

**Supporting Statement for Paperwork Reduction Act Submissions
U.S. Official Order Forms for Schedules I and II Controlled Substances
(DEA Form 222)
OMB Approval # 1117-0010**

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).

Part A. Justification

1. Necessity of Information:

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. Needs and Uses:

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 protect 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. Use of Information Technology:

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. Efforts to Identify Duplication:

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. 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:

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. Special Circumstances Influencing Collection:

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. Consultation with persons outside the Agency:

Public comment was solicited in the notice of proposed rulemaking published on February 21, 2019, 84 FR 5395. The DEA received a number of comments concerning this collection, seeking clarification of the details of the new DEA Form 222 and requesting features for the new form. The comments will be responded to in the final rule.

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 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. Justification for Sensitive Questions:

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

12. Estimate of Hour Burden:

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 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.

Manufacturers and distributors are generally both purchasers and suppliers. Importers may only act as suppliers. All other listed registrants are purchasers. Only suppliers that do not file with ARCOS file order forms with the DEA.

| Registrant Type | Number of Registrants* |
|------------------------|-------------------------------|
| Manufacturers | 406 |
| Distributors | 558 |
| Hospitals/Clinics | 16,848 |
| Pharmacies | 71,979 |
| Practitioners | 35,644 |
| TOTAL | 125,435 |

* Number of registrants that ordered schedules I or II controlled substances in 2017.

| | Number of Annual Respondents | Number of Annual responses* | Average Time per Response (minutes)** | Total Annual Hours |
|--|-------------------------------------|------------------------------------|--|---------------------------|
| | | | | |

| | | | | |
|-----------------------|----------------|------------------|----|------------------|
| DEA-222 (paper) | 125,435 | 3,300,000 | 15 | 825,000 |
| DEA-222/CSOS (online) | | 2,050,000 | 6 | 205,000 |
| TOTAL | 125,435 | 5,350,000 | | 1,030,000 |

* Number of annual responses for “paper” is estimated by counting the number of DEA Forms 222 printed and shipped to registrants. Number of annual responses for “online” is estimated by dividing the number of transaction items by 20. This normalization is required to accurately compare the number of responses on paper versus online. Some pre-printed DEA Forms 222 are anticipated to go unused, in cases where the registrant information has changed or discontinues operation, etc., overestimating the number of paper responses. However, the amount of unused forms is not anticipated to be excessive, and any overestimate is not significant.

** The burden estimate includes initial execution of DEA Form 222, subsequent annotations by the supplier and purchaser, and submission to DEA by the supplier.

Total number of respondents: 125,435
 Number of responses per respondent per year: 42.7 (average)
 Total annual responses: 5,350,000
 Total annual hour burden: 1,030,000

Average Burden: Per Collection: 0.1925 hour
 Per Respondent: 8.2 hour

Total responses received on paper: 3,300,000
 Total responses received electronically: 2,050,000
 Percentage of responses received electronically: 38.3%

Burden dollars:

| | |
|---|----------------------|
| Estimate hourly wage (\$/hour): ¹ | \$57.68 |
| Load for benefits (percent of labor rate): ² | 43.7% |
| Loaded labor rate (\$/hour): ³ | \$82.89 |
| Number of responses | 5,350,000 |
| Total annual hours | 1,030,000 |
| Average burden per response (hour) | 0.1925 |
| Burden dollars per response (\$) | <u>\$ 15.9583</u> |
| Total burden dollars | \$ 85,376,700 |

13. Estimate of Cost Burden:

Respondents are not estimated to incur any additional start-up cost or capital expenditure as a result of this information collection. Any cost associated with retention is nominal. However,

¹ The average of the median hourly wages for 11-3061 Purchasing Managers and 29-1051 Pharmacists was used for simplicity to represent all registrant types. Bureau of Labor Statistics, Occupational and Employment and Wages, May 2017 (http://www.bls.gov/oes/current/oes_nat.htm).

² The Bureau of Labor Statistics’ “Employer Costs for Employee Compensation – December 2017” (ECEC) reports that average benefits for private industry are 30.4% of total compensation. The 30.4% of total compensation equates to a 43.7% (30.4% / 69.6%) load on wages and salaries.

³ \$57.68 x (1 + 0.437) = \$82.89.

respondents that are purchasing controlled substances using a paper DEA Form 222 are estimated to incur copying and printing costs. DEA multiplied the quoted median per-page printing rate of \$0.0395 of a major office supply and printing services firm by 3.3 million copies, resulting in a total material cost of \$130,350. The per-page printing rate of \$0.0395 includes the cost of ink, equipment maintenance, employee labor, and some profit margin.

Printing/copying Cost (Purchasers)

| | |
|--|------------------|
| Cost of material and equipment (per Form 222): | \$0.0395 |
| Total responses received on paper: | 3,300,000 |
| Total Equipment and Material Cost: | \$130,350 |
| Total Cost Burden: | \$130,350 |

14. Estimated Annualized Costs to Federal Government:

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

| | | |
|----------------------|----|---------|
| Government Employees | \$ | 2,577 |
| Contract Employees | \$ | 96,092 |
| Cost of Forms | \$ | 55,517 |
| Mailing (Postage) | \$ | 241,378 |
| Custom Envelopes | \$ | 10,682 |
| Total | \$ | 406,246 |

Estimated annual labor cost to the Federal government for the DEA Form 222 system:

| Labor Category | Number | Annual rate | Load | % of time | Cost |
|--|--------|---------------|------|-----------|------------------|
| Unit Chief - GS-14 | 1 | \$ 123,405.00 | 1.41 | 20% | \$ 34,860 |
| Technical Information Specialist - GS-14 | 1 | \$ 123,405.00 | 1.41 | 20% | \$ 34,860 |
| Import/Export Specialist - GS-13 | 3 | \$ 104,431.00 | 1.41 | 100% | \$ 442,504 |
| Secretary - GS-7 | 1 | \$ 49,506.00 | 1.41 | 5% | \$ 3,496 |
| Total | | | | | \$ 515,721 |
| Grand Total Costs to Federal Government | | | | | \$921,967 |

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

15. Reasons for Change in Burden:

The DEA is adjusting its burden estimates to account for the new single-sheet format of DEA Form 222. The decrease in annual responses reflects efficiencies of the new DEA Form 222 format including having more lines per form, an anticipated reduction in instances of form failure, allowing the use of a printer, and general ease of use over the current format. DEA also adjusted its methodology to estimate the amount of online responses relative to paper responses due to the change in paper format, causing the amount of online responses to decrease. The new DEA Form 222 format doubles the amount of ordering lines per form from 10 to 20, requiring the number of online transaction items to be divided by 20 instead of 10. The decrease in annual burden hours reflects the decrease in annual responses. The decrease in annual burden dollars reflects the decrease in annual burden hours and includes an estimated increase in burden dollar per hour.

| | 2016 Approved Burden | 2019 Requested Burden | Difference |
|-----------------------|-----------------------------|------------------------------|-------------------|
| Annual responses | 9,079,980 | 5,350,000 | 3,729,980 |
| Annual burden hours | 1,453,348 | 1,030,000 | 423,348 |
| Annual burden dollars | 127,240,638 | 85,376,700 | 41,863,938 |

16. Plans for Publication:

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

17. Expiration Date Approval:

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. Exceptions to the Certification Statement:

The 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.