Supporting Statement for Paperwork Reduction Act Submission
ARCOS Transaction Reporting
DEA Form 333

OMB Approval Number 1117-0003

Part A. Justification

1. Necessity of Information:

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The Controlled Substances Act (21 U.S.C. 801 et seq.) requires the Drug Enforcement Administration (DEA) to establish a closed system of control for substances that have a potential for abuse. The Act requires anyone who manufactures, distributes, dispenses, imports, or exports controlled substances to register with DEA. Section 827 of the Act requires registrants to maintain records of the controlled substances under their control. DEA's implementing regulations on recordkeeping are published in 21 CFR part 1304.

Section 827 of the Act specifically exempts practitioners from recordkeeping if they only prescribe controlled substances or if they dispense or administer controlled substances only occasionally. Practitioners who regularly dispense or administer controlled substances to patients and charge them for the substances 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 individual practitioners are contained in 1304.04(g), 1304.11, and 1304.22.

2. Needs and Uses:

Drug Enforcement Administration (DEA) and the practitioner use the required records to maintain complete accountability for all controlled substances dispensed by a practitioner. The CSA requires DEA to maintain a closed system of distribution for controlled substances. Without practitioner accountability, a closed system of distribution would not be maintained for all controlled substances dispensed (e.g., complimentary samples) or substances that the practitioner both dispenses and administers from common stock. Information obtained from the records is used to target possible sources of controlled substances diversion for investigation.

3. Use of Technology:

This requirement does not involve reporting and, therfore, issues related to electronic submission are not applicable. DEA's regulations allow practitioners to maintain the records in any format they find appropriate, including electronically.

4. Efforts to Identify Duplication:

DEA is the only Federal agency that requires recordkeeping on controlled substances. Although DEA dictates the data that must be maintained, it does not specify the format. Practitoners may use existing records to meet the requirement if those records include the data required.

5. Methods to Minimize Burden on Small Businesses:

This information collection does not have a significant impact on small entities. Certain practitioners are required to maintain the records, but may do so in any format (paper or electronic). The burden of such recordkeeping is minimal. Even without DEA's rules, practitioners who routinely administer or dispense controlled substances would maintain records of their use, both standard business practice to be sure adequate supplies are available and as a precaution against theft.

6. Consequences of Less Frequent Collection:

21 U.S.C. § 827 requires that records be maintained for a period of two years. DEA does not have the authority to reduce the burden or period of recordkeeping. Failure to record this information would make it more difficult for DEA and state agencies to identify the source of diverted substances.

7. Special Circumstances Influencing Collection:

There are no special circumstances in item 7 of the supporting statement that are applicable to this information collection.

8. Reasons for Inconsistencies with 5 CFR 1320.6:

DEA meets regularly with the affected industry to discuss policies, programs, and regulations. The 60 and 30 day federal register notices were posted for this collection and DEA did not receive any comments concerning this collection.

9. Payment or Gift to Claimants:

There are no such gifts or payments to respondents.

10. Assurance of Confidentiality:

Confidential business information is protected under Department of Justice regulations, 28 CFR 16.8 and 16.9.

11. Justification for Sensitive Questions:

Questions of a sensitive nature are not included in reporting requirements.

12. Estimate of Hour Burden:

Number of Respondents

DEA estimates that 103,000 practitioners are subject to these rules because they routinely administer and dispense controlled substances.

Activities

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 the 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 initial 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 dispense.

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. DEA assumes that most practitioner offices either record the information by hand or enter the information into an electronic log.

Medical records such as these are maintained by medical records technicians. According to the May 2007 National Occupational Employment and Wage Estimate, their median wage rate is $14.08. Their wage rate, including fringe at 45 percent, is $20.42. Fringe rare is based on BLS data for the health care industry (Employer Costs for Employee Compensation, December 2007).

Number of Respondents:	103,000
Frequency of Response:	Annually
Average time per response:	30 minutes
Total annual responses:	103,000

Total annual burden: 51,500 hours

13. Estimate of Cost Burden:

There are no capital or operating and maintenance costs associated with these requirements. Practitioners may maintain these records on computers, but every practitioner's office is expected to have computers for other reasons.

14. Estimated Annualized Costs to Federal Government:

Since DEA does not collect this information, this collection of information imposes no costs to the Federal government.

DEA does not routinely review these records. Therefore, there are no costs of this information directly attributable to this collection.

15. Reasons for Change in Burden:

There has been no program change. DEA has adjusted the population based on the nuber of practitioners dispensing and administering contrlolled substances.

16. Plans for Publication:

There are no plans to publish the information collected.

17. Expiration Date Approval:

No forms are required for these records.

18. Exceptions to the Certification Statement:

There are no exceptions to the certification statement.

Part B. Statistical Methods

The Drug Enforcement Administration does not employ statistical methods in this information collection.