

**Supporting Statement for Paperwork Reduction Act Submissions
Registration for Controlled Substances Act Data-Use Request
OMB Approval #1117-00XX**

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for a new collection of information, Registration for Controlled Substances Act Data-Use Request.

Part A. Justification

1. Necessity of Information:

The Controlled Substances Act (CSA) (21 U.S.C. 801-971) requires all persons that manufacture, distribute, dispense, conduct research with, import, or export any controlled substance to obtain a registration issued by the Attorney General. 21 U.S.C. 822, 823, and 957. Once registered, the person becomes a DEA registrant and has the means to conduct DEA registration verifications at any time via the DEA Diversion Website. On the website, registrants can use their registration information for access to the Controlled Substance Database system (CSA Dataset). The CSA Dataset gives one access to the list of DEA-registrants and their registration status.

Non-registrants do not have an obligation to register under the CSA because they do not handle controlled substances. However, they do have obligations to the healthcare sector to do things such as: conducting verifications before hiring a practitioner, verifying that a practitioner has an active registration when an insurance company is paying for a controlled substance prescriptions that could be covered by Medicaid or Medicare, or a prescription paper printing company conducting a verification that a practitioner has an active registration when ordering prescription pads. States use the CSA information to ensure practitioners are prescribing controlled substances within the scope of their professional practice. There are many other instances where a non-registrant has an obligation to verify the registration status of a DEA registrant.

2. Needs and Uses:

From the late 1980's until November 17, 2020, the Department of Commerce (NTIS) and a third party vendor has been the primary source for dissemination of the information from the CSA Dataset. NTIS approached this dissemination as a come-one come-all approach, selling the information to all that would pay a fee. This has resulted in many criminal cases involving the use of the data in criminal endeavors. This in turn resulted in the DEA terminating the relationship with NTIS and bringing the access and distribution of the CSA dataset in-house. As of November 17, 2020, NTIS no longer had access to the CSA Dataset.

This collection will be used by all non-registrants who need to verify the registration status of a DEA registrant by way of the CSA Dataset. In order to provide a secure uninterrupted solution for efficient access to the CSA dataset by non-registrants, this form is necessary to ensure a proper vetting process of those non-registrant entities wishing to use the CSA Datasets to

conduct Primary Source Verification of those registered with the DEA. Non-registrants will be required to complete the form in order to get official approval to conduct a vetting of those non-registrants that are expressing a need for access to the CSA Dataset. Failure to be able to conduct this vetting process will result in a severe interruption in commerce within the health sector.

Non-registrants will be required to complete this form and submit it to DEA annually. They will be required to create a new password with each submission. The annual completion of this form will ensure that the non-registrants, along with the change of passwords, will help to decrease the risks of diversion and ensure that the data is not being used in criminal endeavors.

3. Use of Information Technology:

The submissions would be 100% electronic. The registration form will be emailed to the applicant upon their request. They will return the form back to DEA by way of email.

4. Efforts to Identify Duplication:

There is no duplication of information requested as a part of this collection. DEA has no other collection that gathers this information from non-registrants.

5. Impact on Small Businesses or Entities:

The DEA expects this collection will not have a significant economic impact on a substantial number of small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601–612.

6. Consequences of Less Frequent Collection:

If this information is not collected annually, there is a risk that the CSA Dataset will be accessed by criminals and used in criminal endeavors.

7. Special Circumstances Influencing Collection:

There are no special circumstances applicable to this information collection.

8. Consultation with persons outside the Agency:

Public comment has been solicited in the 60 Day Notice of Information Collection published in the *Federal Register* at 85 FR 79035, on December 8, 2020. No comments were received. Public comment was also solicited in the 30 day Notice of Information Collection published in the *Federal Register* at 86 FR 10598, on February 22, 2021.

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 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 DEA.

11. Justification for Sensitive Questions:

This collection of information does not ask any questions of a sensitive nature.

12. Estimate of Hour Burden:

Activity	Number of Annual Responses	Number of Annual Responses	Average Time per Response (Minutes)	Total Annual Hours
Registration CSA Data-Use Request	1,000	1,000	15	250
Total	1,000	1,000		250

Based on the number of unique respondents. A respondent submits one information collection.

Total Number of respondents: 1,000
 Number of responses per respondent per year: 1
 Total annual responses: 1,000
 Total annual hour burden: 250 hours
 Average Burden: Per Collection: 0.25 hour
 Per Respondent: 0.25 hour

Total responses received: 1,000

Burden dollars:

Estimated hourly wage(\$/hour):¹ 33.20

Load for benefit (percent of labor rate):²

42.85%

Loaded labor rate (\$/hour):³

47.43

	DEA Information collection
Number of responses	1,000
Total annual hours	250
Average burden per response (hour)	0.25
Burden dollars per response (\$)	11.86
Total burden dollars (\$)	11,860

13. Estimate of Total Annual Cost Burden:

The estimated annual cost burden is zero. Respondents are not estimated to 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 Costs to Federal Government:

There is no cost to the Federal government.

15. Reasons for Change in Burden:

This is a new information collection. Therefore, there is no change in burden.

16. Plans for Publication:

DEA will not publish the results of the information collected.

17. Expiration Date Approval:

DEA is not seeking approval not to display the expiration date for OMB approval of this information collection.

18. Exceptions to the Certification Statement:

1 Hourly median wage, 13-1041 Compliance Officer. Bureau of Labor Statistics, Occupational Employment and Wages, May 2019, <https://www.bls.gov/oes/2019/may/oes131041>.

2 Average benefits for private industry are 30% of total compensation. Bureau of Labor Statistics, Employer Costs for Employee Compensation – September 2020 (ECEC), https://www.bls.gov/news.release/archives/ecec_09182018.pdf. The 30% of total compensation equates to 42.86% (30% / 70%) load on wages and salaries.

3 $\$33.20 \times (1 + 0.4286) = \47.43 .

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