

**Supporting Statement for Paperwork Reduction Act Submissions
U.S. Official Order Forms for Schedules I and II Controlled Substances
(DEA Form 222)**

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for an existing collection of information that was previously approved by OMB – OMB Approval # 1117-0010, U.S. Official Order Forms for Schedules I and II Controlled Substances (DEA Form 222).

A. JUSTIFICATION

1. The Controlled Substances Act (CSA) (21 U.S.C. 801–971) establishes a closed system of distribution for controlled substances. To this end, controlled substances are closely monitored and tightly regulated as they are distributed through the supply chain. One tool that helps maintain the closed system of distribution is the CSA provision that states “It shall be unlawful for any person to distribute a controlled substance in schedule I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) of this section.” 21 U.S.C. 828(a). The regulations implementing this provision are contained in 21 CFR part 1305 and 21 CFR part 1311, subpart B.

Pursuant to the CSA, the DEA provides authorized registrants (purchasers) with DEA Forms 222 for ordering schedules I and II controlled substances. Registrants are prohibited from distributing schedules I or II controlled substances except pursuant to a written order made on a DEA Form 222. In certain circumstances, suppliers must submit copies of DEA Forms 222 to the DEA. These processes help maintain the closed system of distribution because each registrant in the transaction serves as a check against the other.

Since 2005, registrants have also been permitted to issue orders for schedules I and II controlled substances electronically, provided that the electronic order is signed using a digital certificate issued by the DEA Certification Authority. This electronic ordering system is called the Controlled Substances Ordering System (CSOS). The regulations governing the creation, transmission, and storage of electronic orders are contained in 21 CFR part 1311, subpart B.

2. The DEA Form 222, or its electronic equivalent, provides the DEA with oversight and control over the distribution of schedules I and II controlled substances. The form is the only document that can authorize the distribution of schedules I and II controlled substances within the closed system of distribution. To ensure distribution is restricted only to authorized registrants, each DEA Form 222 is serially numbered and pre-printed with the date the order form was issued, the registrant’s name, registered address, and DEA registration number, the type of registrant, and the schedules of controlled substances the registrant is authorized to handle.

The DEA Form 222 must be signed by a person authorized to sign an application for registration or reregistration on behalf of the registrant, or a person authorized to sign the DEA Form 222 by a properly executed power of attorney. Upon execution of an order form, the purchaser makes and retains a copy and sends the original to the supplier. The supplier fills out the original with the date and quantity shipped and retains the original. If the supplier is not required to report acquisition/distribution transactions to the Automation of Reports and Consolidated Orders System, the supplier submits a copy of the original DEA Form 222 to DEA headquarters. Upon receipt of the order, the purchaser is required to complete its copy of the DEA Form 222 with the date and quantity received. As mandated by 21 U.S.C. 828(c), the purchaser and supplier must make DEA Forms 222 available for inspection for a period of two years. These requirements ensure that only authorized registrants can order schedules I and II controlled substances, that these orders are delivered to the registrant at the registered location, and protects against diversion.

To ensure the security of orders obtained pursuant to CSOS, registrants must obtain a CSOS digital certificate from the DEA Certification Authority to sign electronic orders for controlled substances. The requirement of a digital signature also helps to ensure that only authorized registrants can order schedules I and II controlled substances.

In addition to restricting the distribution of schedules I and II controlled substances only to authorized registrants, the DEA uses the information to ensure accountability of controlled substances and to detect diversion.

3. The DEA allows, but does not require, registrants to utilize electronic orders for the distribution of schedules I and II controlled substances rather than the DEA Form 222. 21 CFR part 1305, subpart C. Once a registrant, or someone authorized to sign electronic orders for the registrant, obtains a digital certificate issued by the DEA Certification Authority, the registrant may issue orders for schedules I and II controlled substances and maintain records of those orders electronically.

Approximately 3.3 million DEA Forms 222 and 2.05 million electronic orders were submitted. Thus, for the period used for this supporting statement, electronic orders represented approximately 38.3% of all orders.

4. The DEA has made efforts to identify and prevent duplication of the collection of information. The existing DEA Form 222 and CSOS are not duplicative. The collection of this information is unique to the DEA.

5. 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. The frequency of orders is driven by the needs of purchasers, not by the regulation. 21 U.S.C. 828 requires that the DEA provide the order forms and that registrants maintain copies of executed order forms for a period of two years. 21 U.S.C. 828(c). The DEA does not have the authority to reduce the period of recordkeeping.

7. If a supplier is not required to report acquisition/distribution transactions to the Automation of Reports and Consolidated Orders System (ARCOS), it instead must submit a copy of each executed DEA Form 222 to the DEA at the close of the month during which the order is filled. The supplier receives the original from the purchaser, fills in the date and quantity shipped, retains the original, and sends a copy to the DEA. This copy provides the DEA with information on the distribution of schedules I and II controlled substances so that potential diversion can be identified and investigated in a timely manner. With respect to electronic orders pursuant to CSOS, suppliers are required to forward to the DEA either a copy of the electronic order or an electronic report of the order within two business days. Because the DEA provides to registrants pre-printed, sequentially numbered DEA Forms 222, the DEA knows how many forms are printed and who holds them. In contrast, with CSOS, the DEA has no information on orders being issued until reported to the DEA. The DEA determined that reviewing electronic orders at the end of the month would unreasonably frustrate the identification and investigation of diversion. Because these reports are generated automatically and transmitted electronically, the decreased reporting time does not impose an unreasonable burden on reporters, particularly when weighed against the need to prevent and detect the diversion of the most dangerous controlled substances—substances in schedules I and II.

Other special circumstances are not applicable to this information collection.

8. Public comment was solicited with a 60-day notice in the Federal Register on July 23, 2026, at 91 FR 46483. DEA received no comments concerning this collection. A 30-day notice was submitted to the Federal Register on October 1, 2026, 91 62561, and will be accepting public comments until November 1, 2026.

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 the 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 the DEA.

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

12. DEA Form 222, or its electronic equivalent, is used for ordering schedules I and II controlled substances. The DEA provides pre-printed order forms to purchasers. Upon execution of an order form, the purchaser makes and retains a copy and sends the original to the supplier. The supplier fills in the original with the date and quantity shipped, retains the original, and, if the supplier is not an Automation of Reports and Consolidated Orders System (ARCOS) filer, forwards a copy to the DEA (in batches, usually monthly). Upon receipt of the order, the purchaser fills in its copy with the actual date and quantity received.

Activity	Number of Respondents	Frequency	Total Annual Responses	Time Per Response (Hours)	Total Annual Burden (Hours)	Hourly Rate*	Monetized Value of Respondent Time
DEA-222 (paper)	114,989	2.916644201	335,382	0.25	83,846	\$96.95	\$ 8,128,870
DEA-222/CSOS (online)		133.9853	15,406,832	0.1	1,539,846	\$96.95	\$149,369,217
Unduplicated Totals	114,989	136.90191	15,742,214	0.10314254	1,623,692	\$96.95	\$157,498,087

Schedule I and II controlled substance transactions are reported to ARCOS in accordance with 21 CFR 1304.33. The number of respondents and responses include all "ARCOS reported" transactions, including transactions of certain controlled substances in schedules III-V that were included on the order form.

***Hourly Rate**

	\$
Estimated hourly wage (\$/hour): ¹	67.75
Load for benefits (percent of labor rate): ²	43.1%
	\$
Loaded labor rate (\$/hour):	96.95

13. Respondents are not estimated to incur any additional start-up cost or capital expenditure as

¹ The median hourly wages for 29-1051 Pharmacists was used for simplicity to represent all registrant types. Bureau of Labor Statistics, Occupational and Employment and Wages, May 2025 (https://www.bls.gov/oes/current/oes_nat.htm).

² The Bureau of Labor Statistics' "Employer Costs for Employee Compensation – March 2026" (ECEC) reports that average benefits for private industry are 30.1% of total compensation. The 30.1% of total compensation equates to a 43.1% (30.1%/69.9%) load on wages and salaries.

a result of this information collection. While the copy retained by the purchaser may be in paper or electronic form, the majority are expected to retain copies in electronic form. Therefore, any cost associated with making and retaining copies of DEA Form 222 is nominal (\$0).

14. Estimated annual production cost to the Federal government for the DEA Form 222 system:

Cost Categories	Cost
Government employees	\$224,427
Contract employees	\$335,610
Mailing Costs	\$90,156
Cost of forms	\$367,041
Totals	\$1,017,234

Total annualized production and labor costs: \$1,017,234.

All costs are recovered from the registrants through registration fees, as required by the CSA. 21 U.S.C. 886a.

15. The change in annual responses and burden hours is primarily due to a change in annual responses calculation method. DEA believes this updated method improves accuracy. Previously, the number of paper responses was based on the number of forms mailed out by DEA, and the number of electronic responses were based on the number of ARCOS transaction line items divided by 20. In this updated method, the number of paper responses is based on the number of unique paper order form numbers in ARCO reports, and the number of electronic responses is based on the number of ARCOS ‘transaction-line-items’ multiplied by the ‘number of paper order forms’ to ‘transaction-line-items’ ratio. There are no statutory or regulatory changes related to this information collection.

	2023 Approved Burden	2026 New Requested Burden	Difference
Annual responses	2,813,327	15,742,214	12,928,887
Annual burden hours	351,565	1,623,692	1,272,127
Annual cost (\$)	-	-	-

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

17. Due to the administrative burdens related to replacing expired forms when no information on those forms has been changed, the DEA is seeking approval not to display the expiration date on any paper forms printed by the agency.

18. The 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.

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