

## 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:

All firms and individuals who administer, dispense or prescribe 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:

DEA Form 224 is used by applicants seeking to become registered to distribute or dispense 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 person's 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, 16 chains participate in this program, holding registrations for 19,088 individual registrants. Registrants applying to modify their pharmacy registrations to operate as online pharmacies apply via the online application (DEA Form 224c).

#### 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 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.

DEA received one comment for this collection. In response to the 30-day notice (74 FR 42328) the National Association of Clinical Nurse Specialists (NACNS) submitted a comment requesting DEA change the registration application to allow for a clear distinction between nurse practitioners and clinical nurse specialists. The NACNS stated that DEA's registration forms use "nurse practitioner" as a generic term equivalent to "advance practice registered nurse" instead of using the term "clinical nurse specialist" which may cause confusion.

The NACNS requested DEA make the following changes to DEA Forms 224 and 224a: (1) expand the identifying terminology used for midlevel practitioners to include the term "clinical nurse specialist," and (2) change Section I of DEA Forms 224 and 224a to expand the education

degree choices to allow CNS to properly list their terminal degrees. NACNS asked that as DEA obtains direction for determining who can prescribe from state law, that DEA expand the choice of degrees to include nursing masters and doctoral degrees and all degrees recognized by state law for nurse prescribers, so clinical nurse specialists who are prescribers can accurately list their degrees.

**DEA Response:**

Currently, DEA Forms 224 and 224a utilize the term “nurse practitioner” as a generic term to encompass all nursing specialties. While the term may not describe precisely every field of expertise, the term is intended to include all nursing categories. Because the titles of the various nursing specialties (and the corresponding prescribing privileges) differ greatly in State law and regulation, and differ from State to State, DEA believes it more practical to use the generic title “nurse practitioner.” DEA will retain the “nurse practitioner” term on DEA Forms 224 and 224a.

Regarding the request to expand the educational degree choices to allow CNS to properly list their terminal degrees, DEA believes Section One of DEA Forms 224 and 224a allow applicants to accurately list their professional degree information. DEA will retain this section without change.

**9. Payment or Gift to Claimants:**

There are no payments or gifts to respondents.

**10. Assurance of Confidentiality:**

Confidential business information is protected under Department of Justice regulations, 28 CFR 16.8 and 16.9.

**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).

**DEA-224: Electronic Form**

**Number of Respondents:** 59,283  
**Average time per response:** 0.13 hours (8 minutes)  
**Annual burden hours:** 7,904.4 hours

**DEA-224: Paper Form**

**Number of Respondents:** 12,094  
**Average time per response:** 0.2 hours (12 minutes)  
**Annual burden hours:** 2,418.8 hours

**DEA-224a Electronic Form**

**Number of respondents:** 209,285  
**Average time per electronic response:** 0.07 hours (4 minutes)  
**Annual burden hours:** 13,952.3 hours

**DEA-224a Paper Form**

**Number of respondents:** 159,678  
**Average time per response:** 0.2 hours (12 minutes)  
**Annual burden hours:** 31,935.6 hours

**DEA-224b**

**Number of respondents:** 16  
**Average time per response:** 5 hours  
**Annual burden hours:** 80 hours

**DEA-224c**

**Number of respondents:** 250  
**Average time per response:** 0.25 hours (15 minutes)  
**Annual burden hours:** 62.5 hours

**Total number of respondents:** 440,606  
**Total annual burden hours:** 56,354 hours

**Percent Electronic (DEA-224) – 83%**  
**Percent Electronic (DEA-224a) – 57%**  
**Percent electronic (DEA-224b) –100%**  
**Percent Electronic (DEA-224c) – 100%**

Electronic responses to DEA-224:

Approximately 59,283 (DEA 224 electronic) respondents at  
0.13 hours per response = 7,904 x \$10 per hour = \$ 79,040

Paper responses to DEA-224

Approximately 12,094 (DEA 224 paper) respondents at

0.2 hours per response = 2,418.8 x \$10 per hour = \$ 24,188

Electronic responses to DEA-224a

Approximately 209,285 (DEA-224a electronic) respondents at  
0.07 hours per response = 13,952.3 x \$10 per hours = \$ 139,523

Paper response to DEA-224a

Approximately 159,678 (DEA-224a paper) respondents at  
0.2 hours per response = 31,935 x \$10 per hour = \$ 319,350

Approximately 16 (DEA-224b) respondents per year at  
5 hours per response = 80 hours x \$10 per hour \$ 800

Approximately 250 (DEA-224c) respondents per year at  
0.25 hours per response = 62.5 hours x \$10 per hour \$ 625

This cost is a usual and customary business expense not directly associated with this information collection.

### 13. Estimate of Cost Burden:

Note, there are 27,673 respondents who are exempt from paying the fee because they are affiliated with a federal, state, or local government agency (21 CFR 1301.21).

Annual Cost to Respondents:

413,183 @  $\frac{\$551}{3}$  per applicant = \$ 76,025,672

Note that the \$551 registration fee is for a three-year period. Thus, the annual fee equivalent is \$184.

71,377 Respondents - DEA Form 224  
369,213 Respondents - DEA Form 224a  
19,088 Registrants in chain renewal process.  
459,678 **Total Registrants represented**  
(Note: 16 respondents complete DEA Form 224b)

Mailing cost: 171,772 @ \$0.42 per response = \$ 72,144

Total Cost \$ 76,097,816

(Note: Estimate 250 respondents will complete DEA-224c which is in electronic format only.)

### 14. Estimated Annualized Cost to Federal Government:

Cost to Federal Government:

Estimated Annual Cost to the Government:

Printing	\$10,000
Automatic Data Processing	\$182,357
Postage	\$82,000
Equipment, Repair Contracts, Rent and Overhead	\$834,900
Total:	\$1,109,257

Review and Notification

Project Manager

1 Unit Chief (Registration Unit) - GS-301-14; (90% of time) = \$127,992

Review & Notification

- 46 Registration Assistants - GS-963-9 (Field); (75% of time) = \$2,407,824
- 7 Registration Assistants - GS-963-9 (HQ); (75% of time) = \$366,408
- 1 Registration Assistants - GS-963-11 (HQ Team Leaders); (80% of time) = \$67,550
- 483 Diversion Investigators - GS-1801-12 (Field) (5% of time) = \$2,444,150
- 4 Program Analyst GS-343-13 (HQ) (45% of time) = \$216,634
- 21 Government Contractor Employees from ASRC (75% of time) = \$1,242,927  
(75% of average contract cost x 21)

Fee Processing

4 Government Contractor Employees from ASRC (65% of time) = \$242,544  
(65% of average contract cost x 4)

Scanning

1 Computer Assistant – GS-335-9 (HQ) (95% of time) = \$66,302

Total: \$ 7,182,331

TOTAL COST: \$ 8,209,670

There is no actual cost to the Federal Government for these activities as 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 time it takes to complete electronic form DEA Form 224c based on new statutory requirements for online pharmacies to obtain a modification to registration (Pub. L. 110-425).

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.