

**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 to 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 (e.g., purchasers) with DEA Forms 222 for ordering schedules I and II controlled substances. 21 U.S.C. 828(d). The DEA Form 222 is subsequently provided by the purchaser to a supplier because, without the appropriate DEA Form 222, the supplier is prohibited from distributing schedules I or II controlled substances to the purchaser. Suppliers must then forward an executed copy of each DEA Form 222 to the DEA. This system in which the DEA provides a pre-printed order form to the purchaser, who then submits the annotated order form to the supplier, who then submits the completed form to the DEA, helps 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, or “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, DEA registration number, type of registrant, and schedules of the registrant. The pre-printed information cannot be altered or changed by any person.

The DEA Form 222 must be signed by either the person who signed the most recent registration, or reregistration, application or a person granted power of attorney by that person. Upon execution of an order form, the purchaser retains one copy and sends the original and one copy to the supplier. The supplier annotates both with the date and quantity shipped, retains the original, and forwards the copy to the DEA. Upon receipt of the order, the purchaser is required to annotate its copy with the date and quantity received. As mandated by 21 U.S.C. 828(c), the purchaser and supplier must retain their copies for two years. These features ensure that only authorized registrants can order schedules I and II controlled substances and that these orders are delivered to the registrant at the registered location. In addition, the requirement of multiple copies of the DEA Form 222, annotated and maintained by each entity in the transaction and forwarded to the DEA, 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. 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.

For the period (CY15) used for this supporting statement, approximately 5 million DEA Forms 222 and 4.1 million electronic orders were submitted. Thus, for the period used for this supporting statement, electronic orders represented 45% 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:

This is a routine renewal of DEA Form 222 and its electronic equivalent CSOS. The DEA does not anticipate any actual additional impact on small businesses or other small entities since the last approval of this form. The collection will not have a significant economic impact on small businesses or other 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:

Suppliers are required to 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 and one copy of the order from the purchaser, annotates them as to date and quantity shipped, retains the original, and sends the copy to the DEA. This report 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 60-day Federal Register Notice of Information Collection, 81 FR 42726, published on June 30, 2016 and the 30-day Federal Register Notice of Information Collection, 81 FR 61251 published on September 6, 2016. The DEA did not receive any comments concerning this collection.

The 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 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 form to purchasers. Upon execution of an order form, the purchaser retains one copy and sends the original and one copy to the supplier. The supplier annotates both with the date and quantity shipped, retains the original, and forwards the copy to the DEA (in batches, usually monthly). Upon receipt of the order, the purchaser annotates 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 file order forms with the DEA.

Registrant Type	Number of Registrants*
Manufacturers	462
Distributors	718
Importers	23
Hospitals/Clinics	16,967
Pharmacies	71,921
Teaching Institutions	66
Exporters	74
Narcotic Treatment Programs, Researchers, Analytical Labs	2,897
Practitioners	32,307
<b>TOTAL</b>	<b>125,435</b>

\* Number of registrants that ordered schedules I or II controlled substances in 2015.

	Number of Annual Respondents	Number of Annual responses*	Average Time per Response (minutes)**	Total Annual Hours
DEA-222 (paper)	125,435	4,996,747	15	1,249,187
DEA-222/CSOS (online)		4,083,233	3	204,162
<b>Total</b>	<b>125,435</b>	<b>9,079,980</b>		<b>1,453,348</b>

\* 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 10. This normalization is required to accurately compare the number of responses on paper versus online. Some pre-printed DEA Forms 222 are anticipated to be not used, in cases where the registrant information has changed or discontinues operation, etc., overestimating the number of paper responses. However, the number of unused forms are anticipated to be not 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: 72.4 (average)

Total annual responses: 9,079,980

Total annual hour burden: 1,453,348

Average Burden:      Per Collection: 0.16 hour  
                                  Per Respondent: 11.6 hour

Total responses received on paper: 4,996,747

Total responses received electronically: 4,083,233

Percentage of responses received electronically: 45%

Burden dollars:

Estimate hourly wage (\$/hour): <sup>1</sup>	\$55.20
Load for benefits (percent of labor rate): <sup>2</sup>	43.5%
Loaded labor rate (\$/hour): <sup>3</sup>	\$79.21

Number of responses	9,079,980
Total annual hours	1,453,348
Average burden per response (hour)	0.1601
Burden dollars per response (\$)	\$ 12.6784
<b>Total burden dollars</b>	<b>\$ 115,119,727</b>

### 13. Estimate of Cost Burden:

1 Used average of median hourly wages for 11-3061 Purchasing Managers and 29-1051 Pharmacists for simplicity to represent all registrant types. Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2015, average of ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)).

2 Bureau of Labor Statistics, “Employer Costs for Employee Compensation – March 2016” (ECEC) reports that average benefits for private industry is 30.3% of total compensation. The 30.3% of total compensation equates to 43.5% (30.3% / 69.7%) load on wages and salaries.

3  $\$55.20 \times (1 + 0.435) = \$79.21$ .

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, respondents are estimated to incur shipping costs.

Based on comments in response to the CSOS final rule (70 FR 16902, published on April, 01, 2005) the DEA assumes that 10 percent of orders are express shipped, 40% are mailed, and the rest are sent via the delivery truck (no charge). FedEx standard overnight shipping orders are assumed to be within the closest zone, and to weigh no more than eight ounces (\$21.27). Mailed order forms are assumed to cost \$0.47 for postage per order and \$0.06 per envelope. There are no shipping costs associated with orders that are sent with the delivery truck.

	Percent of paper annual responses	Number of paper annual responses	Unit cost	Cost
Express ship	10%	499,675	21.27	10,628,087
Mailed (USPS)	40%	1,998,699	0.53	1,059,310
Delivery truck	50%	2,498,373	-	-
<b>Subtotal</b>		<b>4,996,747</b>		<b>11,687,398</b>

Order forms shipped at the end of each month to the DEA are assumed to be express shipped, to weigh no more than 5 pounds, and to be shipped to the closest zone (\$30.03) (FedEx standard overnight).

	Number of responders	Number of monthly submissions	Unit cost	Cost
Suppliers	1,20	14,	30	433,
(manufacturer/distributor/importer)	3	436	.03	513

Total Cost of Burden: \$12,120,911

#### 14. Estimated Annualized Costs to Federal Government:

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

Government Employees	\$	3,347
Contract Employees	\$	73,538
Cost of Forms	\$	180,550
Mailing (Postage)	\$	1,017,387
Custom Envelopes	\$	16,479
Equipment Maintenance	\$	31,713
Equipment cost per year	\$	<u>18,103</u>
<b>Total</b>	<b>\$</b>	<b>1,341,117</b>

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 annual responses, burden hours, and annual burden dollars to reflect actual orders issued in calendar year 2015. The 2013 annual responses of 152,609 was an error and should have been 5,751,635. The increase in annual responses reflects adjustments related to normal business activity. The increase in annual burden hours reflects the increase in annual responses and an adjustment to estimated burden per paper response, from 11 minutes to 15 minutes. The 2013 annual burden dollars erroneously excluded labor burden and should have been 68,070,345. The increase in annual burden dollars reflects the increase in annual burden hours and an estimated increase in burden dollar per hour. There are no statutory or regulatory changes related to this information collection.

	2013 Approved Burden	2016 Requested Burden	Difference
Annual responses	152,609	9,079,980	8,927,371
Annual burden hours	942,315	1,453,348	511,033
Annual burden dollars	9,560,978	127,240,638	117,679,660

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.