

**Supporting Statement for Paperwork Reduction Act Submissions  
Recordkeeping Requirements for the Transfer of Electronic Prescriptions for Controlled  
Substances (EPCS) in Schedules II-V between Pharmacies for Initial Filling  
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 the Transfer of Electronic Prescriptions for Controlled Substances (EPCS) in Schedules II-V between Pharmacies for Initial Filling.

This information collection request is associated with DEA's rulemaking, Transfer of Prescription Information between Pharmacies for Initial Filling of Electronic Prescriptions for Schedules II-V Controlled Substances, DEA-637, RIN 1117-AB64. DEA is proposing to permit the transfer of unfilled electronic prescriptions for controlled substances (EPCS) in schedules II-V between registered pharmacies. This information request would require pharmacies to create and maintain records documenting the transfer between pharmacies of unfilled EPCS.

**Part A. Justification**

1. Necessity of Information:

DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242 (1970), as amended (collectively, the CSA). 21 U.S.C. 801-971. In accordance with the 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 form that required information is readily retrievable from 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 records must be in accordance with and contain such relevant information as may be required by regulations promulgated by DEA. 21 U.S.C. 827(b)(1).

DEA is proposing to require pharmacies to create and maintain certain records relating to the transfer of unfilled EPCS between pharmacies for initial filling. The rule, proposes to require the transferring pharmacy to note in the electronic prescription record that the prescription was transferred. The transferring pharmacy would also be required to add to the prescription record the name, address, and DEA registration number of the pharmacy to which the prescription was transferred, as well as the name of the pharmacist receiving the transfer the name of the transferring pharmacist, and the date of the transfer. Similarly, the rule would require the pharmacy receiving the transfer to record the name, address, and DEA registration number of the transferring pharmacy, the name of the transferring pharmacist, the name of the pharmacist receiving the transfer, and the date of the transfer. In addition, the rule would require the records to be maintained by both pharmacies for at least two years from the date of the transfer.

## 2. Needs and Uses:

The transferring pharmacy would be required to update the electronic prescription record to note that the prescription was transferred, and to add the following information: the name, address, and DEA registration number of the pharmacy to which the prescription was transferred; the name of the pharmacist receiving the transfer; the name of the transferring pharmacist; and the date of the transfer. The pharmacy receiving the transfer would be required to update the electronic prescription record with the name, address, and DEA registration number of the pharmacy transferring the prescription, the name of the transferring pharmacist, the name of the pharmacist receiving the transfer, and the date of the transfer.

DEA would use the required records to maintain complete accountability for all electronic controlled substance prescriptions dispensed by a pharmacy. This accountability would allow DEA to maintain a closed system of distribution for EPCS. These records would also allow DEA to reduce opportunities for diversion.

## 3. Use of Information Technology:

These requirements do not involve reporting, and therefore, issues related to electronic submission are not applicable. The records of EPCS transfers between pharmacies will be maintained electronically in the pharmacies' electronic prescription applications.

## 4. Efforts to Identify Duplication:

DEA has made efforts to identify and prevent duplication of information. The collection of this information is unique to DEA and is not duplicative.

## 5. Impact on Small Businesses or Entities:

In accordance with the Regulatory Flexibility Act (RFA), DEA evaluated the impact of this proposed rule on small entities. DEA's evaluation of economic impact by size category indicates that the rule will not, if promulgated, have a significant economic impact on a substantial number of these small entities.

## 6. Consequences of Less Frequent Collection:

Pursuant to 21 U.S.C. 827(b), records must be maintained for a period of at least two years. 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.

## 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 notice of proposed rulemaking (NPRM) associated with this collection, which published in the *Federal Register* on November 19, 2021 at 86 FR 64881. The NPRM had a 60-day comment period. Any comments received regarding the information collection will be addressed in the final rule.

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 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 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 number of respondents: 70,567  
Number of responses per respondent per year: 354.273244  
Total annual responses: 25,000,000  
Total annual hour burden: 1,250,000

Average Burden:      Per Collection: 0.05  
                                 Per Respondent: 17.713662

Total responses on paper: 0  
Total responses electronically: 25,000,000  
Percentage of responses electronically: 100%

Burden dollars:

Estimate hourly wage (\$/hour): <sup>1</sup>	\$61.58
Load for benefits (percent of labor rate): <sup>2</sup>	42.9%
Loaded labor rate (\$/hour): <sup>3</sup>	\$88.00
Number of responses	25,000,000
Total annual hours	1,250,000
Average burden per response (hour)	0.05
Burden dollars per response (\$)	\$4.40
<b>Total burden dollars</b>	<b>\$110,000,000</b>

13. Estimate of 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 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 DEA's Transfer of Prescription Information between Pharmacies for Initial Filling of Electronic Prescriptions for Schedules II-V Controlled Substances rulemaking, RIN 1117-AB64.

16. Plans for Publication:

DEA will not publish the results of the information collected.

17. Expiration Date Approval:

DEA is not seeking approval not to display the expiration date for OMB approval of this information collection.

18. Exceptions to the Certification Statement:

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1 Used average of median hourly wages for 29-1051 Pharmacists to represent the occupation of the responding person. Bureau of Labor Statistics (BLS), May 2019 National Occupational Employment and Wage Estimates United States. [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)

2 BLS, "Employer Costs for Employee Compensation – September 2020" (ECEC). The ECEC reports that average benefits for private industry is 30.3% of total compensation. The 30.0% of total compensation equates to 42.9% (30.0% / 70.0%) load on wages and salaries.

3  $\$61.58 \times (1 + 0.429) = \$88.00$ .

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**

DEA will not be employing statistical methods in this information collection.