Supporting Statement for Paperwork Reduction Act Submissions
Application for Registration (DEA Form 224)
Renewal Application for Registration (DEA 224A)
OMB Approval #1117-0014

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for an existing collection of information that was previously approved by OMB – OMB Approval #1117-0014 Application for Registration (DEA Form 224) and Renewal Application for Registration (DEA Form 224A).

This information collection request is associated with DEA's Final Rule (FR), "Amending Regulations to Require Online Submission of Applications for and Renewal of DEA Registration," RIN 1117-AB58. DEA is finalizing the revise regulations for application and renewal by requiring all DEA registrants to apply for registration online using the agency's secure portal. This will eliminate the need for paper forms and payments, streamline the registration process, and save time and expense for both the agency and registration population.

Part A. Justification

1. Necessity of Information:

DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242 (1970), as amended (collectively, the CSA). 21 U.S.C. 801–971. Through the enactment of the CSA, Congress established a closed system of distribution making it unlawful to handle any controlled substance except in a manner authorized by the CSA. In order to maintain this closed system of distribution, the CSA generally requires all persons who handle controlled substances to obtain a registration from the Attorney General. 21 U.S.C. 822, 823, 831, 957, and 958.

The Controlled Substances Act (CSA) (21 U.S.C. 801–971) requires all persons that manufacture, distribute, dispense, conduct research with, import, or export any controlled substance to obtain a registration issued by the Attorney General. 21 U.S.C. 822, 823, 957. This includes persons that reverse distribute, or conduct research or chemical or other laboratory analysis of any controlled substance (including canine handlers). See 21 CFR 1301.13. Generally, any person who is registered may apply to be reregistered no more than 60 days before the expiration date of their registration. 21 CFR 1301.13(b). However, a bulk manufacturer of a schedule I or II controlled substance or an importer of a schedule I or II controlled substance may apply to be reregistered no more than 120 days before the expiration date of their registration. 21 CFR 1301.13(b).

Any person who is required to be registered, but is not so registered, must make an application for registration. Registration is a necessary control measure that helps to detect and prevent diversion by ensuring that the closed system of distribution of controlled substances can be monitored by DEA, and that the businesses and individuals handling controlled substances are accountable.

2. Needs and Uses:

DEA Form 224 and related sub-forms are utilized by various applicants (e.g., physicians, hospitals/clinics, retail pharmacies, central fill pharmacies, and teaching institutions) seeking to become registered to dispense controlled substances (including through administering and prescribing). 21 CFR 1301.13(a) and (e). DEA Form 224A is utilized for renewals of such registrations on a triennial basis. 21 CFR 1301.13(d) and (e). The purpose of registration or reregistration is to ensure the persons handling controlled substances are qualified and have the experience necessary to handle controlled substances. The purpose is to also ensure the integrity of the closed system of distribution as well as track/monitor the movement of controlled substances in accordance with the CSA. 21 U.S.C. 823, 824, and 831; 21 CFR 1301.31, 1301.37.

3. Use of Information Technology:

Currently, DEA permits online registration and renewal of registration through the secure network application on the DEA Diversion Control Division Web site (*http://www.deadiversion.usdoj.gov*). Applicants may complete and submit the required DEA Registration Forms online, along with credit card payment. This final rule will require 100% online submissions.

4. Efforts to Identify Duplication:

DEA has made efforts to identify and prevent duplication of the collection of information. The existing DEA Registration Forms are not duplicative of any other DEA forms. The collection of this information is unique to the DEA.

5. Impact on Small Businesses or Entities:

DEA does not anticipate any additional impact on small businesses or other small entities since the initial approval of this form. The collection will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601–612.

6. Consequences of Less Frequent Collection:

By law, this information must be collected at least every three years. The CSA states that: "Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period for such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years." 21 U.S.C. 822(a)(2).

7. Special Circumstances Influencing Collection:

There are no special circumstances applicable to this information collection.

8. Consultation with persons outside the Agency:

Public comment has been solicited in the NPRM associated with this collection, which was published in the *Federal Register*, 86 FR 1030, on January 7, 2021. During the 60-day comment period, DEA received no comments regarding the information being collected. The comments have been responded in the final rule published on April 11, 2022, 87 FR 21019.

DEA meets regularly with the affected industry to discuss policies, programs, and regulations. These meetings provide an open forum to discuss matters of mutual concern with representatives of those entities from whom the information is obtained.

9. Payment or Gift to Claimants:

This collection of information does not propose to provide any payment or gift to respondents.

10. Assurance of Confidentiality:

Information requested in this collection may be considered confidential business information if marked as such in accordance with 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). Submitters who are required to furnish commercial or financial information to the government are protected from the competitive disadvantages that could result from disclosure of such information. The information is protected by DEA through secure storage, limited access, and federal regulatory and DEA procedures. In the event a FOIA request is made to obtain information that has been designated as confidential business information per 28 CFR 16.8(c) and Exemption 4 of FOIA, DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by DEA.

11. Justification for Sensitive Questions:

This collection of information does not ask any questions of a sensitive nature.

12. Estimate of Hour Burden:

DEA Form 224 is submitted on an as-needed basis by persons seeking to become registered. DEA Form 224A is submitted on a triennial basis thereafter.

	Number of Annual Respondents	**Average Time per Response**	**Total Annual Hours**
DEA-224	131,508	0.33 hours (20 minutes)	43,836
DEA-224a	485,578	0.17 hours (10 minutes)	80,930
Total	**617,086**		**124,766**

* Based on three-year average, 2017-2019. Practitioners are registered for a three-year cycle and the number of registrants is not equally distributed between years. The growth rate in the number of practitioners is low enough where the actual numbers for this period would not be materially different from the number expected for the next several years.

Total number of respondents: 617,086
Number of responses per respondent per year: 1
Total annual responses: 617,086
Total annual hour burden: 124,766

Average Burden: Per Collection: 0.202186 hour
Per Respondent: 0.202186 hour

Total registration applications received on paper: 0
Total registration applications received online: 617,086

Percentage of applications received electronically: 100%

Burden dollars:

Estimated hourly wage ($/hour):[1]	99.28
Load for benefits (percent of labor rate):[2]	42.7%
Loaded labor rate ($/hour):[3]	141.67

	DEA Form 224	DEA Form 224a	Combined
Number of responses	131,508	485,578	617,086
Total annual hours	43,836	80,930	124,766
Average burden per response (hour)	0.3333	0.1667	0.202186
Burden dollars per response ($)	47.22	23.62	28.649427
Total burden dollars ($)	**6,209,808**	**11,469,352**	**17,679,160**

Thus, the labor cost of this information collection is $17,679,160 annually.

13. Estimate of Cost Burden:

The estimated annual cost burden is zero. Respondents are not estimated to incur any a) additional start-up cost or capital expenditure, or b) additional operation and maintenance costs or purchase services as a result of this information collection.

14. Estimated Annualized Costs to Federal Government:

1 Average of median hourly wages for 29-1228 Physicians, All Other; and Ophthalmologists, Except Pediatric is used to represent the occupation of persons completing the DEA Form 224 and 224a. May 2019 National Occupational Employment and Wage Estimates United States. http://www.bls.gov/oes/current/oes_nat.htm.
2 Bureau of Labor Statistics, "Employer Costs for Employee Compensation – December 2019" (ECEC) reports that average benefits for private industry is 29.9% of total compensation. The 29.9% of total compensation equates to 42.7% (29.9% / 70.1%) load on wages and salaries.
3 $99.28 x (1 + 42.7%) = $141.67.

Estimated Annual Labor Cost to Government:

Labor Category	Number[4]	% of time[5]	Cost[6]
Registration Program Specialists – GS-963-9 (Field)	69	97.0 %	$ 7,248,745
Total			**$ 7,248,745**

All costs are recovered from registrants through registration fees, as required by the CSA. 21 U.S.C. 886a.

15. Reasons for Change in Burden:

The regulatory change affecting this information collection, requiring all forms be submitted online, is expected to lower burden. However, the increase in burden hours is a result of adjusting up, the average burden hours per response. Increase in annual cost are attributed to increase in burden hours and adjustment in burden cost per response. The decrease in the number of respondents reflect the change in method for estimating the number of respondents from using the previous year actual registration to a three-year average of the previous three years, as respondents are on a three year registration cycles. The table below summarizes the changes since the last renewal of this information collection.

	2019 Approved Burden	New Requested Burden	Difference
Annual respondents	617,979	617,086	(893)
Annual burden hours	61,226	124,766	63,540
Annual cost ($)	9,080,036	17,679,160	8,599,124

16. Plans for Publication:

DEA will not publish the results of the information collected.

17. Expiration Date Approval:

DEA does not object to displaying the expiration date for this collection.

18. Exceptions to the Certification Statement:

DEA is not seeking an exception to the certification statement "Certification for Paperwork Reduction Act Submissions" for this collection of information.

Part B. Statistical Methods

4 Based on number of allocated positions, February 19, 2020.
5 Based on percent 224 and 224a forms of all registration application forms.
6 Government salary figures include 60.5% load for benefits based on the ECEC for "State and local government." The ECEC does not include figures for the Federal Government.

DEA does not employ statistical methods in this information collection.