Supporting Statement for Paperwork Reduction Act Submission

Reports of dispensing of controlled substances by online pharmacies
DEA Form 332

OMB Approval Number 1117-0050

Part A. Justification

1. Necessity of Information:

The Controlled Substances Act requires online pharmacies to report the total quantity of each controlled substance that the pharmacy has dispensed during each calendar month (21 U.S.C. 827(d)(2)). Reports are required to be filed by every pharmacy that holds a modified registration authorizing it to operate as an online pharmacy. The implementing regulations are found at 21 CFR 1304.55.

2. Needs and Uses:

The reporting of controlled substances dispensed by online pharmacies is mandated by the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (21 U.S.C. 827(d)(2)). This information will permit DEA to monitor the dispensing of controlled substances by online pharmacies.

3. Use of Technology:

Since this reporting requirement is applied to a specific business acitivty, the overall burden is controlled by the number of pharmacies that apply for a modified registration and by the amount of controlled substances they dispense each month. As the online pharmacy business activity relies on the use of the Internet, the burden is significantly reduced because the preferred method of reporting is to be accomplished via the online reporting process are available on the DEA Diversion Control Program website (http://www.DEAdiversion.usdoj.gov).

4. Efforts to Identify Duplication:

The collection of this information is unique to DEA. While the new reporting requirement requests information not previsously required, much of the information required to be provided is readily available and retrievable thus limiting the impact of the burden for the reporting of dispensing of controlled substances by online pharmacies.

5. Methods to Minimize Burden on Small Businesses:

Although some online pharmacies may fall within the category of a small business, the burden is minimal.

6. Consequences of Less Frequent Collection:

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 mandates that a pharmacy that has obtained a modified registration authorizing it to dispense controlled substances by means of the Internet must report to DEA, on a monthly basis, the total amount of each controlled substance it dispenses (21 U.S.C. 827(d)(2)).

7. Special Circumstances Influencing Collection:

The Controlled Substances Act requires each online pharmacy to report the total quantity of each controlled substance that the pharmacy has dispensed each calendar month. Such reporting is required for every calendar month in which the total quantity of controlled substances dispensed by the pharmacy meets or exceeds one of the following thresholds: (1) 100 or more prescriptions for controlled substances filled; or (2) 5,000 or more dosage units dispensed of all controlled substances combined. Online pharmacies are required to submit a negative response if, during a given calendar month, its total dispensing of controlled substances falls below the thresholds. As the monthly reporting is a statutory requirement, DEA has no discretion to implement this reporting requirement less frequently. No other special circumstances apply to this collection.

8. Reasons for Inconsistencies with 5 CFR 1320.6:

There are no inconsistencies with the Paperwork Reduction Act. DEA meets regularly with the affected industry to discuss policies, programs and regulations. A 60 and 30 day federal register notice has been published and no comment were received.

9. Payment or Gift to Claimants:

There are no such gifts or payments 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 reporting requirements.

12. Estimate of Hour Burden:

DEA Form 332 (electronic only):

Number of Respondents: 250
Frequency of Response: Monthly
Average time per response: 0.25 hours (15 minutes)
Total annual responses: 3,000
Total annual burden: 750 hours

250 respondents reporting at
0.25 hours = 62.5 x $104.40 per hour = $ 6,525.00

13. Estimate of Cost Burden:

As this collection is submitted electronically, there are no costs beyond the labor costs described above.

14. Estimated Annualized Costs to Federal Government:

Estimated annual cost to Government (personnel costs):

Development and implementation of reporting application

Contract support: $ 50,000.00

Analysis: 1 Diversion Investigator (GS-14): 3% of time = $ 4,470.00

Total: $ 54,470.00

All costs to the government for operation of the Diversion Control Program, including the above costs, are recovered by DEA from registrants through registration fees, as required by the Department of Justice and Related Agencies Appropriations Act.

15. Reasons for Change in Burden:

This is a new information collection as set forth in the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (21 U.S.C. 827(d)(2)). Online pharmacies must submit monthly reports (or a negative response) via new electronic form DEA Form 332.

16. Plans for Publication:

There are no plans to publish the information collected.

17. Expiration Date Approval:

DEA will display the current date of expiration on the form.

18. Exceptions to the Certification Statement:

There are no exceptions to the certification statement.

Part B. Statistical Methods

The Drug Enforcement Administration does not employ statistical methods in this information collection.