

SUPPORTING STATEMENT FOR Reporting and Recordkeeping for Digital Certificates

The Drug Enforcement Administration (hereinafter, “DEA”) seeks approval by the Office of Management and Budget (hereinafter, “OMB”) for an existing collection of information that was previously approved by OMB – OMB Approval number 1117-0038, Reporting and Recordkeeping for Digital Certificates.

A. JUSTIFICATION

- 1.** The Controlled Substances Act (hereinafter, “CSA”) grants the Attorney General authority to promulgate rules and regulations relating to: the registration and control of manufacture, distribution, and dispensing of controlled substances and listed chemicals; reporting changes to professional or business addresses; and the efficient execution of his statutory functions. 21 U.S.C. 821, 822(a), 827(h), 871(b), 957(a). Under 21 U.S.C. 828, a person may distribute a schedule I and II controlled substance pursuant to an order made on a DEA-provided form. The Attorney General will issue forms pursuant to subsections (a) and (c)(2) of 21 U.S.C. 828 only to persons validly registered under section 823 or exempted under section 822(d).

The current CSOS regulations are found in 21 CFR sections 1305 and 1311. DEA registrants use CSOS to track schedule I and II controlled substance orders. The system allows for orders to be placed through a secure electronic system, which uses Public Key Infrastructure. The secure CSOS system allows for the controlled substance orders to be submitted without the need for a paper DEA form 222. Each individual supplier and purchaser enroll with DEA to acquire a CSOS digital certificate. Once the applicant agrees to the CSOS User Agreement the applicant can then apply for one of the three system user roles, including: registrant, coordinator, or Power of Attorney. The proposed amendment to 21 CFR section 1311.25 eliminates the manual paper process and requires all registrants or authorized representatives with a power of attorney to enroll using the secure online portal. The proposal revises 21 CFR 1311.25 so that a registrant, coordinator, or person with Power of Attorney authorized to obtain a certificate for signing electronic orders for controlled substances for a registrant, must complete the online enrollment by: completing the online identification proofing process, providing a current listing of DEA registrations which the individual has authority to sign, uploading all power of attorney forms, and acknowledging the subscriber agreement and terms.

- 2.** DEA Registrants use CSOS as a secure system to track schedule I and II controlled substance orders. Currently, registrants who wish to participate in CSOS have to enroll using paper applications, causing delays in the enrollment process as well as risking applications being lost. By requiring CSOS applications to be submitted online, the application process will be simplified. Electronic enrollment through the secure web-based system would benefit both DEA and CSOS participants as the process will be both secure and streamlined. Applicants will be redirected to login.gov from the CSOS login page for identification verification and to create an account with login.gov.

3. The proposed rule would amend current regulations to require online enrollment for all registrants, coordinators, and authorized representatives with Power of Attorney. Through the online enrollment process, the registrant, coordinator, and authorized representative with Power of Attorney can obtain a certificate to use for signing electronic orders for controlled substances. Renewal applications for CSOS certificate holders will be submitted online. The online system will simplify the process as paper forms will no longer be needed.
4. DEA has made efforts to identify and prevent duplication of information. The collection of this information is unique to DEA.
5. In accordance with the Regulatory Flexibility Act (RFA), DEA evaluated the impact of this proposed rule on small entities. DEA's evaluation of economic impact by size category indicates that the rule will not, if promulgated, have a significant economic impact on a substantial number of these small entities.
6. Pursuant to 21 U.S.C. 827(b), records must be maintained for a period of at least two years. DEA does not have the authority to reduce the burden or period of recordkeeping.
7. There are no special circumstances applicable to this information collection.
8. Public comment was solicited in the notice of proposed rulemaking (NPRM) published on February 2, 2023, 88 FR 7033. The comment period ended on April 3, 2023. Eight (8) total comments were received.

DEA meets regular 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. This collection of information does not propose to provide any payment or gift to respondents.
10. 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, 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. This collection of information does not ask any questions of a sensitive nature.

12. Responses can be new applications or renewals. DEA received 31,172 new applications in 2021. For every third renewal, the CSOS certificate holder must submit a new application. Therefore, DEA estimates that new applications are approximately one-third of total applications and the number of renewals is approximately twice the number of new applications which is 62,344. The estimated total applications in 2021 is 93,516.

The response frequency is 0.994735 (94,011/93,516)

DEA estimates the required time to complete a new application would be 1.75 hours which includes an estimated 1.5 hours to prepare and provided the necessary information and an estimated 0.25 hours for logging to CSOS system or calls to DEA for assistance. On the other hand, the estimated time spent requesting a renewal is 0.25 hours using the online method.

Based on the reported hourly wage of \$62.81¹ and the loaded benefits of 41.8%,² DEA estimates hourly loaded labor rate of a pharmacist is \$87.65.

Estimated Annualized Respondent Cost and Hour Burden

Activity	Number of Respondents	Frequency	Total Annual Responses	Time Per Response	Total Annual Burden (Hours)	Hourly Rate*	Monetized Value of Respondent Time
New applications	31,337	0.994735	31,172	1.75hrs	54,551	87.65	4,781,395
Renewals	62,674	0.994735	62,344	0.25hrs	15,586	87.65	1,366,113
Unduplicated Totals	94,011	0.994735	93,516	0.75 hrs	70,137		6,147,508

13. Estimate of the total annual cost burden

Respondents are not estimated to incur any additional start-up cost or capital expenditure as a result of this information collection

14. Estimate of the annualized cost to the Federal Government

Certification Authority Cost: \$732,922
 Registration Authority Cost: \$597,688 for year 1 and \$418,382 for year 2 and thereafter.
 Call Center Support Cost: \$1,749,946.
 Information Technology Cost: \$2,935,200.
 Total Cost: \$5,836,519 for year 1 and \$5,521,909 for year 2 and thereafter.

For simplicity, DEA uses the “year 2” figure of \$5,521,909 as the annualized cost.

15. Reason in changes for burden

¹ Hourly median wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2021, 29-1051 Pharmacists (<http://www.bls.gov/oes/current/oes>).

² Bureau of Labor Statistics, “Employer Costs for Employee Compensation – December 2021” (ECEC) reports that average benefits for private industry is 29.5% of total compensation. The 29.5% of total compensation equates to 41.8% (29.5% / 70.5%) load on wages and salaries.

Changes in the annual burden estimate is the result of the decreases in the expected time to complete the new applications or renewals using online portal. The estimated required time to complete a new application and a renewal is 1.75 hours and 0.25 hours respectively compared to 3 hours and 1.5 hours using paper application. The change in requested cost burden is due to change in methodology. The 2022 annual cost burden was based on the labor burden calculated in section 12; whereas, the new requested annual cost burden is based on the annual cost burden in section 13. The table below summarizes the changes since the last renewal of the collection of this information.

	2022 Approved Burden	New Requested Burden	Difference
Annual responses	93,516	93,516	-
Annual burden hours	187,032	70,137	(116,895)
Annual cost burden (\$)	16,393,355	0	(16,393,355)

16. DEA will not publish the results of the information collected.

17. DEA does not object to OMB displaying the expiration date.

18. DEA is not seeking an exception to the certification statement “Certification for Paperwork Reduction Act Submissions” for this collection of information.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS.

DEA will not be employing statistical methods in this information collection.