.[13] This fee schedule was intended to cover the "full costs" of the DCP for FY 2012 through FY 2014, or October 1, 2011 through September 30, 2014. The DCP has continued to operate under this fee schedule by being fiscally responsible, optimizing its organizational structure, maximizing the use of technological enhancements, as well as unforeseen delays in hiring. As indicated by the above-referenced 2008 OIG report, the DCP has assumed a number of costs since the last fee increase, including indirect pay and rightsizing, additional salary, and other costs attributable to diversion control activities. In addition, Congress has expanded DCP's responsibility to address the opioid epidemic public health

[13] 77 FR 15234, March 15, 2012.

emergency. DEA's 360 Strategy was launched with the purpose of ending the deadly cycle of prescription opioid misuse through coordinated law enforcement, diversion control, and community outreach efforts.

Due to increased diversion and prescription drug abuse, as well as an increase in the production and use of chemicals that contribute to the opioid epidemic, the DCP has increased its use of TDS groups to meet its enforcement mission, and hired more DIs working in Diversion Groups (DG) and Diversion Staff (DS) across the nation to support its increased regulatory mission. In April 2012, DEA had 48 TDSs, 65 DGs and 17 DSs. At the end of FY 2019, DEA had 86 TDSs, 87, DG, 15 DSs, and 16 TDS-Extensions.[14]

The DCP continues to draw technical expertise from DIs, and the DCP has incorporated greater numbers of Special Agents, Chemists, Information Technology Specialists, Attorneys, Intelligence Research Specialists, and state and local personnel to meet its increased responsibilities. In April 2012, DEA had 1,167 employees in DCFA funded positions; at the end of FY 2019, DEA had 1,681. To continue to meet diversion control challenges and to staff and support the increased number of regulatory and enforcement groups, DEA must expand the DCP's enforcement and regulatory capacity, as well as its support functions. DEA plans to increase its full-time-equivalent (FTE) staffing level of 1,782 in FY 2020, DEA plans to increase FTEs by 90, 147, and 134, in FY 2021, FY 2022, and FY 2023, respectively, for a total of 2,153 FTEs in FY 2023. The estimated increase for the three year period is 371 FTEs.

DEA has been, and will continue to be fiscally responsible and seek to improve efficiencies and identify other cost saving measures. As discussed above, however, a new fee calculation is

[14] A TDS-Extension is an extension of a TDS into a location, usually staffed by two Special Agents to provided law enforcement coverage while not incurring the full cost of a TDS.

needed. Without an adjustment in the registration fees, DEA will be unable to continue current operations and will be in violation of the statutory mandate that fees charged "shall be set at a level that ensures the recovery of the full costs of operating the various aspects of [the diversion control program]." 21 U.S.C. 886a(1)(C). For example, collections under the current fee schedule will require the DCP to significantly cut existing and planned DCP operations vital to its mission. DEA relies on the DCP to maintain the integrity of the closed system for pharmaceutical controlled substances and listed chemicals, particularly at this time of dramatic increases in drug abuse and diversion.

Fee Calculation

As described above, DEA is delegated the task of determining the details of how to fulfill the statutory requirement to recover the full costs of operating the DCP and charging registrants reasonable fees relating to the registration and control "of the manufacture, distribution, dispensing"[15] and "importers and exporters" [16] of controlled substances and listed chemicals. In advance of actual expenditures, DEA must determine reasonable fees to be charged. To project the annual costs of the DCP, DEA uses historical data and projections, together with actual and current costs. Additionally, a reasonable fee must be calculated that will fully recover the costs of the DCP based on a variable number of registrants in the different categories of registration (e.g., manufacturers, distributors, importers, exporters, reverse distributors, practitioners, and individual researchers). Because 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), DEA must collect more than is actually spent to avoid running a deficit and being in violation of

[15] 21 U.S.C. 821.
[16] 21 U.S.C. 958(f).

federal fiscal law.[17] In operating the DCP, DEA must be prepared for changes in investigative priorities, diversion trends, and emerging drugs or chemicals posing new threats to the public health and safety. By definition, it is an inexact effort. Consequently, the agency must select and follow a single methodology throughout any given fee cycle.

Since the inception of the fee, the agency has selected a weighted-ratio method to determine a reasonable fee for each category of registrants. Under this method, registrants are assigned to a business activity or category (e.g., researcher, practitioner, distributor, manufacturer, etc.) based on the statutory fee categories, and the projected population is calculated for each category or business activity. Then, DEA estimates the full cost of the DCP for the analysis period, which is generally three years. The corresponding registration fees required to pay the full cost of the DCP for the analysis period are then calculated by employing 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. These are long-established ratios, utilized in previous fee increases, and repeatedly determined to be reasonable.[18] By utilizing these different ratios, DEA 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.

The current 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. Practitioners, mid-level practitioners, dispensers, researchers, and narcotic treatment programs pay an annual registration fee of $244. For administrative convenience, both

[17] 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.
[18] 77 FR 15234 (March 15, 2012); 71 FR 51105 (August 29, 2006).

the collection and the payment, practitioners pay a combined registration fee of $731 every three years. Distributors, importers, and exporters pay an annual fee of $1,523, while manufacturers pay an annual fee of $3,047. 21 CFR 1301.13 and 1309.11.

Since the last fee schedule adjustment in March 2012,[19] DEA continued to review possible alternative methodologies to differentiate registration fees between various registration business activities. In developing this rule, DEA examined three alternative methodologies to calculate the registration and registration fees: Flat Fee Option, Past-Based Option, and Weighted-Ratio Option (current and selected method). In examining each alternative methodology, DEA considered whether the fee calculation (1) was reasonable, and (2) could fully fund the costs of operating the various aspects of the DCP. DEA has determined that the current "weighted-ratio" fee structure is the most reasonable. Therefore, DEA selected the current weighted-ratio method to calculate and differentiate fees between registrant groups. A detailed discussion of the alternatives is provided below. Additionally, the selected fee calculation method is summarized below and detailed in "Proposed Registration Fee Schedule Calculation" in the rulemaking docket at *https://www.regulations.gov*.

Projected Costs for the Diversion Control Program

In calculating fees to recover the mandated full costs of operating the DCP, DEA estimated the cost of operating the DCP for the next three fiscal years. To develop the DCFA budget request estimates for FY 2021 to FY 2023, DEA compiled: (1) the DCFA Budget for FY 2020, which forms a base spending level for the current level of service, (2) the estimated additional required funds for FY 2021 to FY 2023, and (3) the required annual $15 million transfer to the United States Treasury as mandated by the CSA (21 U.S.C. 886a). The following paragraphs

[19] 77 FR 15234, March 15, 2012.

explain the annual revenue calculations and how the total amount to be collected for the FY 2021 to FY 2023 period was calculated. In developing this figure, DEA began 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 adding staffing resources that support the regulatory and law enforcement activities of the program. The basis of current fees was to fund the DCP for the time period of FY 2012 to FY 2014, and the fees need to be adjusted to reflect these factors. Specific details on the DCP budget are available in the annual President's Budget Submission and supplemental budget justification documents provided to Congress. [20]

DEA must set fees to recover the full cost of the DCP. Therefore, the estimated budget for FY 2021 to FY 2023 forms the basis for required collections (target collections) from registration fees. The process for estimating the budget for each year is the same. Generally, the budget for a particular year is set by starting from the previous year (base year), adjusting for inflation, and then adding enhancements (growth) to the budget. DCP personnel growth is the key factor in formulating the budget.

The estimated budget is based on two estimated components: 1) payroll obligations based on estimated FTEs, and 2) non-payroll obligations based on changes to payroll obligations. The estimated payroll obligations are based on the payroll cost of the FTEs described earlier. The estimates also account for the difference in payroll cost between personnel leaving the program, usually at a higher grade level, and personnel entering the program. Additionally, the payroll obligations include a yearly inflation factor of two percent to cover Within-Grade Increases,

[20] *See* this rulemaking docket found at www.regulations.gov.

Career Ladders,[21] Cost of Living Adjustment, and increased benefits costs. Non-payroll obligations generally follow payroll obligations. As FTE and payroll obligations increase, non-payroll obligations increase accordingly. Non-payroll obligations include items such as rent, communications, utilities, services, equipment, travel, etc.[22] DEA believes its methodology supports the estimated budget for the three-year period, FY 2021 to FY 2023. The estimated payroll obligations and non-payroll obligations are added to obtain the estimated total obligations.

In April 2012, when the last fee increase was made effective, DEA had 48 TDSs, 65 DGs, and 17 DSs. At end of FY 2019, DEA had 86 TDSs, 87 DGs, 15 DSs, and 16 TDS-Extensions. To continue to meet diversion control challenges, DEA continues to increase its field regulatory and enforcement groups. DEA anticipates having 88 TDSs, 89 DGs, 17 DSs, and 14 TDS-Extensions by end of FY 2020 (beginning of FY 2021), expanding to 94 TDSs, 95 DGs, 10 DSs, and 10 TDS-Extensions by end of FY 2023. Table 3 summarizes the estimated number of field groups by year.

Table 3: Number of Field Groups by Year

Regulatory and Enforcement Groups	As of 4/2012	Estimated EOY FY 2020	Estimated EOY FY 2023
TDS	48	88	94
DG	65	89	95
DS	17	13	10
TDS-Extension	-	14	10

[21] The position is structured to allow for entry at a lower grade level and allows for progression at predetermined GS-grade level (usually multi-level) interval to the full performance grade level.
[22] The full list of non-payroll obligations is available in the FY 2020 Congressional Budget Submission, Exhibits: Diversion Control Fee Account (DCFA). https://www.justice.gov/doj/fy-2020-congressional-budget-submission.

Additionally, in April 2012, DEA had 1,167 employees in DCFA funded positions; at the end of FY 2020, DEA will have an estimated 1,803 employees in such positions. To continue to meet diversion control challenges, and to staff and support the increased number of regulatory and enforcement groups described above, DEA plans to expand the DCP's enforcement and regulatory capacity, as well as its support functions. From an estimated FTE of 1,782 DEA plans to increase FTEs by 90, 147, and 134, in FY 2021, FY 2022, and FY 2023, respectively, for a total of 2,153 FTEs in FY 2023. The estimated increase for the three year period is 371 FTEs.

The estimated payroll obligations are based on the payroll cost of the FTEs described above. The estimates also account for the difference in payroll cost between personnel leaving the program, usually at higher grade level, and personnel entering the program. Additionally, the payroll obligations include a yearly inflation factor to cover Within-Grade Increases, Career Ladders,[23] Cost of Living Adjustment, and increased benefits costs. From an estimated base of $289,450,003 in FY 2020, estimated payroll obligations increase to an estimated $311,587,162, $344,462,812, and $376,513,554 in FY 2021, FY 2022, and FY 2023, respectively, reflecting the increase in FTEs.

Non-payroll obligations include items such as rent, communications, utilities, services, equipment, travel, etc.[24] Non-payroll obligations generally follow payroll obligations. As FTE and payroll obligations increase, non-payroll obligations also increase. The year-over-year increases to payroll are 7.6 percent, 10.6 percent and 9.3 percent in FY 2021, 2022, and FY 2023, respectively. From an estimated base of $225,747,874 non-payroll obligations in FY

[23] Position structured to allow for entry at a lower grade level that allows for progression at predetermined GS-grade level (usually multi-level) interval to the full performance grade level.
[24] Full list of non-payroll obligations is available in the FY 2020 Congressional Budget Submission, Exhibits: Diversion Control Fee Account (DCFA). https://www.justice.gov/doj/fy-2020-congressional-budget-submission.

2020, increasing non-payroll obligations at the same rate as payroll obligations results in estimated non-payroll obligations of $243,013,089, $268,653,469, and $293,650,487 in FY 2021, FY 2022, and FY 2023, respectively.

Table 4: Estimated Total Obligations (Budget)

	FY 2020	FY 2021	FY 2022	FY 2023
Payroll Obligations ($)	289,450,003	311,587,162	344,462,812	376,513,554
Non-payroll Obligations ($)	225,747,874	243,013,089	268,653,469	293,650,487
Total Obligations ($)	515,197,876	554,600,250	613,116,281	670,164,040
FTE	1,782	1,872	2,019	2,153

In addition to the budget for each of the fiscal years, DEA also considers the cost components outlined below 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, or not at all. Changes in obligations can occur for a variety of reasons, (i.e., changes in planned operations, delays in staffing, implementation of cost savings, changes in vendor capabilities, etc.). When DEA does not spend the obligated money as planned, that obligation is "deobligated." The "deobligated" funds are "recovered," and the funds become available for DCP use. Based on historical trends, the recovery of money not spent as planned (deobligation of prior year obligations) is estimated at 3.5 percent of obligations.

Payment to Treasury

In the 1993 appropriations for DEA, Congress determined that the DCP would be fully funded by registration fees and no longer by appropriations.[25] Congress established the DCFA as a separate account of the Treasury to "ensure the recovery of the full costs of operating the various aspects of [the Diversion Control Program]" by those participating in the closed system established by the CSA. 21 U.S.C. 886a(1)(C). Fees collected are deposited into a separate Treasury account. Each fiscal year, the first $15 million of collected fees is transferred to the Treasury and is not available for use by the DCP. Therefore, DEA needs to collect an additional $15 million per year beyond estimated costs for payment to the Treasury.

DCFA Balance

DEA maintains a DCFA balance, as working capital, to maintain DCP operations during low collection periods.[26] Monthly collections and obligations fluctuate throughout the year. There are times when obligations (i.e., spending) exceed collections. This can happen consecutively for several months. Therefore, DEA maintains a DCFA balance to avoid operational disruptions due to these fluctuations. The estimated DCFA balance at beginning of FY 2021 is $69 million. Based on the history of these fluctuations, DEA has determined that an end-of-year DCFA balance of $50 million is adequate. Therefore, the target DCFA balance at the end of FY 2023 is $50 million.

[25] Departments of Commerce, Justice, and State, the Judiciary and Related Agencies Appropriations Act of 1993, Pub. L. 102-395, codified in relevant part at 21 U.S.C. 886a.

[26] "DCFA balance" was called the "Operational Continuity Fund (OCF)" in the last fee schedule adjustment in March 2012.

Other Collections

DEA derives revenue from the sale/salvage of official government vehicles dedicated for use in the DCP. Additionally, under the Combat Methamphetamine Epidemic Act of 2005 (CMEA), DEA collects a self-certification fee of $21 for regulated sellers of scheduled listed chemical products. 21 CFR 1314.42(a). The fee is waived for any person holding a current DEA registration in good standing, such as a pharmacy authorized to dispense controlled substances. 21 CFR 1314.42(b). DEA's estimate for these other collections is $1 million per year.

Estimated Total Required Collections (Target Collections)

Based on the estimated total obligations and other financial components outlined above, DEA determined a 21 percent increase in total collections is required to fund the DCP for the three-year period and have a $50 million in DCFA balance at the end of FY 2023.

The target collections are $576 million, $596 million, and $624 million, for FY 2021, FY 2022, and FY 2023, respectively. In total, DEA needs to collect $1.8 billion (or $1,796 million) in registration fees over the three-year period, FY 2021 to FY 2023, to fully fund the DCP.

Table 5: Estimated DCFA Cash Flow under New Fee Calculation

	FY 2021 ($M)	**FY 2022 ($M)**	**FY 2023 ($M)**	**3-Years Combined ($M)**
DCFA Balance Carried Forward From Prior Year	69	95	86	69
Total Collections	576	596	624	1,796
Treasury Amount	(15)	(15)	(15)	(45)
Other Collections (OGV, CMEA)	1	1	1	3
Net Collections	562	582	610	1,755
Total Obligations	555	613	670	1,838
Recoveries from Deobligations	(20)	(22)	(24)	(65)
Net Obligations	535	591	647	1,773
End of Year DCFA Balance	95	86	50	50

Note: This projection is based on the "target" collections for the purposes of calculated fees. To end with exactly $50 million DCFA Balance, the calculated fees will need to have many decimal places. When fees are rounded to the nearest whole dollar, the projected cash flow will vary slightly.

Without a fee increase, under current fee structure, the estimated collection is $474 million, $491 million, and $514 million, for FY 2021, FY 2022, and FY 2023, respectively, for a total of $1.5 billion (or $1,479 million) for the three-year period. Without a fee increase, DEA would have obligations that would exceed the collections and DCFA balance beginning in FY 2021.

Table 6: Estimated DCFA Cash Flow Under Current Fee Structure (if no actions are taken to reduce obligations*)

	FY 2021 ($M)	FY 2022 ($M)	FY 2023 ($M)	3-Years Combined ($M)
DCFA Balance Carried Forward From Prior Year	69	(6)	(121)	69
Total Collections (at Current Fee)	474	491	514	1,479
Treasury Amount	(15)	(15)	(15)	(45)
Other Collections (OGV, CMEA)	1	1	1	3
Net Collections	460	477	500	1,437
Total Obligations	555	613	670	1,838
Recoveries from Deobligations	(20)	(22)	(24)	(65)
Net Obligations	535	591	647	1,773
End of Year DCFA Balance	(6)	(121)	(267)	(267)

*This is a hypothetical scenario. DEA would not allow DCFA balance to go negative.

Selected Methodology for New Fee Calculation

As shown in Table 5 above, the target collections are $576 million, $596 million, and $624 million, for FY 2021, FY 2022, and FY 2023, respectively. In total, DEA needs to collect $1.8 billion in registration fees over the three-year period, FY 2021 to FY 2023, to fully fund the

DCP. DEA must select a method for determining fees for various business activities that would generate the target collections.

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

Moreover, the CSA requires that DEA charge fees to fully fund the DCP, but that the fees collected by DEA are to be expended through the budget process only. Specifically, each year, DEA is required by statute to transfer the first $15 million of fee revenues into the general fund of the Treasury, while the remainder of the fee revenues is deposited into a separate fund of the Treasury called the DCFA. 21 U.S.C. 886a(1). On at least a quarterly basis, the Secretary of the Treasury is required to refund DEA an amount from the DCFA "in accordance with estimates made in the budget request of the Attorney General for those fiscal years" for the operation of the DCP. 21 U.S.C. 886a(1)(B) and (D).

In developing this rule, DEA considered three methodologies to calculate registration and reregistration fees: Flat Fee Option, Past-Based Option, and Weighted-Ratio Option (current and selected method). While the fee increases may be passed down to the registrants' customers, the analysis below assumes they are absorbed fully by the registrants.

For each of the alternatives, the calculated fees are analyzed for reasonableness by examining: (1) the absolute amount of the fee increase, (2) the change in fee as a percentage of revenue from 2012-2021, and (3) the relative fee increase across registrant groups. Additionally, each calculation methodology is re-evaluated for its overall strengths and weaknesses.

Flat Fee Option

Option 1 is called the Flat Fee Option. The flat fee option would provide equal fees across all registrant groups, regardless of the proportion of DCP costs and resources the registrant group may require (e.g., investigation resources). The fee calculation is straightforward: the total amount needed to be collected over the three-year period is divided by the total number of registration fee transactions over the three year period, adjusting for registrants on a three year registration cycle (so that the fees for a three-year period are three times the annual fee).

DEA calculated the annual registration fees under Option 1 and compared these fees to the current fees.

Table 7: Registration Fees Under Flat Fee Option

Business Activity	Current Fees ($)	Option 1: Flat Fee ($)	Difference ($)	Increase over current
*Registrants on Three Year Registration Cycle**				
Pharmacy	731	896	165	23%
Hospital/Clinic	731	896	165	23%
Practitioner	731	896	165	23%
Teaching Institution	731	896	165	23%
Mid-level Practitioner (MLP)	731	896	165	23%
Registrants on Annual Registration Cycle				
Manufacturer	3,047	299	(2,748)	-90%
Distributor	1,523	299	(1,224)	-80%
Researcher/Canine Handler	244	299	55	23%
Analytical Lab	244	299	55	23%
Importer	1,523	299	(1,224)	-80%
Exporter	1,523	299	(1,224)	-80%

Business Activity	Current Fees ($)	Option 1: Flat Fee ($)	Difference ($)	Increase over current
Reverse Distributor	1,523	299	(1,224)	-80%
Narcotic Treatment Program	244	299	55	23%
Chemical Manufacturer	3,047	299	(2,748)	-90%
Chemical Importer	1,523	299	(1,224)	-80%
Chemical Distributor	1,523	299	(1,224)	-80%
Chemical Exporter	1,523	299	(1,224)	-80%

*Pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners currently pay a fee for a three-year period. This current three-year fee is $731. The fee under the flat fee scenario for the three year registration period would be $896. The three-year difference is $165 or an annual difference of $55.

In the flat fee option, the registration fee for practitioners increases by 23 percent to $299 on an annual basis. The registration fees for manufacturers and distributors are reduced significantly, from $3,047 for manufacturers and $1,523 for distributors to $299 for both. This reduction represents a 90 percent and 80 percent reduction for manufacturers and distributors, respectively.

The calculation considered in Option 1 results in a disparity in fee change among registrant groups. For each registrant group to pay the same flat fee, the registration fee for practitioners increases by 23 percent, while registration fees for manufacturers and distributors decrease 90 percent and 80 percent, respectively.

The flat fee option has positive and negative aspects. The calculation is simple and straight-forward. The fee that DEA is required to charge registrants is based on a statutory requirement – it is not a user fee. A user fee calculation would require a calculation of the direct and indirect costs associated with each registrant group, and set fees to recover the costs associated with each group. Because the registration fee is not a user fee, DEA is not required to calculate fees according to the regulatory and enforcement costs associated with each registrant group. However, general historical costs of regulatory and enforcement activities support different fees

among the categories. DEA believes that setting the same fees for all registrants, from multi-national corporations to mid-level practitioners, is unreasonable.

Conclusion for Flat Fee Option

After consideration of the flat fee option, DEA did not select this option to calculate the new fees. The fee disparity among registrant groups caused by this calculation alternative is too great. Under this option, the calculation would result in reduced fees for manufacturers and distributors by 90 percent and 80 percent respectively, while practitioner fees would increase by 23 percent. Setting the fees at the same level across all registrant groups is therefore not "reasonable" as required by statute. While the vast majority of registrants are practitioners, such as individual physicians and nurse practitioners, DEA registrants also include some of the largest corporations in the world. . To satisfy the "reasonable" standard, registration fees should be different among the categories to account for cost and economic differences among the registrant categories. Option 1 did not satisfy this requirement.

Past-Based Option

Option 2 is called the Past-Based Option, and uses historic investigative work hour data to apportion the cost to each registrant category. In considering Option 2, DEA used historic investigative work hour data from FY 2016 – FY 2018. DEA's records provide an accurate apportionment of work hours for certain types of diversion control activities (e.g., investigations) among different classes of registrants. DEA estimates that approximately three percent of costs can be directly linked to pre-registration and scheduled investigations. Although some criminal investigations can be attributed to registrant groups, DEA did not include the cost of criminal investigations for the fee calculation under the Past-Based Option due to the unpredictable nature of this investigations. While DEA develops annual work plans for the number of scheduled

investigations by registrant type, DEA does not develop such plans for criminal investigations. Therefore, the cost of criminal investigations is allocated equally across all registrant groups, regardless of business activity. The remaining costs associated with DCP activities and components benefit all registrants (e.g., policy, registration, and legal activities); however, DEA records cannot attribute these costs by registrant class. Under Option 2, pre-registration and scheduled investigation costs are assigned to registrant classes and all other costs are recovered on an equal, per-registrant basis.

DEA calculated the annual registration fees under Option 2 and compared these fees to the current fees. Although distributors and importers/exporters are in the same fee class in the current fee structure (Weighted-Ratio Option), in this analysis, distributors are separated from importers and exporters based on the available historic work hour data and reported work hours by type of registrant.

Table 8: Registration Fees Under Past-Based Option

Business Activity	Current Fees ($)	Option 2: Past-Based ($)	Difference ($)	% increase over current
Registrants on Three Year Registration Cycle				
Pharmacy	731	1,030	299	41%
Hospital/Clinic	731	872	141	19%
Practitioner	731	873	142	19%
Teaching Institution	731	1,694	963	132%
Mid-level Practitioner (MLP)	731	868	137	19%
Registrants on Annual Registration Cycle				
Manufacturer	3,047	4,212	1,165	38%
Distributor	1,523	3,303	1,780	117%
Researcher/Canine Handler	244	565	321	132%
Analytical Lab	244	565	321	132%
Importer	1,523	1,906	383	25%
Exporter	1,523	1,906	383	25%
Reverse Distributor	1,523	3,303	1,780	117%
Narcotic Treatment Program	244	2,332	2,088	856%
Chemical Manufacturer	3,047	1,703	(1,344)	-44%

Chemical Importer	1,523	1,386	(137)	-9%
Chemical Distributor	1,523	1,824	301	20%
Chemical Exporter	1,523	1,386	(137)	-9%

In the Past-Based option, the percent change in fees from current fees ranges from negative 44 percent (reduction of 44 percent) for list I chemical manufacturers to an increase of 856 percent for narcotic treatment programs. The increase for a large majority of registrations, practitioners, mid-level practitioners, and hospital/clinics, is 19 percent.

While Option 2 is based on accurate historical data, it does not allow for future needs, demands, and shifting responsibilities of the DCP, including Agency priorities, new legislation, control of substances, new investigative requirements, and other program needs.

Conclusion for Past-Based Option

DEA did not select the Past-Based option for two key reasons. First, the fee increase is disproportionately burdensome to a small number of registrants. Narcotic treatment program fees would increase by 856 percent, while the change for the remaining registrant groups range from a decrease of 44 percent to an increase of 131 percent. DEA deemed this unreasonable. Second, the Past-Based option is backward looking and implicitly assumes that the future will be similar to the past. DEA cannot assume that future workload will reflect past DEA work hour data. For example, DEA plans to conduct more scheduled investigations in accordance with the new scheduled investigation work plan. As a result, DEA has concluded that past data is not a reasonable basis for the calculation of new fees.

Weighted-Ratio Option (Current and Selected Method)

The Weighted-Ratio Option has been used since the inception of the fee. This option distinguishes among the categories to establish a “reasonable” fee for each category. In this option, fees are assigned to different registrant categories based on DEA’s general historical cost

data expressed as weighted ratios. The different fees are expressed in ratios: 1.0 for researchers, canine handlers, analytical labs, and narcotics treatment programs; 3.0 for registrants on three-year registration cycles, pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners; 6.25 for distributors and importers/exporters; and 12.5 for manufacturers. The adopted ratios are applied for administrative convenience because historically costs vary and a fee must be set in advance. To determine the fee, the amount needed to be collected over the FY 2021 to FY 2023 period is divided by the weighted number of estimated registrations.

Table 9: Registration Fees Under Weighted-Ratio Option

Business Activity	Current Fees ($)	Option 3: Weighted Ratio ($)	Difference ($)	Increase over current
*Registrations on Three Year Registration Cycle**				
Pharmacy	731	888	157	21%
Hospital/Clinic	731	888	157	21%
Practitioner	731	888	157	21%
Teaching Institution	731	888	157	21%
Mid-level Practitioner (MLP)	731	888	157	21%
Registrations on Annual Registration Cycle				
Manufacturer	3,047	3,699	652	21%
Distributor	1,523	1,850	327	21%
Researcher/Canine Handler	244	296	52	21%
Analytical Lab	244	296	52	21%
Importer	1,523	1,850	327	21%
Exporter	1,523	1,850	327	21%
Reverse Distributor	1,523	1,850	327	21%
Narcotic Treatment Program	244	296	52	21%
Chemical Manufacturer	3,047	3,699	652	21%
Chemical Importer	1,523	1,850	327	21%
Chemical Distributor	1,523	1,850	327	21%
Chemical Exporter	1,523	1,850	327	21%

*Pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners currently pay a fee for a three-year period. This current three-year fee is $731. The fee under the weighted-ratio scenario for the three-year registration period would be $888. The three-year difference is $157, or an annual difference of $52.

In the Weighted-Ratio Option, the registration fees for all registrant groups increase by 21 percent from current fees, although the absolute dollar amount may differ. The registration fees range from $296 annually (or annual equivalent) to $3,699, and a corresponding increase of $52 annually (or annual equivalent) to $652. Registration fees are collected by location and by registered business activity. Registration fees for all registrant groups increase by 21 percent, and as a result, there is no disparity in the percentage fee increase among registrant groups. Furthermore, a 21 percent increase ($731 to $888) over nine years, from FY 2012 to FY 2021, equates to a 2.2 percent annual rate (on a compound annual growth rate basis), which is comparable to the rate of inflation. The same increase equates to a 1.8 percent annual rate over 11 years, from FY 2012 to FY 2023.

The Weighted-Ratio methodology, much like the flat fee, is straightforward and easy to understand, but unlike the flat fee, it applies historic weighted ratios to differentiate fees among registrant groups. This methodology has the advantage of differentiating fees based on historic weighted ratios, but does not create a disproportionate fee increase in any registrant group.

Conclusion for Weighted-Ratio Option

DEA selected this option to calculate the new fees. 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 generally larger revenues and costs pay higher fees than registrants with lower revenues and costs. Furthermore, the Weighted-Ratio option 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 current fee have proven effective and reasonable over time, and generally reflects the differences in activity level, notably in inspections, scheduled

investigations, and other control and monitoring, by registrant category (i.e., these costs are higher for manufacturers). DEA selected this option because it is the only option that resulted in "reasonable" fees for all registrant groups.

REGULATORY ANALYSES

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)

This rule has been developed in accordance with the principles of Executive Orders (EO) 12866 and 13563. EO 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, public health and safety, and environmental advantages, distributive impacts, and equity). EO 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in EO 12866. The Executive Order classifies a "significant regulatory action" requiring review by OMB as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

DEA estimates that this rule will have an annual effect, in the form of transfers, on the economy of $100 million or more and, therefore, is an economically significant regulatory

action. Fees paid to DEA are considered transfer payments and not costs.[27] The analysis of benefits and transfers is below. The OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is a significant regulatory action under the meaning of EO 12866, and it therefore has been reviewed by the OMB.

a. Need for the Rule

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 the DCP. 21 U.S.C. 886a(1)(C).

DEA continually monitors the anticipated budget and collections to determine whether the registration fees need to be adjusted. DEA has determined that the fees need to increase in beginning October 1, 2020, FY 2021, to the amounts indicated above in order to fully fund the DCP as required by statute. Therefore, this rulemaking is required for DEA to recover the full costs of operating the DCP.

b. Alternative Approaches

As described in detail above, DEA examined three alternative methodologies to calculate the registration and registration fees: Flat Fee Option, Past-Based Option, and Weighted-Ratio Option (current and selected method).

For each of the alternatives considered, the calculated fees are analyzed for reasonableness by examining: (1) the absolute amount of the fee increase; (2) the change in fee as a percentage of revenue from 2012 to 2021; and (3) the relative fee increase across registrant groups.

[27] OMB Circular A-4.

Additionally, each calculation methodology is re-evaluated for its overall strengths and weaknesses.

Flat Fee Option

Option one is called the Flat Fee Option. The flat fee option would provide equal fees across all registrant groups, regardless of the proportion of DCP costs and resources the registrant group may require (*e.g.*, investigation resources). The calculation results in a dramatic disparity in fee change among registrant groups. After consideration of the flat fee option, DEA did not select this option to calculate the new fees. The fee disparity among registrant groups caused by this calculation alternative is too great. Under this option, the practitioner fees would increase by 23 percent to $299 on an annual basis, while manufacturer and distributor fees would decrease by 90 percent and 80 percent respectively, to an annual fee of $299. Setting the fees at the same level across all registrant groups is therefore not "reasonable" as required by statute. While the vast majority of registrants are practitioners, such as individual physicians and nurse practitioners, DEA registrants also include some of the largest corporations in the world. To satisfy the "reasonable" standard, registration fees should be different among the categories to account for cost and economic differences among the registrant categories. This option did not satisfy this requirement.

Past-Based Option

Option two is called the Past-Based Option, and uses historic investigative work hour data to apportion the cost to each registrant category. Under Option two, pre-registration and scheduled investigation costs are assigned to registrant classes and all other costs are recovered on an equal, per-registrant basis. In the Past-Based option, the percent change in fees from current fees ranges from negative 44 percent (reduction of 44 percent) for list I chemical manufacturers to an

increase of 856 percent for narcotic treatment programs. The increase for a large majority of registrations, practitioners, mid-level practitioners, and hospital/clinics, is 19 percent. DEA did not select the Past-Based option for two key reasons. First, the fee increase is disproportionately burdensome to a small number of registrants. Narcotic treatment program fees would increase by 856 percent, while the change for the remaining registrant groups range from a decrease of 44 percent to an increase of 131 percent. DEA deemed this unreasonable. Second, the Past-Based option is backward looking and implicitly assumes that the future will be similar to the past. The past may not necessarily be a bad estimate. However, DEA develops a work plan for scheduled investigations annually and investigation frequency may be modified based on need or diversion risk. DEA cannot assume that future workload will reflect past DEA work hour data. As a result, DEA has concluded that past data is not a reasonable basis for the calculation of new fees.

Weighted-Ratio Option (Current and Selected Method)

The Weighted-Ratio Option has been used since the inception of the fee. This option distinguishes among the categories to establish a "reasonable" fee for each category. In this option, fees are assigned to different registrant categories based on DEA's general historical cost data expressed as weighted-ratios. The Weighted-Ratio methodology, much like the flat fee, is straightforward and easy to understand, but unlike the flat fee, it applies historic weighted ratios to differentiate fees among registrant groups. This method would result in across-the-board 21 percent increase in fees for all registrations.

DEA selected this option to calculate the new fees. 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 generally larger revenues and costs pay higher fees than

registrants with lower revenues and costs. Furthermore, the Weighted-Ratio option 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 current fee have proven effective and reasonable over time, and generally reflects the differences in activity level, notably in inspections, scheduled investigations, and other control and monitoring, by registrant category (i.e., these costs are higher for manufacturers). DEA selected this option because it is the only option that resulted in "reasonable" fees for all registrant groups.

c. Summary of Impact of New Fees Relative to Current Fees

Affected Entities

As of September 2019, DEA issued 1,840,501 issued controlled substances and chemical registrations (1,839,556 controlled substances registrations and 945 chemical registrations), as shown in Table 10.

Table 10: Number of Registrations by Business Activity (September 2019)

Registrant Class/Business	Controlled Substances	Chemicals
Pharmacy	70,851	
Hospital/Clinic	18,305	
Practitioner	1,324,438	
Teaching Institute	264	
Mid-Level Practitioner	408,468	
Researcher	11,986	
Analytical Labs	1,514	
Narcotic Treatment Program	1,738	
Manufacturer	570	207
Distributor	843	370
Reverse Distributor	68	
Importer	253	209
Exporter	258	159
Total	**1,839,556**	**945**
Grand Total (all registrations)	**1,840,501**	

*Includes fee-paying and fee-exempt registrations.

Not all registrants listed in Table 10 are subject to the fees. Any hospital or other institution operated by an agency of the U.S. of any state, or any political subdivision of an agency thereof, is exempt from the payment of registration fees. 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.[28] Fee-exempt registrants are not affected by the new fees.

Based on historical registration data and estimated growth trends, DEA estimates the average total registration population over the three-year period, FY 2021 to FY 2023, will be 2,004,358 as shown in Table 11. Estimated annual growth in fee-paying registrations is approximately 3.8 percent. The largest growth is in the MLPs. Approximately eight percent of all registrations are fee-exempt.

Table 11: Estimated Average Fee-Paying Registrations, FY 2021-FY 2023

Registrant Class/Business	Controlled Substances	Chemicals
Pharmacy	80,199	
Hospital/Clinic	16,638	
Practitioner	1,356,876	
Teaching Institute	130	
Mid-Level Practitioner	539,899	
Researcher	5,038	
Analytical Labs	908	
Narcotic Treatment Program	1,978	
Manufacturer	578	208
Distributor	666	329
Reverse Distributor	73	
Importer	222	202
Exporter	264	150
Total	**2,003,469**	**889**
Grand Total (all registrations)	**2,004,358**	

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

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

Characteristics of Entities

This 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. As of September 2019, DEA issued 1,840,501 total controlled substances and chemical registrations (1,839,556 controlled substances registrations and 945 chemical registrations), as shown above in Table 10. DEA estimates an average total fee-paying population of 2,004,358 over the three-year period, FY 2021 to FY 2023, as shown in Table 11.

The registrations on a three-year cycle (i.e., pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners), make up 99.5 percent of all registrations not exempt from paying registration applications fees. All other categories of registration (i.e., manufacturers, distributors, reverse distributors, importers, exporters, chemical manufacturers, chemical distributors, chemical importers, and chemical exporters) maintain an annual

registration. Registration and reregistration costs vary by registrant category as is described in more detail in the sections below.

The new fees would affect a wide variety of entities. Table 12 indicates the sectors, as defined by the North American Industry Classification System (NAICS), affected by the rule and their enterprise average annual revenue, provided by the U.S. Census Bureau, Statistics of U.S. Businesses (SUSB). Most DEA registrants are, or are employed by, small entities under Small Business Administration (SBA) standards.

Table 12: Industrial Sectors of DEA Registrants

Business Activity	NAICS Code	NAICS Code Description	Average Annual Revenue ($)
Manufacturer	325411	Medicinal and Botanical Manufacturing	33,905,094
	325412	Pharmaceutical Preparation Manufacturing	148,265,482
Distributor, Importer, Exporter	424210	Drugs and Druggists' Sundries Merchant Wholesalers	103,097,459
Reverse Distributor	5621	Waste Collection	5,168,825
	5622	Waste Treatment and Disposal	11,553,838
Pharmacy	445110	Supermarkets and Other Grocery (except Convenience) Stores	12,740,365
	446110	Pharmacies and Drug Stores	12,533,279
	452210*	Department Stores	2,899,338,610
	452311*	Warehouse Clubs and Supercenters	13,159,528,688
Analytical Labs	541380	Testing Laboratories	3,031,746
Teaching institute	611310	Colleges, Universities and Professional Schools	97,657,501
Researcher	541715*	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)	11,331,597
Canine Handler	561612	Security Guards and Patrol Services	3,740,383
Practitioner, Mid-level Practitioner,** Narcotic Treatment Program, Hospital/ Clinic	541940	Veterinary Services	1,067,601
	621111	Offices of Physicians (except Mental Health Specialists)	2,299,354
	621112	Offices of Physicians, Mental Health Specialists	476,408
	621210	Offices of Dentists	836,911
	621330	Offices of Mental Health Practitioners (except Physicians)	393,471
	621391	Offices of Podiatrists	550,257
	621420	Outpatient Mental Health and Substance Abuse Centers	2,982,804

Business Activity	NAICS Code	NAICS Code Description	Average Annual Revenue ($)
	621491	HMO Medical Centers	68,506,712
	621493	Freestanding Ambulatory Surgical and Emergency Centers	5,844,323
	622110	General Medical and Surgical Hospitals	284,660,783
	622210	Psychiatric and Substance Abuse Hospitals	48,476,596
	622310	Specialty (except Psychiatric and Substance Abuse) Hospitals	97,844,233
Chemical Manufacturer	325	Chemical Manufacturing	80,834,558
Chemical Distributor, Chemical Importer, Chemical Exporter	424690	Other Chemical and Allied Products Merchant Wholesalers	26,492,119

Source: SUSB, 2012 SUSB Annual Datasets by Establishment Industry. (latest available) https://www.census.gov/data/datasets/2012/econ/susb/2012-susb.html (accessed 10/5/2019)
*NAICS code was updated in the 2017 NAICS. The annual revenue figures for these industries are based on corresponding 2012 SUSB industry data.
**Practitioners and mid-level practitioners are generally employed in one of these industries.

Additionally, while many practitioner and mid-level practitioner registration application fees may be paid by the employer, some may pay out-of-pocket. Table 13 indicates the labor categories and average annual wages, as provided by the U.S. Department of Labor, Bureau of Labor Statistics (BLS), affected by the rule.

Table 13: Labor Categories of DEA Registrants

Occupation Code	Occupation Title	Annual Mean Wage
29-1021	Dentists, General	$175,840
29-1060	Physicians and Surgeons	$210,980
29-1071	Physician Assistants	$108,430
29-1171	Nurse Practitioners	$110,030

Source: BLS, May 2018 National Occupational Employment and Wage Estimates, United States. https://www.bls.gov/oes/current/oes_nat.htm (accessed 10/5/2019).

The listing of industry sectors and labor categories in Tables 12 and 13 are not intended to be exhaustive, but to generally represent DEA registrants.

Economic Impact Analysis of New Fee

The new fees are expected to have two levels of impact. Initially, the fee increase will impact the registrants. Then, the fee increase, or portion of the fee increase, is expected to be

eventually passed on to the general public. To be analytically conservative, the analysis below assumes that the impact of the fee increase is absorbed entirely by the registrants.

DEA assumes that the registration fees are business expenses for all registrants. As a result, the increase in registration fees may result in reduced tax liability, which may diminish the impact of the increase. For example, if a practitioner pays an additional $52 per year in registration fees, and the combined federal and state income tax is 35 percent, the net cash impact is $34, not $52. The additional expense of $52 causes income/profit to decrease by $52, decreasing the tax liability by $18. The net cash outlay is $34.[29] However, to be analytically conservative, the analysis does not consider the impact of reduced tax liability.

As individual practitioners and small businesses are expected to experience the greatest impact, DEA examined the new fees as a percentage of income for physicians, dentists, physician assistants, nurse practitioners, and small businesses. Physicians, dentists, physician assistants, and nurse practitioners reflect a representative sub-group of the practitioner and mid-level practitioner registrant groups. The new fee for practitioners and mid-level practitioners of $888 per three years represents a $157 increase over the current fee of $731 per three years. The annual increase is $52, representing 0.025 percent, 0.030 percent, 0.048 percent, and 0.048 percent of average annual income for physicians, dentists, physician assistants, and nurse practitioners, respectively. Table 14 indicates the annual effect as a percentage of income. The impact on small businesses is discussed in the Regulatory Flexibility Act section.

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

Table 14: Fee Increase as Percentage of Annual Mean Wage

Occupation Code	Occupation Title	Annual Mean Wage	Annual Fee Increase of Annual Mean Wage
29-1060	Physicians and Surgeons	$210,980	0.025%
29-1021	Dentists, General	$175,840	0.030%
29-1071	Physician Assistants	$108,430	0.048%
29-1171	Nurse Practitioners	$110,030	0.048%

Additionally, the impact of the fee increase is also diminished by an estimated increase in registrant income. The table below describes the annual-equivalent fee as a percentage of income in 2012, the year of the last fee increase, and 2021. This analysis assumes that the fee increase is absorbed personally by each practitioner or mid-level practitioner. In 2012, the new fee of $244 (on an annual basis) represented approximately 0.15 percent, 0.13 percent, 0.26 percent, and 0.27 percent of annual income for dentists, physicians, physician assistants, and nurse practitioners, respectively. While the new fees are 21 percent above the current fees implemented in 2012, the average incomes for dentists, physicians, physician assistants, and nurse practitioners increased an average 12 percent, 17 percent, 26 percent, and 30 percent, respectively, since that time.[30] This estimated increase in average income lessens the impact of the fee increase as a percentage of average income. The new fees are estimated to represent approximately 0.16 percent, 0.13 percent, 0.25 percent, and 0.25 percent of annual income for dentists, physicians, physician assistants, and nurse practitioners, respectively. Furthermore, a 21 percent increase ($731 to $888) over nine years, from FY 2012 to FY 2021, equates to a 2.2 percent annual rate (on compound annual growth rate basis), which is comparable to the rate of

[30] From Table 14, the increase in annual mean wages from 2012 to 2021 are for dentists 12 percent (182,140/163,240-1), physicians 17 percent (221,440/190,060-1), physician assistants 26 percent (116,415/92,460-1), and nurse practitioners 30 percent (119,320/91,450-1).

inflation. The same increase equates to a 1.8 percent annual rate over 11 years, from FY 2012 to FY 2023. This analysis ignores the dampening effect of registration fees as a business expense and the potential that the fee increase might be passed on to customers. Table 15 represents fees as percentage of average income.

Table 15: Fees as Percentage of Annual Mean Wage in 2012 and 2021

	2012			2018	2021		
Occupation Title	**Annual Mean Wage ($)**	**Annual Fee ($)***	**Fee of Wage**	**Annual Mean Wage ($)**	**Annual Mean Wage ($)****	**Annual Fee ($)*****	**Fee of Wage**
Dentists, General	163,240	244	0.15%	175,840	182,140	296	0.16%
Physicians and Surgeons	190,060	244	0.13%	$ 210,980	221,440	296	0.13%
Physician Assistants	92,460	244	0.26%	108,430	116,415	296	0.25%
Nurse Practitioners	91,450	244	0.27%	110,030	119,320	296	0.25%

Source: BLS. https://www.bls.gov/oes/tables.htm (accessed 10/5/2019).
*The current fee is $731 per three years, annual-equivalent of $244.
**Annual mean wage data for 2012 and 2018 is provided by the Bureau of Labor Statistics. The 2021 annual mean wage figures are estimated based on linear extrapolation, where an average annual increase is calculated from years 2012 to 2018, then extending out the increase for three more years to 2021.
***The new fee is $888 per three years, annual-equivalent of $296.

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

d. Analysis of Benefits, Costs, and Transfers

Benefits

The primary benefit of the rule is continued support to the DCP, without the need for any additional congressional appropriations. The DCP is a strategic component of U.S. 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 U.S. due to the diversion of controlled substances and listed chemicals into the illicit market as discussed earlier in this document.

Costs

This rule has little or no cost, as fees to DEA are transfer payments.

Transfers

The difference between the current fees and the new fees – the fee increase – is $318 million over the three year period, from FY 2021 to FY 2023, or approximately $106 million annually. The difference in the fees projected to be collected under the current fee rates and the new fee rates is $102 million, $105 million, and $110 million in FY 2021, FY 2022, and FY 2023, respectively. Table 16 summarizes the estimated collections under the current fees, estimated collections under the new fees, and the difference between the current and the new fees.

Table 16: Estimated Collections under Current and New Fees

Estimated Collections	FY 2021 ($M)	FY 2022 ($M)	FY 2023 ($M)	Total ($M)
Current Fee	474	491	514	1,479
New Fee	576	596	625	1,797
Difference	102	105	110	318

The present value of the transfer is $299 million at a three percent discount rate and $277 million at a seven percent discount rate.

E.O. 13771 was issued on January 30, 2017, and published in the *Federal Register* on February 3, 2017. 82 FR 9339. This rule is not subject to the requirements of E.O. 13771 because this rule is expected to result in no more than *de minimis* costs.

Executive Order 12988, Civil Justice Reform

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

Executive Order 13132, Federalism

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

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities between the Federal government and Indian tribes**.**

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this rule and by approving it, certifies that it will not, if promulgated, have a significant economic impact on a substantial number of small entities.

The RFA requires agencies to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. DEA evaluated the impact of this rule on small entities, and discussions of its findings are below.

As discussed above and in the Economic Analysis section above, DEA analyzed three fee calculation methodologies – Flat Fee, Past-Based, and Weighted-Ratio. DEA selected the

Weighted-Ratio (current) methodology to calculate the new fee structure. This approach has been used since Congress established registration fees, and continues to be a reasonable reflection of differing costs. The registration fees under the Weighted-Ratio option result in differentiated fees among registrant groups, where registrants with larger revenues pay higher fees than registrants with lower revenues. Furthermore, the Weighted-Ratio option 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 current fee have proven effective and reasonable over time. Additionally, the weighted-ratio calculation methodology generally reflects the differences in activity level, notably in inspections, scheduled investigations and other control and monitoring, by registrant category; for example, these costs are greatest for manufacturers. DEA selected this option because it is the only option that results in reasonable fees for all registrant groups.

This approach increases fees proportionally (21 percent) across all registrant groups, maintaining the weighted-ratio of 1.0, 3.0, 6.25, and 12.5. The annual increase in fees are $52, $327, and $652 based on business activity. The table below summarizes the difference in fees between the new and current fees.

Table 17: Difference in Fees under Current and New Fees

Business Activity	Total Registrations (FY 2021-FY 2023)	Current Fees ($)	New Fees ($)	Total Collections Under New Fees ($)	Difference in Fees ($)*
Registrants on Three Year Registration Cycle					
Pharmacy	80,199	731	888	71,216,712	157
Hospital/Clinic	16,638	731	888	14,774,544	157
Practitioner	1,356,876	731	888	1,204,905,888	157
Teaching Institution	130	731	888	115,440	157
Mid-level Practitioner (MLP)	539,899	731	888	479,430,312	157
Registrants on Annual Registration Cycle					
Manufacturer	1,733	3,047	3,699	6,410,367	652

Distributor	1,999	1,523	1,850	3,698,150	327
Researcher/Canine Handler	15,113	244	296	4,473,448	52
Analytical Lab	2,724	244	296	806,304	52
Importer	666	1,523	1,850	1,232,100	327
Exporter	792	1,523	1,850	1,465,200	327
Reverse Distributor	219	1,523	1,850	405,150	327
Narcotic Treatment Program	5,935	244	296	1,756,760	52
Chemical Manufacturer	624	3,047	3,699	2,308,176	652
Chemical Importer	606	1,523	1,850	1,121,100	327
Chemical Distributor	988	1,523	1,850	1,827,800	327
Chemical Exporter	450	1,523	1,850	832,500	327
Total	**2,025,591**	**N/A**	**N/A**	**1,796,779,951**	**N/A**

*The difference for registrations on a three-year cycle is $157 or $52 on annual basis.

As shown in Table 12, the new fees would affect a wide variety of entities across many industry sectors. As some industry sectors are expected to consist primarily of DEA registrants, *i.e.*, 446110-Pharmacies and Drug Stores, 622110-General Medical and Surgical Hospitals, etc., this rule is expected to affect a substantial number of small entities.

DEA compared the annual increase in fees from current fees to new fees for the smallest of small businesses in each industry sectors. For each of the affected industry sectors, the annual increase was not more than 0.1 percent of average annual revenue. The table below summarizes the results.

Table 18: Fee Increase as Percentage of Annual Revenue

NAICS Code	NAICS Code Description	Enterprise Size (number of employees)	Number of Establish-ments	Average Revenue per Establishment ($)	Fee Increase ($)	Fee Increase of Revenue
325	Chemical Manufacturing	0-4	3,148	1,938,546	652	0.0319%
325411	Medicinal and Botanical Manufacturing	0-4	108	727,444	652	0.0851%
325412	Pharmaceutical Preparation Manufacturing	5-9*	129	2,639,287	652	0.0235%
424210	Drugs and Druggists' Sundries Merchant Wholesalers	0-4	3,630	1,367,131	327	0.0239%
424690	Other Chemical and Allied Products Merchant Wholesalers	0-4	3,352	2,007,996	327	0.0154%

NAICS Code	NAICS Code Description	Enterprise Size (number of employees)	Number of Establish-ments	Average Revenue per Establishment ($)	Fee Increase ($)	Fee Increase of Revenue
445110	Supermarkets and Other Grocery (except Convenience) Stores	0-4	23,710	453,787	52	0.0108%
446110	Pharmacies and Drug Stores	0-4	6,360	1,069,655	52	0.0046%
452112	Discount Department Stores	0-4	6	266,167	52	0.0184%
452910	Warehouse Clubs and Supercenters	0-4	12	326,333	52	0.0150%
541380	Testing Laboratories	0-4	2,415	297,737	52	0.0165%
541712	Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)	0-4	5,013	427,790	52	0.0115%
541940	Veterinary Services	0-4	8,881	292,166	52	0.0168%
561612	Security Guards and Patrol Services	0-4	2,162	114,198	52	0.0429%
5621	Waste Collection	0-4	3,853	365,902	327	0.0844%
5622	Waste Treatment and Disposal	0-4	616	461,159	327	0.0670%
611310	Colleges, Universities, and Professional Schools	0-4	372	913,078	52	0.0054%
621111	Offices of Physicians (except Mental Health Specialists)	0-4	95,648	447,715	52	0.0109%
621112	Offices of Physicians, Mental Health Specialists	0-4	8,980	253,837	52	0.0193%
621210	Offices of Dentists	0-4	50,781	330,868	52	0.0148%
621320	Offices of Optometrists	0-4	10,939	269,348	52	0.0182%
621330	Offices of Mental Health Practitioners (except Physicians)	0-4	16,149	145,005	52	0.0338%
621391	Offices of Podiatrists	0-4	5,300	288,546	52	0.0170%
621420	Outpatient Mental Health and Substance Abuse Centers	0-4	1,810	211,249	52	0.0232%
621491	HMO Medical Centers	5-9*	16	620,188	52	0.0079%
621493	Freestanding Ambulatory Surgical and Emergency Centers	0-4	1,011	549,974	52	0.0089%
622110	General Medical and Surgical Hospitals	0-4	39	10,621,308	52	0.0005%
622210	Psychiatric and Substance Abuse Hospitals	20-99*	27	5,142,444	52	0.0010%
622310	Specialty (except Psychiatric and Substance Abuse) Hospitals	0-4	21	8,561,238	52	0.0006%

*Where the revenue figure for the smallest size category is unavailable, the next size up with available revenue figure is used.

While this rule affects a substantial number of small businesses, because the economic impact for the smallest of small businesses is not significant, the rule will not have a significant

impact on small entities as a whole. In summary, DEA's evaluation of economic impact by size category indicates that the rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $154 million or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed subject to the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.

Paperwork Reduction Act of 1995

This rulemaking does not create or modify a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rulemaking will not impose additional recordkeeping or reporting requirements on State or local governments, individuals, businesses, or other organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number.

Congressional Review Act

This final rule is a major rule as defined by the Congressional Review Act, 5 U.S.C. 804. This rule will result in an annual effect on the economy of $100,000,000 or more in the form of transfers, as fees paid to DEA are considered transfer payments and not costs. However, this rule will not cause a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign-based companies in domestic and export markets. DEA submitted a copy of the final rule to both Houses of Congress and to the Comptroller General.

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 forth above, DEA amends 21 CFR parts 1301 and 1309 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, 956, 957, 958, 965.

2. Amend § 1301.13 by revising the fourth sentence in paragraph (e) introductory text and 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) * * * Generally, the application fees are not refundable; however, they may be issued in limited circumstances at the discretion of the Administrator. These circumstances include: applicant error, such as duplicate payments, payment for incorrect business activities, or payments made by persons who are exempt under this section from application or renewal fees; DEA error; and death of a registrant within the first year of the three-year registration cycle. *

* *

(1)

Summary of Registration Requirements and Limitations

Business Activity		Controlled Substances	DEA Application Forms	Application Fee ($)	Registration Period (years)	Coincident Activities Allowed
(i) Manufacturing		Schedules I –V	New—225 Renewal—225a	3,699	1	Schedules I-V: May distribute that substance or class for which registration was issued; may not distribute or dispose any substance or class for which not registered. Schedules II-V: May conduct chemical analysis and preclinical research (including quality control analysis) with substances listed in those schedules for which authorization as a mfr. was issued.
(ii) Distributing		Schedules I-V	New—225 Renewal---225a	1,850	1	May acquire Schedules II-V controlled substances from collectors for the purposes of destruction.
(iii) Reverse distributing		Schedules I-V	New—225 Renewal---225a	1,850	1	
(iv) Dispensing or instructing (includes Practitioner, Hospital/ Clinic, Retail Pharmacy, Central fill pharmacy, Teaching Institution)		Schedules II-V	New---224 Renewal---224a	888	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	296	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	296	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	296	1	
(viii) Importing		Schedules I-V	New—225 Renewal—225a	1,850	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	1,850	1	

(x) Chemical Analysis		Schedules I-V	New—225 Renewal—225a	296	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 continues 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 for distribution the applicant shall pay an annual fee of $3,699.

(b) For each application for registration or reregistration to distribute (either retail distribution or non-retail distribution), import, or export a list I chemical, the applicant shall pay an annual fee of $1,850.

5. Amend §1309.12 by revising the last sentence in paragraph (b) to read as follows:

§ 1309.12 Time and method of payment; refund.

* * * * *

(b) * * * Generally, the application fees are not refundable; however, they may be issued in limited circumstances at the discretion of the Administrator. These circumstances include: applicant error, such as duplicate payments, payment for incorrect business activities, or payments made by persons who are exempt under this section from application or renewal fees; DEA error; and death of a registrant within the first year of the three-year registration cycle.

6. Amend § 1309.21 by revising the table in 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
(1) Manufacturing	List I, Drug products containing ephedrine, pseudoephedrine, phenylpropanolamine	New–510 Renewal–510a	3,699	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
(2) Distributing	List I, Scheduled listed chemical products	New–510 Renewal–510a	1,850	1	
(3) Importing	List I, Drug Products containing ephedrine, pseudoephedrine, phenylpropanolamine	New–510 Renewal–510a	1,850	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
(4) Exporting	List I, Scheduled listed chemical products	New–510 Renewal–510a	1,850	1	

_____

Timothy J. Shea,
Acting Administrator.

[FR Doc. 2020-16169 Filed: 7/23/2020 8:45 am; Publication Date: 7/24/2020]