SUPPORTING STATEMENT FOR
Application for Registration-DEA 224, Application of Registration Renewal-DEA 224A

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).

A. JUSTIFICATION

1. 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 (CSA)). 21 U.S.C. 801–971. The CSA 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).

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. 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)(iv). 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.

Under proposed 21 U.S.C. 823(k)(1)-(3)[1], EMS agencies, if authorized by state law, may register

[1] Consistent with 21 U.S.C. 823(k)(3), DEA is implementing regulations that will continue to allow an EMS agency based in a hospital that is registered under § 1301.13 to use the hospital's registration to administer controlled substances, without being separately registered as an EMS agency.

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. 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 will require 100% online submissions.

4. 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. 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. 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. There are no special circumstances.

8. The 60-Day Notice was published on October 7, 2024 (89 FR 81109). The comment period ended on December During the 60-day comment period, DEA received no comments regarding the information being collected. The 30-day notice published in the Federal Register on December 12, 2024, at 89 FR 100536.

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. No government funds will be used as payment or for gifts to respondents.

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

12.

Estimated Annualized Respondent Cost and Hour Burden

Activity	Number of Respondents	Frequency	Total Annual Responses	Time Per Response	Total Annual Burden (Hours)	Hourly Rate*	Monetized Value of Respondent Time
DEA-224	146,285	1	146,285	20 minutes	48,761	$165.11	$8,050,929
DEA-224a	524,196	1	524,196	10 minutes	87,366	$165.11	$14,425,000
Total	**670,481**	**1**	**670,481**	**0.203029 hours**	**136,127**	**$165.11**	**$22,475,929**

Based on three-year average, 2020-2022. 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.

*Hourly Rate:

Estimated hourly wage ($/hour):[2]	$116.44
Load for benefits (percent of labor rate):[3]	41.8%

[2] Average of median hourly wages for 29-1216 General Internal Medicine Physicians is used to represent the occupation of persons completing the DEA Form 224 and 224a. May 2021 National Occupational Employment and Wage Estimates United States. https://www.bls.gov/oes/2021/may/oes_nat.htm.

[3] Bureau of Labor Statistics, "Employer Costs for Employee Compensation – December 2021" (ECEC) reports that

Loaded labor rate ($/hour):[4] $165.11

13. 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 annual production cost to the Federal government:

Labor Category	Number	Annual rate	Load	% of time	Cost
Registration Program Specialists - GS-963-9 (Field)	70[5]	$ 73,617[6]	1.616[7]	92.0%	$ 7,664,713
Total					**$ 7,664,713**

Total annual cost: $7,664,713.

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

15. DEA is revising the proposed information collections by adding a checkbox to the new application and renewal application for applicants to affirm that they have completed the new eight-hour training requirement. DEA is also adding three questions to the applications in regards to the training requirements, in which they will be required to answer yes to at least one of the questions in order to proceed.

The change in annual burden hours is due to rounding in the calculation. The change in annual cost burden is due to change in method. Previously, the approved 2023 figure represents the annual labor burden hours calculated in section 12. The new requested annual cost burden represents the figure from section 13.

	2023 Approved Burden	New Requested Burden	Difference
Annual respondents	670,481	670,481	-
Annual burden hours	136,128	136,127	(1)
Annual cost ($)	22,475,937	-	(22,475,937)

average benefits for private industry is 29.5 percent of total compensation. The 29.5 percent of total compensation equates to 41.8 percent (29.5% / 70.5%) load on wages and salaries.

[4] $116.44 x (1 + 0.418) = $165.11.

[5] Number of Registration Program Specialists (RPS) personnel from DEA's 2021 RPS study

[6] Annual Rate based on GS grade 9 step 5 in 2023 OPM Washington-Baltimore-Arlington Salary Table

[7] Bureau of Labor Statistics, "Employer Costs for Employee Compensation – September 2022" (ECEC) reports that average benefits for state and local workers is 38.1 percent of total compensation. The 38.1 percent of total compensation equates to 61.6 percent (38.1% / 61.9%) load on wages and salaries. Figures for state and local workers were used as an estimate for federal workers.

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

17. We are requesting no exemption.

18. This collection of information does not include any exceptions to the certificate statement.

B. COLLECTIONS OF INFORMATON EMPLOYING STATISTICAL METHODS.

This collection does/does not contain statistical data.