

investment adviser appoints an agent for service of process in the United States. The Commission will maintain files of the information on Form ADV-NR and will make the information publicly available. Any member of the public may direct to the Commission any comments concerning the accuracy of the burden estimate on page one of Form ADV-NR, and any suggestions for reducing this burden. This collection of information has been reviewed by the Office of Management and Budget in accordance with the clearance requirements of 44 U.S.C. § 3507.

By the Commission.

Dated: November 4, 2021.

**Vanessa A. Countryman,**

*Secretary.*

[FR Doc. 2021–24522 Filed 11–18–21; 8:45 am]

**BILLING CODE 8011–01–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1306

[Docket No. DEA–637]

RIN 1117–AB64

#### **Transfer of Electronic Prescriptions for Schedules II–V Controlled Substances Between Pharmacies for Initial Filling**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Drug Enforcement Administration (DEA) is proposing to amend its regulations to allow the transfer of electronic prescriptions for schedule II–V controlled substances between registered retail pharmacies for initial filling on a one-time basis. This amendment will specify the procedure that must be followed and the information that must be documented when transferring an electronic controlled substance prescription between DEA-registered retail pharmacies.

**DATES:** Electronic comments must be submitted, and written comments must be postmarked, on or before January 18, 2022. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget (OMB) on or before January 18, 2022

**ADDRESSES:** To ensure proper handling of comments, please reference “Docket No. DEA–637” on all correspondence, including any attachments.

DEA encourages all comments be submitted electronically through the

Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment. Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, VA 22152.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117–AB64/Docket No. DEA–637.

**FOR FURTHER INFORMATION CONTACT:** Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 776–2265.

#### **SUPPLEMENTARY INFORMATION:**

##### **Posting of Public Comments**

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by DEA for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want

it to be made publicly available, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at <http://www.regulations.gov> for easy reference.

##### **Legal Authority**

The Controlled Substances Act (CSA or Act) grants the Attorney General the authority to promulgate and enforce any rules, regulations, and procedures that he may deem necessary and appropriate for the efficient executions of his functions under subchapter I (Control and Enforcement) of the CSA.<sup>1</sup> The Attorney General has delegated this authority to the Administrator of the Drug Enforcement Administration (DEA).<sup>2</sup>

<sup>1</sup> 21 U.S.C. 871(b).

<sup>2</sup> 28 CFR 0.100(b).

### Purpose of the Proposed Rule

Currently, DEA regulations do not address the transfer of controlled substance prescriptions (paper or electronic) between pharmacies for initial filling.<sup>3</sup> If a paper prescription is presented at a pharmacy that is unable to fill it, the paper prescription could be returned to the patient, and the patient could then take the prescription to another pharmacy. Although the transfer of paper prescriptions between pharmacies for initial dispensing is not addressed in the regulations, these prescriptions are inherently portable due to the format of the prescription itself.

However, electronic prescriptions are generated using an electronic application and are transmitted directly from the practitioner to the pharmacy in the form of an electronic data file. Consequently, if a pharmacy receives an electronic prescription for a controlled substance (EPCS) that it is unable to fill, the pharmacy cannot give the prescription (*i.e.*, electronic data file) to the patient to take to another pharmacy. Further, DEA regulations do not include provisions for a pharmacy to transfer an EPCS to another pharmacy; the regulations also do not describe how a pharmacy should handle an EPCS that it receives but cannot fill. At present, a pharmacy that receives an EPCS that it is unable to fill can only notify the patient that the prescription cannot be filled. In this scenario, the patient could then call the prescribing practitioner to request that a new EPCS be sent to a different pharmacy. DEA realizes that this scenario creates the potential for duplication of prescriptions if the practitioner transmits a new EPCS to a different pharmacy and does not cancel or void the original EPCS that was sent to the first pharmacy. It also recognizes that this scenario creates additional burden for patients, who have to get back in touch with the original prescribing doctor and request a new prescription.

Therefore, DEA is proposing to revise its regulations to state that, upon request, a registered retail pharmacy may transfer an EPCS to another registered retail pharmacy for initial filling. This proposed rule will also specify the procedures that retail pharmacies must follow and the

information that must be documented when transferring electronic prescriptions for controlled substances in schedules II–V. DEA believes that allowing the electronic transfer of controlled substance prescriptions will decrease the potential for duplicate prescriptions and thus reduce the opportunity for diversion or misuse.

### Background

The CSA and its implementing regulations specify the requirements for issuing and filling prescriptions for controlled substances. DEA regulations permit a pharmacist to dispense a controlled substance in schedule II only pursuant to a written prescription (including an EPCS), except in limited emergency situations, when dispensing pursuant to an oral prescription is permitted.<sup>4</sup> No prescription for a controlled substance in schedule II may be refilled.<sup>5</sup> DEA regulations permit a pharmacist to dispense a controlled substance in schedules III, IV, and V pursuant to a paper prescription, a facsimile of a signed paper prescription, an EPCS, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist.<sup>6</sup> Prescriptions for schedule III and IV substances may not be filled or refilled more than six months after the date of issuance or be refilled more than five times.<sup>7</sup> The CSA does not address the transfer of controlled substance prescriptions between pharmacies for initial filling. DEA regulations address the transfer of controlled substances prescriptions between pharmacies for refills, but not for initial filling.<sup>8</sup> Hence, DEA is proposing to revise its regulations to state that the transfer of EPCS is permissible between registered retail pharmacies for initial filling on a one-time basis.

### Why the Proposed Rule Is Necessary

On March 31, 2010, DEA published an interim final rule, *Electronic Prescriptions for Controlled Substances* (EPCS IFR), which provides practitioners with the option of issuing, and pharmacies with the option of receiving, dispensing, and archiving electronic prescriptions for schedule II–

V controlled substances.<sup>9</sup> The EPCS IFR provides the regulations governing the electronic creation, signature, transmission, and processing of schedule II–V controlled substance prescriptions. The regulations, codified at 21 CFR parts 1300, 1304, 1306, and 1311, specifically define an electronic prescription as “a prescription that is generated on an electronic application and transmitted as an electronic data file.”<sup>10</sup> The regulations also provide the security and recordkeeping requirements imposed on prescription and pharmacy applications that create, process, and archive electronic controlled substance prescriptions.

Although DEA regulations permit the transfer of prescription information between pharmacies for refill dispensing of schedules III–V controlled substance prescriptions on a one-time basis, the regulations do not address the transfer of controlled substance prescriptions (paper or electronic) for initial dispensing.<sup>11</sup> As previously discussed, a patient can choose to take a paper prescription to another pharmacy if the first pharmacy is unable to fill it. However, because patients do not have a physical copy of an electronic prescription, the patient cannot take the prescription to another pharmacy if it cannot be filled by the first pharmacy.

DEA emphasized in the EPCS IFR that the option for EPCS is in addition to, not a replacement of, the requirements and provisions that exist for paper prescriptions for controlled substances.<sup>12</sup> Thus, the same rules and regulations applicable to paper prescriptions, as well as the same permissions, were also intended to apply to electronic prescriptions for controlled substances. Patients prescribed controlled substances electronically should have the same ability as patients issued paper controlled substance prescriptions to choose an alternate pharmacy if the first pharmacy is unable to fill a prescription. As more practitioners begin to issue controlled substance prescriptions electronically, as discussed below, there is an increasing need to address this issue.

<sup>9</sup> 75 FR 16236 (Mar. 31, 2010). DEA subsequently reopened the comment period in 2020 to solicit public comment on certain issues. 85 FR 22018 (Apr. 21, 2020).

<sup>10</sup> 21 CFR 1300.03.

<sup>11</sup> 21 CFR 1306.25.

<sup>12</sup> 75 FR 16244.

<sup>4</sup> 21 CFR 1306.11(a) and (d).

<sup>5</sup> 21 U.S.C. 829(a).

<sup>6</sup> 21 CFR 1306.21(a).

<sup>7</sup> 21 CFR 1306.22(a).

<sup>8</sup> 21 CFR 1306.25.

<sup>3</sup> In contrast, as discussed below, 21 CFR 1360.25 already addresses the transfer of controlled substance prescriptions between pharmacies for refill purposes.

In a recently published request for information, the Centers for Medicare and Medicaid Services (CMS) reported that it has seen a steady increase in the volume of controlled substance prescriptions submitted electronically since the EPCS IFR was published in 2010.<sup>13</sup> Further, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) was signed into law on October 24, 2018.<sup>14</sup> Section 2003 of the SUPPORT Act mandates the electronic prescribing of schedule II–V controlled substances (with some exceptions) covered under Medicare Part D, beginning on or after January 1, 2021.<sup>15</sup> In addition, in its 2019 National Progress Report, Surescripts, a health information network and electronic prescribing intermediary, noted that more than half of all States now require electronic prescribing of opioids, all controlled substances, or all prescriptions.<sup>16</sup> Thus, it is essential that procedures for transferring an EPCS are established as electronic prescribing of controlled substances becomes more prevalent. This rulemaking is being proposed to address this issue.

If finalized, this proposed rule would allow for the transfer of electronic prescriptions for schedules II–V controlled substances between DEA-registered retail pharmacies for initial filling. This proposed rule would also establish the procedures that must be followed and the information that must be documented when transferring an EPCS. For reasons discussed previously, this proposed rule focuses only on electronic prescriptions for controlled substances for initial dispensing and does not propose to amend 21 CFR 1306.25 which permits the transfer of paper, oral, or electronic prescriptions in schedules III, IV, and V for refill dispensing. A cross-reference to § 1306.25 is included in § 1306.08(i) to provide an easy reference to the regulations regarding the transfer of electronic prescriptions for refill purposes. DEA believes this proposed rule, if finalized, will reduce the potential for duplicate prescriptions, as well as the opportunity for diversion.

<sup>13</sup> Medicare Program: Electronic Prescribing of Controlled Substances; RFL, 85 FR 47151 (August 4, 2020).

<sup>14</sup> Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), Public Law 115–271, 132 Stat. 3894 (2018).

<sup>15</sup> SUPPORT Act, sec. 2003(a)(b). This requirement is codified at 21 U.S.C. 1395w–104(e)(7).

<sup>16</sup> Surescripts, National Progress Report 2019 <https://surescripts.com/news-center/national-progress-report-2019/> (Accessed March 31, 2021).

### Summary of Proposed Changes

DEA proposes to amend its regulations to allow the transfer of EPCS between registered retail pharmacies for initial filling on a one-time basis only. The proposed amendment would explicitly state that a DEA-registered retail pharmacy may transfer schedules II–V EPCS to another DEA-registered retail pharmacy for initial dispensing. The proposed amendment would stipulate that: The transfer must be communicated directly between two licensed pharmacists; the prescription must remain in its electronic form; and the contents of the prescription required by part 1306 must be unaltered during the transmission. This proposed rule also stipulates that the transfer of EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law.

In addition, the proposed amendment would also describe the documentation requirements for pharmacies transferring an EPCS for initial dispensing. Specifically, the pharmacist transferring the EPCS must update the electronic prescription record to note that the prescription was transferred. The transferring pharmacist must also update the prescription record with 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. Likewise, the pharmacist receiving the transferred EPCS must record the transferring pharmacy's name, address, and DEA registration number, the name of the transferring pharmacist, the date of the transfer, and the name of the pharmacist receiving the transfer. Finally, under the proposed amendment, the electronic records documenting the transfer must be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the EPCS and the pharmacy receiving the EPCS. This proposed rule does not change the existing requirements for all prescriptions, as outlined in 21 CFR part 1306, Prescriptions, or the requirements for prescribing and pharmacy applications, as outlined in 21 CFR part 1311, Requirements for Electronic Orders and Prescriptions.

### Regulatory Analyses

*Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)*

This proposed rule was developed in accordance with the principles of

Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. DEA has determined that this proposed rule is not a “significant regulatory action” under E.O. 12866, section 3(f).

### Analysis of Benefits and Costs

DEA is proposing to amend its regulations to allow the transfer of electronic prescriptions for schedule II–V controlled substances between registered retail pharmacies for initial dispensing on a one-time basis only. This amendment will specify the procedure that must be followed and the information that must be documented when transferring an EPCS between registered retail pharmacies. As described below, DEA estimates the annual cost savings of this proposed rule is \$22.0 million.

The proposed amendment would stipulate that: The transfer must be communicated directly between two licensed pharmacists; the prescription must remain in its electronic form and the required prescription information must be unaltered during the transmission. In addition to the above, the pharmacist transferring the prescription must update the electronic prescription record to note that the prescription was transferred. The transferring pharmacist must also record the name, address, and DEA registration number of the pharmacy to which the prescription is being electronically transferred, the name of the pharmacist receiving the transfer, the name of the transferring pharmacist, and the date of the transfer. Likewise, the pharmacist receiving the transferred prescription must record the transferring pharmacy's name, address, and DEA registration number, the name of the transferring pharmacist, and the name of the pharmacist receiving the transfer. Finally, under the proposed amendment, the electronic records documenting the transfer must be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the electronic prescription and the pharmacy receiving the prescription.

As current DEA regulations do not address the transfer of schedule II–V controlled substance prescriptions in

any form (paper or electronic) from one retail pharmacy to another retail pharmacy for initial filling, DEA anticipates the proposed rule will affect the following parties: The first (transferring) pharmacy, patient, prescriber, and second (receiving) pharmacy. To quantify the economic impact of this proposed rule, DEA estimated the average cost and cost savings for each transfer and applied this cost or cost savings to the estimated number of transfers.<sup>17</sup>

#### Estimated Cost or Cost Savings per Transfer

To estimate the unit cost or cost savings, DEA compared the anticipated activities for each of the affected parties when a pharmacy receives an EPCS it cannot fill under current practices versus the proposed regulations. The anticipated activities for each of the affected parties under current practices are described below. DEA understands there may be many operational variations; however, DEA believes the scenarios described below are good representations for the purposes of estimating costs.

The anticipated activities for each of the affected parties under current practice are described below.

<sup>17</sup> DEA expects minor system and implementation expenses, which consist of modifying software configurations, updating business processes, and minimal personnel training. DEA estimates the cost of these changes is minimal.

1. The first pharmacy contacts the patient to inform the patient that they are unable to fill the prescription.

2. The first pharmacy notes action taken, as needed.

3. Patient receives call from the first pharmacy that they are unable to fill the prescription.

4. Patient contacts prescriber and requests new prescription.

5. Prescriber's secretary or administrative personnel receives phone call from the patient (likely by an administrative personnel at the prescriber's office).

6. Prescriber cancels the EPCS at the first pharmacy and issues a new EPCS at an alternate (receiving) pharmacy.

7. Receiving pharmacy receives and fills EPCS.

8. Patient receives filled prescription from the alternate pharmacy.

The anticipated activities for each of the affected parties under the proposed regulations and the economic impact are described below.

1. Transferring pharmacy contacts patient to inform that they are unable to fill the prescription. Assume duration of the call to the patient is same under current and proposed scenarios. Therefore, no impact.

2. The patient receives a call from the transferring pharmacy that they are unable to fill the prescription; the patient requests the prescription be transferred to an alternate (receiving) pharmacy. Assume duration of the call

from the transferring pharmacy is same under current and proposed scenarios. Therefore, no impact.

3. Transferring pharmacy transfers prescription (including contacting the receiving pharmacy, exchanging information, and recording the required information regarding transfer). Transferring will take longer than simply informing the patient that the prescription cannot be filled. Therefore, additional cost to transfer.

4. Patient does not need to contact prescriber to request a new prescription under proposed regulations. Therefore, cost savings from not needing to contact prescriber.

5. Patient receives filled prescription from receiving pharmacy. Assume same burden, no impact.

6. Prescriber does not receive a call from the patient. Therefore, cost savings.

7. Prescriber does not need to issue a new EPCS. Therefore, cost savings.

8. Receiving pharmacy receives transfer and fills transferred EPCS (including being contacted by the transferring pharmacy, exchanging information, and recording the required information regarding transfer). Anticipate additional costs related to being contacted by the transferring pharmacy and exchanging information.

Table 1 summarizes the activity scenarios under current practices and proposed regulations and the anticipated economic impact.

**Table 1: Persons and Activities, Current vs. Proposed**

Persons	Change in Activity		Economic Impact
	Current	Proposed	
First or Transferring Pharmacy	First pharmacy contacts patient to inform that they are unable to fill the prescription.	Transferring pharmacy contacts patient to inform that they are unable to fill the prescription.	Assume duration of call/contact is same ==> no impact
	Note action taken (i.e., void, cancel, etc.), as needed.	Transfer prescription. "Transfer" includes: contacting the receiving pharmacy, exchanging information, and recording the required information regarding transfer.	Additional cost to transfer vs. noting action taken.
Patient	Receive call from pharmacy that they are unable to fill the prescription.	Receive call from pharmacy that they are unable to fill the prescription, request transfer of the prescription to an alternate (receiving) pharmacy.	Assume duration of call/contact is same ==> no impact.
	Contact prescriber to request new prescription.	N/A.	Cost savings from not having to contact prescriber.
	Receive filled prescription from second (receiving) pharmacy.	Receive filled prescription from receiving pharmacy.	Assume same burden ==> no impact.
Prescriber	Receive call from patient. (prescriber's secretary)	N/A.	Cost savings.
	Cancel prescription sent to first pharmacy and issue new prescription at second (receiving) pharmacy.	N/A.	Cost savings.
Second (Receiving) Pharmacy	Receive prescription and fill.	Receive transfer and fill. "Transfer" includes: being contacted by the transferring pharmacy, exchanging information, and recording the required information regarding transfer.	Additional cost to receive and record transfer.

Cost or cost savings is based on applying the loaded labor rate for each of the affected persons to the estimated time to conduct the activity. The Bureau of Labor Statistics (BLS) hourly wage data for various occupation codes was used to estimate the labor rates for each of the affected persons. Using the occupation codes 29–1051 Pharmacists, 00–0000 All Occupations, 43–6013 Medical Secretaries and Administrative Assistants, and 29–1215 Family Medicine Physicians as best representations of first (transferring) and second (receiving) pharmacists, patient,

prescriber's secretary, and prescriber, respectively, DEA estimates the median hourly wages for the first (transferring) and second (receiving) pharmacy, patient, prescriber's secretary, and prescriber are \$61.58, \$19.14, \$17.59, and \$98.84, respectively.<sup>18</sup> Additionally, BLS reports that average benefits for private industry is 30.0 percent of total compensation. The 30.0 percent of total compensation equates to

<sup>18</sup> 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).

42.9 percent (30.0 percent/70.0 percent) load on wages and salaries.<sup>19</sup> The load of 42.9 percent is added to each of the hourly rates to estimate the loaded hourly rates. The loaded hourly rates for the first (transferring) and second (receiving) pharmacy, patient, prescriber's secretary, and prescriber are \$88.00, \$27.35, \$25.14, and \$141.24, respectively. Table 2 summarizes the calculation for the loaded hourly wages for each of the affected persons.

<sup>19</sup> BLS, "Employer Costs for Employee Compensation—September 2020" (ECEC).

TABLE 2—LOADED HOURLY WAGES

Affected persons	Occupation code	Occupation code description	Median hourly wage	Loaded hourly median wage
Patient .....	00–0000	All Occupations .....	\$19.14	\$27.35
Pharmacist .....	29–1051	Pharmacists .....	61.58	88.00
Medical secretary .....	43–6013	Medical Secretaries and Administrative Assistants .....	17.59	25.14
Prescriber .....	29–1215	Family Medicine Physicians .....	98.84	141.24

The below sections describe the calculation conducted to quantify the economic impact associated with the changes in activities under the current and proposed scenarios described above.

1. Currently, the first pharmacy contacts the patient to inform the patient that the pharmacy is unable fill the prescription. DEA estimates that it takes three minutes for the first pharmacist to call the patient. From Table 2, the estimated loaded hourly rate of a pharmacist is \$88.00. Multiplying the loaded hourly rate of \$88.00 by 0.05 (3/60) hours results in a cost of \$4.40. Under the proposed rule, the first (transferring) pharmacist would also contact the patient regarding the inability to fill the prescription. DEA estimates that it would also take three minutes for the transferring pharmacist to call the patient under the proposed rule, resulting in the same cost of \$4.40. Therefore, there is no economic impact associated with this activity under the proposed rule.

2. Currently, the first pharmacist notes in the electronic prescription record that the prescription was not filled. DEA estimates that it takes one minute for the first pharmacist to make the entry in the electronic prescription record. From Table 2, the estimated loaded hourly rate of a pharmacist is \$88.00. Multiplying the loaded hourly rate of \$88.00 by 0.0167 (1/60) hours results in a cost of \$1.47. Under the proposed rule, the transferring pharmacy may transfer the prescription, upon request from the patient, to the receiving pharmacy. Additionally, the transferring pharmacy must also contact the receiving pharmacy and exchange and document information such as the transferring pharmacy's name, address and DEA registration number, the name of the transferring pharmacist, and the name of the pharmacist receiving the transfer. DEA estimates that it takes three minutes for the transferring pharmacist to transfer the prescription. From Table 2, the estimated loaded hourly rate of a pharmacist is \$88.00. Multiplying the loaded hourly rate of \$88.00 multiplied by 0.05 (3/60) hours results in a cost of \$4.40. Therefore, the net cost to the transferring pharmacy

under the proposed rule is \$2.93 (\$4.40 – \$1.47) per transfer.

3. Under current practices, the patient first receives a call from the pharmacist who informs them that their prescription cannot be filled. DEA estimates that the call between the pharmacist and the patient lasts three minutes. From Table 2, the estimated loaded hourly rate of a patient is \$27.35. Multiplying the loaded hourly rate of \$27.35 multiplied by 0.05 (3/60) hours results in a cost of \$1.37 to the patient. Under the proposed rule, this activity does not change. With transfers of an EPCS, the pharmacist must still contact the patient. Thus, under the proposed rule, the patient also receives a call from the pharmacist. Estimating three minutes for the call, there is still a cost of \$1.37 to the patient. Therefore, there is no economic impact associated with this activity under the proposed rule.

4. Under current practices, the patient must contact the prescriber to request a new prescription. DEA estimates that it takes five minutes for the patient to contact the prescriber. From Table 2, the estimated loaded hourly rate of the patient is \$27.35. Multiplying the loaded hourly rate of \$27.35 by 0.083 (5/60) hours results in a cost of \$2.28. Under the proposed rule, the patient no longer needs to contact the prescriber; the patient requests an electronic transfer of the prescription from the first (transferring) pharmacy to the second (receiving) pharmacy; thus there is zero cost to the patient. Therefore, this activity under the proposed rule results in a cost savings of \$2.28 per transfer.

5. Under current practices, DEA assumes that the patient is informed that the first pharmacy is unable to fill the prescription prior to travelling to pick it up; thus, the patient only makes one trip to the second pharmacy where the prescription was transferred. DEA estimates that it takes 20 minutes for the patient to pick up the filled prescription. From Table 2, the estimated loaded hourly rate of a patient is \$27.35. Multiplying the loaded hourly rate of \$27.35 by 0.33 (20/60) hours results in a cost of \$9.12. Under the proposed rule, DEA also assumes that the patient is informed about the pending transfer of the prescription

prior to travelling to pick up the prescription, thus the patient only makes one trip. Estimating 20 minutes for the patient to pick up the filled prescription, under the proposed rule, there is still a cost of \$9.12 to the patient. Therefore, there is no economic impact associated with this activity under the proposed rule.

6. Under current practices, the patient has to contact the prescriber asking for a new prescription. DEA estimates that it takes five minutes for the prescriber's medical secretary to receive the call from the patient. From Table 2, the estimated loaded hourly rate of a medical secretary is \$25.14. Multiplying the loaded hourly rate of \$25.14 by 0.083 (5/60) hours results in a cost of \$2.10. Under the proposed rule, the patient no longer needs to contact the prescriber; thus, this interaction will not occur. Therefore, this activity under the proposed rule results in a cost savings of \$2.10 per transfer.

7. Under current practices, after the medical secretary receives the call from the patient and the information is relayed to the prescriber, the prescriber issues a new prescription. DEA estimates the prescriber takes two minutes to cancel the first prescription and issue a new prescription. From Table 2, the estimated loaded hourly rate of a prescriber is \$141.24. Multiplying the loaded hourly rate of \$141.24 by 0.03 (2/60) hours results in a cost of \$4.71. Under the proposed rule, the prescriber does not need to issue a new prescription. The original prescription is simply transferred to the receiving pharmacy; thus, this activity will not occur. Therefore, this activity under the proposed rule results in a cost savings of \$4.71 per transfer.

8. Under current practices, the second (receiving) pharmacy receives and fills the prescription. DEA estimates that it takes 15 minutes for the second (receiving) pharmacy to receive and fill the prescription. From Table 2, the estimated loaded hourly rate of a pharmacist is \$88.00. Multiplying the loaded hourly rate of \$88.00 by 0.25 (15/60) hours results in a cost of \$22.00. Under the proposed rule, DEA also estimates the receiving pharmacist still conducts this activity at the same

loaded labor rate and time duration, resulting in a cost of \$22.00. However, under the proposed rule, the receiving pharmacist must also receive and record transfer information from the transferring pharmacy. DEA estimates that it takes three minutes for the

receiving pharmacy to receive and record transfer information. From Table 2, the estimated loaded hourly rate of a pharmacist is \$88.00. Multiplying the loaded hourly rate of \$88.00 by 0.05 (3/60) hours results in a cost of \$4.40. Therefore, this activity under the

proposed rule results in a cost of \$4.40 per transfer.

As shown by Table 3, the proposed rule results in a total cost of \$8.80 and a total cost savings of \$10.56 per transfer. This results in an overall net cost savings of \$1.76 per transfer.

**Table 3: Cost/Cost Savings Calculation, Current vs. Proposed**

Person/Activity	Current		Proposed		Costs/ (Cost Savings) (\$)
	Estimated time (minutes)	Cost, Current (\$)	Estimated time (minutes)	Cost, Proposed (\$)	
Transferring pharmacist					
1. Contact patient	3	4.40	3	4.40	-
2.a. Void/transfer prescription	1	1.47			(1.47)
2.b. Transfer prescription			3	4.40	4.40
Patient					
3. Receive call from pharmacist	3	1.37	3	1.37	-
4. Contact prescriber	5	2.28	-	-	(2.28)
5. Received filled prescription	20	9.12	20	9.12	-
Prescriber					
6. Receive call from patient (secretary)	5	2.10	-	-	(2.10)
7. Issue new prescription (prescriber)	2	4.71	-	-	(4.71)
Receiving pharmacist					
8.a. Receive prescription and fill	15	22.00	15	22.00	-
8.b. Receive and record transfer info			3	4.40	4.40
<b>Total Costs</b>					<b>8.80</b>
<b>Total Cost Savings</b>					<b>(10.56)</b>
<b>Net Cost Savings</b>					<b>(1.76)</b>

#### Estimated Number of Transfers

As mentioned earlier, in order to calculate the total cost savings, DEA applied the \$1.76 net cost savings per transaction, from above, to the estimated number of total transfers. DEA estimated the number of total transfers by estimating the number of EPCS from 2022 to 2026, the analysis period, and applying an estimated percentage of EPCS that will be transferred.<sup>20</sup>

Surescripts' reports, "2019 National Progress Report" and "2020 National Progress Report" form the basis for estimating the number of EPCS from 2022 to 2026.<sup>21</sup> The reports indicate that the rate of electronic prescribing for non-controlled substances (E-RX) was 76, 83, and 86, and 89 percent in 2017, 2018, 2019, and 2020, respectively.<sup>22</sup> Additionally, the reports indicate that the rate of electronic prescribing for controlled substances (EPCS) is rising

rapidly; the rate was 17, 26, 38, and 58 percent in 2017, 2018, 2019, and 2020, respectively.<sup>23</sup> Furthermore, there were 65.0, 96.8, 134.2, and 203.6 million EPCS filled in 2017, 2018, 2019, and 2020 respectively.<sup>24</sup> Dividing the total EPCS by the rate of EPCS, DEA estimates the total controlled substances prescriptions, electronic and non-electronic, were 382.4, 372.3, 353.2, and 351.0 million in 2017, 2018, 2019, and 2020, respectively. Table 4 summarizes the data provided by the report and the

<sup>20</sup>Due to the rapidly evolving industry and regulatory conditions, the analysis period is from 2022 to 2026.

<sup>21</sup>Surescripts, "2019 National Progress Report" for 2017 data and "2020 National Progress Report" for 2018–2020 data.

<sup>22</sup>Ibid.

<sup>23</sup>Ibid.

<sup>24</sup>Ibid.

estimated total prescriptions for controlled substances for years 2017–2020.

controlled substances for years 2017–2020.

TABLE 4—ESTIMATED TOTAL PRESCRIPTIONS FOR CONTROLLED SUBSTANCES, 2017–2020

	2017	2018	2019	2020
<i>Non-Controlled Substances:</i>				
Rate of E-Rx (%) .....	76	83	86	89
<i>Controlled Substances:</i>				
Total Rx, E and non-E (millions of Rx) .....	382.4	372.3	353.2	351.0
Rate of EPCS (%) .....	17	26	38	58
Total EPCS (millions of Rx) .....	65.0	96.8	134.2	203.6

As shown in Table 4, the estimated total prescriptions for controlled substances decreased from 382.4 million in 2017 to 351.0 million in 2020. For the purposes of this analysis, DEA estimates the total number of controlled substances prescriptions will stay constant at 351.0 million from 2022 to 2026.

Also from Table 4, the rate of electronic prescribing for non-controlled substances is higher than that of controlled substances. However, DEA estimates the rate of electronic prescribing for controlled substances will match that of non-controlled substances in 2022 due to a recently published CMS rule, which requires electronic prescribing for all controlled substances (with some exceptions) covered under Medicare Part D.<sup>25</sup> The 2020 rate of electronic prescriptions for non-controlled substances was 89 percent. While it is possible that this rate could continue to increase in the future, DEA has no basis to estimate how much higher the rate would go. As the rate of increase has been slowing over the past several years, DEA conservatively estimates that the rate of electronic prescribing for non-controlled substances has peaked at 89 percent and the rate of electronic prescribing for controlled substances will be 89 percent for the analysis period of 2022–2026. Multiplying the estimated total number of controlled substance prescriptions, 351.0 million per year, by the estimated rate of EPCS of 89 percent, the estimated total EPCS is 312.4 million per year for the analysis period 2022–2026.

CMS estimates that as much as four percent of electronic prescriptions for non-controlled substances in 2019 were transfers.<sup>26</sup> Applying the four percent transfer rate to the total EPCS prescriptions, DEA estimates the

number of transfers are 12.5 million per year from 2022–2026.

Total Cost Savings

In order to calculate the total cost savings, DEA applied the \$1.76 net cost savings per transaction to the estimated 12.5 million transfers, resulting in a total annual net cost savings of \$22.0 million over the analysis period, 2022–2026. The net present value (NPV) of the cost savings is \$100.8 million at three percent discount rate and 90.2 million at seven percent discount rate. The annualized cost savings from 2022 to 2026 is \$22.0 million at three percent and seven percent. Table 5 summarizes the NPV and annualized cost savings calculation.

TABLE 5—NPV AND ANNUALIZED COST SAVINGS

	3 percent	7 percent
NPV of Cost Savings .....	\$100.8	\$90.2
Annualized Cost Savings .....	22.0	22.0

*Executive Order 12988, Civil Justice Reform*

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

*Executive Order 13132, Federalism*

This proposed rule does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

*Executive Order 13175, Consultation and Coordination With Indian Tribal Governments*

This proposed rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

*Regulatory Flexibility Act*

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 proposed rule will not, if promulgated, have a significant economic impact on a substantial number of these small entities.

The RFA requires an agency to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on a substantial number of small entities. DEA has analyzed the economic impact of each provision of this proposed rule and estimates that it will have minimal economic impact on affected entities, including small businesses, nonprofit organizations, and small governmental jurisdictions.

DEA is proposing to amend its regulations to allow the electronic transfer of schedule II–V controlled substance prescriptions between registered retail pharmacies for initial filling on a one-time basis only. This amendment will specify the procedure that must be followed and the information that must be documented when electronically transferring an EPCS between pharmacies. The proposed amendment would stipulate that the transfer must be communicated directly between two licensed pharmacists, the prescription must remain in its electronic form, and the required prescription information must be unaltered during the transmission.

<sup>25</sup> 85 FR 84472 (Dec. 28, 2020).

<sup>26</sup> Conference call between CMS and DEA, January 2021. CMS’s estimate is a “high” estimate and “4 percent” is considered the maximum percent of electronic prescriptions that are transfers.

Nothing in this proposed rule alters the existing pharmacy application requirements as specified in 21 CFR 1311.205.

In addition to the above, the pharmacist transferring the prescription must update the electronic prescription record to include information noting that the prescription was transferred. The transferring pharmacist must also record the name, address, and DEA registration number of the pharmacy to which the prescription is being transferred, the name of the pharmacist receiving the transfer, the name of the transferring pharmacist, and the date of the transfer. Likewise, the pharmacist

receiving the transferred prescription must record the transferring pharmacy's name, address and DEA registration number, the name of the transferring pharmacist, and the name of the pharmacist receiving the transfer. Finally, under the proposed amendment, the electronic records documenting the transfer must be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the electronic prescription and the pharmacy receiving the transfer.

DEA anticipates the proposed rule will affect pharmacies, offices of physicians, and hospitals, as the

majority of prescribers are employed by offices of physicians or hospitals. Table 6 indicates the sectors, as defined by the North American Industry Classification System (NAICS), affected by the proposed rule. There may be other small entities under Small Business Administration size standards in other NAICS code industries affected by this proposed rule. However, DEA believes the list in Table 6 is a good general representation of affected small entities and their industries as defined by NAICS.

TABLE 6—AFFECTED INDUSTRIAL SECTORS

Business activity	NAICS code	NAICS code description
Pharmacy .....	446110	Pharmacies and Drug Stores.
Prescriber .....	621111	Offices of Physicians (except Mental Health Specialists).
	622110	General Medical and Surgical Hospitals.

Although transfers of EPCS may not be common, as much as four percent of prescriptions, DEA estimates, for the purposes of this analysis, such transfers of EPCS are distributed proportionally across all prescribers and pharmacies. Therefore, DEA estimates a substantial number of small entities in the affected industries would be affected by this proposed rule.

In order to determine if the proposed rule will result in a significant impact on small entities, the following steps were taken:

1. Estimate the cost or cost savings per transfer.
2. Estimate the total cost or cost savings of transfers.
3. Allocate the total cost or cost savings across all affected entities in proportion to their revenue to estimate the cost or cost savings per entity.
4. Compare the cost or cost savings to the annual revenue for the smallest of small entities. If the impact is not significant for the smallest of small entities, then the impact is not significant for the larger small entities.

Table 3 summarizes the cost or cost savings on a per-transfer basis. The net cost to the transferring pharmacy is \$2.93 (the cost of transferring the prescription, \$4.40 (2.b.), minus the cost of updating the prescription record to note that the prescription was not filled, \$1.47 (2.a.)). The cost to the receiving

pharmacy is \$4.40 (8.b.) per transfer, resulting in a combined net cost of \$7.33. Each transfer affects two different pharmacies, transferring and receiving pharmacies. However, to be conservative, the estimated cost per transfer to a pharmacy is \$7.33 because the transferring and receiving pharmacies may be different establishments of the same parent entity. Also from Table 3, the total cost savings to a prescriber (office of physician or hospital) is \$6.81, sum of the cost savings from not receiving a call from the patient \$2.10 (6.) and the cost savings from not issuing a new prescription \$4.71 (7.).

To calculate the total cost to pharmacies and total cost savings to prescribers, the unit cost and cost savings are multiplied by the estimated total annual transfers. From above, the estimated number of transfers is 12.5 million per year. Multiplying the net cost of \$7.33 per transfer for pharmacies by 12.5 million transfers, the estimated total cost of transfers to all pharmacies is \$91,625,000 per year. Multiplying the cost saving of \$6.81 per transfer for prescribers (office of physician or hospital) by 12.5 million transfers, the estimated total cost saving to all prescribers is \$85,125,000 per year.

The U.S. Census Bureau's Statistics of U.S. Businesses (SUB) is an annual series that provides national and

subnational data on the distribution of economic data by enterprise size and industry. SUB data includes the number of firms at various size ranges. For the purposes of this analysis, the term "firm" as defined in the SUB is used interchangeably with "entity" as defined in the RFA. Based on SUB data, there are 18,852, 174,901, and 2,904 firms in 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively.<sup>27</sup> Furthermore, the total receipts for all firms, including all size ranges, are \$236 billion, \$402 billion, and \$827 billion (rounded) for 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively.<sup>28</sup> Table 7 summarizes the SUB data and provides receipt values without rounding.

<sup>27</sup> SUB, 2012 SUB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size, U.S., 6-digit NAICS, <https://www.census.gov/data/tables/2012/econ/sub/2012-susb-annual.html> ([https://www2.census.gov/programs-surveys/sub/tables/2012/us\\_6digitnaics\\_r\\_2012.xlsx](https://www2.census.gov/programs-surveys/sub/tables/2012/us_6digitnaics_r_2012.xlsx)). (Accessed February 25, 2021.) 2012 data by enterprise receipt size is the latest available.

<sup>28</sup> Ibid.

TABLE 7—NUMBER OF FIRMS AND TOTAL RECEIPTS

NAICS code	NAICS code description	Receipt size (\$)	Number of firms	Receipts (\$000)
446110 .....	Pharmacies and Drug Stores .....	All size ranges .....	18,852	236,277,373
621111 .....	Offices of Physicians (except Mental Health Specialists) .....	All size ranges .....	174,901	402,159,295
622110 .....	General Medical and Surgical Hospitals .....	All size ranges .....	2,904	826,654,913

SUSB data also includes the number of firms and receipts for various receipt-size ranges. The smallest size range is firms with annual revenue less than \$100,000. The average receipt per firm was calculated based on the number of firms and for the receipts for the firms in the size range. For example, in the 446110—Pharmacies and Drug Stores

industry sector, there are 751 firms with receipts under \$100,000, and their combined receipts is \$36,066,000. Dividing \$36,066,000 by 751 results in an average receipt of \$48,024 per firm. Performing the same calculation for all three industries, the average receipt per firm is \$48,024, \$50,493, and \$272,286 for the smallest size category in

446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively. Table 8 summarizes the calculation for the average receipt per firm.

TABLE 8—AVERAGE RECEIPT PER FIRM

NAICS code	NAICS code description	Receipt size (\$)	Number of firms	Receipts (\$000)	Average receipt per firm (\$)
446110 .....	Pharmacies and Drug Stores .....	<100,000	751	36,066	48,024
621111 .....	Offices of Physicians (except Mental Health Specialists) ..	<100,000	15,275	771,280	50,493
622110 .....	General Medical and Surgical Hospitals .....	* 100,000–499,999	14	3,812	272,286

\* “Receipts” not available for the smallest size range of “< 100,000”; therefore, used next size range of “100,000–499,000” for comparison.

To compare the average cost per firm with the average receipt per firm, DEA allocated the cost and cost savings proportionally by revenue, divided by the number of firms to calculate the average cost per firm, and compared the average cost per firm as a percent of receipt per firm. For example, the receipts for the 751 firms with receipts under \$100,000 in 446110—Pharmacies and Drug Stores industry sector is \$36,066,000. This is 0.015264 percent of total receipt of \$236,277,373,000 for all size ranges. Allocating 0.015264 percent of total cost to pharmacies of \$91,625,000 to the 751 firms, the

average cost per firm is \$19.<sup>29</sup> Dividing the average cost per firm of \$19 by the average receipt per firm of \$48,024, the average cost per firm is 0.03956 percent of average receipt per firm.

This calculation is repeated for 621111—Offices of Physicians (except Mental Health Specialists) and 622110—General Medical and Surgical Hospitals industry sectors. However, the economic impact for 621111—Offices of Physicians (except Mental Health Specialists) and 622110—General Medical and Surgical Hospitals industry sectors is a cost savings, rather than a cost. Although employment of

prescribers are expected to be split between these two industries, to be conservative, the total cost savings (rather than estimating a split between the two industries) is compared to the average receipt per firm. In summary, the average cost or cost savings per firm as percent of receipt is 0.03956 percent, 0.02179 percent, and 0.01028 percent for 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively. Table 9 summarizes the calculation and results.

TABLE 9—COST OR COST SAVINGS PER FIRM AS PERCENTAGE OF RECEIPTS

NAICS code	NAICS code description	Receipt size (\$)	Number of firms	Receipt as percent of total (percent)	Allocated cost to firms in size range (\$)	Average cost per firm (\$)	Average cost/ cost savings per firm as percent of receipt (percent)
446110 .....	Pharmacies and Drug Stores	<100,000	751	0.015264	13,762	19	0.03956
621111 .....	Offices of Physicians (except Mental Health Specialists).	<100,000	15,275	0.191785	160,645	11	*(0.02179)
622110 .....	General Medical and Surgical Hospitals.	100,000–499,999	14	0.000461	386	28	*(0.01028)

\* Cost savings.

In conclusion, the average cost or cost savings per firm as percent of receipt of 0.03956 percent, 0.02179 percent, and

0.01028 percent are not significant economic impacts. Therefore, DEA concludes this proposed rule will not, if

promulgated, have a significant economic impact on a substantial number of small entities.

<sup>29</sup> (\$91,625,000 × 0.015264 percent)/751 = \$19.

*Unfunded Mandates Reform Act of 1995*

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this proposed rule would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

*Paperwork Reduction Act of 1995*

Pursuant to section 3507(d) of the Paperwork Reduction Act of 1995 (PRA), DEA has identified the following collection of information related to this proposed rule.<sup>30</sup> If adopted, this proposed rule would create additional recordkeeping requirements for pharmacies electronically transferring of schedules II–V EPCS for initial dispensing. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at <http://www.reginfo.gov/public/do/PRAMain>.

## A. Collections of Information Associated With the Proposed Rule

*Title:* Recordkeeping Requirements for the electronic transfer of electronic prescriptions for schedules II–V controlled substances between pharmacies for initial filling.

*OMB Control Number:* 1117–NEW.

*DEA Form Number:* N/A.

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 rulemaking 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 proposed 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 proposed

rule would require the records to be maintained by both pharmacies for at least two years from the date of the transfer. DEA estimates the following number of respondents and burden associated with this collection of information:

- *Number of respondents:* 70,567.
- *Frequency of response:* 354.273244 (calculated average).
- *Number of responses:* 25,000,000.
- *Burden per response:* 0.05 hour.
- *Total annual hour burden:* 1,250,000.

The activities described in this information collection are usual and ordinary business activities and no additional cost is anticipated.

## B. Request for Comments Regarding the Proposed Collections of Information

• Written comments and suggestions from the public and affected entities concerning the proposed collections of information are encouraged. Under the PRA, the DEA is required to provide a notice regarding the proposed collections of information in the **Federal Register** with the notice of proposed rulemaking and solicit public comment. Pursuant to section 3506(c)(2) of the PRA, the DEA solicits comment on the following issues: The need for the information collection and its usefulness in carrying out the proper functions of DEA.

- The accuracy of DEA’s estimate of the burden the proposed collection of information, including the validity of the methodology and assumptions used.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117–AB64/Docket No. DEA–637. All comments must be submitted to OMB on or before January 18, 2022. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

**List of Subjects 21 CFR Part 1306**

Drug traffic control, Prescription drugs.

For the reasons stated in the preamble, DEA proposes to amend 21 CFR part 1306 as follows:

**PART 1306—PRESCRIPTIONS**

- 1. The authority citation for part 1306 continues to read as follows:

**Authority:** 21 U.S.C. 821, 823, 829, 829(a), 831, 871(b), unless otherwise noted.

- 2. Amend § 1306.08 by adding paragraphs (e) through (i) to read as follows:

**§ 1306.08 Electronic prescriptions.**

\* \* \* \* \*

(e) The transfer for initial dispensing of an electronic prescription for a controlled substance in schedule II–V is permissible between retail pharmacies on a one-time basis only.

(f) The transfer of an electronic prescription for a controlled substance in schedule II–V between retail pharmacies for the purpose of initial dispensing is subject to the following requirements:

(1) The prescription must be transferred from one retail pharmacy to another retail pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription to another form (e.g., facsimile) for transmission.

(2) The contents of the prescription required by part 1306 of this chapter must not be altered during transfer between retail pharmacies. Any change to the content during transfer, including truncation or removal of data, will render the electronic prescription invalid.

(3) The transfer must be communicated directly between two licensed pharmacists.

(4) The transferring pharmacist must add the following to the electronic prescription record:

(i) Information that the prescription has been transferred.

(ii) The name, address, and DEA registration number of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information.

(iii) The date of the transfer and the name of the pharmacist transferring the prescription information.

(5) The receiving pharmacist must do the following:

(i) Add the word “transfer” to the electronic prescription record at the receiving pharmacy.

(ii) Annotate the prescription record with the name, address, and DEA registration number of the pharmacy from which the prescription was transferred and the name of the pharmacist who transferred the prescription.

(iii) Record the date of the transfer and the name of the pharmacist receiving the prescription information.

(g) The transfer of an electronic prescription for a controlled substance in schedule II–V for the purpose of initial dispensing is permissible only if

<sup>30</sup> 44 U.S.C. 3501 *et seq.*

allowable under existing State or other applicable law.

(h) The electronic records documenting the transfer of the electronic prescription must be maintained for a period of two years from the date of the transfer by both the

pharmacy transferring the electronic prescription and the pharmacy receiving the electronic prescription.

(i) A pharmacy may transfer electronic prescription information for a controlled substance in schedule III, IV, and V to another pharmacy for the

purpose of refill dispensing pursuant to § 1306.25.

**Anne Milgram,**  
*Administrator.*

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