

Supporting Statement for Paperwork Reduction Act Submissions
Application for Registration (DEA Form 224)
Application for Registration Renewal (DEA Form 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 Application for Registration Renewal (DEA Form 224A).

Part A. Justification

1. Necessity of Information:

The 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 (the “CSA”). 21 U.S.C. 801–971. Through the enactment of the CSA and its amendments, 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 issued by the Attorney General. 21 U.S.C. 822, 823, 957, and 958.

A practitioner (a person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research) who is required to be registered, but is not so registered, may make an application for registration. 21 CFR 1301.13. Additionally, any registered practitioner may apply to be reregistered not more than 60 days before the expiration date of his or her registration. 21 CFR 1301.13. Registrants are permitted to handle controlled substances to the extent authorized by their registration and must comply with the requirements associated with their registration. 21 U.S.C. 822(b), 958(g). It is unlawful for any person to knowingly or intentionally handle a controlled substance except as authorized by the CSA. 21 U.S.C. 841(a).

2. Needs and Uses:

DEA Form 224 is utilized by various practitioners (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)(iv). DEA Form 224A is utilized for renewals of such registrations on a triennial basis. 21 CFR 1301.13(d) and (e)(iv). The information submitted on these forms is used to identify persons seeking registration or renewal of registration and to provide information so that the DEA can determine whether

registration would be in accordance with the CSA. 21 U.S.C. 823 and 824; 21 CFR 1301.31, 1301.37.

3. Use of Information Technology:

The DEA permits online registration and renewal of registration through the secure network application on the DEA Office of Diversion Control Web site (<http://www.deadiversion.usdoj.gov>). Applicants may complete and submit DEA Forms 224 and 224A online, along with credit card payment. Approximately 89.7% (479,269 of 534,082) of applications for initial registration and renewal registration for applicable practitioners were submitted online during calendar year 2014.

4. Efforts to Identify Duplication:

The DEA has made efforts to identify and prevent duplication of the collection of information. The existing DEA Forms 224 and 224A 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:

This is a routine renewal of DEA Forms 224 and 224A. The 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 small businesses or other small entities within the meaning and intent 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 was solicited in the 60-day Federal Register Notice of Information Collection, 83 FR 64367, published December 14, 2018 and the 30-day Federal Register Notice of Information Collection, 84 FR 5721, published February 22, 2019. The DEA did not receive any comments concerning this collection.

The DEA meets regularly with 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 the 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, the DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by the 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 (paper)	3,838	0.22 hours (13 minutes)	832
DEA-224 (electronic)	125,848	0.15 hours (9 minutes)	18,877
DEA-224A (paper)	6,193	0.22 hours (13 minutes)	1,342
DEA-224A (electronic)	482,100	0.08 hours (5 minutes)	40,175
Total	617,979		61,226

*Although practitioners are registered for a three-year cycle and the number of registrants is not equally distributed between years of the cycle, October 1, 2017 to September 30, 2018 is a reasonable approximation of the average annual burden as it is very close to the average of the three years. Additionally, 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.

**An extra minute has been added to each average time per response to reflect the proposal for the first liability question in the application to now be broken down into two parts.

***Figures are rounded.

Total number of respondents: 617,979

Number of responses per respondent per year: 1

Total annual responses: 617,979

Total annual hour burden: 61,226

Average Burden: Per Collection: 0.10 hour

Per Respondent: 0.10 hour

Total registration applications received on paper: 10,031

Total registration applications received online: 607,948

Percentage of applications received electronically: 98.4%

Estimates are based on the population of the regulated industry participating in this business activity. Because the vast majority of respondents are practitioners, the DEA utilizes the wage rate for “physicians and surgeons” (SOC 29-1060, 2010 Standard Occupational Classification, http://www.bls.gov/soc/2010/soc_alpha.htm) as an estimate for all persons who will complete the form on behalf of the applicant or registrant. The mean hourly wage for that position according to the Bureau of Labor Statistics’ (BLS) 2017 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm) is \$103.22. Based on the BLS report, “Employer Costs for Employee Compensation – June 2018,” (ECEC) (<http://www.bls.gov/news.release/pdf/ecec.pdf>) an additional 43.7% load (for “private industry”) is added to the wage rate to account for benefits.

Thus, the labor cost of this information collection is \$9,080,036 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 Cost to Federal Government:

Estimated Annual Production Cost to Government:¹

Production Item	Cost*
Government Employees:	\$ 2,235
Contract Employees:	\$ 6,063

¹ Based on percent paper 224 and 224a forms of total paper forms.

Cost of Paper:	\$	1,191
Mailing (Postage):	\$	27,681
Custom Envelopes	\$	1,964
Equipment Maintenance:	\$	3,412
Equipment/10 years:	\$	<u>5,062</u>
Total	\$	47,608

*Figures are rounded.

Estimated Annual Labor Cost to Government:

Labor Category	Number	% of time	Cost*
Registration Program Specialists – GS-963-9 (Field) ²	54	97%	\$ 5,350,548
Legal Instrument Examiners – GS-963-9 (HQ) ³	1	95%	\$ 96,670
Legal Instrument Examiner – GS-963-11 (HQ) ⁴	1	95%	<u>\$ 116,961</u>
Total			\$ 5,564,179

*Figures are rounded.

Grand Total: **\$5,611,787**

All costs are recovered from registrants through registration fees, as required by the CSA, 21 U.S.C. 886a. Government salary figures include 60.26% load for benefits based on the ECEC for “State and local government.” The ECEC does not include figures for the Federal Government.

15. Reasons for Change in Burden:

Changes reflect population adjustments and greater use of online applications, which take less time to complete. Although there was a slight increase in the percentage of applicants applying online, having a greater number of respondents from October 2017 to September 2018 results in a net increase in the annual burden hours. Although practitioners are registered for a three-year cycle and the number of registrants is not equally distributed between years of the cycle, October 1, 2017 to September 30, 2018 is a reasonable approximation of the average annual burden as it is very close to the average of the three years. Additionally, 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. Although there is a small increase in the burden hours, the increase in the annual cost is attributed to the mean hourly wage increase of physicians and surgeons. There have been no statutory or regulatory changes affecting this information collection. The table below summarizes the changes since the last renewal of this information collection.

2 Based on percent 224 and 224a forms of all registration application forms.

3 See note 1.

4 See note 1.

	2015 Approved Burden	2019 Requested Burden	Difference
Annual respondents	534,082	617,979	83,897
Annual burden hours	47,756	61,226	13,470
Annual cost (\$)	6,459,789	9,080,036	2,620,247

16. Plans for Publication:

The DEA will not publish the results of the information collected.

17. Expiration Date Approval:

The DEA does not object to OMB displaying the expiration date.

18. Exceptions to the Certification Statement:

The 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

The DEA does not employ statistical methods in this information collection.