

Supporting Statement for Paperwork Reduction Act Submissions

Application for Registration (DEA Form 224)
Application for Registration Renewal (DEA Form 224a)
Affidavit for Chain Renewal (DEA Form 224b)
Application for Modification of Registration for Online Pharmacies (DEA Form 224c)

OMB Number 1117-0014

Part A. Justification

1. Necessity of Information:

Purpose of collection: All firms and individuals who administer, dispense, prescribe and/or procure controlled substances must register with DEA under the Controlled Substances Act (21 U.S.C. 822; 21 CFR 1301.11). Registration is needed for control measures over legal handlers of controlled substances and is used to monitor their activities. DEA-registered pharmacies that fall within the definition of an online pharmacy (21 U.S.C. 802(52)) must apply for a modified registration authorizing the pharmacy to dispense controlled substances by means of the Internet (21 U.S.C. 823(f)).

2. Needs and Uses:

Intended uses: Registration is needed for control measures over legal handlers of controlled substances and is used to monitor their activities. DEA-registered pharmacies that fall within the definition of an online pharmacy (21 U.S.C. 802(52)) must apply for a modified registration authorizing the pharmacy to dispense controlled substances by means of the Internet (21 U.S.C. 823(f)).

DEA Form 224 is used by applicants seeking to become registered to administer, dispense, or prescribe any controlled substances. DEA Form 224a is used for renewal of such registrations on a triennial basis. DEA Form 224b is an affidavit used for the renewal of chain registrants, primarily retail pharmacies, on a triennial basis. DEA Form 224c is used to apply for a modification of registration allowing online pharmacies to dispense controlled substances by means of the Internet. The information submitted is used to identify persons seeking registration and provide information to determine whether registration would be consistent with the public interest.

3. Use of Technology:

DEA has a system which permits fully electronic registration using a credit card. Currently, the referenced forms are available on the DEA Diversion Control Program website (<http://www.DEAdiversion.usdoj.gov>). Applicants complete the form online and submit electronically, along with credit card payment.

Aside from these activities, DEA currently permits chain registrants (primarily retail pharmacies) to register through the use of an affidavit and a computerized listing of all registrants. Currently, 68 chains participate in this program, holding registrations for 36,660 individual registrants. During calendar year 2011, the year for which estimates were calculated, 32 chains registered 6,472 individual locations.

Registrants applying to modify their pharmacy registrations to operate as online pharmacies apply via the online application (DEA Form 224c).

In calendar year 2011, the year for which estimates are calculated, approximately 85% of all applications were received electronically.

4. Efforts to Identify Duplication:

The Federal requirement of registration to handle controlled substances is unique to DEA. The information provided is specific to the applicant's use of controlled substances and is not available from other sources.

5. Methods to Minimize Burden on Small Businesses:

Although many of the registrants affected may be classified as small businesses according to the Small Business Administration, the information collected is maintained as a normal course of business. Therefore, this collection does not have a significant economic impact upon small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq.

6. Consequences of Less Frequent Collection:

The Controlled Substances Act requires that registration for these activities be issued on a triennial basis. The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 requires all pharmacies that plan to conduct business as an online pharmacy to obtain a modified registration.

7. Special Circumstances Influencing Collection:

Changes to the online pharmacy's Internet site address or any information submitted under 21 CFR 1304.40 must be reported to DEA at least 30 days in advance. There are no other special circumstances applicable to this information collection.

8. Reasons for Inconsistencies with 5 CFR 1320.6:

There are no circumstances that require the collection of data that would be inconsistent with the guidelines set forth in 5 CFR 1320.6. 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, including application and registration procedures, with representatives of those from whom the information is obtained.

9. Payment or Gift to Claimants:

There are no payments or gifts to respondents.

10. Assurance of Confidentiality:

Opportunities for consent: Applicants and registrants must register with DEA in order to handle controlled substances and List I chemicals. Failure to provide the requested information precludes processing of the application. The parameters for consent and the use and sharing of the information collected are conveyed to applicants and registrants whether they are using the online forms or paper forms.

Each form in the information collection states the purposes for which DEA will use the information and whether disclosure of the information is voluntary or mandatory. Each form in the information collection also states that DEA will disclose the information without prior written consent only when DEA has legal authority to do so.

Information requested in this collection may be considered confidential business information if marked as such pursuant to 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 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.

System of Records Notice: The System of Records Notice for this information collection is the Controlled Substances Act Registration Records (DEA-005). The publication of the complete notice may be found at 52 FR 47208, December 11, 1987; modified at 66 FR 8425, January 31, 2001; modified at 72 FR 3410, January 25, 2007.

11. Justification for Sensitive Questions:

Questions of a sensitive nature are not included in this information collection.

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. DEA Form 224b is submitted triennially for renewals of chain (retail pharmacy) registrants. DEA Form 224c is submitted when a pharmacy applies for a modification of registration to conduct business as an online pharmacy as set forth in 21 U.S.C. 802(52).

	Number of Annual	Average Time per	Total Annual Hours
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	Respondents	Response	
DEA-224 (paper)	5,867	0.2 hours (12 minutes)	1,173.4
DEA-224 (electronic)	79,057	0.13 hours (8 minutes)	10,540.9
DEA-224a (paper)	66,200	0.2 hours (12 minutes)	13,240
DEA-224a (electronic)	323,758	0.07 hours (4 minutes)	21,583.8
DEA-224b (chain renewal)*	32	5 hours	160
DEA-224c	0	0.25 hours (15 minutes)	0
Total	474,914		46,698.1

* In total, 64 chain pharmacies represent 36,660 individual pharmacy registrants. Pharmacies register for a three-year registration period. In calendar year 2011, the year for which estimates are calculated, 32 chains registered 6,472 individual pharmacies.

Total registration applications received on paper: 72,067

Total registration applications received electronically: 409,287 (includes 6,472 chain locations)

Percentage of applications received electronically: 85%

Estimates are based on the population of the regulated industry participating in this business activity. DEA assumes that a general and operations manager (SOC 11-1021, 2010 Standard Occupational Classification) (http://www.bls.gov/soc/2010/soc_alph.htm) 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' 2010 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 446110 –Pharmacies and Drug Stores (http://www.bls.gov/oes/current/naics5_446110.htm) is \$36.33. Thus the labor cost of this information collection is \$1,696,542 annually.

13. Estimate of Cost Burden:

Note, there were 33,820 respondents who were exempt from paying the fee during calendar year 2011 because they are affiliated with a Federal, State, or local government agency (21 CFR 1301.21).

Three-year Cost to Respondents:

481,354 total registrations – 33,820 fee exempt registrants = 447,534 fee-paying registrants

447,534 Fee paying registrants @ \$731 per applicant = \$327,147,354 for three-year registration

Note that each registration is for three years and the \$731 registration fee is for a three-year period.

Mailing cost (DEA Forms 224 and 224a paper): 72,067 @ \$0.45 per response = \$32,430.15

Total Cost: \$327,179,784.15

As this information collection is calculated on an annual basis, the three-year fee can be calculated as an annual fee equivalent. Thus, the \$731 three-year fee equates to a \$244 annual fee equivalent.

447,534 Fee paying registrants @ \$244 annual fee equivalent per applicant = \$109,198,296 annual fee equivalent per registration

Mailing cost (DEA Forms 224 and 224a paper): 72,067 @ \$0.45 per response = \$32,430.15

Annual cost using fee equivalent: \$109,230,726.15

14. Estimated Annualized Cost to Federal Government:

Estimated Annual Production Cost to Government:

Government Employees:	\$959.89
Contract Employees:	\$86,030.40
Cost of Paper:	\$6,896.68
Mailing (Postage):	\$151,726.08
Custom Envelopes:	\$7,655.31
Equipment Maintenance:	\$52,872.00
Equipment/10 years:	\$57,377.00
Per Print Charges:	\$9,103.00

Total: \$372,620.36

Estimated Annual Labor Cost to Government:

Section Chief – GS-301-15 (90% of time)	\$126,233
Deputy Section Chief – GS-1801-14 (50% of time)	\$59,664

Project Manager	
1 Unit Chief – GS-343-14 (90% of time)	\$107,314

Review & Notification	
54 Registration Program Specialists - GS-963-9 (Field) (75% of time)	\$2,369,682
6 Legal Instrument Examiners – GS-963-9 (HQ) (75% of time)	\$263,298
1 sup Legal Instrument Examiner– GS-963-11 (HQ) (80% of time)	\$56,635
461 Diversion Investigators –GS-1801-12 (Field) (5% of time)	\$1,956,023

7 Program Analysts – GS-343-13 (HQ) (65% of time)	\$459,116
21 Government Contractor Call Center Employees, 3 Supervisors and 1 Task Manager (85% of time for an average annual contract cost x 25)	\$1,618,578
Fee Processing and Mail Room 6 Government Contractor Employees (95% of time) (95% of average annual contract cost x 6)	\$479,950
Scanning 1 Computer Assistant – GS-335-9(HQ) (95% of time)	\$60,403
Total labor costs:	\$7,556,896.00
Grand Total:	\$7,929,516.36

All costs are recovered from registrants through registration fees, as required by the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993.

15. Reasons for Change in Burden:

Changes reflect population adjustments and registrants' and applicants' greater use of online applications, which take less time to complete. It is important to note that these estimates reflect calendar year 2011 numbers, whereas the previous renewal reflected calendar year 2010 numbers. Although registrants are registered for a three-year cycle, the number of registrants is not evenly distributed between years of the cycle, as is evidenced by the changes in burden in this renewal of the information collection. There have been no statutory or regulatory changes affecting this information collection. The table below summarizes the changes since the last renewal of this information collection.

	2012 Approved Burden	2012 Requested Burden	Difference
Annual respondents	458,136	474,914	16,778
Annual burden hours	45,208.13	46,698.1	1,489.97
Annual cost	\$110,637,849.95	\$109,230,726.15	(\$1,407,123.8)

16. Plans for Publication:

There are no plans to publish this information.

17. Expiration Date Approval:

DEA is not requesting approval.

18. Exceptions to the Certification Statement:

There are no exceptions to the certification requirement.

Part B. Statistical Methods

The Drug Enforcement Administration will not be employing statistical methods in this information collection.