

**Supporting Statement for Paperwork Reduction Act Submissions  
Self-Certification, Training, and Logbooks for Regulated Sellers and Mail-Order  
Distributors of Scheduled Listed Chemical Products -- DEA Form 597  
OMB Approval # 1117-0046**

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for an existing collection that was previously approved by OMB – OMB Approval Number 1117-0046, Self-Certification, Training, and Logbooks for Regulated Sellers and Mail-Order Distributors of Scheduled Listed Chemical Products, DEA Form 597.

**Part A. Justification**

1. Necessity of Information:

The Combat Methamphetamine Epidemic Act of 2005 (CMEA), which is Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005 (Pub. L. 109-177), requires that on and after September 30, 2006, a regulated seller must not sell at retail over-the-counter (non-prescription) products containing the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine (referred to here as "scheduled listed chemical products"), unless it has self-certified to the DEA, through the DEA's Web site. The Combat Methamphetamine Enhancement Act of 2010 (Pub. L. 111-268) (MEA) requires that on and after April 10, 2011, a regulated person that sells scheduled listed chemical products at retail and uses or attempts to use the U.S. Postal Service or a private or commercial carrier to deliver the product to the customer (referred to as a "mail-order distributor"), must not sell those products unless it has self-certified to DEA, through DEA's Web site. The Methamphetamine Production Prevention Act of 2008 (MPPA) (Pub. L. 110-415) was enacted in 2008 to clarify the information entry and signature requirements for electronic logbook systems permitted for the retail sale of scheduled listed chemical products. The MPPA expressly permits the regulated seller to capture information regarding the name of the product and the quantity sold through bar code, electronic data capture, or similar technology.

The regulated seller or mail-order distributor is also responsible to train any employee who will be involved in selling scheduled listed chemical products, document the training, and self-certify annually to DEA that all affected employees have been trained and that the regulated seller or mail-order distributor is in compliance with all the CMEA and MEA provisions. Finally, the CMEA mandates that each sale at retail by a regulated seller be documented in a written or electronic logbook and that the logbooks be retained for two years from the date of the transaction.

2. Needs and Uses:

Regulated sellers and mail-order distributors are required to self-certify with DEA to sell scheduled listed chemical products at retail. Such self-certification is required for DEA to enforce the Controlled Substances Act (CSA).

3. Use of Information Technology:

The CMEA and MEA specifically require that self-certification to the DEA occur through a Web site operated by DEA. At this time, all self-certifications must be filed electronically through the DEA website: [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov).

4. Efforts to Identify Duplication:

DEA has made efforts to identify and prevent duplication of the collection of information. The existing DEA Form 597 is not duplicative. This specific information is only required by CMEA and MEA, therefore, no similar information is being collected.

5. Impact on Small Businesses or Entities:

DEA has concluded that the collection will not have a significant economic impact on small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601-612.

6. Consequences of Less Frequent Collection:

If the collection is not conducted or conducted less frequently, DEA would not have sufficient data to enforce the CSA. The information collected by DEA Form 597 is vital to the enforcement of the CSA, which mandates that regulated sellers of scheduled listed chemical products maintain a written or electronic logbook of sales. The CSA requires that regulated sellers and mail-order distributors selling scheduled listed chemical products must self-certify with DEA. Collection of information on each sale is statutorily mandated.

7. Special Circumstances Influencing Collection:

There are no special circumstances 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, 85 FR 44927, published July 24, 2020 and the 30-day Federal Register Notice of Information Collection, 85 FR 68091, published October 27, 2020. DEA did not receive any comments concerning this collection.

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:

The disclosure of information regarding sensitive business information pertaining to listed chemicals is governed by the Administrative Procedure Act (APA), Department of Justice (DOJ) Regulations, and the CSA. 5 U.S.C. 552; 28 CFR 16.8; 21 U.S.C. 830.

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 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 disclosure by DEA.

More specifically, information related to listed chemicals which are obtained pursuant to 21 U.S.C. 830 is generally not disclosed. Circumstances which allow for disclosure include government personnel engaged in carrying out controlled substance or chemical laws, investigations or proceedings related to the CSA or customs laws, or compliance with treaties or international agreements. 21 U.S.C. 830(c)(2). Finally, aggrieved persons harmed by an improper disclosure of information are afforded further protection by the grant of a private right of action. 21 U.S.C. 830(c)(4).

#### 11. Justification for Sensitive Questions:

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

#### 12. Estimate of Hour Burden

Reporting self-certification is required on DEA Form 597. The form is completed online and must be renewed annually. The required information is limited to the DEA number (where applicable), Taxpayer ID, business address, point of contact information, number of employees trained, total employees at the location, scheduled listed chemical products sold (by chemical), and the type of establishment. The DEA estimates that applying for a new self-certification takes 30 minutes and renewing an existing self-certification requires 15 minutes each year. Since the vast majority of self-certifications are renewals, 15 minutes per self-certification is used for estimating hour burden. Based on active annual self-certifications as of 5/22/2020, the DEA estimates there will be 51,657 self-certifications per year.

Regulated sellers will need to maintain a record of employee training as well as maintain a logbook of transactions. Mail-order distributors will need to maintain a record of employee training. Completing a roster of employees trained is estimated to take 3 minutes. Based on the ratio of the number of employees trained to the number of self-certifications of 13.2, the DEA estimates 681,872 employees will be trained.<sup>1</sup>

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<sup>1</sup> Sample of 13 self-certifications indicates a total of 172 employees or an average of 13.2 employees were trained.

The DEA estimates that having the customer enter information and sign the logbook while the sales person checks the photographic identification of the purchaser (as required by CMEA) will take one minute per transaction. Based on latest data on retail sales of OTC ephedrine, pseudoephedrine, or phenylpropanolamine, the DEA estimated that total of 48,003,476 units of over-the-counter scheduled listed chemical products were sold in 2019.<sup>2</sup> Conservatively assuming one transaction per unit, the DEA estimates there were 48,003,476 transactions in 2019. The units sold have been declining slowly over the past several years and the DEA believes this is a reasonable conservative estimate for the next several years. The rule implementing the retail sales provisions of the CMEA and this associated information collection impose no additional burden for the transactions on either purchasers or sellers in those states. Based on Bureau of Census state population numbers for 2005, these states represent 49 percent of the U.S. population. The DEA assumes that the number of transactions is proportionate to the population, resulting in an estimated 24,481,773 transactions. The table below presents the burden hour calculations including the certification burden.

Activity	Number of Annual Respondents	Number of Annual Responses	Average Time per Response (minutes)	Total Annual Hours
Training record	51,657	681,872	3	34,094
Self-certification		51,657	15	12,914
Transaction record (regulated seller)		24,481,773	1	408,030
Transaction record (customer)	24,481,773	24,481,773	1	408,030
<b>Total</b>	<b>24,533,430</b>	<b>49,697,075</b>		<b>863,068</b>

\* Assuming one unit of scheduled listed product per respondent.

Total responses received on paper (self-certification only): 51,657

Total responses received electronically (self-certification only): 51,657

Percentage of responses received electronically (self-certification only): 100%<sup>3</sup>

Burden dollars:

	<u>Pharmacist</u>	<u>Pharmacy</u>	<u>All Occupations</u>
	<u>s</u>	<u>Technicians</u>	
Estimate hourly wage (\$/hour): <sup>4</sup>	61.58	16.32	19.14
Load for benefits (percent of labor rate): <sup>5</sup>	<u>42.7%</u>	<u>42.7%</u>	<u>42.7%</u>
Loaded labor rate (\$/hour): <sup>6</sup>	87.87	23.29	27.31

<sup>2</sup> IQVIA, NSP.

<sup>3</sup> The electronic submission figures are for self-certifications only. The DEA has no basis to estimate the percentage of other recordkeeping requirements that are electronic.

<sup>4</sup> As the vast majority of non-customer respondents are pharmacies the median hourly wages for 29-1051 Pharmacists was used to estimate burden dollars for Training Records and Self-certification and 29-2052 Pharmacy Technicians was used to estimate burden dollars for Transaction record for the regulated seller. The median hourly wages for 00-0000 All occupations was used to estimate burden dollars for transaction record for the customer. Bureau of Labor Statistics (BLS) May 2019 National Occupational Employment and Wage Estimates. [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm). (accessed 5/4/2020)

<sup>5</sup> Bureau of Labor Statistics, “Employer Costs for Employee Compensation – December 2019” (ECEC) reports that average benefits for private industry is 29.9% of total compensation. The 29.9% of total compensation equates to 42.7% (29.9% / 70.1%) load on wages and salaries.

	<b>Training Record</b>	<b>Self-Certification (DEA Form 597)</b>	<b>Transaction Record (regulated seller)</b>	<b>Transaction Record (customer)</b>	<b>Total</b>
Number of respondents	51,657	51,657	51,657	24,481,773	24,533,430
Number of responses per year	13.2000	1.0000	473.92944	1.0000	N/A
Number of responses	681,872	51,657	24,481,773	24,481,773	49,697,075
Average burden per response (hour)	0.0500	0.2500	0.0167	0.0167	N/A
Total annual hours	34,094	12,914	408,030	408,030	863,068
Burden dollars per response (\$)	4.39	21.97	0.39	0.46	N/A
Total burden dollars (\$)	2,993,418	1,134,904	9,547,891	11,261,616	24,937,829

### 13. Estimate of Cost Burden:

The CMEA mandates that each sale at retail by a regulated seller be documented in a written or electronic logbook and that the logbooks be retained for two years from the date of the transaction. If every retail seller used bound logbooks, the annual cost of logbooks needed to record 24,481,773 transactions would be \$188,600 (\$41.60 for a bound logbook that has 150 pages and 36 lines/pages). The DEA expects that many retail sellers will use existing computer systems and signature capture devices to meet the requirement, which will reduce the costs. The DEA expects that training records will be maintained electronically on existing computer systems.

Total Cost of Burden: \$188,600

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

Self-certifications are reported on existing electronic form on DEA's website. While DEA systems require routine maintenance, the cost to the Federal Government as a result of this information collection is minimal. Furthermore, 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 increase in annual responses, annual burden hours, and annual burden dollars reflect adjustments related to increase in estimated number of training records, estimated labor rates, and normal business activity. There have been no statutory or regulatory changes affecting this information collection. The table below summarizes the changes since the last renewal of this information collection.

	<b>2017 Approved Burden</b>	<b>2020 Requested Burden</b>	<b>Difference</b>
Annual responses	49,016,246	49,697,075	680,829

<sup>6</sup> \$61.58 x (1 + 0.427) = \$87.87. \$16.32 x (1 + 0.427) = \$23.29. \$19.14 x (1 + 0.427) = \$27.31.

Annual burden hours	841,764	863,068	21,304
Annual burden dollars	21,028,089	24,937,829	3,909,740

16. Plans for Publication:

DEA will not publish the results of the information collected.

17. Expiration Date Approval:

DEA has no issues with OMB displaying the expiration date.

18. Exceptions to the Certification Statement:

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 does not employ statistical methods in this information collection.