Supporting Statement for Paperwork Reduction Act Submission
Dispensing Records of Individual Practitioners
OMB Approval # 1117-0021

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 1117-0021, Dispensing Records of Individual Practitioners.

A. Justification

1. Necessity of Information

In accordance with the Controlled Substances Act (CSA), every DEA registrant must make a biennial inventory and maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. 21 U.S.C. 827 and 958. These records must be maintained separately from all other records of the registrant or, alternatively, in the case of non-narcotic controlled substances, be in such a form that required information is readily retrievable from the ordinary business records of the registrant. 21 U.S.C. 827(b)(2). The records maintained by registrants must be kept and be available for at least two years for inspection and copying by officers or employees of the United States as authorized by the Attorney General. 21 U.S.C. 827(b)(3). The DEA may promulgate regulations that specify the information that registrants must maintain in the required records. 21 U.S.C. 827(b)(1).

Pursuant to 21 U.S.C. 827(c), practitioners who regularly dispense or administer controlled substances to patients and charge them for the substances and those practitioners who administer controlled substances in the course of maintenance or detoxification treatment shall keep records of such activities, and accordingly must comply with the regulations on recordkeeping. Paragraphs (b), (c), and (d) of 21 CFR 1304.03 identify when individual practitioners are required to maintain records of controlled substances. The recordkeeping requirements for these practitioners are contained in 1304.04(g), 1304.11, 1304.22, and 1304.24.

2. Needs and Uses

The DEA and registrants use the required records to maintain accountability for controlled substances, and to deter and detect diversion. Without these recordkeeping requirements, the closed system of distribution would be compromised. Controlled substances that are dispensed or administered could easily be diverted without detection.

The DEA is authorizing reverse distributors to acquire controlled substances from law enforcement and authorized collectors that have acquired those substances from ultimate users and other non-registrants through one of the approved collection methods: take back event, mail-back program, or collection receptacle. The DEA is also authorizing distributors to acquire controlled substances from authorized collectors that have acquired those substances from

ultimate users and other non-registrants through one of the above-listed collection methods. The DEA is requiring these reverse distributors and distributors to maintain complete and accurate records of controlled substances received, delivered, or otherwise disposed of.

3. Use of Technology

These requirements do not involve reporting and, therefore, issues related to electronic submission are not applicable. The DEA's regulations allow registrants to maintain the required records in any format they find appropriate, including electronically.

4. Efforts to Identify Duplication

The DEA made efforts to identify and prevent duplication of the collection of information. Although the DEA specifies the data that must be recorded and maintained, it does not specify the format. Registrants may use existing records to meet the requirements if those records include the data that must be maintained. The DEA does not believe that there is a duplication of an existing collection of information.

5. Impact on Small Businesses or Entities

The 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

Pursuant to 21 U.S.C. 827(b) requires that records be maintained for a period of at least two years. The DEA does not have the authority to reduce the burden or period of recordkeeping. Failure to collect the information or to conduct the collection less frequently will contravene the CSA, reduce accountability, and increase the risks of diversion. The information collected in accordance with the Disposal Act is vital to the enforcement of the CSA, ensures accountability, and helps to deter and detect the diversion of controlled substances outside of legitimate channels into the illicit market. Furthermore, the information collected, in accordance with the Disposal Act, helps to deter and detect the diversion of controlled substances during the disposal process. In implementing the Disposal Act, the DEA was required to promulgate disposal regulations that prevent the diversion of controlled substances. 21 U.S.C. 822(g)(1).

7. Special Circumstances Influencing Collection

The DEA does not foresee any special circumstances that would cause an information collection.

8. Consultation with persons outside the Agency

Public comment was solicited in the 60-day Federal Register Notice of Information Collection, 82 FR 29330, published on June 28, 2017 and the 30-day Federal Register Notice of

Information Collection, 82 FR 41658, published on September 1, 2017. 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 provided pursuant to 21 U.S.C. 827(b)(3) 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. The information is protected by the DEA through secure storage, limited access, and federal regulatory and DEA procedures.

11. Justification for Sensitive Questions

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

12. Estimated Hour Burden

a. Dispensing Records of Individual Practitioners

The DEA estimates that 62,392 individual practitioners are subject to these rules because they routinely administer and dispense controlled substances.

Practitioners who routinely administer or dispense controlled substances must do the following:

- Once every two years, conduct an inventory of controlled substances present at the time of the inventory. The information that must be recorded for each controlled substance includes the name of the substance, the finished form (e.g., 10 mg tablet), the number of units, and the number of containers. For Schedule II substances, the practitioner must provide an exact count of the units on hand; for Schedule III-V substances, the practitioner may estimate the number if it is less than 1,000.
- On a continuing basis, maintain records of controlled substances, including the name, the finished form, and the number of units on hand, and the name and address of the person to whom the drug was dispensed, the number of units dispensed, and the name or initials of the person dispensing.
- Maintain records of Schedule II substances separately from other records. Schedule III-V records must be readily retrievable from other files.

The requirement of continuing records is not a perpetual inventory. Practitioners must keep a record of substances received; for Schedule II substances, this record is the annotated order form required under a separate rule; for Schedule III-V controlled substances, the shipping record. After that point, the practitioner must maintain a log of the substances dispensed.

The DEA estimates that it takes 30 minutes per year to maintain the log and, biennially, to conduct the inventory. Most practitioners keep very limited stocks of controlled substances and, therefore, require little time to record the information on a log. The DEA assumes that most practitioner offices either record the information by hand or enter the information into an electronic log. The table below presents the burden hour calculations.

b. Recordkeeping Requirements for DEA Registrants Authorized to Collect

In accordance with 21 U.S.C. 827(a), registrants make an initial and biennial inventory and maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. Collectors operating collection receptacles and mail-back programs are required to conduct initial one-time instruction development for mail-back program operators and signage for collection receptacle operators as well as information collection responses based on certain operational events, such as collection receptacle inner liner replacements. While all respondents will have initial and biennial information collection events, the frequency of responses based on operational events is estimated to vary by business activity.

Based on the actual number of collectors as of June 9, 2017, the DEA estimates there are 2,359 respondents. Collectors include 2,339 collection receptacle operators, 6 mail-back program operators, and 14 operators of both collection receptacle and mail-back programs. While the actual burden hours may vary between collectors, the DEA estimates that it takes an average of 30 minutes per year to comply with the above requirements. The table below presents the burden hour calculations.

Activity	Number of Annual Respondents	Number of Annual Responses	Average Annual Time per Response (minutes)	Total Annual Hours
Dispensing records of individual practitioners	62,392	62,392	30	31,196
Recordkeeping requirements of collectors	2,359	2,359	30	1,180
Total	**64,751**	**64,751**	**N/A**	**32,376**

Total number of respondents: 64,751
Number of responses per respondent per year: 1 (see footnote[1])
Total annual responses: 64,751

[1] Includes various one-time, event-based, and biennial responses. DEA has no basis to estimate the number of event-based responses. For simplicity, the entire information collection for collectors is modeled as a single requirement occurring annually at an annual burden of 30 minutes per response.

Total annual hour burden: 32,576

Average Burden: Per Collection: 0.5 hour
Per Respondent: 0.5 hour

Burden dollars:

	Medical Records and Health Information Technician	Pharmacy technicians
Estimate hourly wage ($/hour):[2]	18.29	14.86
Load for benefits (percent of labor rate):[3]	43.7%	43.7%
Loaded labor rate ($/hour):[4]	26.28	21.35

	Dispensing records of individual practitioners	**Recordkeeping requirements of collectors**	**Combined Total**
Number of responses	62,392	2,359	64,751
Total annual hours	31,196	1,180	32,376
Average burden per response (hour)	0.5000	0.5000	0.5000
Burden dollars per response ($)	13.1394	10.6753	13.0496
Total burden dollars ($)	**819,791**	**25,183**	**844,974**

13. Estimated Total Annual Cost Burden

The estimated annual cost burden is zero. Respondents are not estimated to incur any a) additional start-up cost or capital expenditure, or b) additional operation and maintenance costs or purchase services because of this information collection.

14. Estimated Annualized Costs to the Federal Government

[2] The vast majority of collectors are pharmacies. The median hourly wages for 29-2071 Medical Records and Health Information Technician was used for dispensing records of individual practitioners and 29-2052 Pharmacy technicians was used for record keeping requirements of collectors based on the Bureau of Labor Statistics (BLS) May 2016 National Occupational Employment and Wage Estimates. http://www.bls.gov/oes/current/oes_nat.htm. (accessed 6/9/2017)

[3] Bureau of Labor Statistics, "Employer Costs for Employee Compensation – March 2017" (ECEC) reports that average benefits for private industry is 30.4% of total compensation. The 30.4% of total compensation equates to 43.7% (30.4% / 69.6%) load on wages and salaries.

[4] $18.29 x (1 + 0.437) = $26.28. $14.86 x (1 + 0.437) = $21.35.

Information recorded by those affected is not submitted to the DEA. The cost to the Federal Government for this information collection is zero. 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 decrease in annual responses reflects the removal of redundant responses that were added in the 2014 information collection request. The decrease in annual burden hours is primarily due to the revised estimated number of respondents for the record keeping requirements of collectors. The decrease in annual burden dollars in 2017 requested annual burden dollars reflects the decrease in burden hours. There are no statutory or regulatory changes related to this information collection.

	2014 Approved Burden	2017 Requested Burden	Difference
Annual responses	1,511,389	64,751	(1,446,638)
Annual burden hours	89,912	32,376	(57,537)
Annual burden dollars	1,680,820	844,974	(835,846)

16. Plans for Publication

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

17. Expiration Date of Approval

The DEA is not seeking approval to display an expiration date for this Information Collection.

18. Exceptions

The DEA is not seeking an exception to the certification statement “Certification for Paperwork Reduction Act Submissions” for this collection of information

B. Statistical Methods

The DEA does not employ statistical methods in this Information Collection.