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 the Office of Management and Budget (OMB) approval for an existing collection of information that was previously approved by OMB – OMB Approval Number 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 schedules 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.

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.

There are multiple means for registrants to request DEA Form 222, to include online requests and the Office of Diversion Control 24-hour Integrated Voice Response (IVR) system, wherein the registrant may call via telephone and select the function of ordering the forms via the IVR or they may elect to speak with a representative in the Office of Diversion Control Registration and Support Call Center.

Since 2005, registrants have 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:

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 registrant's name, registered address, DEA registration number, authorized activity, 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. 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 C.F.R. 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 (CY13) used for this supporting statement, approximately 4.8 million DEA Forms 222 represented approximately 27.8 million transactions, or about 6 per order form. Furthermore, approximately 924,257 electronic orders represented about 21.2 million transactions or slightly more than 23 per electronic order. Whereas paper order forms are restricted to no more than 10 transactions per order (10 line items per form), electronic orders are not subject to the same requirement and may contain an unlimited number of transactions (line

items) per order (FYI, for the purposes of this Supporting Statement, “orders” , rather than “respondents” or “registrants” equates to “responses). Thus, for the period used for this supporting statement, electronic orders represented 16% 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. The DEA does not anticipate any additional impact on small businesses or other small entities since the initial approval of this form. The move to electronic orders (CSOS) will reduce the burden on small entities. 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. Title 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 eletronic 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, 79 FR 41705-41706, published on 07/17/2014 and the 30-day Federal Register Notice of Information Collection, 79 FR 56404 published on 09/19/2014. 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:

Regulated Entities

Table 1 shows the number of registrants, by business activity, that ordered schedules I or II controlled substances in 2013. These numbers are used as the basis for all other calculations. Registrants are allowed to delegate authority to sign orders through a formal power of attorney (POA). 21 CFR 1305.05.

The number of POAs is estimated based on information from industry on the number of people who hold a POA at different types of facilities. All pharmacies are assumed to have two POAs per pharmacy. The DEA assumes six people with POAs per manufacturer and per distributor,

two people with POAs per hospital/clinic and per teaching institution, and one person with a POA per importer/exporter and per chemical analyst.

Manufacturers and distributors are generally both purchasers and suppliers. Importers may only act as suppliers. All other listed registrants are purchasers. Only suppliers file reports with the DEA.

Table 1: Number of Registrants

Registrant Type	Number of Registrants	Number of POAs
Manufacturers	325	1,950
Distributors	654	3,924
Importers	7	N/A
Hospitals/Clinics	11,522	23,044
Pharmacies	68,022	136,044
Teaching Institutions	125	250
Exporters	81	81
Narcotic Treatment Programs, Researchers, Chemical Analysts	3,538	3,538
Practitioners	68,335	Negligible
TOTAL	**152,609**	**168,831**

For the purposes of this supporting statement, the DEA defines the number of respondents to the forms as the number of registrants.

Activities

This Information Collection Request (ICR) includes details on activities for both paper and electronic orders because the DEA registrants are adopting electronic orders over time. As previously noted, based on unique order numbers, approximately 4.8 million paper orders represented about 27.8 million transactions, or about 6 per order. Furthermore, approximately 924,257 electronic orders represented about 21.2 million transactions or slightly more than 23 per order. Whereas paper orders are restricted to no more than 10 transactions per order (10 line items per form), electronic orders are not subject to the same requirement and may contain an unlimited number of transactions (line items) per order.

Paper Forms

Registrants who order schedules I and II controlled substances on paper (purchasers) must do the following:

- Order DEA Forms 222 through the DEA's website, or by way of the Office of Diversion Control 24-hour Integrated Voice Response (IVR) system, wherein the registrant may call via telephone and select the function of ordering the forms via the IVR or they may elect to speak with a representative in the Office of Diversion Control Registration and Support Call Center.
- Prepare and execute the DEA Form 222 simultaneously in triplicate for each order for each supplier. Each form may contain orders for up to 10 schedules I and II controlled substances, and may not contain orders for other controlled substances or any non-controlled substances.
- Send copy 1 (the original) and copy 2 of DEA Form 222 to the supplier. Retain copy 3.
- When the filled order is received, the purchaser must record on copy 3 the number of commercial or bulk containers furnished for each item and the dates on which the containers are received.
- File and maintain copy 3 for two years.
- Create a POA letter for each POA, signed by the registrant, the POA, and two witnesses. The POA is retained at the registrant's location and has no time limit. A new POA is only required when the registrant wants another individual to be able to sign DEA Form 222.

The supplier must do the following when executing a DEA Form 222 order:

- Record on copies 1 (the original) and the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser..
- Send copy 2 to the DEA at the close of the month.
- File and maintain copy 1 for two years.

In 2013, the number of requests for order forms (via website, call center, or IVR) submitted to the DEA was 167,554.

In 2013, the number of respondents that forwarded executed DEA Forms 222 to the DEA was 82,143.

The number of POA letters (168,831) is based on information provided by the industry. Based on a 2011 report by the American Society of Health System Pharmacists, there is a 6.1% turnover of pharmacists within the health care industry. DEA estimates that 6.1% of the POA letters need to be re-issued each year, or about 10,129 annually.

Electronic Orders

For registrants that utilize CSOS, the following activities will occur:

- The purchaser will access the digital certificate (using a password), digitally sign, and archive each order. Digitally signing an order is done with a keystroke, while archiving is assumed to take place automatically.
- The purchaser submits the order to a specific supplier. The order may include controlled substances in schedules III through V, and any non-controlled substances.
- The supplier must validate the order before filling it. Validation is handled by the computer (e.g., verify the integrity of the digital signature or the order; verify that the digital certificate has not expired), with the only certificate holder action being a keystroke.
- The supplier must retain an electronic record of each order, and link to each order, a record of the number of containers furnished for each item ordered and the date shipped to the purchaser, for two years.
- For each order filled, the purchaser must retain the original digitally signed order and all linked records, for two years.
- Within two business days of filling orders, the supplier's computers will either transmit copies of the orders to the DEA or extract data on schedules I and II orders from orders filled and transmit a computer-generated report of the orders to the DEA.

The creation of the electronic order and the annotation of the record with information on the quantity shipped or received, and date of shipping or receipt are not included in this analysis, because these activities are a necessary and usual course of business for registrants who utilize CSOS. These registrants utilize electronic inventory management systems in the normal course of business. The DEA assumes, based on business models and state requirements, that registrants keep their own records of all activites listed above, therefore performing activites on their own system.

The number of respondents is the number of registrants issuing orders. The total number of activities is based on the number of orders (for ordering) plus twice that number (for shipped orders annotated with the date and quantity shipped/received and filed). This is based on both the purchaser and the supplier indicating date and quantity shipped or received and both filing their respective copies. The number of times orders are sent to the DEA is the number of suppliers (i.e., manufacturers, distributors, and importers/exporters) multiplied by 12 months for the paper system. Table 2 presents the number of annual activities.

Table 2: Number of Annual Activities

Activity	Number of Respondents	Activities per Respondent	Total Number of Activities	Total Number of Responses
Completing orders*	152,609	1/order	5,591,824	152,609
Requisitioning Forms 222	167,554	Varies	167,554	167,554
Annotating and filing**	152,609	1/order	11,183,648	152,609
Logging, tracking, and sending orders to DEA	899	12	10,788	899
POA letters	10,130	2 to 6/respondent/5 years	21,815	10,130
Total***	152,609	1/order		152,609

* Some registrants may purchase schedules I and II controlled substances, but might not distribute schedules I or II controlled substances. The most likely reason is that the schedules I or II controlled substance is manufactured into another substance that is not in schedules I or II.
** Both suppliers and purchasers must annotate their individual copy of DEA Form 222. Thus, the annotating requirement occurs once per order for purchasers and once per order for suppliers, doubling the overall count.
*** As discussed above, 152,609 registrants participate as either purchasers or suppliers in this system. These registrants complete at least some, but not necessarily all, activities listed above. Some registrants may place (purchase) or fill (supply) orders throughout the year, using the forms on an as-needed basis. Activities associated with orders occur once per order. Other activities, including issuance of POA letters, occur on an as-needed basis less frequently than orders.

Burden Hours and Costs

To monetize time spent on various activities in either the paper or electronic system, wage rates were based on the latest industry information from the Bureau of Labor Statistics (BLS). Activities are divided about equally among pharmacists and purchasing managers (for wholesalers) and pharmacy technicians and order clerks. For simplicity, a single wage rate was developed that included the median wage rate for each labor category, loaded with fringe at 40 percent and overhead at 56 percent for an average loaded compensation of $64.09. Rates were obtained from BLS Occupational Employment Statistics and BLS Employer Costs for Employee Compensation.

Table 3 presents the unit hours and unit costs for the paper system and costs for electronic orders.

Table 3: Unit Costs

Activity	Hours	Unit Cost
Paper		
Complete and send order	0.05	$3.10
Requisition order	0.05	$3.10
Annotate order	0.05	$3.10
File orders	0.017	$1.06
Compile and send to DEA	0.01	$0.62
Execute POA letter	0.1	$6.21
Electronic		
Sign order	0.05	$3.10

To estimate the burden for the three years, the DEA assumed that the total number of transactions and orders will remain constant. This is conservative, because as registrants shift to electronic orders, the number of paper orders will decline. Table 4 presents the data.

Table 4: Projected Paper and Electronic Orders*

* These projections are based on rounded totals from 2013.

	222 Orders	**CSOS Orders**	**All Transactions**	**CSOS Transactions**
2013	4,809,310	924,257	49,009,878	21,250,291

Table 5 presents the total annual burden hours and labor costs by activity for years covered by this ICR. Table 6 presents the 3-year costs.

Table 5: Burden Hours and Labor Costs

ICR	Activities	Hours	Labor $
Paper			
Requisitions	167,554	8,378	$520,181
Execute orders	4,809,310	240,466	$14,930,772
Validate, annotate, log, track	9,618,620	480,931	$29,861,544
File	9,618,620	163,517	$10,152,925
Send to DEA	899	1,798	$111,640
POA	10,130	1,013	$62,897
Subtotal		**896,102**	**$55,639,960**
Electronic Orders	924,257	46212.85	$2,869,408
Total		**942,315**	**$58,509,367**

Table 6: Total Annual and Three-Year Hours and Labor Costs

Year	Total Burden Hours	Labor $
First	942,315	$58,509,367
Second	942,315	$58,509,367
Third	942,315	$58,509,367
Total	**2,826,944**	**$175,528,102**
Annual	**942,315**	**$58,509,367**
Average annual hours per registrant	6.17	

13. Estimate of Cost Burden:

Both suppliers and purchasers are required to retain a copy of each order for two years. DEA Form 222 must be retained on paper. A file cabinet that holds 1,150 files currently costs approximately $165; depreciated over 15 years, the annualized cost per file cabinet is $11. Approximately 17,043 file cabinets nationwide would be needed to store two years of executed order forms. In addition, the file cabinets take space (about 2.75 square feet for a letter-sized file cabinet); the average rental cost per square foot is $20 for retail space (Marcus & Millichap 2012 National Retail Report).

Operation & Maintenance (O&M) costs cover purchasers mailing DEA Forms 222 to the suppliers, and suppliers mailing executed forms to the DEA. 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 percent 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 ($15.50). Mailed order forms are assumed to cost $0.44 for postage per order and $0.06 per envelope. There are no O&M costs attached to orders that are sent with the delivery truck. 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 ($22.60) (FedEx standard overnight).

Table 7 presents the annual costs.

Table 7: Annual and 3-Year Capital and O&M Costs

	Capital	**O&M**	**Total**
Customer mailing order forms to supplier		$8,416,293	$8,416,293
Supplier mailing order forms to the DEA		$40,635	$40,635
Files and space	$184,008	$920,042	$1,104,050
Total	**$184,008**	**$9,376,969**	**$9,560,978**
Total-3 years	**$552,025**	**$28,130,908**	**$28,682,933**

14. Estimated Annualized Costs to Federal Government:

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

Government Employees:	$959.89 Contract Employees:	$191,604 x .30 = 57,481.00
Cost of Forms:	$234,135.88	
Mailing (Postage):	$1,103,784.00	
Custom Envelopes	$8,362.00	
Printer Maintenance:	$34,127.28	
Printers/10 years:	$16,003.00	
Total:	$1,454,853.05	

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

Summary

Table 8 presents the burden hours and costs for DEA Form 222 and the ordering aspects of the CSOS (electronic orders). Table 9 presents the total burden hours, labor costs, and O&M costs for this ICR. Table 10 presents the average annual burden hours per registrant for issuing orders. Table 11 represents the average non-labor cost (storage, postage, etc.) to the registrant using the DEA Form 222. Many registrants are likely to continue to issue orders both on paper, and electronically, over the period covered by this ICR, depending on whether their suppliers accept electronic orders. It is, therefore, not possible to assign separate average burden hours to registrants based on the type of order issued.

Table 8: Total Hours and Costs for Forms

Form 222	
Hours	**Costs**
896,102	**$55,639,960**
Electronic orders 46212.85	$2,869,408

Table 9: Summary of Burden Hours and Costs

Year	**Total Burden Hours**	**Labor**	**Other Costs**	**Total**
Annual	942,315	$58,509,367	$9,560,978	$68,070,345
Three Year	2,826,944	$175,528,102	$28,682,933	$204,211,035

Table 10: Average Annual Hour per Respondent

	# Registrants	**Total Hours**
	152,609	**942,315**
Average Annual Hours/Registrant		**6**
Average # of Orders/Registrant		**37**

Table 11: Average Annual Cost per Respondent

Year	**# Registrants**	**Other Costs**
Annual Costs	**152,609**	**$9,560,978**
Average Annual Cost/Registrant		**$62.65**

15. Reasons for Change in Burden:

The DEA is adjusting burden hours to reflect actual orders issued in calendar year 2013. These changes reflect population adjustments related to normal business activity. There are no statutory or regulatory changes related to this information collection.

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 DEA does not employ statistical methods in this information collection.