

Supporting Statement for Paperwork Reduction Act Submissions
Application for Registration (DEA Form 224)
Application for Registration Renewal (DEA Form 224A)
OMB Approval #1117-0014¹

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:

¹ In previous information collection requests pertaining to OMB Approval #1117-0014, DEA also sought approval for DEA Form 224B (Affidavit for Chain Renewal) and DEA Form 224C (Application for Modification of Registration for Online Pharmacies). However, the DEA has recently determined that the data provided to the DEA by DEA Forms 224B (Affidavits) and 224C (Modifications) do not constitute “information” pursuant to 5 CFR 1320.3(h)(1). Rather, this data is regarded as routine inquiries and entail no burden to the respondent. Responding to these requests rarely requires examination of records, and usually does not require much consideration to provide the correct answer. Therefore, DEA Form 224B (Affidavit for Chain Renewal) and DEA Form 224C (Application for Modification of Registration for Online Pharmacies) are excluded from this information collection request.

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, 80 FR 61239, published October 9, 2015 and the 30-day Federal Register Notice of Information Collection, 80 FR 77020, published December 11, 2015. 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)	4,548	0.2 hours (12 minutes)	910
DEA-224 (online)	97,763	0.13 hours (8 minutes)	13,035
DEA-224A (paper)	50,265	0.2 hours (10 minutes)	8,378
DEA-224A (online)	381,506	0.07 hours (4 minutes)	25,434
Total	534,082		47,756

* Although practitioners are registered for a three-year cycle and the number of registrants is not equally distributed between years of the cycle, 2014 is a reasonable approximation of the average annual burden as it is the median of the three years and 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 2014 would not be materially different from the number expected for the next several years.

**Figures are rounded.

Total number of respondents: 534,082

Number of responses per respondent per year: 1

Total annual responses: 534,082

Total annual hour burden: 47,756

Average Burden: Per Collection: 0.09 hour

Per Respondent: 0.09 hour

Total registration applications received on paper: 54,813

Total registration applications received online: 479,269

Percentage of applications received electronically: 89.7%

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) 2014 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm) is \$93.74. Based on the BLS report, “Employer Costs for Employee Compensation – March 2015,” (ECEC) (<http://www.bls.gov/news.release/pdf/ecec.pdf>) an additional 43.3% load (for “private industry”) is added to the wage rate to account for benefits. Thus, the labor cost of this information collection is \$6,459,789 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:

Production Item	Cost*
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Government Employees:	\$	1,608
Contract Employees:	\$	73,538
Cost of Paper:	\$	7,378
Mailing (Postage):	\$	177,075
Custom Envelopes	\$	10,698
Equipment Maintenance:	\$	32,774
Equipment/10 years:	\$	<u>48,623</u>
Total	\$	351,695

*Figures are rounded.

Estimated Annual Labor Cost to Government:

Labor Category	Number	% of time	Cost*
Section Chief – GS-301-15	1	90%	\$ 201,205
Deputy Section Chief – GS-1801-14	1	50%	\$ 95,027
Project Manager/Unit Chief – GS-343-14	1	90%	\$ 171,049
Registration Program Specialists – GS-963-9 (Field)	52	75%	\$ 3,637,298
Legal Instrument Examiners – GS-963-9 (HQ)	6	75%	\$ 419,688
Legal Instrument Examiner – GS-963-11 (HQ)	1	80%	\$ 90,274
Diversion Investigators – GS-1801-12 (Field)	468	5%	\$ 3,164,996
Program Analysts – GS-343-13 (HQ)	7	65%	\$ 731,782
Computer Assistant – GS-335-9 (HQ)	1	95%	\$ 88,601
Government Contractor Call Center Employees, 3 Supervisors and 1 Task Manager	25	85%	\$ 1,618,578
Fee Processing and Mail Room, 6 Government Contractor Employees	6	95%	<u>\$ 479,950</u>
Total			\$10,698,449

*Figures are rounded.

Grand Total: **\$11,050,144**

All costs are recovered from registrants through registration fees, as required by the CSA, 21 U.S.C. 886a. Government salary figures include 56.25% 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 in 2015 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, 2014 is a reasonable approximation of the average annual burden as it is the

median of the three years and 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 2014 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 decrease in the annual cost is attributed to a change in calculation method.* 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.

	2012 Approved Burden	2015 Requested Burden	Difference
Annual respondents	474,914	534,082	59,168
Annual burden hours	46,698	47,756	1,058
Annual cost (\$)	109,230,726	6,459,789	(102,770,937)

(* In prior information collection requests, the associated registration fee was included in the cost burden calculation. The DEA believes the registration fee should be excluded from the information collection cost burden because the time and capital expense burden to provide the information is not tied to the registration fee. (77 FR 15234, March 15, 2012.) This change in calculation method is employed in this and future information collection requests.)

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.