

Supporting Statement for Paperwork Reduction Act Submissions
Application for Registration (DEA Form 363)
Application for Registration Renewal (DEA Form 363a)
OMB Approval #1117-0015

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 #1117-0015, Application for Registration (DEA Form 363) and Application for Registration Renewal (DEA Form 363a).

This information collection request is associated with DEA's notice of proposed rulemaking (NPRM), "Amending Regulations to Require Online Submission of Applications for and Renewal of DEA Registration," RIN 1117-AB58. DEA is proposing to revise the 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:

The Narcotic Addict Treatment Act of 1974 (NATA) (Pub. L. 93-281) amended the Controlled Substance Act (CSA) to provide for the registration of practitioners conducting narcotic treatment programs. NATA required a separate registration of practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment.¹ 21 U.S.C. 823(g). These practitioners register as Narcotic Treatment Programs using DEA Form 363, and using DEA Form 363a for renewals.

2. Needs and Uses:

DEA Form 363 is utilized by applicants seeking to become registered as narcotic treatment programs to dispense narcotic drugs for maintenance treatment or detoxification treatment. 21 U.S.C. 823(g). DEA Form 363a is utilized for renewals of registrations on an annual basis. The information submitted is used to identify persons seeking registration and provide information so that DEA can determine whether such registration would be in accordance with the Controlled Substances Act. See 21 U.S.C. 823, 824. 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.

3. Use of Information Technology:

¹ Pursuant to 21 U.S.C. 823(g)(2) this registration requirement is waived for certain practitioners under specified circumstances.

Currently, DEA has a system which permits online 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 form online, along with credit card payment. This proposed rulemaking would 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 Form 363 and 363a 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 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:

The CSA requires all persons who dispense, or propose to dispense, controlled substances to obtain a registration. 21 U.S.C. 822(a)(2). The NATA specified that “practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose.” 21 U.S.C. 823(g)(1). Accordingly, DEA has no discretion with respect to less frequent collection in instances of Narcotic Treatment Program registrations or registration renewals. The information submitted is used to identify persons seeking registration and provide information so that DEA can determine whether such registration would be in accordance with the Controlled Substances Act. See 21 U.S.C. 823, 824.

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 NPRM associated with this collection, which was published in the *Federal Register*, 86 FR 1030, on January 7, 2021. The NPRM will have a 60-day comment period.

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.

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 363 is submitted on an as-needed basis by persons seeking to become registered; DEA Form 363a is submitted on an annual basis thereafter to renew existing registrations.

	Number of Annual Respondents	Average Time per Response	Total Annual Hours
DEA-363	244	0.33 hours (20 minutes)	81
DEA-363a	1,656	0.17 hours (10 minutes)	276
Total	1,900		357

Total number of respondents: 1,900
 Number of responses per respondent per year: 1
 Total annual responses: 1,900
 Total annual hour burden: 357

Average Burden: Per Collection: 0.187895 hour
 Per Respondent: 0.187895 hour

Total registration applications received on paper: 0
 Total registration applications received online: 1,900

Percentage of applications received electronically: 100%

Burden dollars:

Estimated hourly wage (\$/hour): ²	48.45
Load for benefits (percent of labor rate): ³	42.7%
Loaded labor rate (\$/hour): ⁴	69.14

	DEA Form 363	DEA Form 363a	Combined
Number of responses	244	1,656	1,900
Total annual hours	81	276	357
Average burden per response (hour)	0.3333	0.1667	0.187895
Burden dollars per response (\$)	23.04	11.53	13.008
Total burden dollars (\$)	5,622	19,094	24,715

Thus, the labor cost of this information collection is \$24,715 annually.

13. Estimate of Cost Burden:

The estimated annual cost burden is zero. Respondents are estimated to not 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 the Federal Government:

Estimated Annual Labor Cost to Government:

Labor Category	Number⁵	% of time⁶	Cost⁷
Registration Program Specialists – GS-963-9	69	0.3%	\$ 22,419

2 Average of median hourly wages for 11-1021 General and Operations Manager is used to represent the occupation of persons completing the DEA Form 363 and 363a. May 2019 National Occupational Employment and Wage Estimates United States. http://www.bls.gov/oes/current/oes_nat.htm.

3 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.

4 $\$48.45 \times (1 + 42.7\%) = \69.14 .

5 Based on number of allocated positions, February 19, 2020.

6 Based on percent 363 and 363a forms of all registration application forms.

7 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.

(Field)

Total

\$ 22,419

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. Additionally, the increase in annual responses, burden hours, and annual cost reflects the increase in DEA’s registrant population and a small increase in average burden per response. The table below summarizes the changes since the last renewal of this information collection.

	2018 Approved Burden	New Requested Burden	Difference
Annual respondents	1,726	1,900	174
Annual burden hours	189	357	168
Annual cost (\$)	11,754	24,715	12,961

16. Plans for Publication:

DEA will not publish the results of the information collected.

17. Expiration Date Approval:

DEA has no objection to OMB 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.

Part B. Statistical Methods

DEA does not employ statistical methods in this information collection.