All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded from and comments submitted through *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, Georgia 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to amend Class D airspace by updating the geographic coordinates and remove Class E airspace extending upward from 700 feet above the surface at Bogue Field Marine Corps Auxiliary Landing Field, Bogue, NC as the airport has no instrument approaches. Therefore, the Class E airspace is no longer necessary. This action would enhance the safety and management of controlled airspace within the national airspace system. This action would also replace the outdated term Airport/Facility Directory with the term Chart Supplement in the legal description of associated Class D airspace.

Class D and E airspace designations are published in Paragraphs 5000 and 6005, respectively, of FAA Order 7400.11D, dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1.

The Class E airspace designation listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal would be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, effective September 15, 2019, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO NC D Bogue, NC [Amended]

Bogue Field MCALF, NC
(Lat. 34°41′24″ N, long. 77°01′45″ W)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 4.5-mile radius of Bogue Field MCALF. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO NC E5 Bogue, NC [Removed]

Issued in College Park, Georgia, on March 5, 2020.

Ryan Almasy,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2020–05214 Filed 3–13–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[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: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes 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.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before May 15, 2020. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''RIN 1117–AB51/Docket No. DEA–501'' on all correspondence, including any attachments.

• *Electronic Comments:* The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment.

• *Paper Comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, VA 22152.

• *Paperwork Reduction Act Comments:* All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117–AB51/Docket No. DEA–501.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received, including attachments and other supporting materials, are considered part of the public record. They will be made available by DEA for public inspection online at *https://www.regulations.gov.* Additionally, the Freedom of Information Act applies to all comments received. Confidential information or personal identifying information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information.

For comments with confidential or personal identifying information, which should not be made available to the public, submit the comment as a written/paper submission. Two written/paper copies should be submitted. One copy will include the confidential information with a heading or cover note that states ''CONTAINS CONFIDENTIAL INFORMATION.'' DEA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy should have the claimed confidential information redacted/blacked out. DEA will make this copy available for public viewing online at *https://www.regulations.gov.* Other information, such as name and contact information, which should not be made available, may be included on the cover sheet but not in the body of the comments. Such information must be identified as ''confidential.'' Any information marked as ''confidential'' will not be disclosed.

An electronic copy of this document and supplemental information, including the Registration Fee Calculation Methodology, to this notice of proposed rulemaking are available in their entirety under the tab ''Supporting Documents'' of the public docket of this action at *https://www.regulations.gov* under [FDMS Docket ID: DEA–501 (RIN 1117–AB51/Docket Number DEA–501)] for easy reference.

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 (U.S.). The DCP is responsible for maintaining a closed system of distribution by preventing diversion of controlled substances and listed chemicals in the U.S. and enforcing the provisions of the Controlled Substances Act (CSA) for DEA. The DCP regulates over 1.8 million registrants, ensuring their compliance with the CSA.

Proposed Changes to the Fees and Regulations

With this Notice of Proposed Rulemaking (NPRM), DEA proposes amendments to the following sections in the Code of Federal Regulations (CFR): 21 CFR 1301.13, 1309.11, 1309.12, and 1309.21. The proposed amendments would codify new registration fees for business activities involving controlled substances, as well as list I chemicals and drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine. The proposed amendments would also codify existing practices of when DEA will issue refunds for application fees. As detailed in the ''Fee Calculation'' section of this NPRM, DEA evaluated three fee structure options (including the current fee structure) and chose the most reasonable option.

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

In developing this proposed rule, DEA examined three alternative methodologies to calculate the registration and reregistration fees: Flat Fee Option, Past-Based Option, and Weighted-Ratio Option (current and proposed 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.

A detailed analysis of these three options can be found under section heading ''Proposed Methodology for New Fee Calculation.''

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. It is primarily the DCP

within DEA that implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the CSA and the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801–971), as amended (hereinafter, ''CSA'').[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 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.

Benefits, Costs, and Transfers

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. This proposed rule would fund the continued operation of the DCP.

The total proposed fee increase is $318 million over the three year period, fiscal year (FY) 2021–FY 2023. Specifically, the difference in the fees projected to be collected under the current fee rates and in the fees projected to be collected under the proposed new fee rates is $102 million, $105 million, and $110 million in FY 2021, FY 2022, and FY 2023, respectively. (Figures are rounded.)

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.''

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] The AMA appealed. Upon 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 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

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

[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)).

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

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

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 the 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 Diversion Control Program. 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 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, that require that the 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 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 an 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 proposed 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 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 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

[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.*

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

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 United States. 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 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 (CHEMS), 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 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.

Increased Need for Diversion Control

Opioid Crisis

The misuse of and addiction to opioids is a serious national crisis affecting the public health and welfare of all Americans. Furthermore, in 2018, there were 67,367 overdose deaths in the United States. The rate of opioid overdose deaths increased by over 70 percent from 2016 through 2018.[9] Some prescription pain relievers are opioids, which are classified by DEA as controlled substances and placed in schedules II–IV.

The misuse of prescription drugs is a serious concern. Misuse occurs when a medication is taken in a manner other than how prescribed, or when the medication is taken by a person, other than the person to whom it was prescribed. Opioids are one of the most common types of misused medication.[10] Statistics show that 21 to 29 percent of patients who are prescribed an opioid misuse it, resulting in 8 to 12 percent of them developing an opioid use disorder.[11] During the past 15 years, there has been an increase in emergency visits, overdose deaths, and treatment admissions for misuse disorders because of the increase in prescription drug misuse. In 2018, the percentage of involvement of prescription opioids in overdose deaths in the United States was over three times higher than in 1999.[12] In 2018, an estimated 2.0 million people in the U.S. were dealing with substance use disorders involving prescription opioids.[13] It is estimated that the misuse of prescription opioids has an economic burden of $78.5 billion annually on the United States.[14]

Due to the rise in prescription opioid abuse and the grave concern for public safety, Congress, as well as DEA, have had to take significant measures to protect citizens. In October 2017, President Trump called the opioid epidemic a ''national health emergency.'' [15] Furthermore, the

[7] 21 U.S.C. 811–814.

[8] See 21 U.S.C. 830, 957–58.

[9] Centers for Disease Control and Prevention. ''Drug Overdose Deaths in the United States, 1999–2018.'' Accessed February 11, 2020. *https://www.cdc.gov/nchs/products/databriefs/db356.htm.*

[10] Substance Abuse and Mental Health Services Administration (SAMHSA). ''The National Survey on Drug Use and Health: 2018.'' Accessed February 11, 2020. *https://www.samhsa.gov/data/release/2018-national-survey-drug-use-and-health-nsduh-releases.*

[11] *Id.*

[12] Centers for Disease Control and Prevention. ''Drug Overdose Deaths in the United States, 1999–2018.'' Accessed February 11, 2020. *https://www.cdc.gov/nchs/products/databriefs/db356.htm.*

[13] Substance Abuse and Mental Health Services Administration (SAMHSA). ''The National Survey on Drug Use and Health: 2018.'' Accessed February 11, 2020. *https://www.samhsa.gov/data/release/2018-national-survey-drug-use-and-health-nsduh-releases.*

[14] *Id.*

[15] Centers for Medicare & Medicaid Services. ''Opioid Crisis.'' Ongoing emergencies & disasters. Accessed October 4, 2019. *https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Ongoing-emergencies.html.*

Department of Health and Human Services (HHS) formally determined there was a public health emergency nationwide in October 2017, which was most recently renewed in January 2020. The overdose and abuse ''has reached epidemic levels and currently shows no signs of abating, affecting large portions of the United States.'' [16] As such, the opioid crisis requires and continues to receive a magnitude of attention from the DC.

Increased Registrant Population

At the time of the last fee increase, there were 1.4 million DEA registrants. Currently, the DCP regulates over 1.8 million registrants. DEA's regulated industry increases approximately 3 percent per year annually. It is estimated that there will be over 2 million registrants by 2023. The DCP must continue to effectively manage and support this growing registrant population through inspections, improvements to the registration process, enhanced information technology tools, and providing informative education and outreach forums.

Changes to the CSA Since the Last Fee Rule

Since implementation of the last fee rule in 2012, Congress has made several changes to the CSA that impact how the DCP operates. These changes have expanded the responsibility and scope of the DCP. Congress' expansion of the CSA aids the DCP in addressing diversion threats and the national opioid crisis. While DEA may not have yet finalized implementing regulations for the CSA amendments, they are Federal law and therefore, followed by DEA. The implementation of these CSA amendments requires a commensurate increase in regulatory and enforcement activities which must be funded by the DCFA in order to fully fund activities related to the DCP.

Designer Anabolic Steroid Control Act of 2014

The Designer Anabolic Steroid Control Act (DASCA) of 2014 [17] became law on December 18, 2014, with the purpose of regulating anabolic steroids more effectively.[18] DASCA amended the CSA by revising and adding specified substances to the definition of ''anabolic steroid.'' DASCA provided a new mechanism for temporary and permanent scheduling of anabolic steroids, and added specific labeling requirements for products containing anabolic steroids. This amendment increased the number of schedule III controlled substances, by adding 22 new substances. As such, the manufacture, import, export, distribution, or sale of the 22 anabolic steroids or a substance meeting the revised definition of an anabolic steroid is a violation of the CSA, unless done by a DEA registrant. These additions have now been brought under the scope of the DCP together with the performance of the applicable regulatory and enforcement functions.

Comprehensive Addiction and Recovery Act of 2016

The Comprehensive Addiction and Recovery Act (CARA) of 2016 [19] became law on July 22, 2016. CARA amended the CSA by temporarily [20] expanding the type of practitioners who may, under certain conditions, dispense a narcotic drug in schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment, through October 1, 2021. In particular, the CARA amended the CSA to temporarily permit certain nurse practitioners and physician assistants to be considered a ''qualifying other practitioner,'' allowing them to meet the requirements for who can dispense a narcotic drug for the purposes of maintenance treatment or detoxification treatment, without requiring a separate registration. This is known as being a DATA-Waived Physician. Under the authorization of the CSA, the DCP conducts periodic on-site inspections of all registrants, including those who are DATA-waived.

The Protecting Patient Access to Emergency Medications Act of 2017

The ''Protecting Patient Access to Emergency Medications Act of 2017,'' [21] which became law on November 17, 2017, amended the CSA to create a new registration category for emergency medical services agencies that handle controlled substances. It also established standards for registering emergency medical services agencies, and set forth new requirements for delivery, storage, and recordkeeping related to their handling of controlled substances. In addition, the Act allows emergency medical services professionals to administer controlled substances outside the physical presence of a medical director or authorizing medical professional pursuant to a valid standing or verbal order. In particular, through this amendment, a registered Emergency Medical Service (EMS) agency is allowed to obtain a single registration for each State in which the agency administers controlled substances, rather than requiring the agency to obtain a separate registration for each location at which it operates within that State. The CSA was also amended to allow DEA to issue regulations regarding the delivery and storage of controlled substances by EMS agencies. The issuance of these regulations, as well as the processing of the registrations, fall within the scope of the DCP's functions.

Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act),[22] was signed into law, addressing the opioid epidemic. The SUPPORT Act affected many of the DCP's regulatory and enforcement functions, falling under the purview of the DCFA. To prevent diversion, the CSA was amended requiring DEA to establish a centralized database for collecting reports of suspicious orders. The SUPPORT act also added the term ''suspicious order'' to the CSA, as well as defined it. Also, the SUPPORT Act's amendments require drug manufacturers and distributors be given access to anonymized Automated Reports and Consolidated Ordering System (ARCOS) data, regarding: (1) The total number of competitors that sold a particular controlled substance to a prospective customer (pharmacy or practitioner); and (2) the quantity and type of opioids distributed. This provision required DEA to launch a new tool to help more than 1,500 drug manufacturers and distributors nationwide to more effectively identify, report, and stop suspicious orders of opioids and reduce diversion rates through the use of ARCOS.

The SUPPORT Act also amended the CSA to allow a pharmacy to deliver a controlled substance to a practitioner at the location listed on the practitioner's

[16] 2018 National Drug Threat Assessment. Drug Enforcement Administration. October 2018.

[17] ''Designer Anabolic Steroid Control Act,'' Public Law 113–260 (128 Stat. 2929).

[18] H.R. Rep. No. 113–587, Part 2.

[19] ''Comprehensive Addiction and Recovery Act of 2016,'' Public Law 114–198.

[20] While CARA temporarily expanded the type of practitioners who could dispense, the ''Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act,'' (Pub. L. 115–271) has eliminated the time limit for some of the practitioners and increased the temporary expansion for other practitioners.

[21] ''Protecting Patient Access to Emergency Medications Act of 2017,'' Public Law 115–83 (131 Stat. 1267).

[22] ''Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act,'' Public Law 115–271.

certificate of registration for the purpose of maintenance or detoxification treatment. Further, the SUPPORT Act allows a hospice employee to handle lawfully-dispensed controlled substances of a hospice patient to assist with the on-site disposal of the controlled substances in three specific circumstances: (1) The disposal occurs after the death of a person receiving hospice care; (2) the controlled substance is expired; or (3) change of care of the patient only, in instances where the employee is a DEA registrant and practitioner of the patient.

Through the SUPPORT Act, DEA gained the authority to establish procurement quotas in terms of pharmaceutical dosage form to avoid overproductions, shortages, or diversion of a controlled substance. This also amended the statutory deadline for manufacturing quotas to be fixed by changing from October 1 to December 1. Further, it is now required that DEA estimate the diversion of the five covered controlled substances—fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone—and make appropriate quota reductions. If the aggregate production quotas (APQ) of any covered controlled substance exceeds the APQ of the previous year, it must be explained why the benefits of higher quota outweigh the risks.

The CSA was also amended through the SUPPORT Act to allow for more flexibility with respect to more medication-assisted treatment for opioid use disorders. The provisions expand the type of practitioners that may obtain a DATA-waiver. It eliminated the time limitation for nurse practitioners and physician assistants to become qualifying practitioners and imposed a five-year time limitation on clinical nurse specialists, registered nurse anesthetists, and certified nurse midwives to become a qualifying practitioner. The provisions also permanently codify the 275 patient limit for DATA-waived practitioners, which the DCP added to its regulations in January, 2018.[23] A new accreditation option for a qualifying physician was added, making a physician eligible for a waiver if they graduated in good standing from a medical school within five years of the date of notification to the Secretary to be DATA-waived, and during the practitioner's curriculum or medical residency, the practitioner completed at least eight hours of training on treating and managing opioid-dependent patients.

Last, the SUPPORT Act required the promulgation of regulations to specify the procedure for obtaining a special registration for telemedicine and the limited circumstances in which a special registration may be issued. The SUPPORT Act also required the updating of regulations for the biometric component of multifactor authentication in electronic prescriptions for controlled substances.

Conclusion

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 proposed increase will fund personnel and operations supporting the DCP mission to prevent and detect diversion, protect the closed system of distribution of the United States, 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).

The Diversion Control Division manages the DCP to maintain the integrity of the closed system of distribution which is essential in combatting the opioid epidemic. DC continues to face unique challenges including supporting a customer base of over 1.8 million DEA registrants, as well as combating the alarming increase in opioid drug abuse. The aforementioned statutory changes, as well as the expanding threat of diversion, required the DCP to implement program and organizational changes funded through the DCFA.

Operational Changes Within the Diversion Control Program Since 2012

Elevation to Division

In October 2016, the Office of Diversion Control was elevated from an Office to a Division, and was renamed the Diversion Control Division. This change was made with the purpose of continuing to enhance operational effectiveness, strengthen internal controls, and support a stronger focus on the agency's mission. Two offices were established when the Division was created: The Office of Diversion Control Regulatory (DR), and the Office of Diversion Control Operations (DO). In 2018, the Office of Diversion Control Policy (DP) was added to the Division to accommodate continued and projected growth of the DCP. The restructure resulted in the increase of regulatory, enforcement, and outreach efforts to allow DEA to minimize diversion opportunities through more regulatory inspections of various registrant groups; increased education and outreach opportunities; and identifying more sources of diversion and taking administrative, civil, and/or criminal action against those operating outside the normal course of medical practice/registrant business. The DCP reorganized to optimize its resources and to improve the ability to identify and respond to diversion threats. Additionally, DEA expanded its resources and targeted its investigation strategies to collaborate with state and local entities and enhance the effectiveness of its diversion investigations. In addition, DEA expanded its use of Tactical Diversion Squads (TDS) to more effectively respond to criminal investigations involving controlled pharmaceuticals.

DEA 360 Strategy

In response to the rising number of opioid-related deaths, DEA launched its 360 Strategy in 2015 with the purpose of ending the deadly cycle of prescription opioid misuse through coordinated law enforcement, diversion control, and community outreach efforts. The DEA 360 Strategy involves coordinated law enforcement operations targeting all levels of drug trafficking organizations and violent gangs supplying drugs to our neighborhoods; engaging drug manufacturers, wholesalers, practitioners, and pharmacists through diversion control to increase awareness of the opioid epidemic and encourage responsible prescribing practices throughout the medical community; and community outreach and partnership with local organizations following enforcement operations, equipping and empowering communities to fight the opioid epidemic.

The DCP's efforts to support this initiative are geared toward preventing the non-medical abuse of controlled pharmaceutical substances through scheduled investigations and by providing education and training within the pharmaceutical and medical

[23] ''Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder.'' (83 FR 3071, January 23, 2018).

community and to pursue those practitioners who are operating outside of reasonable medical standards. The DCP continues to engage with industry, practitioners, and government health organizations to facilitate an honest discussion about prescription drug abuse. Since FY 2015, there has been a significant increase in the total number of outreach activities. These activities are 80 percent funded by the DCFA and 20 percent of the project receives appropriated funding. The number of total outreach activities has increased from 191 in FY 2015 to 2,394 in FY 2019, an increase of 1,153.40 percent, the costs of which must be funded by the DCFA.

National Take-Back Initiative

The DCP continues to be proactive in its efforts to prevent diversion and focus on enhancing outreach efforts as they relate to controlled substances and listed chemicals. As of October 26, 2019, a total of 18 separate National Prescription Drug Take-Back Initiative (NTBI) events have collected a total of 9,964,714 pounds (4,982.357 tons) of unused pharmaceuticals from the medicine cabinets of U.S. citizens across the country and its territories, at 75,283 collection sites, in conjunction with 66,013 law enforcement partners.

The diversion of pharmaceutical controlled substances is a significant problem in the United States, as all reliable studies indicate that the abuse (non-medical use) of these drugs has reached alarming levels in recent years. One potential factor that may contribute to the increase in abuse is the availability of these drugs in household medicine cabinets. 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. 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 do not know how to dispose of them.

The NTBI effort is an example of the DCP's commitment to community outreach efforts and the extreme need for options for the disposal of 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.

Tactical Diversion Squads

To respond to the increasing rate of criminal diversion and a growing registrant population, DEA has expanded its resources and targeted investigation strategies in ways to collaborate with state and local entities and enhance the effectiveness of its Diversion Control Program. Specifically, DEA has expanded its use of TDSs, which work with DEA's state, local, and other federal partners, to maximize resources and improve efforts to investigate, disrupt, and dismantle individuals or organizations involved in diversion schemes related to controlled substances and listed chemicals.

TDSs were established to investigate the criminal actions of DEA registrants. In 2011, there were 40 operational TDSs in the DCP. As of FY 2020, there were 86 operational TDSs in 48 states, the District of Columbia, and Puerto Rico.

TDSs investigate suspected violations of the CSA and other Federal statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. 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 law enforcement abilities 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 per year and have made more than 2,100 arrests per year.

Regulatory

DEA continues its focus on regulatory oversight of the more than 1.8 million DEA registrants to ensure registrants comply with the CSA and its implementing regulations. DEA accomplishes this by conducting scheduled investigations of DEA registrants that are registered to handle controlled prescription drugs and listed chemicals. This proactive approach is designed to identify and prevent diversion of controlled substances and listed chemicals into the illicit market. Registrant compliance is determined primarily through the conduct of pre-registration, scheduled, and complaint investigations. DCP's regulatory activities also have an inherent deterrent function; 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 and identify those registrants who violate the CSA and implementing regulations. Pre-registration investigations reduce the possibility of registering unauthorized entities, ensure that the means to prevent diversion are in place, and help determine whether registration is consistent with the public interest.

Scheduling

The DCP continues to evaluate diversion trends, patterns, routes, and techniques in order to appropriately focus its administrative, regulatory, civil, and criminal enforcement activities. The continued spread of synthetic drugs to include synthetic cannabinoids, cathinones, phenethylamines, and opioids remains a considerable concern across the U.S. The trafficking and abuse of these dangerous and often deadly substances is a significant concern for public health and law enforcement.

DCP's efforts to identify and establish controls over dangerous drugs of abuse involves collecting scientific information to evaluate the substances for possible scheduling actions. Since the last fee rule, 23 temporary scheduling actions have been issued to control 74 new drugs of abuse and a control of fentanyl-related substances. Since 2011, 61 substances have been permanently controlled, one precursor chemical has been controlled, rulemaking has been initiated to control six precursor chemicals, and two substances have been decontrolled.

Quotas

To address prescription drug abuse and increased production and use of chemicals that contribute to the public health emergency, the DCP increased its ability to respond to diversion threats by establishing quotas and monitoring imports of narcotic raw materials, which are critical to ensuring an adequate and uninterrupted supply of legitimate medicines containing controlled substances and listed chemicals without creating an oversupply. The APQ and annual assessment of needs (AAN) are established each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the U.S., for lawful export requirements, and for the establishment and maintenance of reserve stocks. Information provided by industry (*e.g.,* import permits and declarations, sales, distributions, inventory, manufacturing schedules, losses, and product

development needs) and corroborated by consumption of these substances (*e.g.,* prescriptions, distributions to retail levels, and input from the Food and Drug Administration (FDA) on new products and indications) is utilized when determining the APQ and AAN and individual manufacturing quotas. APQs and AANs for individual substances cannot be trended and can either increase, decrease, or remain constant within a calendar year or over years, depending on any number of factors, including product development, research needs, FDA requirements for manufacturers, or changes in export requirements.

Once the APQ and AAN are established, DEA issues three different quota types (manufacturing, procurement, and import quotas) to DEA-registered manufacturers and importers for substances with the highest abuse potential (schedule I and II controlled substances and certain list I chemicals used for the production of cough and cold medicines and clandestine methamphetamine). Annually, DEA allocates over 4,000 separate quotas to over 300 different DEA bulk manufacturers and dosage form manufacturers. The quota system ensures an adequate and uninterrupted supply for the medical, scientific, research, and industrial needs of the United States, while preventing the diversion of the drugs to the illicit market.

Additionally, prior to and building upon the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA), DEA continues to work with FDA and industry on anticipating and mitigating the potential for drug shortages. In addition to the domestic quota program, DCP is responsible for the annual establishment of the UN estimates and assessments for legitimate imports and exports of all internationally controlled substances.

In accordance with changes made to the scope of the DCP to address the opioid epidemic public health emergency, DEA finalized the Controlled Substance Quotas rule in June 2018 to strengthen the process for setting controls over controlled substances and to make improvements in the quota management regulatory system for the production, manufacturing, and procurement of controlled substances.

The final rule made two additions to the list of factors that must regularly be considered in setting the APQ. First, it added the extent of any diversion of the controlled substance in the class. Second, the final rule amended the list of factors to be considered in establishing these quotas to include relevant information from HHS, FDA, Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), and the states. The amendment will ensure that information will be requested from the relevant HHS components and will be considered in setting the aggregate production quotas.

DEA has published proposed rules to improve its ability to oversee the production of drugs scheduled under the CSA and limit excess quantities of medications that might be vulnerable to diversion for illicit distribution and use at the height of the national opioid crisis. DEA is proposing important and necessary changes to DEA's quota regulations resulting from the SUPPORT Act, which requires that appropriate quota reductions be made after estimating potential for diversion. This estimate is based on rates of overdose deaths and abuse, as well as the overall public health impact related to specific controlled substances, and it may include other factors as appropriate.

DEA also proposes to amend the manner in which DEA grants quotas to manufacturers for maintaining inventories. These proposed levels align with current manufacturing standards aimed at promoting quality and efficiency, while also ensuring that the country has sufficient quantities of schedule II substances necessary for the medical, scientific, research and industrial needs of patients nationwide.

DEA has also proposed several new types of quotas that DEA would grant to certain DEA-registered manufacturers. If finalized, these use-specific quotas include quantities of controlled substances for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These use-specific quotas will greatly improve the timeliness of DEA's responses to applications filed by manufacturers while simultaneously improving DEA's ability to respond quickly to drug shortages.

Community Outreach Efforts

DCP's regulatory activities require education and outreach to ensure understanding of, and compliance with, the CSA and other applicable policies and regulations. Providing such guidance to registrants is also necessary to reduce the likelihood of diversion from the closed system of distribution outlined in the CSA. One aspect of DCP's outreach efforts is establishing and maintaining working relationships with other federal agencies, foreign, state, and local governments, industry, and the registrant population. Other educational efforts include developing and maintaining manuals and other publications; organizing and conducting national conferences on current issues, policies, and initiatives; and providing guidance to the general public. Since the last fee rule, DCP has drafted 2,700 policy letters; answered over 23,400 policy inquiries from the public, regulated industry, and DEA field personnel; and responded to 16,380 emails primarily from the public, regulated community, and DEA field personnel.

Additionally, the DCP has hosted conferences designed to educate pharmacists and pharmacy technicians regarding the growing problem of diversion and subsequent abuse of pharmaceutical controlled substances as well as proactive steps they can take towards preventing diversion. Pharmacy Diversion Awareness Conferences (PDACs) give pharmacy personnel the tools they need to identify and respond to potential diversion activity. There have been a total of 100 conferences, at 54 separate locations, in 50 states, and two territories, with over 13,401 pharmacists, pharmacy technicians, and loss prevention specialists in attendance.

As a result of the success of the PDACs, in response to the persistent opioid drug crisis, and a recognition of the need for a comparable conference for DEA registered practitioners, DEA has designed, developed, and implemented a similar type of conference for practitioners—Practitioner Diversion Awareness Conferences.

Since May 2018, DEA has held a total of 35 Practitioner Diversion Awareness Conferences, in 19 different states, with over 7,354 physicians, dentists, physician assistants, nurse practitioners, and veterinarians in attendance. To continue to support and grow these efforts, the DCP must rely on increased funding available through collection of DCFA fees.

Personnel

The DCP must maintain staffing levels sufficient to carry out its regulatory and enforcement missions and perform education and outreach activities to combat the opioid crisis and effectively respond to emerging diversion threats in order to protect public health and safety. Personnel are hired specifically into DCFA-funded positions for the sole purpose of supporting DCP activities. Obligations have increased since the last fee rule to keep pace with a growing registrant population and the need to expand the DCP footprint across the

nation to meet its regulatory and enforcement mission. The DCP has continued to control costs since the last fee increase; however, the DCP's mission has been expanded by changing diversion schemes and laws passed by Congress, which require an increase in registrant fees in order to maintain operations and protect public health and safety.

DEA has taken steps to ensure that the cost of diversion work in DEA Headquarters (HQs) is fully funded by the DCFA. In 2016, DEA realigned 161 HQs Professional/Administrative and Technical/Clerical (PATCO) positions from the Salaries & Expenses (S&E) account to the DCFA. In February 2018, DEA took a similar action with Special Agent positions and determined that the DCFA should fund 57 additional Special Agent positions in DEA Headquarters.

The cost impact of such efforts to fully fund DCP-related activities totals $124.3 million as summarized below:

TABLE 1—SUMMARY OF RIGHTSIZED POSITIONS

Rightsized positions	FY 2016	FY 2017	FY 2019	FY 2019
161 PATCO	$23,699,057	$23,699,057	$24,172,523	$24,617,315
57 Special Agents	.....	.....	9,379,236	18,758,472
Total Costs to DFCA	23,699,057	23,699,057	33,551,759	43,375,787

As mandated by 21 U.S.C. 886a(1)(C), DEA is required to collect fees adequate to fully fund the controlled substance and chemical diversion control activities of the DCP. In 2008, the DOJ's Office of the Inspector General, reported the results of its review of the DCP (I–2008–002) *Review of the Drug Enforcement Administration's Use of the Diversion Control Fee Account,* stating that the ''review concluded that DEA did not fully fund all Diversion Control Program salary costs with the Fee Account, as required by 21 U.S.C. 886a(1)(C).''

In FY 2016, Diversion Program Manager (DPM) positions were established in all field division offices. The role of the DPM is to serve as the subject matter expert on all regulatory matters and is responsible for establishing and implementing the division's strategic objectives and priorities related to the DCP. Each DPM plans and leads its division's efforts to prevent, detect, and disrupt diversion activities within its area of responsibility, ensuring consistent implementation of agency policy and priorities. The nature of the diversion control problem has increased in size and complexity making the role of the DPM increasingly critical and demanding than in previous years. With a registrant population of over 1.8 million, DPMs maintain an intricate knowledge of the registrant community in the division's area of responsibility as well as the various relevant state and local laws. DPMs lead outreach and education efforts to establish and maintain liaison and working relationships with other federal agencies; foreign, state, and local governments; industry and associations; community organizations; and the regulated community. Outreach is critical to increasing awareness of the diversion trends and methods to ensure understanding of and compliance with the CSA and applicable policies and regulations, and reduce the likelihood of diversion. The standardization of the DPM positions nationwide strengthened the DCP's ability to combat diversion and prescription drug abuse by optimizing the unique skill set of DPMs.

Technology Enhancements

The scope of the DCP has been expanded by Congress, continued diversion threats and schemes, and the opioid crisis. Ensuring availability of critical infrastructures requires comprehensive planning, investment in resources, and the ability to respond to the regulated community with appropriate remediation actions in a timely manner.

In February 2018, DEA launched a new tool in its ARCOS Online Reporting System to assist drug manufacturers and distributors with their regulatory obligations under the CSA. The enhancement allows DEA-registered manufacturers and distributors to view and download the number of distributors and the amount (anonymized data in both grams and dosage units) each distributor sold to a prospective customer in the last available six months of data. This resource is one of many steps DEA is taking to collaborate with its 1.8 million registrants to combat the ongoing opioid epidemic in the United States.

Additionally, the DCP determines the appropriate procedures necessary to order and distribute all schedule I and II controlled substances and schedule III narcotics. This enables the DCP to monitor the flow of those controlled substances from their point of manufacture through commercial distribution. It also monitors registrant compliance through reporting systems such as the ARCOS and manages the cataloging of controlled substances based on the National Drug Code (NDC) system, including the Drug Ingredients, Trade Name, DEA Generic Name, UN Code/Name, and the conversion factor to calculate the base weight of the controlled substance within product. Other oversight activities include maintaining the Controlled Substance Ordering System (CSOS), monitoring CSOS activities through the initial certification process, and periodic auditing of registrant systems. CSOS provides registrants with an electronic platform that reduces costs to registrants while ensuring a more efficient and effective ordering process. The DCP has also made improvements by streamlining the application process for registrants and implementing an online system for new applications and renewal applications for registrations. These technological advancements are crucial to the furtherance of DEA's mission to support registrants, which would be funded by the increase in registrant fees.

To improve customer support to registrants, the DCP is changing the technology infrastructure of its service center's phone system to implement a new Interactive Voice Response (IVR) system. This will provide enhanced call flows and interactive features to registrants and provide efficiencies within the service center daily activities.

In support of the International Trade Data System (ITDS), as mandated by Executive Order 13659, the DCP has successfully implemented the online versions of its import and export applications for controlled substances and listed chemicals (DEA Form 161, 236, 357, and 486). The DCP has also enhanced its communications system to allow interconnectivity between many different systems. Data connectivity was established with U.S. Customs and Border Protection (CBP) and all Import

and Export declarations and permits are now electronically transmitted to CBP. The online DEA Form 161R and 161EEA are in the process of being adjusted due to the passage of recent legislation that will require modifications to the form.

The DCP continues to improve the quality and accessibility of its registration and reporting systems, such as the CSA, Combat Methamphetamine Epidemic Application (CMEA), Quota Management System, ARCOS, Bulk Chemical Manufacturer Reports, Drug Theft/Loss, NTBI, and the Online Conferencing Registration System. These systems generate timely, accurate, and actionable data that provide the DCP's registrant population an efficient means for online submissions of their regulatory obligations and improve the DCP's enforcement and control efforts.

For purposes of efficiency, to reduce the cost of maintaining the equipment, and to allow DEA registrants greater ease of ordering schedule I and/or II controlled substances electronically, DEA implemented a single-sheet Form 222 for order forms. The new single-sheet format is expected to lower labor burden to government employees due to efficiencies gained from having more lines per form, anticipated reduction of instances of form failure, allowing the use of a printer, and general ease of use for registrants. Additionally, it removes the requirement for ARCOS-reporting suppliers to mail completed order forms to DEA field offices.

IV. Provisions of the Proposed Rule

Proposed New Fees

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

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

TABLE 2—PROPOSED REGISTRATION AND REREGISTRATION FEES BY BUSINESS ACTIVITY

Business activity	Current fees ($)	Proposed fees ($)	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 proposed fee for the three-year registration period is $888. The three-year difference is $157 or an annual difference of $52.

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

TABLE 3—OVERVIEW OF PROPOSED 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 proposes 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. Now that registration fees have been increasing, DEA recognizes that the issuance of refunds in limited circumstances is warranted. These provisions of the proposed rule will give DEA's 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 given for applicant error when there has been a duplicate payment for the same renewal, incorrect billing or incorrect transposing of credit card digits, or payment for incorrect business activity or when they are fee-exempt. Refunds will be issued based on DEA error when DEA caused the error, for example when DEA advised a new application is needed or advised a registration to submit payment for a wrong business activity. While these proposed provisions will have no economic costs or benefits, DEA believes there are benefits to accurately codify existing practices.

V. Need for a New Fee Calculation

DEA last adjusted the fee schedule in March 2012, with collections beginning April 2012.[24] This fee schedule was intended to be sufficient 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, indirect pay, rightsizing, additional salary, and other costs attributable to diversion control activities were incorporated into the DCP since the last fee increase. In addition, DCP's responsibility has been expanded by Congress and by the need to address the opioid epidemic public health emergency. The 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 health emergency, 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 Staffs (DS) across the nation to support its increased regulatory mission. In April 2012, there were 48 TDSs, 65 DGs, and 17 DSs. At the end of FY 2019, there were 86 TDSs, 87, DG, 15 DSs, and 16 TDS-Extensions.[25]

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 achieve its increased responsibilities. Corresponding with increases in field groups, in April 2012, there were 1,167 employees in DCFA funded positions, and at end of FY 2019, there were 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. From an estimated 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 will remain vigilant toward identifying methods to improve efficiencies or identifying other cost saving measures. As discussed above, however, a new fee calculation is needed. Without an adjustment in the 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 abuse and diversion.

Fee Calculation

DEA is delegated the task of determining the details of fulfilling the statutory requirements of ensuring the recovery of the full costs of operating the DCP as described above, while charging registrants participating in the closed system of distribution reasonable fees relating to the registration and control ''of the manufacture, distribution, dispensing'' [26] and ''importers and exporters'' [27] of controlled substances and listed chemicals. For the DCP to have funds to function, DEA must determine, in advance of actual expenditures, a reasonable fee to be charged. As a result, historical data and projections, together with actual and current costs are used to project the annual costs of the DCP. Additionally, a reasonable fee must be calculated that will fully recover the costs of the DCP based on the variability over time of the number of registrants in the different categories of registration (*e.g.,* manufacturers, distributors, importers, exporters, reverse distributors, practitioners, and individual researchers). Since the fees collected must be available to fully fund the DCFA and to reimburse DEA for expenses incurred in the operation of the DCP (21 U.S.C. 886a), there must always be more collected than is actually spent to avoid running a deficit and being in violation of federal fiscal law.[28] In operating the DCP, DEA must be prepared for changes in investigative priorities, diversion trends, and emerging drugs or chemicals posing new threats to the public health and safety. By definition, it is an inexact effort. Given that fact, the agency must select a single methodology that it consistently follows throughout any given fee cycle.

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, the full cost of the DCP is estimated for the analysis period, generally three

[24] 77 FR 15234, March 15, 2012.

[25] 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.

[26] 21 U.S.C. 821.

[27] 21 U.S.C. 958(f).

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

years. While maintaining a difference in registration fees for each category by a ratio of 1.0 for researchers, 3.0 for practitioners (for administrative convenience, the fee is collected every three years for practitioners), 6.25 for distributors, and 12.5 for manufacturers, the registration fees required to pay the full cost of DCP for the analysis period is calculated. These are long-established ratios, utilized in previous fee increases, as repeatedly determined to be reasonable.[29] By utilizing these different ratios, the agency recognizes the statutory need to charge reasonable fees relating to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and listed chemicals.

Thus, 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. Specifically, practitioners, mid-level practitioners, dispensers, researchers, and narcotic treatment programs pay an annual registration fee of $244. For administrative convenience for both 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 and manufacturers pay an annual fee of $3,047. 21 CFR 1301.13 and 1309.11.

Since the last fee schedule adjustment in March 2012,[30] DEA continued to review possible alternative methodologies for differentiating registration fees between various registration business activities. In developing this proposed 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 proposed 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 proposes the current weighted-ratio method for calculating fees and differentiating fees between registrant groups. A detailed discussion of the alternatives is provided below. Additionally, the proposed 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 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 begins with annual projected DCP obligations, including payroll, operational expenses, and necessary equipment. The DCP budget has increased due to inflationary adjustments for rent and payroll and adding staffing resources that support the regulatory and law enforcement activities of the program. The fees have not been adjusted to reflect these factors as the basis of the last fee adjustment was to fund the DCP for the time period of FY 2012 to 2014. Specific details on the DCP budget are available in the annual President's Budget Submission and supplemental budget justification documents provided to Congress.[31]

DEA needs to 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 2 percent to cover Within-Grade Increases, Career Ladders,[32] Cost of Living Adjustment, and increased benefits costs. Non-payroll obligations generally follow payroll obligations. As FTE and payroll obligations increase, non-payroll obligations also increase correspondingly. Non-payroll obligations include items such as rent, communications, utilities, services, equipment, travel, etc.[33] DEA believes its methodology supports the estimate amount 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, there were 48 TDSs, 65 DGs, and 17 DSs. At end of FY 2019 there were 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 4 summarizes the estimated number of field groups by year.

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

[30] 77 FR 15234, March 15, 2012.

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

[32] 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.

[33] 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.*

TABLE 4—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

Corresponding with increases in field groups, in April 2012, there were 1,167 employees in DCFA funded positions, and at the end of FY 2020, there will be an estimated 1,803 employees. 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 DCP's enforcement and regulatory capacity, as well as its support functions. From an estimated FTE 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.

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,[34] Cost of Living Adjustment, and increased benefits costs. From an estimated base of $289,450,003 in FY 2020, estimated payroll obligations increase as projected net hiring increases to an estimated $311,587,162, $344,462,812, and $376,513,554 in FY 2021, FY 2022, and FY 2023, respectively.

Non-payroll obligations include items such as: Rent, communications, utilities, services, equipment, travel, etc.[35] Non-payroll obligations generally follow payroll obligations. As FTE and payroll obligations increase, non-payroll obligations also increase. Year-over-year increase in payroll increase is 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 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 5—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, the cost components outlined below are also considered in determining required registration fee collections.

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

At times, DEA enters into an obligation to purchase a product or service that is not delivered immediately, such as in a multi-year contract, 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.[36] Congress established the DCFA as a separate account of the Treasury to ''ensure the recovery of the full costs of operating the various aspects of [the Diversion Control Program]'' by those participating in the closed system established by the CSA. 21 U.S.C. 886a(1)(C). Fees collected are deposited into a separate Treasury account. Each fiscal year, the first $15 million is transferred to the Treasury and is not available for use by the DCP. Therefore, DEA needs to collect an additional $15 million per year beyond estimated costs for payment to the Treasury.

DCFA Balance

DEA maintains a DCFA balance, as working capital, to maintain DCP operations during low collection periods.[37] Monthly collections and obligations fluctuate throughout the year. There are times when obligations

[34] 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.

[35] 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.*

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

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

(spending) exceed collections. This can happen consecutively for several months. Therefore, a DCFA balance is maintained to avoid operational disruptions due to these fluctuations and monthly differences in collections and obligations (spending). The estimated DCFA balance at beginning of FY 2021 is $69 million. Based on history, 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.

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 above, DEA calculated the total amount required to be collected for the FY 2021–FY 2023 period, for purposes of calculating the fee levels, as follows. Using the estimated collections under the current fee schedule as baseline, 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–FY 2023, to fully fund the DCP.

TABLE 6—ESTIMATED DCFA CASH FLOW UNDER PROPOSED 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, the costs associated with the anticipated increases in programmatic and personnel responsibilities would place DEA in the position of having obligations that would exceed the collections and DCFA balance carried forward. DEA would realize this DCFA deficit in FY 2021.

TABLE 7—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.

Proposed Methodology for New Fee Calculation

As shown in Table 6 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 (or $1,796 million) in registration fees over the three-year period, FY 2021 to FY 2023, to fully fund the DCP. DEA needs to propose a method for determining fees for various business activities that would generate the target collections.

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

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

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

For each of the alternatives considered, the calculated fees are analyzed for reasonableness by examining: (1) The absolute amount of the fee increase, (2) the change in fee as a percentage of revenue from 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 the 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 8—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
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. From current fees, to arrive at 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 of the registrant groups and set fees to recover the costs associated with each of these groups. Since the registration fee is not a user fee, DEA is not required to calculate fees according to its costs by registrant groups. 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

After consideration of the flat fee option, DEA did not select this option to calculate the proposed new fees. The fee disparity among registrant groups caused by this calculation alternative is too great. Under this option, the calculation would result in reduced fees for manufacturers and distributors by 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. DEA registrants include some of the largest corporations in the world although the vast majority of registrants are practitioners, such as physicians and nurses. To satisfy the ''reasonable'' standard, registration fees should be different among the categories to account for cost and economic differences among the registrant categories. Option 1 did not satisfy this requirement.

Past-Based Option

Option 2 is called the Past-Based Option, and is based on historic investigation work hour data to set the apportionment of cost to each registrant category. In considering Option 2, DEA used historic investigation work hour data from FY 2016–2018. DEA's records permit an accurate apportionment of work hours for certain types of diversion control activities (*e.g.,* investigations) among classes of registrants. DEA estimates that approximately 3 percent of costs can be directly linked to pre-registration and scheduled investigations. Although some criminal investigations can be attributed to registrant groups, DEA did not include the cost of criminal investigations for the fee calculation under the Past-Based Option. While DEA develops annual work plans for the number of scheduled investigations by registrant type, DEA does not develop such plans for criminal investigations. Therefore, the cost of criminal investigations is allocated equally across all registrant groups, regardless of business activity. The remaining costs associated with DCP activities and components benefit all registrants (*e.g.,* policy, registration, and legal activities); however, DEA records cannot attribute these costs by registrant class. Under Option 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 9—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, such as agency priorities, new legislation, control of substances, new investigative requirements, and other program needs.

Conclusion

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

Weighted Ratio Option (Current and Proposed Method)

The Weighted-Ratio Option is the method that 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 for researchers, canine handlers, analytical labs, and narcotics treatment programs; 3 for registrants on three-year registration cycles, pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners; 6.25 for distributors and importers/exporters; and 12.5 for manufacturers. The adopted ratios are applied for administrative convenience since historically costs vary and a fee must be set in advance. To determine the fee, a weighted ratio is assigned based on registrant group, and the amount needed to be collected over the FY 2021—FY 2023 period is divided by the weighted number of estimated registrations to determine the fees.

TABLE 10—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. These registration fee increases range from $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 similar to the inflation rate. The same increase equates to 1.8 percent annual rate over 11 years, 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, this applies historic weighted ratios to differentiate fees among registrant groups. While differentiating fees based on historic weighted ratios, this methodology does not create a disproportionate fee increase in any registrant group.

Conclusion

DEA selected this option to calculate the proposed 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 proposed fees. The weighted ratios used by DEA to calculate the current fee have proven effective and reasonable over time. Additionally, the weighted ratio 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 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 12866 and 13563. Executive Order 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). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. The Executive Order classifies a ''significant regulatory action'' requiring review by the Office of Management and Budget (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 expects that this proposed 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.[38] The analysis of benefits and transfers is below. The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined and it has been determined to be a significant regulatory action under Executive Order 12866, and 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 proposed 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. 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 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 proposed 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. DEA registrants include some of the largest corporations in the world although the vast majority of registrants are practitioners, such as physicians and nurses. To satisfy the ''reasonable'' standard, registration fees should be different among the categories to account for cost and economic differences among the registrant categories. This option did not satisfy this requirement.

Past-Based Option

Option 2 is called the Past-Based Option, and is based on historic investigation work hour data to set the apportionment of cost to each registrant category. 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. In the past-based option, the percent change in fees from current fees range 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 does not propose 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. 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 estimated. 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 the best basis for the calculation of proposed fees.

Weighted Ratio Option (Current and Proposed Method)

The Weighted-Ratio Option is the method that 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, this method applies historic weighted ratios to

[38] OMB Circular A–4.

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 proposed 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 proposed fees. The weighted-ratios used by DEA to calculate the current fee have proven effective and reasonable over time. Additionally, the weighted-ratio 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 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 Proposed New Fee Relative to Current Fee

Affected Entities

As of September 2019, there were a total of 1,840,501 controlled substances and chemical registrations (1,839,556 controlled substances registrations and 945 chemical registrations), as shown in Table 11.

TABLE 11—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 11 are subject to the fees. Any hospital or other institution operated by an agency of the United States, 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.[39] Fee-exempt registrants are not affected by the proposed fees.

Based on historical registration data and estimated growth trends, DEA estimates the average total registration population over the three-year period, FY 2021- FY 2023, will be 2,004,358 as shown in Table 12. Estimated annual growth in fee-paying registrations is approximately 3.8 percent. The largest growth is in the MLPs. Approximately 8 percent of all registrations are fee-exempt.

TABLE 12—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	114	39
Manufacturer (small)	464	169
Distributor	221	112
Distributor (small)	445	217
Reverse Distributor	24	
Reverse Distributor (small)	49	

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

TABLE 12—ESTIMATED AVERAGE FEE-PAYING REGISTRATIONS, FY 2021–FY 2023—Continued

Registrant class/business	Controlled substances	Chemicals
Importer	74	68
Importer (small)	148	134
Exporter	88	51
Exporter (small)	176	99
Total	2,003,469	889
Grand Total (all registrations)	2,004,358	

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

Characteristics of Entities

This proposed rule affects those manufacturers, distributors, dispensers, importers, and exporters of controlled substances and list I chemicals that are required to obtain and pay a registration fee with DEA pursuant to the CSA. As of September 2019, there were a total of 1,840,501 controlled substances and chemical registrations (1,839,556 controlled substances registrations and 945 chemical registrations), as shown above in Table 11. DEA estimates an average total fee-paying population of 2,004,358 over the three-year period, FY 2021–FY 2023, as shown in Table 12.

The registrations on a three-year cycle, 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 (manufacturer, distributor, reverse distributor, importer, exporter, chemical manufacturer, chemical distributor, chemical importer, and chemical exporter) maintain an annual registration. Registration and reregistration costs vary by registrant category as is described in more detail in the sections below.

The proposed fees would affect a wide variety of entities. Table 13 indicates the sectors, as defined by the North American Industry Classification System (NAICS), affected by the proposed 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 13—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
	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

TABLE 13—INDUSTRIAL SECTORS OF DEA REGISTRANTS—Continued

Business activity	NAICS code	NAICS code description	Average annual revenue ($)
	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 14 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 proposed rule.

TABLE 14—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 13 and 14 are not intended to be exhaustive but to generally represent DEA registrants.

Economic Impact Analysis of Proposed Fee

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

DEA assumes that the registration fees are business expenses for all registrants. As a result, the increase in the fee will be dampened by reduced tax liability, as a result of the increase in registration fee expense. For example, if a practitioner pays an additional $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.[40] Again, 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 effect, DEA examined the proposed 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 proposed fee for practitioners and mid-level practitioner of $888 per 3 years represents a $157 increase over the current fee of $731 per 3 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 15 indicates the annual effect as a percentage of income. The impact on small businesses is discussed in the Regulatory Flexibility Act section.

TABLE 15—PROPOSED 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

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

Additionally, the effect of the fee increase is diminished by an estimated increase in registrant income. The table below describes the annual-equivalent fee as a percentage of income in 2012, year of the last fee increase, and 2021. This analysis assumes that the fee increase is absorbed personally by each practitioner/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 proposed fees are 21 percent above the current fees implemented in 2012, average incomes for dentists, physicians, physician assistants, and nurse practitioners are estimated to increase 12 percent, 17 percent, 26 percent, and 30 percent, respectively.[41] This estimated increase in average income lessens the effect of the fee increase as a percentage of average income. The proposed 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 2.2 percent annual rate (on compound annual growth rate basis), which is similar to the inflation rate. The same increase equates to 1.8 percent annual rate over 11 years, 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 16 represents fees as percentage of average income.

TABLE 16—FEES AS PERCENTAGE OF ANNUAL MEAN WAGE IN 2012 AND 2021

Occupation title	2012	2018	2021				
	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 3 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 3 more years to 2021.
*** The proposed fee is $888 per 3 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 United States, of any State, or any political subdivision of an agency thereof. Likewise, an individual who is required to obtain a registration in order to carry out his/her duties as an official of a federal or State agency is also exempt from registration fees.[42] Fee exempt registrants are not affected by the proposed fees.

d. Analysis of Benefits, Costs, and Transfers

Benefits

Benefits of the proposed rule are an extension of the benefits of the DCP, without the need for any additional congressional appropriations. The DCP is a strategic component of United States law and policy aimed at preventing, detecting, and eliminating the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes. The absence of or significant reduction in this program would result in enormous costs for the citizens and residents of the U.S. due to the diversion of controlled substances and listed chemicals into the illicit market as discussed earlier in this document.

Costs

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

Transfers

The difference between the current fees and the proposed new fee—the fee increase—is $318 million over the three year period, FY 2021–FY 2023, or approximately $106 million annually. Specifically, the difference in the fees projected to be collected under the current fee rates and in the fees projected to be collected under the proposed new fee rates is $102 million, $105 million, and $110 million in FY 2021, FY 2022, and FY 2023, respectively. Table 17 summarizes the estimated collections under the current fee, estimated collections under the proposed fee, and the difference between the current and the proposed fees.

TABLE 17—ESTIMATED COLLECTIONS UNDER CURRENT AND PROPOSED FEES

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

[41] From Table 15, 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).

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

The present value of the transfer is $299 million at 3 percent discount rate and $277 million at 7 percent discount rate.

Executive Order 13771 was issued on January 30, 2017, and published in the **Federal Register** on February 3, 2017. 82 FR 9339. This proposed rule is not expected to be subject to the requirements of Executive Order 13771 because this proposed 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 Executive Order 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 Executive Order 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 proposed 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 proposed 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 does not create a disparity in the relative increase in fees from the current to the proposed fees. The weighted ratios used by DEA to calculate the 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 would increase fees proportionally (21 percent) across all registrant groups, maintaining the weighted ratio of 1, 3, 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 proposed and current fees.

TABLE 18—DIFFERENCE IN FEES UNDER CURRENT AND PROPOSED FEES

Business activity	Total registrations (FY 2021–FY 2023)	Current fees ($)	Proposed fees ($)	Total collections under proposed 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 13, the proposed 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 proposed rule is expected to affect a substantial number of small entities.

DEA compared the annual increase in fees from current fees to proposed 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 19—PROPOSED FEE INCREASE AS PERCENTAGE OF ANNUAL REVENUE

NAICS code	NAICS code description	Enterprise size (number of employees)	Number of establishments	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
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 proposed 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, if promulgated, 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 $154,000,000 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 would 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 proposed 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 United States-based companies to compete with foreign-based companies in domestic and export markets. If this rule remains a major rule in the final rule, DEA will 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 proposes to amend 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 and adding a new fifth 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.

Business activity	Controlled substances	DEA application forms	Application fee	Registration period (years)	Coincident activities allowed
(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 and adding a new 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	

Dated: March 9, 2020.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–05159 Filed 3–12–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Office of Investment Security

31 CFR Parts 800 and 802

RIN 1505–AC65

Filing Fees for Notices of Certain Investments in the United States by Foreign Persons and Certain Transactions by Foreign Persons Involving Real Estate in the United States; Correction

AGENCY: Office of Investment Security, Department of the Treasury.

ACTION: Proposed rule; correction.

SUMMARY: On March 9, 2020, the Department of the Treasury published a proposed rule that would establish a fee for parties filing a voluntary notice of certain transactions for review by the Committee on Foreign Investment in the United States. This rule corrects the comment due date for the proposed rule.

DATES: Written comments on the proposed rule on CFIUS filing fees (85 FR 13586) must be received by April 3, 2020.

FOR FURTHER INFORMATION CONTACT: Laura Black, Director of Investment Security Policy and International Relations; Meena R. Sharma, Deputy Director of Investment Security Policy and International Relations; David Shogren, Senior Policy Advisor; or James Harris, Senior Policy Advisor, at U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220; telephone: (202) 622–3425; email: *CFIUS.FIRRMA@treasury.gov.*

SUPPLEMENTARY INFORMATION: On March 4, 2020, the proposed rule, ''Filing Fees for Notices of Certain Investments in the United States by Foreign Persons and Certain Transactions by Foreign Persons Involving Real Estate in the United States'' was filed with the Office of the Federal Register. The proposed rule that was filed included a comment due date that was 30 days after the date of filing. An inadvertent error caused the rule document that was published in the **Federal Register** on March 9, 2020 (85 FR 13586) to include an incorrect comment due date. This correction confirms the due date for comments on the proposed rule is April 3, 2020.

Correction

In proposed rule document 2020–04641 beginning on page 13586 in the issue of Monday, March 9, 2020, make the following correction:

On page 13586, in the first column, in the **DATES** section in the 35th line, ''April 8, 2020'' should read ''April 3, 2020''.

Dated: March 10, 2020.

Meena R. Sharma,

Deputy Director, Office of Investment Security Policy and International Relations.

[FR Doc. 2020–05298 Filed 3–13–20; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2020–0066]

RIN 1625–AA08

Special Local Regulation; Marine Event Within the Fifth Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish temporary special local regulation for certain waters of the Choptank River. This action is necessary to provide for the safety of life on these navigable waters located at Cambridge, MD, during a high-speed power boat racing event on May 16, 2020, and May 17, 2020. This proposed rulemaking would prohibit persons and vessels from entering the regulated area unless authorized by the Captain of the Port Maryland-National Capital Region or the Coast Guard Patrol Commander. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before April 15, 2020.

ADDRESSES: You may submit comments identified by docket number USCG–2020–0066 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed