ECONOMIC IMPACT ANALYSIS
of
Final Rule on Controlled Substances and List I Chemical Registration and Reregistration Fees, DEA-346

Drug Enforcement Administration
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CHAPTER 1: PURPOSE

Pursuant to the final rule, DEA-346, the fee schedule for DEA registration and reregistration fees is adjusted as necessary to recover the full costs of the Diversion Control Program (DCP) relating to the registration and control of the manufacture, distribution, dispensing, importation and exportation of controlled substances and List I chemicals as mandated by the Controlled Substances Act (CSA).

The purpose of this document is to:

- Describe the need for the new fee schedule.
- Analyze alternative methodologies considered for calculating fees across registrant groups/business activities.
- Demonstrate that the annual impact of the fee is not a significant regulatory action under Executive Order (E.O.) 12866 and E.O. 13563.
- Describe the small entities that are impacted by the rule and the impact of the rule on those small entities as required by the Regulatory Flexibility Act (5 U.S.C. 601- 612).
- Provide an analysis of costs and benefits.

Since publication of the Notice of Proposed Rulemaking (NPRM), DEA has revised the fee calculation based on end of year financial information for Fiscal Year (FY) 2011 and updated budget and registrant population estimates for FY 2013 and FY 2014. The update resulted in minor reductions in fees from the fees described in the NPRM for some registrant groups. The economic impact of the selected alternative has been updated to reflect the revised fees.

CHAPTER 2: STATEMENT OF NEED FOR A NEW FEE SCHEDULE

2.1 STATUTORY AUTHORITY

A new fee schedule is required by statute and the final rule, DEA-346, implements a new fee calculated pursuant to federal law. The final rule adjusts the registration and re-registration fees relating to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and List I chemicals. For calculation purposes, the collection of the new fee is estimated to begin on March 1, 2012, for the Fiscal Year 2012-2014 period.

The Drug Enforcement Administration (DEA) implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801-971), as amended (hereinafter "CSA").[1] DEA drafts and publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1321. The Diversion Control Program (DCP) is a strategic component of DEA that carries out the mandates of the CSA and its regulations to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes.

All manufacturers, distributors, dispensers, importers, and exporters of controlled substances and List I chemicals are required to maintain an annual registration with DEA (21 U.S.C. 822 and 958(f)). Under the CSA, DEA is authorized to charge reasonable fees relating to

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

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). 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.

2.2 REGISTRATION AND REREGISTRATION FEES

Currently, handlers of controlled substances and List I chemicals pay registration and reregistration fees as required by statute. These fees (some of which are paid annually and some of which are paid every three years) range from $184 to $2,293, depending on registrant category. Practitioners, mid-level practitioners, dispensers, researchers, and narcotic treatment programs pay an annual registration or annual equivalent of $184 (practitioners pay a registration fee of $551 every three years). Distributors, importers, and exporters pay an annual fee of $1,147, and manufacturers pay an annual fee of $2,293.

In accordance with the statutory requirements of the CSA, DEA continually monitors the anticipated budget and collections to determine whether the registration fees need to be adjusted.

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

DEA has determined that the fees need to increase in Fiscal Year (FY) 2012 to the amounts indicated in Table 1: Registration and Reregistration Fees by Class/Business in order to fully fund the DCP. For purposes of calculating the fee, collections are estimated to begin on March 1, 2012.

Table 1: Registration and Reregistration Fee by Class/Business

Registrants on Three Year Registration Cycle

Registrant Class/Business	Current Three Year Fee*	New Three Year Fee*	Difference Per Year
Pharmacy	$551	$731	$60
Hospital/Clinic	$551	$731	$60
Practitioner	$551	$731	$60
Teaching Institution	$551	$731	$60
Mid-Level Practitioner	$551	$731	$60

*Pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners currently pay a fee for a three year period. This current three-year fee is $551. The new fee for the three-year registration period would be $731. The three year difference is $180 or an annual difference of $60.

Registrants on Annual Registration Cycle

Registrant Class/Business	Current Annual Fee	New Annual Fee	Difference
Researcher/Canine Handler	$184	$244	$60
Analytical Lab	$184	$244	$60
Maintenance	$184	$244	$60
Detoxification	$184	$244	$60
Maintenance and Detoxification	$184	$244	$60
Compounder/Maintenance	$184	$244	$60
Compounder/Detoxification	$184	$244	$60
Compounder/Maintenance/ Detoxification	$184	$244	$60
Distributor (chemical and controlled substances)	$1,147	$1,523	$376
Reverse distributor	$1,147	$1,523	$376
Importer (chemical and controlled substances)	$1,147	$1,523	$376
Exporter (chemical and controlled substances)	$1,147	$1,523	$376
Manufacturer (chemical and controlled substances)	$2,293	$3,047	$754

DEA last adjusted the registration fees in 2006 for the Fiscal Year 2006-2008 period. Since that time, the diversion control responsibilities and activities of the DCP have grown but the fees have not. For example, Congress has passed several amendments to the CSA which

have resulted in additional responsibilities and activities within the DCP. Such amendments include the Methamphetamine Production Prevention Act of 2008, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, and the Secure and Responsible Drug Disposal Act of 2010. Without an adjustment of the fees, DEA will face a projected budgetary shortfall by mid FY 2012 that would require dramatic program reductions to maintain budget solvency.

CHAPTER 3: REGISTRANT LANDSCAPE

This rule affects those manufacturers, distributors, dispensers, importers, and exporters of controlled substances and List I chemicals that are required to obtain and pay a registration fee with DEA pursuant to the CSA (21 U.S.C. 822 and 958(f)). As of August 2011, there were 1,407,119 controlled substances and chemical registrants (1,406,021 controlled substances registrants and 1,098 chemical registrants), as shown in Table 2.

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

Table 2: Number of Registrants by Business Activity

Registrant Class/Business	Controlled Substances	Chemicals
Pharmacy	66,934	
Hospital/Clinic	15,737	
Practitioner	1,115,398	
Teaching Institution	336	
Mid-Level Practitioner	193,877	
Researcher/Canine Handler	9,120	
Analytical Lab	1,500	
Narcotic Treatment Program	1,267	
Distributor	828	550
Reverse Distributor	60	
Importer	209	182
Exporter	233	159
Manufacturer	522	207
Total	1,406,021	1098
Total (all registrants)	1,407,119	

***Data as of August 2011.**

The fees affect a wide variety of entities. Table 3 indicates the sectors affected by the rule and their average annual revenue/income. Most DEA registrants are small entities under

Small Business Administration (SBA) standards. Almost all practitioners, which are the largest category of registrants, are considered small businesses (annual revenues of less than $6 million to $8.5 million, depending on specialty). Practitioners and mid-level practitioners make up the largest registration category with total 1,309,275 registrants (as of August 2011).

Table 3: Industrial Sectors of DEA Registrants

Sector	NAICS Code	Average Annual Revenue per Establishment
Manufacturers		
Petro-chemical Manufacturing (organic, inorganic)	32511	$1,390,485,971
Medicinal and Botanical Manufacturing	325411	$27,601,834
Pharmaceutical Manufacturing	325412	$144,173,821
Adhesive Manufacturing	325520	$17,482,468
Toilet Preparation Manufacturing	325620	$50,322,290
Other Chemical Manufacturing	325998	$13,720,807
Distributors		
Drugs and Druggist Sundries Wholesalers	424210	$64,793,480
General Line Grocery Wholesalers	424410	$45,518,407
Confectionary Merchant Wholesalers	424450	$17,175,982
Chemical Wholesalers	424690	$12,856,993
Tobacco Wholesalers	424940	$71,437,205
Miscellaneous Wholesalers	424990	$2,741,857
Pharmacies		
Supermarkets	445110	$7,247,540
Drug Stores	446110	$4,829,487
Discount Stores	452112	$26,535,201
Warehouse Clubs and Superstores	452910	$76,300,280
Other		
Testing Labs	541380	$1,907,414
Packaging and Labeling Services	561910	$2,696,904
Other Practitioners		
Professional Schools	611310	$1,373,855
Ambulatory Health Care Services	621	$1,236,852
Hospitals	622	$108,286,641

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

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

CHAPTER 4: ALTERNATIVE FEE CALCULATION METHODOLOGIES CONSIDERED

4.1 SCOPE OF ANALYSIS

As presented in the NPRM and analyzed in the Economic Impact Analysis of the Proposed Fee Rule, DEA considered four methodologies to calculate registration and reregistration fees: Past-Based Option, Future-Based Option, Flat Fee Option, and Weighted-Ratio Option. Although the increase in the fees may be passed down to the registrants' customers, the alternatives are analyzed assuming that the increase in the fee is absorbed fully by the registrants. Some commenters have confirmed this statement and have indicated some registrants may decide not to renew their registration as a result of the higher fees.

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

Based on the analysis provided in the NPRM, DEA did not adopt the "Past-Based Option." There are two key reasons for rejecting this methodology. First, the fee increase would be disproportionately burdensome to a small number of registrants. Distributors' fees would increase by over three fold, while the fees for the remaining registrant groups would increase from 10 percent to 32 percent. DEA believes this is 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 registration fees.

The second option analyzed in the NPRM is the "Future-Based Option" which is based on projected work hours for each registrant class using scheduled investigation work plan goals and anticipated/planned resources. Under this option, DEA based its calculations on projected work hour data by registrant group for FY 2012-2014. In other words, the future-based option is based on DEA's projection of work plan goals and the resources required for these years—specifically examining the direct cost of anticipated scheduled investigations.

DEA rejects this methodology because DEA believes it would result in an unreasonable increase in fees for some registrants and reflect a severe disparity of increased fees among the registrant groups. The large proportional increase in fees for two registrant categories would not pass the "reasonable" standard required by statute. The vast disparity in the increase, where fees for manufacturers increase by more than 700 percent while fees for dispensers increase by 26 percent, is unreasonable.

The third option analyzed in the NPRM is called the "Flat Fee Option." This methodology 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.

DEA did not select this methodology because of the great disparity in fees among registrant groups. Under this option, the calculation results in reduced fees for manufacturers and distributors by 89 percent and 78 percent respectively, while practitioner fees would increase

by 34 percent. Thus, setting the fees at the same level across all registrant groups is not "reasonable." DEA registrants include some of the largest corporations in the world although the vast majority of registrants are practitioners, such as physicians, dentists and nurse practitioners. To satisfy the "reasonable" standard, registration fees should not be a flat fee regardless of the category of registrant. There are cost differences for scheduled investigations and other DCP costs among the registrant categories.

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

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

disproportionate fee increase in any registrant group. The proposed fee published in the NPRM calculated proposed fees using this methodology with an increase of approximately 33 percent from current fees for all registrant groups.

Since the publication of the NPRM, DEA has revised the fee calculation based on new financial information for Fiscal Year (FY) 2011 and updated budget and registrant population estimates for FY 2013 and FY 2014. The update resulted in minor reductions in fees for some registrant groups from the fees described in the NPRM. The economic impact of the weighted-ratio methodology has been updated to reflect the revised fees. The revised fees result in an increase of approximately 33 percent from current fees for all registrant groups.

4.2 WEIGHTED-RATIO OPTION (Selected Methodology)

4.2.1 Description

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

Table 4: Annual Registrant Fees Under Weighted-Ratio Option

Registrants on Three Year Registration Cycle

Registrant Class/Business	Current Three Year Fee*	New Three Year Fee*	Difference Per Year
Pharmacy	$551	$731	$60
Hospital/Clinic	$551	$731	$60
Practitioner	$551	$731	$60
Teaching Institution	$551	$731	$60
Mid-Level Practitioner	$551	$731	$60

*Pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners currently pay a fee for a three year period. This current three year fee is $551. The new fee for the three year registration period would be $731. The three year difference is $180 or an annual difference of $60.

Registrants on Annual Registration Cycle

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Detoxification	$184	$244	$60
Maintenance and Detoxification	$184	$244	$60
Compounder/Maintenance	$184	$244	$60
Compounder/Detoxification	$184	$244	$60
Compounder/Maintenance/ Detoxification	$184	$244	$60
Distributor (chemical and controlled substances)	$1,147	$1,523	$376
Reverse distributor	$1,147	$1,523	$376
Importer (chemical and controlled substances)	$1,147	$1,523	$376
Exporter (chemical and controlled substances)	$1,147	$1,523	$376
Manufacturer (chemical and controlled substances)	$2,293	$3,047	$754

4.2.2 Analysis

Analysis of Fees

In the weighted-ratio option, the registration fees for all registrant groups increase 33 percent from current fees. The new registration fees range from $244 annually (or annual equivalent) to $3,047. Registration fees are collected by location and by registered business

activity. Most small registrants are expected to pay a single registration fee of $244 ($60 annual increase), $1,523 ($376 annual increase) or $3,047 ($754 annual increase).

(See Chapter 6 for analysis of fees as percentage of revenue).

Registration fees for all registrant groups increase by 33 percent and, as a result, there is no disparity in the fee increase among registrant groups.

Evaluation of Methodology

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

Conclusion

DEA selected the weighted-ratio option to calculate the new fee schedule. This approach has been used since Congress established registrant fees and continues to be a reasonable reflection of differing costs. The registration fees under the weighted-ratio option result in differentiated fees among registrant groups, where registrants with larger revenues pay higher fees than registrants with lower revenues. Furthermore, the weighted-ratio does not create a disparity in the relative increase in fees from the current to the new fees. The weighted ratios used by DEA to calculate the new fee have proven effective and reasonable over time. Additionally, the selected calculation methodology accurately reflects the differences in activity level, such as in pre-registration and scheduled investigations by registrant category; for

example, these costs are greatest for manufacturers. DEA selected this option because it is the only option that resulted in "reasonable" fees for all registrant groups.

CHAPTER 5: IMPACT ANALYSIS OF NEW FEES

Executive Order 12866 provides that agencies must submit a regulatory impact analysis only for those regulatory actions that are "significant." A regulatory action is significant if it is anticipated to: (1) have an annual effect on the economy of $100 million or more, (2) adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities, (3) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency, (4) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof, or (5) raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.[3]

DEA has concluded that this rule is not an economically significant regulatory action pursuant to Executive Order 12866 (58 FR 51735, October 4, 1993) as supplemented and affirmed by Executive Order 13563 (76 FR 3821, January 18, 2011). This rule does not meet any of the criteria set forth for "significant" regulatory action, including:

1. Annual effect on the economy of $100 million or more.
2. Adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

5.1 ANNUAL ECONOMIC EFFECT LESS THAN $100 MILLION

DEA estimates that it would collect approximately $812,254,676 in registration fees at current fee levels for the Fiscal Year 2012 – FY2014 period. This estimated collection amount is

[3] E.O. 12866. See also Office of Management and Budget, Office of Information and Regulatory Affairs, "Regulatory Impact Analysis: Frequently Asked Questions," February 7, 2011.

insufficient to fully fund the DCP as mandated by law. However, the new fees are estimated to result in a total registration fee collection of $1,040,934,380 for the FY 2012-2014 period. The estimated increase in collections is $228,679,704 for the three year period. The average annual increase in estimated registration fee collections is $76,226,568. Therefore, the annual effect on the economy is less than $100 million and does not meet the "annual effect on the economy of $100 million or more" criteria for "significant" regulatory action.

5.2 NO MATERIAL ADVERSE AFFECT

The fee 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 eventually be passed on to the general public. The analysis below assumes that the impact of the fee increase is absorbed entirely by the registrants. Some commenters have confirmed this statement and have indicated some registrants may decide not to renew their registration as a result of the higher fees.

5.2.1 Registration Fees as Business Expense

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 from the increase in registration fee expense. For example, if a practitioner pays an additional $60 per year in registration fees and the combined federal and state income tax is 35 percent, the net cash impact is $39, not $60. The additional $60 causes income/profit to decrease by $60, decreasing the tax liability by $21. The net cash outlay is $39.[4]

[4] This example is for illustration purposes only. Each entity should seek competent tax advice for tax consequences of the fees established by this rule.

5.2.2 Registration Fees as Percentage of Income

DEA examined the new fees as a percentage of income for physicians, dentists, and physician's assistants. The fee increase is expected to have the greatest effect on small businesses. The majority of practitioners and mid-level practitioners work in small businesses. Physicians, dentists, and physician's assistants reflect a representative sub-group of the practitioner and mid-level practitioner registrant groups.

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

Table 8: Fee as Percentage of Income FY 2004 - 2012

	Average Income[5]			Fee	Fee as % of Average Income		
Year	Physicians	Dentists	Physician Assistants	(Annual Basis)	Physicians	Dentists	Physician Assistants
2004	137,610	130,300	68,780				
2005	138,910	133,680	71,070				
2006	142,220	140,950	74,270	184	0.129%	0.131%	0.248%
2007	155,150	147,010	77,800	184	0.119%	0.125%	0.237%
2008	165,000	154,270	81,610	184	0.112%	0.119%	0.225%
2009	173,860	156,850	84,830	184	0.106%	0.117%	0.217%
2010	179,370	163,901	87,933	184	0.103%	0.112%	0.209%
2011	187,154	169,632	91,230	184	0.098%	0.108%	0.202%
2012	194,939	175,363	94,528	244	0.125%	0.139%	0.258%
Increase from 2007 to 2012	26%	19%	22%	33%	6%	11%	9%

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

Increase from 2006 to 2012	37%	24%	27%	33%	-3%	7%	4%

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

In 2007, the current fee of $184 on an annual basis represented 0.119 percent, 0.125 percent, and 0.237 percent of average annual income for physicians, dentists, and physician's assistants respectively. In 2012, the fee of $244 (on an annual basis) would represent approximately 0.125 percent, 0.139 percent, and 0.258 percent of average annual income for physicians, dentists, and physician's assistants respectively. This is a negligible difference. While fees are 33 percent above the current fees implemented at the end of 2006, average incomes for physicians, dentists, and physician's assistants increased 26 percent, 19 percent, and 22 percent respectively over the same period. This estimated increase in average income dampens the effect of the fee increase as a percentage of average income. The 33 percent fee increase as a percentage of average income is 6 percent for physicians (0.125%/0.119% - 1), 11 percent for dentists, and 9 percent for physician's assistants from 2007 to 2012. The diminishing effect is more apparent when comparing 2012 to 2006, the year for which the current fee was calculated and implemented. Additionally, as the average income grows in 2013 and 2014, the adjusted fees relative to average income are not any higher than in recent history.

5.2.3 Fee-Exempt Registrants

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.[6] Fee exempt registrants are not affected by the fees.

5.2.4 Conclusion

DEA concludes that this rule is not a significant regulatory action because it does not result in a materially adverse effect on the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.[7] The fee will initially affect all fee paying registrants. The fees may eventually be passed on to the general public, diminishing the impact of the fee increase on individual registrants. The impact of the fee on registrants is also diminished by a reduction in tax liabilities and an increase in average income. Additionally, hospitals and institutions operated by federal, State, or local governments and for their employees are exempt from registration fees.[8] Moreover, DEA believes that this rule will enhance public health and safety.

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

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

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

CHAPTER 6: IMPACT OF RULE ON SMALL ENTITIES

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 601-612) (RFA), DEA has evaluated the impact of this rule on small entities and has determined that this rule will not have a significant economic impact on a substantial number of small entities. As discussed in Chapter 3, most DEA registrants are small entities under Small Business Administration (SBA) standards. DEA has concluded that the adjustments in registration fees will not have a significant effect on these small business entities.

6.1 IMPACT OF FEES ON SMALL BUSINESSES

To assess whether the new fee schedule could impose a significant economic impact on a substantial number of small entities, DEA compared the fees as a percentage of revenue in 2012 to the current fees as a percentage of revenue in 2007.[9] DEA has determined that the rule will not have a significant economic impact on a substantial number of small entities. Economic impact by registrant classes is discussed in the following sections. Practitioners and mid-level practitioners represent 93 percent of all registrants and nearly all practitioners and mid-level practitioners are employed by small businesses pursuant to SBA standards. Among all registrants, practitioners and mid-level practitioners have the lowest annual revenues. While there are many specialists listed in the Bureau of Labor Statistics income data, incomes for physicians, dentists, and physician's assistants are representative of the practitioner and mid-level practitioner registrant groups.

Below is the table from Chapter 5.

[9] 2007 is the first full year of the previous registration fee increase. DEA proposes that 2012 be the first full year of the proposed new fee increase. Due to annual increases in annual income, the fees as a percentage of income would also change. Comparing the fees to annual income at the first full year of fee increase would be a like comparison.

Table 6: Fee as Percentage of Income FY 2004 - 2012

	Average Income[10]			Fee	Fee as % of Average Income		
Year	Physicians	Dentists	Physician Assistants	(Annual Basis)	Physicians	Dentists	Physician Assistants
2004	137,610	130,300	68,780				
2005	138,910	133,680	71,070				
2006	142,220	140,950	74,270	184	0.129%	0.131%	0.248%
2007	155,150	147,010	77,800	184	0.119%	0.125%	0.237%
2008	165,000	154,270	81,610	184	0.112%	0.119%	0.225%
2009	173,860	156,850	84,830	184	0.106%	0.117%	0.217%
2010	179,370	163,901	87,933	184	0.103%	0.112%	0.209%
2011	187,154	169,632	91,230	184	0.098%	0.108%	0.202%
2012	194,939	175,363	94,528	244	0.125%	0.139%	0.258%
Increase from 2007 to 2012	26%	19%	22%	33%	6%	11%	9%
Increase from 2006 to 2012	37%	24%	27%	33%	-3%	7%	4%

For practitioners and mid-level practitioners, the new fee, on an annual basis, is $244; the annual increase is $60 from the current fee. Physicians constitute the largest percentage of all practitioner registrants. Based on Bureau of Labor Statistics annual salary data, the current fee in 2007, the first full year of the current fee, represented 0.119 percent, 0.125 percent, and 0.237 percent of annual income for physicians, dentists, and physician's assistants respectively. In

[10] Source: Bureau of Labor Statistics, http://www.bls.gov. Average income data for 2004 to 2009 is provided by the Bureau of Labor Statistics. 2010 to 2012 are estimated figures based on linear regression, where a straight-line increase is calculated from years 2004 to 2009, then using the line to estimate average income for 2010 to 2012.

2012, the fee of $244, on an annual basis, is estimated to be approximately 0.125 percent, 0.139 percent, and 0.258 percent of annual income for physicians, dentists, and physician's assistants respectively. The annual impact of the rule is the difference between the fee as a percentage of income in 2012 to the current fee as a percentage of income in 2007, which are 0.007 percent (0.125% - 0.119% = 0.007%, rounded), 0.014 percent, and 0.022 percent for physicians, dentists, and physician's assistants respectively. (Numbers are rounded to the third decimal point.)

As discussed in Chapter 5, there are additional mitigating factors not included in the above analysis. The fee increase may be passed on to consumers; however, this analysis does not consider that the fees may be passed onto consumers in the form of higher prices for medical services or products. The fees may be treated as business expenses where after-tax impact is diminished; however, this analysis does not take potential deductions into account.

For consideration of the impact of the fee increase on small businesses, DEA analyzed the registration fee as a percentage of annual income for a representative group: physicians, dentists, and physician's assistants. The impact of the fees, $60 per year increase from current fees, were found to be 0.007 percent, 0.014 percent, and 0.022 percent of annual income for physicians, dentists, and physician's assistants respectively, when normalized for income increases. In consideration of the calculated impact and potentially further mitigating factors discussed in Chapter 5, DEA concludes that the rule will not have a significant economic impact on a substantial number of small entities.

6.2 IMPACT OF FEES ON OTHER REGISTRANTS

6.2.1 Impact on Pharmacies

Pharmacies represent 4.8 percent of all registrants. Many pharmacies are parts of chains, and some chains have thousands of stores. A corporate chain has the choice of having each store

in the chain pay a registration fee on the individual location's behalf or having the corporation pay for all locations at one time. Regardless of how the fee is paid, registration fees for a large chain can be substantial. For example, the registration fee for each pharmacy is $244 on an annual basis. Therefore, a chain with 4,000 stores would have a combined annual fee equivalent of $976,000. The increase in fees would be $240,000. Such fees are large, but compared to revenue, they are a much smaller percentage than those for physicians and dentists. The incremental increase in the fee from current fees as a percentage of revenue is even lower. Table 9 shows the new fees (annual equivalent) as percentage of average yearly revenue for various types of pharmacies.

Table 7: New Fees as Percentage of Revenue for Pharmacies

Pharmacy Types	Current fee (annual)	New fee (annual)	Amount of increase from Current fee	Ratio: New fee to Current fee	% of Annual Revenue Current fee**	% of Annual Revenue New fee**
Supermarkets	$ 184	$ 244	$ 60	1.33	0.003%	0.003%
Drug Stores	$ 184	$ 244	$ 60	1.33	0.004%	0.005%
Discount Stores	$ 184	$ 244	$ 60	1.33	0.001%	0.001%
Warehouse Clubs and Superstores	$ 184	$ 244	$ 60	1.33	0.000%	0.000%

Source: 2007 Economic Census.

** Current and Proposed Fees divided by average revenue in 2007, first full year the current fee.

6.2.2 Impact on Manufacturers and Distributors

The impact of the fee increase on manufacturers and distributors is minimal. For manufacturers, the new fee as a percentage of revenue ranges from 0.000 to 0.022 percent of a manufacturing establishment. For distributors, it is slightly higher: 0.002 to 0.055 percent. The

incremental increase in the fee from current fees as a percentage of revenue is even lower. Manufacturers' and distributors' fees are high relative to practitioners' fees, but they are a much lower fraction of revenue than is the case for individual practitioners. Most manufacturers and distributors do not qualify as small businesses under SBA standards.

Even for manufacturers and distributors that have multiple facilities and pay a registration fee for each facility, the percentage of revenue (economic impact) does not change. The percentages cited above are based on average revenue per establishment; increasing the number of establishments will not change the fee as a fraction of revenue.

Table 8: New Fees as Percentage of Annual Revenue for Manufacturers and Distributors

Business Types	Current fee (annual)	New fee (annual)	Amount of increase from Current fee	Ratio: New fee to Current fee	% of Annual Revenue Current fee**	% of Annual Revenue New fee**
Manufacturer						
Petrochemical Manufacturing	$ 2,293	$ 3,047	$ 754	1.33	0.000%	0.000%
Medicinal & Botanical Manufacturing	$ 2,293	$ 3,047	$ 754	1.33	0.008%	0.011%
Pharmaceutical Manufacturing	$ 2,293	$ 3,047	$ 754	1.33	0.002%	0.002%
Adhesive Manufacturing	$ 2,293	$ 3,047	$ 754	1.33	0.013%	0.017%
Toilet Preparation Manufacturing	$ 2,293	$ 3,047	$ 754	1.33	0.005%	0.006%
Other Chemical Manufacturing	$ 2,293	$ 3,047	$ 754	1.33	0.017%	0.022%
Distributor						
Drugs and Druggist Sundries Wholesalers	$ 1,147	$ 1,523	$ 376	1.33	0.002%	0.002%
General Line Grocery Wholesalers	$ 1,147	$ 1,523	$ 376	1.33	0.003%	0.003%
Confectionary Merchant Wholesalers	$ 1,147	$ 1,523	$ 376	1.33	0.007%	0.009%
Chemical Wholesalers	$ 1,147	$ 1,523	$ 376	1.33	0.009%	0.012%

Tobacco Wholesalers	$	1,147	$	1,523	$	376	1.33	0.002%	0.002%
Miscellaneous Wholesalers	$	1,147	$	1,523	$	376	1.33	0.042%	0.056%

Source: 2007 Economic Census.

** Current and Proposed Fees divided by average revenue in 2007, first full year the current fee.

CHAPTER 7: COST-BENEFIT ANALYSIS OF REGULATORY ACTION

In developing the Cost-Benefit Analysis (CBA), DEA focused on the costs and benefits that accrue to citizens and residents of the United States over the three year period, 2012 to 2014. The costs and benefits are measured against a baseline to capture the incremental costs and benefits of the rule.

7.1 COSTS OF THE RULE

The cost of the rule is the incremental increase in the combined registration fees paid by registrants. DEA estimates that it will collect approximately $812,254,676 in registration fees at current fee levels for the FY 2012 – FY2014 period. This figure, $812,254,676, represents the baseline. The fees are estimated to result in a total registration fee collection of $1,040,934,380 for Fiscal Years 2012-2014. The estimated increase in collections above the baseline is $228,679,704 for the three year period. Thus, the average annual increase in estimated registration fee collections is $76,226,568. Therefore, the cost of the rule is $76,226,568 per year during FY 2012 – FY2014. Although registration fees are paid by registrants, some or all of the registration fees are passed on to the citizens and residents of the United States. For this CBA, DEA assumes the annual cost of the rule is $76,226,568.

7.2 BENEFITS OF THE RULE

Benefits of the rule are an extension of the benefits of the DCP. The DCP is a strategic component of DEA that carries out the mandates of the CSA and its regulations to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes.

The citizens and residents of the United States bear an enormous cost from the diversion of controlled substances and listed chemicals into the illicit market. To capture the benefits of the rule, DEA estimated the cost of diversion to the citizens and residents of the United States: (1) at a baseline, without implementation of the rule, and (2) under the rule.

DEA used "Economic Costs of Nonmedical Use of Prescription Opioids"[11] and "Estimated Costs of Prescription Opioid Analgesic Abuse in the United States in 2001"[12] as primary sources for obtaining costs to the citizens and residents of the U.S. associated with the diversion of controlled substances and listed chemicals into the illicit market. While opioids discussed in the publications represent a subset of all controlled substances regulated by the DCP, the cost estimates in the publications represent a conservative estimated cost of diversion of all controlled substances and listed chemicals from a reputable source.

The researchers gathered data from numerous sources including emergency department information from the Drug Abuse Warning Network (DAWN), nonmedical use of prescription opioids information from the National Survey on Drug Use and Health (NSDUH), substance abuse treatment information from the Treatment Episode Data Sets (TEDS), statistical information from the U.S. Department of Justice Bureau of Justice Statistics, Federal Bureau of

[11] Clin J Pain (The Clinical Journal of Pain), Volume 27, Number 3, March/April 2011.
[12] Clin J Pain (The Clinical Journal of Pain), Volume 22, Number 8, October 2006.

Investigation, National Forensic Laboratory, and Drug Enforcement Administration Budget Summaries. Data related to the total cost of treatment for the abuse of prescription opioids also included input from the Substance Abuse and Mental Health Services Administration at the U.S. Department of Health and Human Services.

According to the research published in *The Clinical Journal of Pain*, costs associated with the nonmedical use of prescription opioids increased from $8.6 billion in 2001 to $53.4 billion in 2006.

Table 9: U.S. Costs of Nonmedical Use of Prescription Opioids 2001 and 2006

($ million)	**2001**	**2006**	**% Increase**
Total Cost	**$ 8,600**	**$ 53,400**	521%
Health Care	$ 2,600	$ 3,200	23%
Criminal Justice[13]	$ 1,400	$ 8,200	486%
Workplace & Lost Productivity	$ 4,600	$ 42,000	813%

The baseline cost of diversion to the citizens and residents of the United States is the estimated cost in 2012 without the rule. The increase from $8.6 billion in 2001 to $53.4 billion in 2006 represents a compound annual growth rate (CAGR) of 44 percent. At the present time, it is reasonable to assume that the baseline cost of nonmedical use of prescription opioids to the citizens and residents of the United States is now much greater than the $53.4 billion identified in 2006.

In FY 2010, the most recent year for which a full year of data is available, DEA initiated 1,011 criminal diversion investigations, imposed 1,519 administrative/civil/criminal sanctions,

[13]DCFA budget is understood to be included in the Criminal Justice cost figure. However, the DCFA budget is relatively low compared to the total Criminal Justice and even lower compared to the Total Cost. Therefore, the analysis does not back out the DCFA budget because it is not material to the discussion and to maintain integrity of the published research.

and conducted 3,553 scheduled investigations. In FY 2012, DEA estimates that it will have 1,802 administrative/civil/criminal sanctions and 3,906 scheduled investigations.[14] DEA believes that each administrative/civil/criminal sanction prevents the diversion of controlled substances and listed chemicals into the illicit market and that scheduled investigations deter the diversion of controlled substances and listed chemicals into the illicit market.

An increase in scheduled investigations and administrative/civil/criminal sanctions, in addition to added resources for criminal diversion investigations, is expected to, at a minimum, slow down the growth in the cost of nonmedical use of prescription opioids and diversion as a whole.

This rule provides additional resources to enhance the performance of the DCP and slow down the growth in the cost of controlled substances and listed chemicals diverted into the illicit market. Although difficult to accurately quantify, the benefit of this rule is the slowdown in the growth of the cost of diversion of controlled substances and listed chemicals into the illicit market.

7.3 EVALUATION OF COSTS AND BENEFITS OF RULE (THRESHOLD ANALYSIS)

In evaluating the costs and benefits of the rule, the annual cost of the rule of $76,226,568, which represents 0.14 percent of the cost of diversion – $53.4 billion – is compared with the anticipated reduction in the growth rate of costs associated with diversion of controlled substances and listed chemicals into the illicit market. The CBA uses the costs associated with the nonmedical use of prescription opioids as a conservative estimate of the total cost associated with diversion of controlled substances and listed chemicals into the illicit market.

[14] FY 2012 Performance Budget Congressional Submission, p. DEA-70.

It is preferable to conduct a discounted cash flow analysis where the costs and benefits are quantified and the net benefits are calculated and presented in today's dollar value. However, the baseline costs associated with diversion of controlled substances and listed chemicals into the illicit market is unreliable. Therefore, a quantitative analysis is not possible and a threshold analysis is utilized.

The threshold analysis considers whether the benefits of the rule are greater than or equal to the cost of the rule.

$$\text{Benefits of Rule} \overset{?}{\geq} \text{Costs of Rule}$$

As discussed above, the cost of the rule is $76,226,568 per year.

$$\text{Benefits of Rule} \geq \$0.076 \text{ billion}$$

The benefits of the rule are represented as the difference between the costs associated with diversion of controlled substances and listed chemicals into the illicit market at the baseline and the costs associated with the diversion of controlled substances and listed chemicals into the illicit market under the rule.

$$\left(\begin{array}{l}\text{Cost Associated with Diversion to illicit market (baseline)}\end{array} - \begin{array}{l}\text{Cost Associated with Diversion to illicit market (rule)}\end{array}\right) \geq \$0.076 \text{ billion}$$

The baseline costs associated with the diversion of controlled substances and listed chemicals into the illicit market is estimated to be at least $53.4 billion (the cost associated with the nonmedical use of prescription opioids in 2006).

$$\left(\begin{array}{l}\text{At least } \$53.4\end{array} - \begin{array}{l}\text{Cost Associated with Diversion to illicit market (rule)}\end{array}\right) \geq \$0.076 \text{ billion}$$

Rearranging the equation,

$$\begin{array}{l}\text{Cost Associated with Diversion to illicit market (rule)}\end{array} \leq \left(\begin{array}{l}\text{At least } \$53.4 \text{ billion}\end{array} - \$0.076 \text{ billion}\right)$$

Therefore, the break-even would occur if the costs associated with diversion of controlled substances and listed chemicals into the illicit market are reduced to $0.076 billion from a baseline of "at least $53.4 billion."

7.4 ALTERNATIVE EVALUATION OF COSTS AND BENEFITS OF RULE

As an alternative way to present the threshold analysis, DEA offers an overall cost-benefit analysis comparing the increased fee collections under this rule, which support essential enhancement in the effective operations of the Diversion Control Program (DCP), in correlation to the societal costs from deaths resulting from the abuse of controlled substance pharmaceuticals.

The DCP is a strategic component of DEA that carries out the mandates of the CSA and its regulations to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes. The citizens and residents of the United States bear an enormous cost from the abuse of controlled substance pharmaceuticals. The National Drug Control Strategy is focused on all aspects of the problem—supply, demand, and treatment. The DCP is focused on the supply side of this serious threat to the public health and safety. DCP enforcement activities are designed to maintain the integrity of the closed system of distribution for controlled substances in order to prevent, detect, and eliminate diversion, thereby reducing the supply of dangerous controlled substance pharmaceuticals available for abuse and the potential for deadly overdoses.

DEA notes that the Department of Transportation, for rulemaking purposes, calculates the value of a statistical life (VSL) saved at an estimated $6.2 million each for purposes of cost-benefit analyses. The last two updates to its estimate and its sources can be found at: http://regs.dot.gov/docs/VSL%20Guidance%202008%20and%202009rev.pdf and http://regs.dot.gov/docs/Value_of_Life_July_29_2011.pdf. See also OMB Circular A-4, which contains more information on the factors that typically go into such an estimate.

For the purposes of this cost-benefit analysis, DEA is using $6.2 million as an appropriate VSL estimate.

With respect to the prevalence of drug overdose deaths, DEA notes that the Centers for Disease Control and Prevention (CDC) reported that the number of poisoning deaths involving any opioid analgesics increased from 4,041 in 1999 to 14,800 in 2008, more than tripling in 9 years.[15]

The estimated annual increase in registration and reregistration fees under this rule is $76 million.

Using these figures, only 13 lives (at a VSL of $6.2 million) would need to be saved each year through enhanced enforcement by the Diversion Control Program in order for the benefits of such increased enforcement to exceed the cost of the additional fees collected in support of the DCP.

[15] Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, November 4, 2011.