

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).

This information collection request would update DEA Forms 224 and 224A to allow EMS agencies, if authorized by state law, to register with DEA as a new type of business activity. This information collection request is associated with DEA’s “Registering Emergency Medical Services Agencies under the Protecting Patient Access to Emergency Medications Act of 2017” rulemaking, RIN 1117-AB37.

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 Controlled Substances Act). 21 U.S.C. 801–971. Through the enactment of the Controlled Substances Act (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 “Protecting Patient Access to Emergency Medications Act of 2017” creates a new registration category under the CSA for Emergency Medical Services (EMS) agencies, directing the Attorney General (and thus the Administrator of DEA by delegation) to register such an agency under the CSA if the agency submits an application demonstrating that it is authorized to conduct emergency medical services under the laws of each State in which the agency practices.

2. Needs and Uses:

Currently, DEA Form 224 is utilized by applicants seeking to become registered to distribute or dispense controlled substances (including through administering and prescribing). 21 CFR 1301.13(a) and (e). DEA Form 224A is currently utilized for renewals of such registrations on a triennial basis. 21 CFR 1301.13(d) and (e). 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, 824, and 831; 21 CFR 1301.31, 1301.37.

Under proposed § 1301.13, EMS agencies, if authorized by state law, may register as a new type of business activity. For Emergency Medical Services, DEA is proposing to add a new business activity to DEA Form 224 for applicants seeking to register as an EMS Agency. Similarly, DEA Form 224A would also be updated to add the EMS Agency business activity for those registrants wishing to renew their registration. This new business activity will allow EMS agencies to obtain a DEA registration that will permit EMS agencies to deliver controlled substances to their designated locations without obtaining a separate registration as a Distributor. This registration will allow EMS personnel to administer controlled substances outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services. Upon issuance of an EMS agency registration, the EMS agency should use the online system to identify all of the locations it intends to designate under the EMS agencies' DEA registration.

To lessen the burden for EMS agencies with several stationhouses in a single state, DEA proposes to allow EMS agencies to choose the option of a single registration in each state where the EMS agency operates. If the agency operates EMS facilities in multiple states, the agency must have a separate registration in each state where the agency operates.

3. Use of Information Technology:

DEA permits online registration and renewal of registration through the secure network application on DEA's 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 98.4 percent of applications for initial registration and renewal registration for applicable practitioners are submitted online.

4. Efforts to Identify Duplication:

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 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 is being solicited in the notice of proposed rulemaking (NPRM) titled, “Registering Emergency Medical Services Agencies under the Protecting Patient Access to Emergency Medications Act of 2017” , which has been published in the *Federal Register* at 85 FR _62634_____, on October 5, 2020. DEA has received 81 comments concerning this collection.

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
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DEA-224	125,848	0.33 hours (20 minutes)	41,530
DEA-224a	495,624	0.17 hours (10 minutes)	84,256
Total	621,472		125,786

Total number of respondents: 621,472

Number of responses per respondent per year: 1

Total annual responses: 621,472

Total annual hour burden: 125,786

Average Burden: Per Collection: 0.202400 hour
Per Respondent: 0.202400 hour

Total registration applications received on paper: 9,943

Total registration applications received online: 611,529

Percentage of applications received electronically: 98.4%

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	125,848	495,624	621,472
Total annual hours	41,530	84,256	125,786
Average burden per response (hour)	0.3333	0.1667	0.202400
Burden dollars per response (\$)	47.22	23.62	28.649427
Total burden dollars (\$)	5,942,523	11,706,639	17,649,162

Thus, the labor cost of this information collection is \$17,649,162 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:

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 percent of total compensation. The 29.9 percent of total compensation equates to 42.7 percent (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	Number⁴	% of time⁵	Cost⁶
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 increase in the number of respondents reflect new “EMS Agency” business activity that will be added to the application for registration and application for registration renewal forms to allow EMS agencies to obtain a DEA registration. Additionally, there is a 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 cycle. The increase in burden hours is a result of adjusting up, doubling, the average time per response. Increase in annual costs are attributed to the increase in registrants and burden hours and the adjustment in burden cost per response. 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	621,472	3,493
Annual burden hours	61,226	125,786	64,560
Annual cost (\$)	9,080,036	17,649,162	8,569,126

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.

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.

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 percent load for benefits based on the ECEC for “State and local government.” The ECEC does not include figures for the Federal Government.

Part B. Statistical Methods

DEA does not employ statistical methods in this information collection.