

**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).

**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.<sup>1</sup> 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 the 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:

The DEA has a system which permits full online registration. Currently, the referenced forms are available on the DEA Office of Diversion Control web site (<http://www.deadiversion.usdoj.gov>). Applicants may complete and submit the form online, along with credit card payment.

During calendar year 2017, the year upon which estimates are based, the DEA received 1,660 online applications out of a total of 1,726 applications, for a response rate of 96% online applications.

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

4. Efforts to Identify Duplication:

The 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:

This is a routine renewal of DEA Form 363 and 363a. 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:

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 the 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 was solicited in the 60-day Federal Register Notice of Information Collection, 83 FR 7494, published on February 21, 2018 and the 30-day Federal Register Notice of Information Collection, 83 FR 16902, published April 17, 2018. The DEA did not receive any comments concerning this collection.

The 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 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 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.

	<b>Number of Annual Respondents</b>	<b>Average Time per Response</b>	<b>Total Annual Hours</b>
DEA Form 363 (paper)	15	0.30 hours (18 minutes)	5
DEA Form 363 (online)	223	0.13 hours (8 minutes)	30
DEA Form 363a (paper)	51	0.22 hours (13 minutes)	11
DEA Form 363a (online)	1,437	0.10 hours (6 minutes)	144
<b>Total</b>	<b>1,726</b>		<b>189</b>

Figures are rounded.

Total number of respondents: 1,726  
Number of responses per respondent per year: 1  
Total annual responses: 1,726  
Total annual hour burden: 189  
Average burden per response: 0.1095 hour

Hour burden cost:

Estimate hourly wage (\$/hour): <sup>2</sup>	\$43.29
Load for benefits (percent of labor rate): <sup>3</sup>	43.7%

2 Estimates are based on the population of the regulated industry participating in this business activity. The DEA assumes that an administrative services manager (11-3011, 2016 Standard Occupational Classification) will complete the form on behalf of the applicant or registrant.

3 Bureau of Labor Statistics, "Employer Costs for Employee Compensation – September 2017" (ECEC) reports that average benefits for private industry is 30.4% of total compensation. The 30.4% of total

Loaded labor rate (\$/hour):	\$62.21
Average burden per response (hour):	<u>0.1095</u>
Burden cost per response:	\$6.81
Number of annual responses:	<u>1,726</u>
Total hour burden cost:	\$11,754

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:**

Review & Notification

54 Registration Program Specialists - GS-963-9 (Field) <sup>4</sup>	\$15,042
1 Legal Instrument Examiner Sup - GS-963-9 (HQ) <sup>5</sup>	\$461
1 Legal Instrument Examiner Sup - GS-963-11 (HQ) <sup>6</sup>	\$471

**Total:** **\$15,974**

**Estimated Annual Production Cost to Government:** <sup>7</sup>

Government Employees:	\$9
Contract Employees:	\$25
Cost of Paper:	\$5
Mailing (Postage):	\$112
Return Envelopes:	\$4
Mailing Envelopes:	\$4
Equipment Maintenance:	\$14
Equipment/10 years:	\$20

**Total:** **\$192**

**Grand Total cost to government (\$15,974 + \$192):** **\$16,166**

*(Figures are rounded.)*

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compensation equates to 43.7% (30.4% / 69.6%) load on wages and salaries.

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

5 Based on percent paper 363 and 363a forms of total paper forms.

6 See note 5.

7 See note 5.

All labor costs are rounded up to the nearest dollar. Costs are calculated by using the DC-Baltimore pay tables for the GS grade listed, at step 5.

All cost to the government for operation of the Diversion Control Program, including the above costs, are recovered by the DEA from registrants through registration fees, as required by 21 U.S.C. 886a.

15. Reasons for Change in Burden:

The increase in annual respondents reflects the increase in the DEA’s registration population for this business activity. The lower rate of increase in hour burden is due to an increase in online registration applications and renewals. For this collection overall, 96% of initial and renewal applications were submitted online; during the previous renewal of this information collection, 89% were submitted online. The increase on annual cost corresponds with the increase in annual responses and the increase in the median hourly wage of administrative service managers. The table below summarizes the changes since the last renewal of this information collection.

	<b>2015 Approved Burden</b>	<b>2018 Requested Burden</b>	<b>Difference</b>
Annual responses	1,046	1,726	680
Annual burden hours	123	189	66
Annual cost	\$6,227	\$11,754	\$5,527

16. Plans for Publication:

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

17. Expiration Date Approval:

The DEA has no objection 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.