

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 #1117-0061

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 final rule, 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 finalizing revisions to the regulations 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 of unfilled EPCS between pharmacies.

Part A. Justification

1. DEA implements and enforces the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA), and the Controlled Substance Import and Export Act (CSIEA), as amended.¹ The CSA requires every DEA registrant to 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.² These records must be maintained separately from all other records of the registrant, or alternatively, in the case of nonnarcotic controlled substances, be in such form that required information is readily retrievable from ordinary business records of the registrant.³ The records maintained by registrants must be retained and available for at least two years for inspection and copying by officers or employees of the United States as authorized by the Attorney General.⁴ The records must be in accordance with and contain such relevant information as may be required by regulations promulgated by DEA.⁵

Under this final rule, DEA is permitting a registered retail pharmacy to transfer unfilled EPCS to another registered retail pharmacy for initial dispensing upon request from the patient. The final rule requires the transferring pharmacy to note in the electronic prescription record that the prescription was transferred, and add to the prescription record 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. Similarly, the rule requires the pharmacy receiving the transfer to record the name,

1 21 U.S.C. 801-971.

2 21 U.S.C. 827 and 958.

3 21 U.S.C. 827(b)(2).

4 21 U.S.C. 827(b)(3).

5 21 U.S.C. 827(b)(1).

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. These records must be retained by both pharmacies for at least two years from the date of the transfer.

2. This information collection would require the transferring pharmacy 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.

These recordkeeping requirements enable DEA to maintain complete accountability for all EPCS dispensed by a pharmacy. This accountability allows DEA to maintain a closed system of distribution for EPCS and reduces opportunities for diversion.

3. 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. 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. 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. 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. There are no special circumstances applicable to this information collection.

8. The 60-day Notice was published in the *Federal Register* on November 19, 2021 at 86 FR 64881. The comment period ended on January 18, 2022. No comments were received. The final rule published in the *Federal Register* on July 27, 2023, at 88 FR 48365.

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. This collection of information does not propose to provide any payment or gift to respondents.

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

12. This rule will affect approximately 70,567 pharmacies who are registering with DEA to handle control substances. DEA estimates that each pharmacy will transfer around 354.273244 EPCS. The total number of transfer a year is 25,000,000 (70,567*354.273244).

DEA estimates the required time to complete a transfer of EPCS would be 3 minutes. Hence, the total annual burden of transferring EPCS is 1,250,000 hours (25,000,000*3/60)

Based on the reported hourly wage of \$61.58⁶ and the loaded benefits of 42.9%,⁷ DEA estimates hourly loaded labor rate of a pharmacist is \$88.

Activity	Number of Respondents	Frequency	Total Annual Responses	Time Per Response	Total Annual Burden (Hours)	Hourly Rate*	Monetized Value of Respondent Time
Transfer of ESCP	70,567	354.273244	25,000,000	3 mins	1,250,000	88	110,000,000
Unduplicate d Totals	70,567		25,000,000		1,250,000		110,000,000

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

6 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

7 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.

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OMB Control Number: 1117-0061

OMB Expiration Date: NA

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

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

18. 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.