**Supporting Statement for Paperwork Reduction Act Submissions**
**Recordkeeping Requirements for Partial Fills of Prescriptions for Schedule II Controlled Substances**
**OMB Approval #1117-New**

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for a new collection of information, Recordkeeping Requirements for Partial Fills of Prescriptions for Schedule II Controlled Substances.

This information collection request is associated with the DEA's Partial Filling of Prescriptions for Schedule II Controlled Substances rulemaking, RIN 1117-AB45. DEA is proposing to revise the regulations to align with the Comprehensive Addiction and Recovery Act of 2016 (CARA) by allowing the partial filling of prescriptions for schedule II controlled substances under certain conditions.

## Part 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). DEA may promulgate regulations that specify the information that registrants must maintain in the required records. 21 U.S.C. 827(b)(1).

On July 22, 2016, the President signed the Comprehensive Addiction and Recovery Act (CARA) of 2016 into law as Public Law 114-198, which included amending the CSA to allow for the partial filling of prescriptions for schedule II controlled substances under certain conditions. The amendment added subsection (f) to 21 U.S.C. 829, allowing a pharmacist to partially fill a prescription for a schedule II controlled substance where requested by the prescribing practitioner or the patient, provided all of the following conditions have been satisfied: (1) the partial filling must not be prohibited by State law; (2) the prescription must be written and filled in accordance with the CSA, DEA regulations, and State law; and (3) the total quantity dispensed in all partial fillings must not exceed the total quantity prescribed. In addition, subsection (f) provides that the remaining portions of a partially filled prescription for a controlled substance in schedule II, if filled, must be filled no later than 30 days after the date on which the prescription is written, unless the prescription is issued as an emergency oral prescription, in which case the remaining portion, if filled, must be filled no later than 72 hours after it was issued. Also, Congress gave DEA explicit authorization to fill in any gaps in the regulatory scheme not addressed by Congress itself in the CARA.

DEA is proposing to require pharmacies to create and maintain certain records relating to partial fills of prescriptions for schedule II controlled substances. Upon partially filling a prescription for a schedule II controlled substance, a pharmacist would need to make a notation of the quantity dispensed on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record). For electronic prescriptions, there would need to be an electronic prescription record and the record would need to be permanently attached to the electronic prescription. Also, for each such partial filling, the pharmacy would be required to maintain a record with the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescription refills. For electronic prescriptions specifically, pharmacy applications would need to allow required information pertaining to the quantity, date, and the dispenser to be linked to each electronic controlled substance prescription record (as currently required by 21 CFR 1311.205(b)(10)).

2. Needs and Uses:

The pharmacist would be required to maintain a record with the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 1306.22(c) for schedule III and IV prescription refills. For electronic prescriptions, pharmacy applications would need to allow required information pertaining to the quantity, date, and the dispenser to be linked to each electronic controlled substance prescription record.

DEA would use the required records to maintain complete accountability for all schedule II controlled substances dispensed by a practitioner. This accountability would allow DEA to maintain a closed system of distribution for schedule II controlled substances. These records would also allow DEA to target possible sources of diversion.

3. Use of Information Technology:

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

4. Efforts to Identify Duplication:

Controlled substance and listed chemical quotas are unique to DEA. Therefore, there is no duplication of information requested as part of this collection.

5. Impact on Small Businesses or Entities:

The DEA expects this collection will not have a significant economic impact on a substantial number of small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601–612.

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 applicable to this information collection.

8. Consultation with persons outside the Agency:

Public comment was solicited in the *Federal* Register on December 4, 2020, in the notice of proposed rulemaking (NPRM) associated with this collection. 85 FR 78282. The NPRM had a 60-day comment period. No comments were received regarding the information 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:

Total annual respondents: 68,676
Number of annual responses per respondent: Per occurrence (264.83255 per year, calculated)
Total annual responses: 18,187,640

Total annual burden hours: 50,521 hours

Average burden per response: 0.002777778 hour (10 seconds)
Average burden per respondent: 0.73565 hour

Hour burden cost:

| | |
|---|---|
| Estimate hourly wage ($/hour):[1] | $60.64 |
| Load for benefits (percent of labor rate):[2] | 42.7% |
| Loaded labor rate ($/hour):[3] | $86.53 |
| Average burden per response (hour): | 0.002777778 |
| Burden cost per response: | $0.24 |
| Number of annual responses: | 18,187,640 |
| Total annual burden dollar: | $4,365,034 |

13. Estimate of Cost Burden:

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

14. Estimated Annualized Costs to Federal Government:

The required information is recorded and maintained by respondents. There is no cost to the Federal Government.

15. Reasons for Change in Burden:

This is a new collection being created as part of the DEA's Partial Filling of Prescriptions for Schedule II Controlled Substances rulemaking, RIN 1117-AB45.

16. Plans for Publication:

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

17. Expiration Date Approval:

The DEA does not object to displaying the expiration date for this collection.

[1] Hourly median wage, 29-1051 Pharmacists. Bureau of Labor Statistics, May 2018 National Occupational Employment and Wage Estimates, United States. Https://www.bls.gov/oes/current/oes_nat.htm.
[2] Average benefits for private industry are 29.9% of total compensation. Bureau of Labor Statistics, *Employer Costs for Employee Compensation – September 2019* (ECEC). The 29.9% of total compensation equates to 42.7% (29.9% / 70.1%) load on wages and salaries.
[3] $60.64 x (1 + 0.427) = $86.53.

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.