

Supporting Statement for Paperwork Reduction Act Submissions
Registrants Inventory of Drugs Surrendered
DEA Form 41
OMB Approval # 1117-0007

Part A. Justification

1. Necessity of Information:

Section 1307.21 of Title 21 of the Code of Federal Regulations requires any person in possession of any controlled substance, which he desires, or is required to dispose of, to contact the DEA Special Agent in Charge for instructions as to how to dispose of the substance. The substance is required to be listed on a DEA Form 41. This form is also used to report the breakage or spillage of controlled substances in the possession of a registrant. This documentation is necessary to properly control the disposal of controlled substances, to prevent their diversion, and to account for the disposition of the substance(s).

2. Needs and Uses:

The DEA Form 41 provides the Drug Enforcement Administration with a control mechanism over the disposal of controlled substances. Only upon the specific approval of the Special Agent in Charge may controlled substances listed on the DEA-41 be destroyed by a non-registrant or a registrant. The DEA-41 is reviewed by DEA Field Offices upon receipt. The form provides a uniform reporting method to cover the destruction of controlled substances. Without the form, accountability of the registrant's disposal of controlled substances would be impossible, representing a diversion potential.

3. Use of Technology:

Currently, the DEA Form 41 is available for download on the DEA Diversion Control Program web site at <http://www.deadiversion.usdoj.gov>. The form is partially interactive—registrants complete the form online, print it, sign it and transmit it to DEA.

4. Efforts to Identify Duplication:

There is no duplication, since the program is unique to DEA.

5. Methods to Minimize Burden on Small Businesses:

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:

This form is completed and submitted to DEA only under specific circumstances (the voluntary destruction of controlled substances, or the breakage, spillage or other explained loss of those controlled substances). The form contains essential controlled substance accountability information required by law.

7. Special Circumstances Influencing Collection:

The collection of this information must take place upon each occurrence of controlled substance destruction as mandated by law to maintain a closed distribution system for controlled substances. Thus, forms are completed as needed, which may be more frequently than quarterly. There are no other special circumstances applicable to this 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. DEA did not receive any comments concerning this collection.

9. Payment or Gift to Claimants:

There are no such gifts or payments 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 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.

11. Justification for Sensitive Questions:

This collection does not include questions of a sensitive nature.

12. Estimate of Hour Burden:

Reporting is required on DEA Form 41

Number of responses: 22,500
Frequency of response: As needed
Average annual responses: 22,500
Average time per response: 30 minutes

Total Annual burden: 11,250 hours

Responses are submitted as needed by any registrant using this form to document the surrender of controlled substances.

DEA assumes that a medical records/health information technician will complete the form on behalf of the registrant. The median hourly wage for that position according to the Bureau of Labor Statistics' 2009 Occupational Employment Statistics is \$15.04. Therefore, the cost of burden hours is \$169,200.00

13. Estimate of Cost Burden:

Cost to reproduce four copies of original form: $(\$0.10 \text{ per form} \times 4 \text{ copies}) \times 22,500 \text{ forms} = \$9,000$

Cost to mail completed form: $\$0.44 \text{ per form} \times 22,500 \text{ paper forms} = \$9,900.00$

These estimates are based on the population of the regulated industry participating in this business activity. There are no costs associated with this information collection aside from the cost of making photocopies and the \$0.44 cost to mail the completed form.

14. Estimated Annualized Costs to Federal Government:

Estimated Annual Cost to Federal Government:

Cost to mail receipt: $22,500 \times \$0.44 = \$9,900$

18 GS-11 (5% of time): \$81,554.69

18 GS-6 (5% of time): \$49,589.00

TOTAL COST TO GOVERNMENT: \$141,043.69

Salaries are estimated using step 5 of each pay grade listed, the DC-Baltimore pay tables for the given year, and an inflator of 28% to cover employee overhead.

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 of 1993.

15. Reasons for Change in Burden:

There has been no program change. The only change relates to the increase in postage for mailing of the forms. It appears that there was no listing of a cost burden to complete the form in the previous approval. This number was provided in the supporting statement as the cost of postage to mail the estimated number of forms, but appears to have been omitted from the final cost burden estimate. For this extension the number has been updated to reflect an increase in the cost of postage.

16. Plans for Publication:

There are no plans to publish the information collected.

17. Expiration Date Approval:

DEA is not seeking approval to not display the expiration date on forms. DEA will update the expiration date on Form 41 upon approval for renewal.

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.