

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

The Drug Enforcement Administration (DEA) seeks Office of Management and Budget (OMB) approval for revision to an existing collection of information that was previously approved by OMB – OMB Approval Number 1117-0021, Dispensing Records of Individual Practitioners. The revised Information Collection is entitled Records of Registrants.

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). As a component of the implementing regulations to the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act) (Pub. L. 111-273), the DEA is revising and establishing new information that registrants are required to record pursuant to the CSA, specifically 21 U.S.C. 827 and 958.

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.

The existing collection of information is affected by the new regulations that implement the Disposal Act. The Disposal of Controlled Substances final rule (RIN 1117-AB18), expands disposal options for ultimate users, reorganizes and consolidates existing regulations on the disposal of controlled substances including the role of reverse distributors, and establishes a comprehensive regulatory framework for the collection and destruction of controlled substances consistent with the CSA.

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 revising and establishing new information that certain registrants are required to record in accordance with the Disposal Act implementing regulations. Below is a summary of the information that certain groups of registrants will be required to record. Ordinary business records will frequently fulfill these specific requirements.

a. Recordkeeping Requirements for Reverse Distributors

The DEA is revising the information that reverse distributors are required to record. This includes reconciling the quantities of controlled substances that reverse distributors are required to record in inventory and continuing records (e.g., a reverse distributor must record the quantity of a controlled substance in both finished and bulk form, and the quantity contained in a commercial container, carton, crate, drum, or other receptacle that has been opened). In addition, the DEA is requiring reverse distributors to keep records regarding each controlled substance received from a particular registrant for a particular purpose together with the corresponding disposition record (i.e., maintain the record of receipt with the corresponding record of return or destruction).

b. Recordkeeping for Registrants that Receive or Deliver Controlled Substances for Return or Recall

The DEA is revising the information that registrants are required to record in the return and recall process. The DEA is deleting the existing rule on return and recall, 21 CFR 1307.12, and implementing separate rules on the return and recall of controlled substances for registrants and non-registrants. The return and recall recordkeeping requirements have been revised to reflect these changes.

In particular, the DEA is continuing to require that registrants that distribute controlled substances to another registrant for the purpose of return or recall shall be required to maintain a record of the activity in accordance with existing 21 CFR 1304.22(b). For registrants that receive controlled substances from another DEA registrant for the purpose of return or recall, those registrants will be required to maintain a record that includes the date of the transaction, the name, form, and quantity of each controlled substance received, and the name, address, and registration number of the distributing registrant from whom the substance was received. For those registrants that receive controlled substances from ultimate users for the purpose of recall, those registrants must maintain a record that includes the date of receipt, and the name, form, and quantity of each controlled substance received.

c. Recordkeeping Requirements for DEA Registrants Authorized to Collect

To implement the Disposal Act, the DEA is authorizing three methods of ultimate user collection: take back events, mail-back programs, and collection receptacles. Registered manufacturers, distributors, reverse distributors, narcotic treatment programs (NTPs), hospitals/clinics with an on-site pharmacy, and retail pharmacies may obtain authorization from DEA to be a collector. A collector is a person authorized to receive a controlled substance for the purpose of disposal from non-registrants in lawful possession of pharmaceutical controlled substances. Collectors are permitted to: (1) conduct mail-back programs if they have and utilize an on-site method of destruction; and (2) maintain collection receptacles at authorized locations. Registered retail pharmacies and hospitals/clinics with an on-site pharmacy may seek DEA authorization to maintain collection receptacles at LTCFs, in addition to their registered locations.

The DEA is requiring that collectors record certain information based on the particular ultimate user collection method utilized (i.e., mail-back program or collection receptacle). The inner liners and mail-back packages that are utilized in the collection of ultimate user controlled substances are intended for the disposal of controlled substances. As a result, the DEA is requiring that collectors make an inventory of all unused inner liners and packages and maintain records on the use of such liners and packages in order to properly account for the disposal of controlled substances in accordance with the CSA.

Collectors that conduct a mail-back program must keep an initial and biennial inventory of the number of unused packages on hand that the collector intends to make available to ultimate users for disposal, the number of packages on hand that the collector has received for disposal, and the unique identification number of each package. For continuing records, a collector that conducts a mail-back program must keep a record of the receipt, storage, and destruction of each package. Collectors that maintain a collection receptacle must maintain an initial and biennial inventory of the number of inner liners on hand. For continuing records, a collector that maintains a collection receptacle must keep a record of the installation, removal, storage, transfer to a reverse distributor or distributor, and destruction of each sealed inner liner.

Mail-back programs and collection receptacles are new activities and new recordkeeping requirements are necessary so that the DEA and registrants can account for registrant-coordinated disposal of ultimate user controlled substances, and to help detect and deter the diversion of controlled substances into the illicit market.

d. Recordkeeping Requirements for Reverse Distributors that Acquire Collected Controlled Substances from Law Enforcement or Authorized Collectors, and Distributors that Acquire Collected Controlled Substances from Authorized Collectors

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 considered alternatives for this collection of information and evaluated the impact of the Disposal of Controlled Substances final rule on small entities. The DEA concluded that the final rule will not have a significant economic impact on a substantial number of small entities. For more detailed information, see the DEA's Regulatory Flexibility Act analysis included in the final rule.

6. Consequences of Less Frequent Collection

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 to be conducted in a particular manner: e.g., requiring respondents to report

information to the agency more than quarterly; requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it; requiring respondents to submit more than an original and two copies of any document; requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years; in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study; requiring the use of a statistical data classification that has not been reviewed and approved by OMB; that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Consultation with Persons Outside the Agency

On January 19 and 20, 2011, the DEA held a public meeting to receive comments regarding the implementation of the Disposal Act (75 FR 80536, December 22, 2010). This meeting allowed all interested persons – the general public, including ultimate users, pharmacies, law enforcement personnel, reverse distributors, and other third parties – to express their views regarding safe and effective methods of disposal of controlled substances consistent with the CSA. Representatives of various industries as well as various Federal, State, and local agencies spoke at the meeting and provided information and suggestions on the implementation of the Disposal Act. The DEA met with other federal agencies, the Office of National Drug Control Policy, congressional staffs, and pharmacy and reverse distributor representatives to discuss and receive feedback on both the proposed rule and the final rule.

The Notice of Proposed Rulemaking on the Disposal of Controlled Substances (RIN 1117-AB18) was published in the Federal Register on December 21, 2012, with a request for public comment. (77 FR 75784). The comments the DEA received regarding recordkeeping requirements included questions about who the new recordkeeping requirements would apply to and the inventory requirements for inner liners and mail-back packages.

The DEA responded that the records that registrants are required to maintain pursuant to law are a vital component of the DEA's enforcement and oversight responsibilities – such records ensure accountability and help to deter and detect diversion.

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 the requirements of the disposal final rule and 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. Recordkeeping Requirements for Reverse Distributors

Number of Respondents: 60

Frequency of Response: Varies.

The DEA estimates that the frequency of response will vary because, in accordance with 21 U.S.C. 827 and 958, 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. The DEA also anticipates the frequency of responses to be increased by a combined total of 68 due to the requirements in the Disposal of Controlled Substances final rule.

Annual Hour Burden: 34 hours

The annual hour burden is estimated to increase by 34 hours due to the requirements in the final rule. Under existing law, reverse distributors are required to maintain, for at least two years, inventory records and records of controlled substances received, delivered, destroyed, or returned to the manufacturer.

Explanation of How the Burden was Estimated:

Reverse distributors should already maintain the types of records required by the final rule pursuant to their responsibilities in 21 U.S.C. 827(a) and (b). However, the final rule requires reverse distributors to destroy or cause destruction of collected controlled substances from other registrants within 30 calendar days of receipt or delivery. Based on review of DEA records and reports, this requirement will result in a combined total of 68 additional information collection events. At an estimated 30 minutes, one-half hour, per information collection event, 68 additional information collection events are expected to result in 34 hours of additional burden.

Annualized Cost to Respondents: \$719

The DEA used the median hourly wage of \$15.97 for 53-0000 Transportation and Material Moving Occupations in the Warehousing and Storage Industry from the Bureau of Labor

Statistics May 2012 Occupational Employment and Wages data and applied a 32.5% load for taxes and benefits for a labor unit cost of \$21.16.

b. Recordkeeping for Registrants that Receive and Distribute Controlled Substances for Return or Recall

Number of Respondents: 1,511,389 (All registrants may distribute controlled substances to the manufacturer or manufacturer's authorized agent for return or recall).

Frequency of Response: Varies.

The DEA estimates that the frequency of response will vary because, in accordance with 21 U.S.C. 827(a), registrants maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. The frequency of distribution and receipt of controlled substances for the purpose of return and recall is unknown. The DEA also anticipates that the frequency of response will not be increased by the requirements in the final rule because the final rule does not alter any of the existing recordkeeping requirements with respect to return and recall; the final rule simply reorganizes the existing recordkeeping requirements with respect to return and recall.

Annual Hour Burden: 0

Because the DEA is continuing to require recordkeeping that registrants already maintain in accordance with 21 U.S.C. 827(a) and (b), the DEA anticipates that the annual hour burden will not be increased by the final rule.

Explanation of How the Burden was Estimated:

Registrants currently maintain detailed records of return and recall transactions as required by the CSA and in the course of their normal business activities. Accordingly, the requirements in the final rule pose no increased burden to registrants.

Annualized Cost to Respondents: \$0

The annual hour burden will not be increased by the requirements in this final rule as affected registrants already maintain records consistent with the requirements, and, therefore, the annualized cost to respondents will not increase.

c. Recordkeeping Requirements for DEA Registrants Authorized to Collect

Number of Respondents: 54,457 (Manufacturers—107, Distributors—166, Reverse Distributors—10, Narcotic Treatment Programs—999, Hospitals/Clinics—2862, Retail Pharmacies—34,513, and an additional 15,800 hospitals/clinics and retail pharmacies operating collection receptacles at LTCFs).

Note: The DEA estimates that the universe of potential participants to this information collection will be 87,736 respondents (Manufacturers—536, Distributors—829, Reverse Distributors—60, Narcotic Treatment Programs—1,332, Hospitals/Clinics—15,953, Retail

Pharmacies—69,026). However, the DEA estimates that the participants to this information collection will be 54,457 respondents.

Frequency of Response: Varies.

The DEA estimates that the frequency of response will vary because different collection activities require varying response frequencies. 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. The rule also requires 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.

Business activity	Initial response (non-recurring)	Event-driven response (responses per year)	Biennial inventory (responses per 2 years)
Manufacturer (collection receptacle)	1	12	1
Distributor (collection receptacle)	1	12	1
Reverse Distributor	1	100	1
NTP (collection receptacle)	1	24	1
Hospital/Clinic (collection receptacle)	1	26	1
Pharmacy (collection receptacle)	1	26	1
LTCF, urban/suburban location (collection receptacle)	1	24	1
LTCF, rural location (collection receptacle)	1	12	1

Annual Hour Burden: 89,406

Explanation of How the Burden was Estimated:

Since initial responses and biennial inventories do not occur on an annual basis, the “annualized” hour burden is calculated to represent the annual hour burden. The annualized hour burden is estimated by dividing the annualized cost by the median hourly rate.

The DEA used the median hourly wage of \$15.97 for ‘53-0000 Transportation and Material Moving Occupations’ in the Warehousing and Storage Industry from the Bureau of Labor Statistics May 2012 Occupational Employment and Wages data as hourly wages for manufacturer, distributor, and reverse distributor information collection. The median hourly wage of \$13.61 for ‘31-0000 Healthcare Support Occupations’ was used as an estimate for NTP information collection hourly wages. The median hourly wage of \$14.10 for ‘29-2052 Pharmacy Technicians’ was used as an estimate for hospital/clinic, pharmacy, and LTCF information

collection hourly wages. An additional 32.5% load for taxes and benefits was applied to the median hourly wages of \$15.97, \$13.61, and \$14.10 for a labor unit cost of \$21.16, \$18.03, and 18.68 per hour, respectively. The response times for each response and median hourly rates are summarized below.

Business activity	Initial response (non-recurring)	Event-driven response (responses per year)	Biennial inventory (responses per 2 years)	Hourly rate (\$)
Manufacturer (collection receptacle)	15 minutes	3 minutes and 40 seconds	15 minutes	21.16
Distributor (collection receptacle)	15 minutes	3 minutes and 40 seconds	15 minutes	21.16
Reverse Distributor	4 hours	49 seconds	15 minutes	21.16
NTP (collection receptacle)	15 minutes	3 minutes and 40 seconds	15 minutes	18.03
Hospital/Clinic (collection receptacle)	15 minutes	3 minutes and 40 seconds	15 minutes	18.68
Pharmacy (collection receptacle)	15 minutes	3 minutes and 40 seconds	15 minutes	18.68
LTCF, urban/suburban location (collection receptacle)	15 minutes	3 minutes and 40 seconds	15 minutes	18.68
LTCF, rural location (collection receptacle)	15 minutes	3 minutes and 40 seconds	15 minutes	18.68

Using the hourly rates, response times are expressed in dollars. The discounted cash flow method is used to calculate the present value of the costs for each respondent at 7% discount rate over 20 years. The annualized cost per participant is determined by calculating equal annual payments for the present value of costs at 7% for 20 years. The annualized cost is multiplied by the number of participants to determine the total annualized cost of participation for each business activity. The total annualized hours is calculated by dividing the total annualized cost by the respective hourly rates. The sum of total annualized hours for all business activities is 89,406. See table below.

Business activity	Annualized Cost per participant (\$)	Number of Participants	Total annualized cost of participation (\$)	Total annualized hours
Manufacturer (collection receptacle)	18.57	107	1,987	94
Distributor (collection receptacle)	18.57	166	3,083	146
Reverse Distributor	154.55	10	1,546	73
NTP (collection receptacle)	29.05	99	29,023	1,609
Hospital/Clinic (collection receptacle)	32.38	2,862	92,676	4,961
Pharmacy (collection receptacle)	32.38	34,513	1,117,587	59,820
LTCF, urban/suburban location (collection receptacle)	30.10	12,049	362,653	19,411
LTCF, rural location (collection receptacle)	16.40	3,751	61,508	3,292
Total		54,457	1,670,064	89,406

Annualized Cost to Respondents: \$1,670,064 (See table above.)

d. Recordkeeping Requirements for Reverse Distributors that Acquire Controlled Substances from Law Enforcement, and Reverse Distributors and Distributors that Acquire Controlled Substances from Authorized Collectors that Collect Controlled Substances from Ultimate Users

Number of Respondents: 889

Note: There is a current population of 889 registrants (829 Distributors; 60 Reverse Distributors) that may participate; however, the DEA has no information to determine the actual number of registrants that will become authorized collectors, and therefore, the DEA has no

information to determine the actual number of reverse distributors and distributors that will accept collected substances for destruction.

Frequency of Response: Varies.

The DEA estimates the frequency of response will vary because, in accordance with 21 U.S.C. 827(a), registrants maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of.

Annual Hour Burden: 472 hours (32 minutes per event)

Note: Upon the effective date of the final rule, reverse distributors and distributors who acquire controlled substances from law enforcement or collectors who collect controlled substances from ultimate users will be required to maintain records of the receipt, transfer, and destruction of controlled substances.

Explanation of How the Burden was Estimated:

The DEA used the median hourly wage of \$15.97 for 53-0000 Transportation and Material Moving Occupations in the Warehousing and Storage Industry from the Bureau of Labor Statistics May 2012 Occupational Employment and Wages data and applied a 32.5% load for taxes and benefits for a labor unit cost of \$21.16.

Reverse Distributor/Distributor Acquisition of Controlled Substances from Law Enforcement or Authorized Collectors

Activity	Estimated Time	Labor Unit (per hour) (\$)	Labor Cost (\$)
Upon Receipt	1 minute	21.16	0.35
Upon Transfer to Secure Storage	1 minute	21.16	0.35
Upon Destruction (Use of DEA Form 41)	30 minutes	21.16	10.58
Total	32 minutes	21.16	11.29

Annualized Cost to Respondents: \$10,037 (\$11.29 per event, see table above).

13. Estimated Total Annual Cost Burden

- *Recordkeeping Requirements for Reverse Distributors*

\$719: As a result of the requirements in the final rule, the number of reporting events and the total annual cost burden is estimated to increase.

- *Recordkeeping for Registrants that Receive and Distribute Controlled Substances for Return or Recall*

\$0: The total annual cost burden will not be increased by the requirements in the final rule as the final rule does not increase the number of return or recall transactions, and registrants that receive controlled substances for return or recall are already required to maintain a record of the transaction, in accordance with existing 21 CFR 1304.22(b)..

- *Recordkeeping Requirements for DEA Registrants Authorized to Collect*

\$1,670,064: While the authorization to collect is a new activity, the DEA estimated the level of participation as detailed in the Economic Impact Analysis accompanying the final rule.

- *Recordkeeping Requirements for Reverse Distributors and Distributors that Acquire Controlled Substances from Law Enforcement or Authorized Collectors that Collect Controlled Substances from Ultimate Users*

\$10,037: Based on a unit of one mailing package, one inner liner, and one destruction event.

14. Estimated Annualized Costs to the Federal Government

\$0: Information recorded by those affected by the final rule is not submitted to the DEA. The information is retained and made available to the DEA upon inspection/request, or is displayed or provided to those ultimate users who participate in collection activities as appropriate.

15. Reasons for Change in Burden

Any program changes or adjustments reported result from the revisions to recordkeeping requirements for registrants as described above.

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.