

**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 2014, the year upon which estimates are based, the DEA received 928 online applications out of a total of 1,046 applications, for a response rate of 89% 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, 80 FR 5138, published on January 30, 2015 and the 30-day Federal Register Notice of Information Collection, 80 FR 18258, published April 3, 2015. 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)	11	0.30 hours (18 minutes)	3
DEA Form 363 (online)	103	0.13 hours (8 minutes)	14
DEA Form 363a (paper)	107	0.22 hours (13 minutes)	23
DEA Form 363a (online)	825	0.10 hours (6 minutes)	83
Total	1,046		123

Figures are rounded.

Total number of respondents: 1,046

Number of registration per respondent per year: 1

Total annual responses: 1,046

Total annual hour burden is 123

Average Burden: Per Collection: 0.12 hour

Per Respondent: 0.12 hour

Total registration applications received on paper: 118

Total registration applications received online: 928

Percentage of applications received online: 88.7%

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, 2013 Standard Occupational Classification) ([http://www.bls.gov/soc/soc\\_2010\\_definitions.pdf](http://www.bls.gov/soc/soc_2010_definitions.pdf)) will complete the form on behalf of the applicant or registrant. The median hourly wage for that position according to the Bureau of Labor Statistics' (BLS) 2014 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 621420 – Outpatient Mental Health and Substance Abuse Centers ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)) is \$35.41. Based on the BLS report, “Employer Costs for Employee Compensation – September 2014,” (<http://www.bls.gov/news.release/ecec.nr0.htm>) an additional 43.3% load is added to the labor rate to account for benefits. Thus the estimated cost burden of this information collection to respondents is \$6,227 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 Production Cost to Government:**

Government Employees:	\$0
Contract Employees:	\$110
Cost of Paper:	\$2
Mailing (Postage):	\$71
Return Envelopes:	\$2
Mailing Envelopes:	\$10
Equipment Maintenance:	\$26
Equipment/10 years:	\$29
Per Print Charges:	\$29

**Total: \$279**

**Estimated Annual Labor Cost to Government:**

Section Chief – GS-301-15 (1% of time)	\$14,026
Deputy Section Chief – GS1801-14 (5% of time)	\$5,962

Review & Notification

54 Registration Program Specialists - GS-963-9 (Field); (1% of time)	\$31,596
461 Diversion Investigators - GS-1801-12 (Field) (0.27% of time)	\$105,619
1 Program Analyst GS-343-13 (HQ) (10% of time)	\$10,090
1 Legal Instrument Examiner Sup - GS-963-11 (HQ); (1% of time)	\$708

21 Government Contractor Call Center Employees, 3 Supervisors, and 1 Task manager (10% of time for an average annual contract cost x 25)	\$202,322
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Fee Processing and Mail Room

6 Government Contractor Employees (1.0% of time for average annual contract cost x 6)	\$5,052
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Scanning

1 Computer Assistant – GS-335-9 (HQ) (1% of time)	\$585
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**Total:** **\$375,960**

**Grand Total cost to government (\$279 + \$375,960):** **\$376,239**

*(Figures are rounded.)*

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 decrease in annual respondents reflects the decrease in the DEA’s registration population for this business activity. The decrease in hour burden is related to both a decrease in annual respondents and an increase in online registration applications and renewals. For this collection overall, 89% of initial and renewal applications were submitted online; during the previous renewal of this information collection, 86% were submitted online. Although the decrease in the burden hour contributed to the decrease in the annual cost, the majority of the decrease in annual cost is attributed to a change in calculation method.\* The table below summarizes the changes since the last renewal of this information collection.

	<b>2012 Approved Burden</b>	<b>2015 Requested Burden</b>	<b>Difference</b>
Annual respondents	1,484	1,046	(438)
Annual burden hours	273	123	(150)

Annual cost	\$331,199	\$6,227	\$(324,972)
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(\* 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. 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 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.