

**Authority:** 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

**§ 73.66 Virginia [Amended]**

■ 2. Section 73.66 is amended as follows:

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**R–6602A Fort Pickett, VA [Removed]**

**R–6602B Fort Pickett, VA [Removed]**

**R–6602C Fort Pickett, VA [Removed]**

**R–6602A Fort Barfoot, VA [New]**

*Boundaries.* Beginning at lat. 37°05'38" N, long. 77°51'53" W; to lat. 37°04'26" N, long. 77°51'44" W; thence along State Highway No. 40; to lat. 37°03'56" N, long. 77°51'04" W; to lat. 37°02'44" N, long. 77°50'37" W; to lat. 37°01'06" N, long. 77°50'42" W; to lat. 36°59'51" N, long. 77°50'33" W; to lat. 36°57'59" N, long. 77°52'13" W; to lat. 36°57'55" N, long. 77°53'18" W; to lat. 36°58'13" N, long. 77°57'41" W; to lat. 37°01'51" N, long. 77°58'39" W; to lat. 37°01'51" N, long. 77°55'57" W; to lat. 37°04'22" N, long. 77°55'57" W; to lat. 37°05'38" N, long. 77°54'41" W; to the point of beginning.

*Designated altitudes.* Surface to but not including 4,000 feet MSL.

*Time of designation.* Continuous May 1 to Sept. 15. Other times by NOTAM 24 hours in advance.

*Controlling agency.* FAA, Washington ARTCC.

*Using agency.* Virginia National Guard, Commander, Fort Barfoot, VA.

**R–6602B Fort Barfoot, VA [New]**

*Boundaries.* Beginning at lat. 37°05'38" N, long. 77°51'53" W; to lat. 37°04'26" N, long. 77°51'44" W; thence along State Highway No. 40; to lat. 37°03'56" N, long. 77°51'04" W; to lat. 37°02'44" N, long. 77°50'37" W; to lat. 37°01'06" N, long. 77°50'42" W; to lat. 36°57'55" N, long. 77°53'18" W; to lat. 36°58'13" N, long. 77°57'41" W; to lat. 37°01'51" N, long. 77°58'39" W; to lat. 37°01'51" N, long. 77°55'57" W; to lat. 37°04'22" N, long. 77°55'57" W; to lat. 37°05'38" N, long. 77°54'41" W; to the point of beginning.

*Designated altitudes.* 4,000 feet MSL to but not including 11,000 feet MSL.

*Time of designation.* By NOTAM 24 hours in advance.

*Controlling agency.* FAA, Washington ARTCC.

*Using agency.* Virginia National Guard, Commander, Fort Barfoot, VA.

**R–6602C Fort Barfoot, VA [New]**

*Boundaries.* Beginning at lat. 37°05'38" N, long. 77°51'53" W; to lat. 37°04'26" N, long. 77°51'44" W; thence along State Highway No. 40; to lat.

37°03'56" N, long. 77°51'04" W; to lat. 37°02'44" N, long. 77°50'37" W; to lat. 37°01'06" N, long. 77°50'42" W; to lat. 36°57'55" N, long. 77°53'18" W; to lat. 36°58'13" N, long. 77°57'41" W; to lat. 37°01'51" N, long. 77°58'39" W; to lat. 37°01'51" N, long. 77°55'57" W; to lat. 37°04'22" N, long. 77°55'57" W; to lat. 37°05'38" N, long. 77°54'41" W; to the point of beginning.

*Designated altitudes.* 11,000 feet MSL to but not including 18,000 feet MSL.

*Time of designation.* By NOTAM 24 hours in advance.

*Controlling agency.* FAA Washington ARTCC.

*Using agency.* Virginia National Guard, Commander, Fort Barfoot, VA.

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Issued in Washington, DC, on July 21, 2023.

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*Acting Manager, Airspace Rules and Regulations.*

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## 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:** Final rule.

**SUMMARY:** The Drug Enforcement Administration (DEA) is amending its regulations to allow the transfer of electronic prescriptions for schedules II–V controlled substances between registered retail pharmacies for initial filling, upon request from the patient, on a one-time basis. This amendment specifies the procedure that must be followed and the information that must be documented when transferring such electronic controlled substance prescriptions between DEA-registered retail pharmacies.

**DATES:** This rule is effective August 28, 2023.

**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) 776–3882.

## SUPPLEMENTARY INFORMATION:

### Executive Summary

On November 19, 2021, the Drug Enforcement Administration (DEA) published a notice of proposed rulemaking (NPRM) proposing to permit the transfer of electronic prescriptions for controlled substances (EPCS) in schedules II–V between registered retail pharmacies for initial filling on a one-time basis only.<sup>1</sup> In this rulemaking, DEA is finalizing the regulatory text proposed in the NPRM with modifications to address concerns brought forth by commenters.

The final rule amends DEA regulations to explicitly state that an electronic prescription for a controlled substance in schedule II–V may be transferred between retail pharmacies for initial filling on a one-time basis only, upon request from the patient, and clarifies that any authorized refills included on a prescription for a schedule III, IV, or V controlled substance are transferred with the original prescription. The final rule requires 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 21 CFR part 1306 must be unaltered during the transmission. The final 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 final rule describes the information that must be recorded to document transfer of EPCS between pharmacies for initial dispensing. It also clarifies that, in lieu of manual data entry, the transferring and/or receiving pharmacy's prescription processing software may, if capable, capture the required information from the electronic prescription and automatically populate the corresponding data fields to document the transfer. The transferring and/or receiving pharmacist, as applicable, must ensure that the populated information is complete and accurate. The electronic records documenting EPCS transfers must be maintained by both pharmacies for two years from the date of the transfer. The existing requirements for all prescriptions, as outlined in 21 CFR part 1306, Prescriptions, and the requirements for prescribing and pharmacy applications, as outlined in 21 CFR part 1311, Requirements for Electronic Orders and Prescriptions, remain unchanged in this final rule.

<sup>1</sup> 86 FR 64881.

## Legal Authority

The Controlled Substances Act (CSA) 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>2</sup> The Attorney General has delegated this authority to the Administrator of the DEA.<sup>3</sup>

## Purpose

DEA is revising its regulations to state that, upon request from the patient, a registered retail pharmacy may transfer an electronic controlled substance prescription in schedules II–V to another registered retail pharmacy for initial filling. This final rule specifies the procedures that retail pharmacies must follow and the information that must be documented when transferring EPCS. 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 prescription in schedule II only pursuant to a written prescription (including an electronic prescription), 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 signed paper prescription, a facsimile of a signed paper prescription, an electronic prescription, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist.<sup>6</sup> Prescriptions for controlled substances in schedules III and IV 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 paper or electronic prescriptions for controlled substances in any schedule

between pharmacies for initial filling. DEA regulations address the transfer of controlled substance prescriptions (schedules III–V) between pharmacies for refill dispensing, but not for initial dispensing.<sup>8</sup>

Unlike paper prescriptions which are issued directly to the patient, electronic prescriptions are transmitted directly from the practitioner to the pharmacy in the form of an electronic data file.<sup>9</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. However, because the pharmacy receives an electronic prescription as an electronic data file and not a physical paper prescription, it cannot give the prescription to the patient to take to another pharmacy. In this scenario, the pharmacy can only inform the patient that the prescription cannot be filled. The patient could then call the prescribing practitioner to request that a new prescription be sent to a different pharmacy.

DEA realizes that this scenario creates the potential for duplication of prescriptions, if the practitioner transmits a new prescription to a different pharmacy and does not cancel or void the original prescription 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 prescribing practitioner to request a new prescription. As more practitioners are issuing controlled substance prescriptions electronically (as discussed below), there is an increasing need to address how a pharmacy should handle an electronic controlled substance prescription that it receives but cannot fill.

DEA's March 2010 interim final rule (IFR), *Electronic Prescriptions for Controlled Substances*, provides practitioners with the option of issuing, and pharmacies with the option of receiving, dispensing, and archiving EPCS in schedules II–V.<sup>10</sup> In a request for information (RFI) published in August 2020, 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 DEA published the EPCS IFR.<sup>11</sup> Additionally, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (“SUPPORT Act”) mandates electronic prescribing of schedules II–V controlled substances (with some exceptions) covered under Medicare Part D, beginning January 1, 2021.<sup>12</sup> Further, Surescripts, a health information network and electronic prescribing intermediary, stated in its 2021 National Progress Report that as of January 2022, 35 States require, or will soon require, electronic prescribing of opioids, all controlled substances, or all prescriptions.<sup>13</sup> In the same report, Surescripts also reported that the rate of electronic prescribing of controlled substances increased from 38 percent in 2019 to 58 percent in 2020 and to 73 percent in 2021. Thus, procedures for transferring EPCS between pharmacies for initial dispensing are needed urgently. In this final rule, DEA is amending its regulations to allow, upon request of the patient, the transfer of electronic prescriptions for schedules II–V controlled substances between registered retail pharmacies for initial filling on a one-time basis.

## Summary of the Notice of Proposed Rulemaking

DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register** on November 19, 2021.<sup>14</sup> The NPRM proposed to permit the transfer of EPCS in schedules II–V between registered retail pharmacies for initial filling on a one-time basis only. The NPRM also proposed the procedures that would need to be followed and the information to be documented when transferring EPCS for initial filling. The proposed rule focused only on the transfer of EPCS for initial dispensing. The NPRM did not propose changes to 21 CFR 1306.25, which permits the transfer of paper, oral, or electronic prescriptions in schedules III, IV, and V for refill dispensing, or the existing requirements for prescriptions (paper or electronic) in 21 CFR part 1306, Prescriptions, and 21 CFR part 1311, Requirements for Electronic Orders and Prescriptions. DEA invited comments

<sup>11</sup> Medicare Program; Electronic Prescribing of Controlled Substances; RFI, 85 FR 47151 (August 4, 2020).

<sup>12</sup> Public Law 115–271, sec. 2003(a)(b) (Oct. 24, 2018). This requirement is codified at 42 U.S.C. 1395w–104(e)(7).

<sup>13</sup> Surescripts, National Progress Report 2021 ([https://surescripts.com/docs/default-source/national-progress-reports/2021-national-progress-report.pdf?sfvrsn=71fcb15\\_12](https://surescripts.com/docs/default-source/national-progress-reports/2021-national-progress-report.pdf?sfvrsn=71fcb15_12)) (accessed June 2, 2022).

<sup>14</sup> 86 FR 64881.

<sup>2</sup> 21 U.S.C. 871(b).

<sup>3</sup> 28 CFR 0.100(b).

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

<sup>5</sup> 21 U.S.C. 829(a) and 21 CFR 1306.12(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>9</sup> An electronic prescription is defined as “a prescription generated on an electronic application and transmitted as an electronic data file.” 21 CFR 1300.03.

<sup>10</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).

from the public to be submitted on or before January 18, 2022.

### Discussion of Public Comments

DEA received 183 comments in response to the NPRM.<sup>15</sup> The commenters included practitioner and professional organizations, pharmacy organizations, pharmacists' associations, State boards of pharmacy, a home delivery pharmacy, a health service organization, a health system, a health information technology developer, a standards developer, and members of the general public. DEA thanks all commenters for their input during the rulemaking process.

The majority of commenters expressed support for the rule. In fact, 89 comments were general statements of support, with no discussion of the proposed regulatory changes. Thirty-seven commenters shared personal accounts of occasions when they or a family member had an electronic prescription sent to the wrong pharmacy or a pharmacy that could not fill the prescription. While most commenters supported the rule in its entirety, some supported the rule's general purpose but were opposed to certain provisions and proposed changes to those particular provisions. Other commenters raised issues of concern, without proposing changes, or sought clarification. Only one commenter opposed the entire rule. Five comments were outside the scope of the rule. These comments, along with DEA's responses, are discussed below.

### Patients' Consent for EPCS Transfers

*Comments.* Two commenters expressed concern that the proposed rule appears to allow the pharmacy to decide when and where a prescription is transferred instead of the patient. One commenter stated that patients should be allowed to request transfers of their prescriptions. Another commenter stated that the rule should require the transferring pharmacy to do the following: (1) Inform the patient of the need to transfer the prescription and the name and location of the pharmacy where the prescription will be transferred, and (2) obtain and document the patient's consent to transfer the prescription to the specified pharmacy location.

*DEA Response.* To prevent treatment delays, reduce patient burden, and minimize opportunities for diversion, DEA is allowing the transfer of EPCS between pharmacies for initial filling upon the patients' request. If a patient

is notified by a pharmacy that the pharmacy is unable to fill an EPCS, the patient may ask to have the prescription transferred to another pharmacy, chosen by the patient, that is able to fill the prescription. For additional clarity, DEA is adding "upon request from the patient" to 21 CFR 1306.08(e) in this final rule. However, DEA believes requiring a pharmacy to obtain and document a patient's consent to transfer a prescription would be unnecessarily burdensome.

### Initial Dispensing Only

*Comments.* Two commenters expressed concern that the NPRM proposed allowing the transfer of EPCS between pharmacies for initial dispensing only, and did not address the transfer of EPCS for refill dispensing.

*DEA Response.* DEA currently permits the transfer of prescription information for refill dispensing of prescriptions for schedule III, IV, and V controlled substances on a one-time basis, if allowed under existing State or other applicable law.<sup>16</sup> DEA notes that prescriptions for controlled substances in schedule II may not be refilled. The existing requirements for transferring EPCS for refill dispensing remain unchanged by this final rule.

### EPCS Transferred as Electronic Data Files

*Comments.* Seventeen commenters mentioned the proposed provision in 21 CFR 1306.08(f)(1), which requires that the prescription be transferred from one pharmacy to another pharmacy in its electronic form. Two commenters supported this provision; one stated that they would no longer support the rule if this provision is removed. Eleven commenters expressed concern that most pharmacies' applications and prescription management software do not have the technology needed to transfer prescriptions electronically. Two commenters noted that pharmacies within the same chain may be able to transfer controlled substance prescriptions electronically because they share a common database but independent community pharmacies are not integrated in this way. Thus, one commenter stated that independent pharmacies would be disproportionately burdened by the rule, and the other commenter stated that the rule appears to be written in favor of keeping a prescription within a chain pharmacy network. One commenter noted that although this functionality became available when the National Council for

Prescription Drug Programs (NCPDP) released the SCRIPT Standard Version 2017071, the technology standard that facilitates electronic prescribing, many pharmacy vendors have not implemented the functionality. However, another commenter stated that the SCRIPT Standard Version 2017071 does not facilitate the electronic transfer of controlled substance prescription information at this time and noted that an updated version of the standard that would facilitate this transfer has been approved by NCPDP. The commenter also stated that implementation of the updated version of the standard will likely be a multi-year process. NCPDP confirmed in its comment that the recently approved changes to the standard include support for the one-time transfer of EPCS between pharmacies.

Two commenters stated that DEA should allow the electronic transfer of controlled substance prescriptions for initial filling as one option, but should not mandate electronic transfer as the only option for transferring EPCS. Six commenters suggested that the final rule should allow the transfer of EPCS between pharmacies through pharmacist-to-pharmacist communication by phone or via facsimile. One commenter, noting that pharmacists have been transferring prescriptions successfully for a long time, stated that pharmacists should be trusted and allowed to transfer EPCS by oral communication between the two pharmacists, or by transmitting via facsimile a printed copy of the prescription, annotated with all the required documentation to indicate that the prescription was transferred.

*DEA Response.* DEA disagrees with the commenter's suggestion that the rule is written in favor of keeping a prescription within a chain pharmacy network and does not believe independent pharmacies will be disproportionately burdened by this rule. DEA has always required, since it began allowing controlled substances to be prescribed electronically, that all records related to such prescriptions must be retained electronically.<sup>17</sup> The final rule permits the transfer of EPCS between pharmacies for initial filling upon request from the patient.<sup>18</sup> Thus, the patient decides if, and to which pharmacy, a prescription is transferred. In addition, NCPDP confirmed in its comment that the new SCRIPT Standard Version 2017071, which is available to both independent and chain

<sup>15</sup> A total of 183 comments were received; however, five commenters submitted duplicate comments.

<sup>16</sup> See 21 CFR 1306.25.

<sup>17</sup> See 75 FR 16235 at 16243 and 21 CFR 1311.305(a).

<sup>18</sup> New 21 CFR 1306.08(e).

pharmacies, enables the transfer of prescriptions between pharmacies. DEA acknowledges that some pharmacies may need to coordinate with their pharmacy technology vendors to have certain SCRIPT transactions, including the transaction used to transfer prescriptions between pharmacies, incorporated into their pharmacy applications. The cost associated with this incorporation, if any, is not set by DEA and is beyond the scope of DEA's authority. Further, in 2018, CMS adopted SCRIPT 2017071 as the official electronic prescribing standard for prescriptions covered under Medicare Part D.<sup>19</sup> Consequently, pharmacies that wish to transfer EPCS covered under a Medicare Part D drug plan are already required to have and use the SCRIPT 2017071 transaction that facilitates the transfer of prescriptions between pharmacies.<sup>20</sup> Hence, the final rule continues to require that once a controlled substance prescription is created electronically, it must remain in its electronic format and all records related to the prescription must be retained electronically.

#### **Transfer of EPCS for Initial Filling on a One-Time Basis Only**

*Comments.* Six commenters mentioned the provision that permits the transfer of EPCS between pharmacies for initial dispensing on a "one-time basis only." Two commenters opposed the one-time only limitation. The commenters stated that DEA should at a minimum, allow pharmacies that share a real-time online database, if not all pharmacies, to transfer EPCS for initial dispensing more than once, if needed. One of the commenters also noted that DEA permits pharmacies that share a real-time, online database to transfer prescriptions for schedule III–V controlled substances for refill dispensing up to the maximum number of refills permitted by law and the prescriber's authorization. Four commenters asked DEA to clarify the applicability of the one-time only limitation in specific scenarios. For example, two commenters noted that a prescription could be transferred from one pharmacy that cannot fill it to another pharmacy that is also unable to fill the prescription. One of the commenters stated that as written, the rule would not allow the prescription to be transferred again and thus the patient would be burdened with having to

contact the prescribing practitioner to request a new prescription, which is the specific scenario the rule seeks to prevent. Two commenters asked about the transfer of EPCS issued with authorized refills. The commenters asked whether the refills would be transferred with the prescription or remain at the pharmacy that received the prescription from the prescribing practitioner. Another commenter asked if the one-time only transfer allowed for initial dispensing is in addition to the transfer allowed for refill dispensing under 21 CFR 1306.25. One commenter asked if the one-time only limit prohibits the transfer of subsequent controlled substance prescriptions issued to the same pharmacy that transferred the previous prescription to an alternate pharmacy for initial dispensing.

*DEA Response.* DEA believes the one-time transfer allowance is sufficient to accommodate most situations in which a transfer would be needed for initial dispensing. In an article discussing the adoption of the SCRIPT Standard Version 2017071, Surescripts notes that the receiving pharmacy has to initiate the prescription transfer, when a transfer is requested.<sup>21</sup> In the interest of patient care, as well as good business practice, DEA believes a pharmacy would not request the transfer of a prescription that it cannot fill. As such, the scenario described by the commenters in which a prescription is transferred from one pharmacy to another pharmacy that is also unable to fill the prescription should occur rarely, if ever. Nonetheless, DEA recommends that the patient confirms the ability of the receiving pharmacy to fill the prescription before requesting the transfer.

DEA wishes to clarify that the one-time basis stipulation for transferring EPCS for initial filling is per prescription. In other words, each prescription transmitted from a practitioner to a retail pharmacy may be transferred one time, upon request from the patient, regardless of whether any previous EPCS were transferred. If the prescription being transferred includes authorized refills, the refills are transferred with the prescription to the pharmacy receiving the transfer. This final rule adds additional text to 21 CFR 1306.08(e) to provide this clarification. As proposed in the NPRM, this final

rule permits the transfer of EPCS between pharmacies for initial dispensing on a one-time basis only. This is consistent with the current regulations at 21 CFR 1306.25 for the transfer of prescription information between pharmacies for refill dispensing of schedule III–V EPCS on a one-time basis only.<sup>22</sup> DEA notes that 21 CFR 1306.25 remains unchanged by this final rule.

*Comments.* One commenter asked that DEA clarify in the final rule that a pharmacy that receives transfers of EPCS will not be held responsible for filling a transferred prescription that may have been transferred multiple times.

*DEA Response.* Pharmacists continue to have a corresponding responsibility to ensure they are filling valid controlled substance prescriptions; nothing in DEA's regulations on EPCS alters a pharmacy's responsibilities to ensure the validity of a controlled substance prescription.<sup>23</sup> Therefore, DEA does not believe any further clarifications are needed in this final rule.

#### **Transfers Communicated Between Two Licensed Pharmacists**

*Comments.* One commenter suggested that DEA allow the transfer of EPCS to be communicated between pharmacy personnel (e.g., pharmacy technicians, pharmacist interns, etc.), as permitted by State laws, instead of requiring the communication to be between two licensed pharmacists.

*DEA Response.* Existing DEA regulations ". . . include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State" in the definition of a pharmacist.<sup>24</sup> As such, DEA does not believe any further clarification is needed, as the existing regulations include the allowance requested by the commenter. However, DEA emphasizes that a pharmacist continues to have a corresponding responsibility to fill only those prescriptions that conform in all respects with the requirements of DEA regulations.<sup>25</sup>

#### **Pharmacy Software that Automatically Populates Prescription Data**

*Comments.* Five commenters asked that DEA allow the transferring and receiving pharmacies' prescription processing software, if capable, to

<sup>19</sup> Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-For-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 FR 16440 (April 16, 2018).

<sup>20</sup> 42 CFR 423.160(b)(2)(iv).

<sup>21</sup> Swartz, L. and Whittemore, K. A giant leap: The industry adopts a new version of the national e-prescribing standard. November 2019. [https://surescripts.com/docs/default-source/intelligence-in-action/ncpa-surescripts\\_script\\_2017071\\_pharmacist\\_ce\\_article\\_11-2019.pdf](https://surescripts.com/docs/default-source/intelligence-in-action/ncpa-surescripts_script_2017071_pharmacist_ce_article_11-2019.pdf) (accessed April 14, 2023).

<sup>22</sup> 21 CFR 1306.25(a).

<sup>23</sup> 21 CFR 1306.04(a) and 1311.100(f).

<sup>24</sup> 21 CFR 1300.01(b).

<sup>25</sup> 21 CFR 1306.04(a).

capture the required information from the electronic prescription and automatically populate the corresponding data fields to document prescription transfers on behalf of the pharmacists.

**DEA Response.** In light of the comments received on this issue, DEA is revising this final rule to permit a transferring or receiving pharmacy's prescription processing software, if capable, to capture the information required from the electronic prescription and automatically populate the corresponding data fields to document the transfer of prescriptions between pharmacies. However, the transferring or receiving pharmacist must ensure that the populated information is complete and accurate. This provision is added in a new paragraph (f)(6) in 21 CFR 1306.08.

### **Schedule II Controlled Substances Prescriptions**

**Comments.** One commenter stated that, when a practitioner issues multiple prescriptions for schedule II controlled substances pursuant to 21 CFR 1306.12, the rule should allow one or all of those prescriptions to be transferred for initial dispensing, if requested by the patient.

**DEA Response.** Although issued at the same time, each prescription for schedule II controlled substances issued pursuant to 21 CFR 1306.12 is a separate prescription. Therefore, if issued electronically, any of these prescriptions may be transferred between pharmacies on a one-time basis for initial dispensing under the conditions set forth in this final rule.

### **Partial Fills**

**Comments.** Two commenters noted that the proposed rule does not address partial fills of EPCS. The commenters requested clarification regarding the ability of a pharmacy to partially fill a controlled substance prescription and then transfer the remainder to another pharmacy for dispensing of the remaining portion. One of the commenters specifically asked about partial filling of schedule II controlled substance prescriptions while the other commenter asked about all controlled substance prescriptions.

**DEA Response.** Current DEA regulations permit partial filling of prescriptions for controlled substances in schedules III–V.<sup>26</sup> Existing regulations also permit partial filling of a prescription for a schedule II controlled substance if the pharmacy is unable to supply the full quantity.<sup>27</sup> In

this case, the remaining portion of the prescription may be filled within 72 hours of the first partial filling; no additional quantity may be supplied after the 72-hour period without a new prescription.<sup>28</sup> In addition, DEA published a final rule<sup>29</sup> on July 21, 2023, which amends 21 CFR 1306.13 to allow a pharmacist to partially fill a prescription for a schedule II controlled substance at the request of the prescribing practitioner or the patient, if permissible under State law.<sup>30</sup> This rule becomes effective on August 21, 2023.

Regarding the transfer of prescriptions for controlled substances, existing regulations permit the transfer of schedules III–V controlled substance prescriptions for refill dispensing only.<sup>31</sup> Further, under this final rule, the regulations will permit the transfer of EPCS in schedules II–V between DEA-registered retail pharmacies for initial dispensing upon request from the patient. At this time, however, no DEA regulation permits a partially-filled controlled substance prescription to be transferred from one DEA-registered pharmacy to another for dispensing of the remaining portion of the prescription. DEA did not propose any revisions related to the partial filling of controlled substances prescriptions in the proposed rule; thus, such a change would be outside the scope of this final rule. Nonetheless, DEA believes these regulations provide adequate options for patients to obtain their medication without significant treatment disruptions or delays when pharmacies are unable to fill controlled substances prescriptions received electronically. DEA does not believe further revisions to these regulations are warranted at this time.

### **Economic Impact Analysis**

**Comments.** Four commenters mentioned the economic impact analysis that was included in the NPRM. One commenter, while supporting the proposed rule, stated that the analysis focused only on monetary benefits and did not include unquantifiable benefits such as the reduced stress and improved productivity patients will experience as a result of the rule. A practitioner organization agreed with DEA's conclusion that the rule will result in net cost savings overall. However, the commenter noted that the analysis assumed that a practitioner's

administrative staff would handle calls from patients requesting new prescriptions, but some practitioners do not employ administrative staff and must handle the calls themselves. Thus, the commenter stated that the actual net cost savings of the rule will be higher than DEA's estimate.

One pharmacists' association supports DEA's proposal to allow the transfer of EPCS between pharmacies for initial filling from a patient care perspective, but expressed concern about the economic impact of the proposed rule on pharmacies. The association noted that although DEA estimates the rule will result in overall health system cost savings of \$22 million annually, pharmacies will actually incur significant costs of \$91,625,000 annually, as estimated by DEA.<sup>32</sup> The association also noted that while DEA acknowledges that pharmacies will incur additional expenses, including modifying software configurations, updating business processes, and training personnel, these costs were not included in DEA's analysis. Another commenter agreed that the analysis did not include costs for software upgrades and further noted that the analysis underestimated the time required to process prescription transfers. The commenter stated that processing a prescription transfer can take 15 minutes or more, depending on how busy the pharmacies are at the time of the request. Moreover, the commenter stated that the economic impact analysis did not include additional time and expenses incurred by patients who may need to travel farther to pick up medication from the pharmacy receiving the transfer.

**DEA Response.** DEA agrees that, in addition to saving time, as indicated in the analysis below, this rule is likely to benefit patients in many other ways, including reducing stress, as noted by the commenter. In addition to minimizing opportunities for diversion, DEA's chief reasons for this rulemaking are to provide patients with the option of transferring EPCS for initial filling to prevent treatment delays and reduce patient burden. However, this final rule does not require a patient to request a transfer. DEA emphasizes that the patient decides if, and to which pharmacy, a prescription is transferred. Thus, this rule does not impose any additional travel burden on patients.

<sup>32</sup> The analysis has been updated since the NPRM using the most recent data available. The updated estimated overall health system cost savings is \$29 million and the cost to pharmacies is \$50,005,000. See the Executive Order 12866 and Regulatory Flexibility Act sections below under Regulatory Analyses for the detailed analysis.

<sup>28</sup> 21 CFR 1306.13(a).

<sup>29</sup> *Partial Filling of Prescriptions for Schedule II Controlled Substances*, 88 FR 46983 (July 21, 2023).

<sup>30</sup> 21 CFR 1306.13(b).

<sup>31</sup> 21 CFR 1306.25.

<sup>26</sup> 21 CFR 1306.23.

<sup>27</sup> 21 CFR 1306.13.

DEA also agrees the cost savings per transfer would be higher for prescribing practitioners who do not have administrative staff and would have to handle calls from patients requesting new prescriptions themselves under current regulations. According to Surescripts' "2021 National Progress Report," the rate of electronic prescribing of controlled substances was 73 percent in 2021.<sup>33</sup> DEA believes it is reasonable to assume that, on average, EPCS utilization will skew toward practitioners with larger infrastructure and administrative staff, while recognizing that there are some small and independent offices without administrative staff that may experience greater cost savings than estimated. This is because, under this final rule, the prescribing practitioners at those small and independent offices (versus administrative staff at larger practices), would no longer have to handle calls from patients requesting new prescriptions be sent to alternate pharmacies for initial dispensing.

In regards to the estimated additional costs that pharmacies will incur, DEA notes that, although the rule allows EPCS to be transferred at the request of a patient, it does not require a pharmacy to transfer EPCS if it is unable to do so (e.g., due to system limitations). In the economic analysis, DEA estimated that there will be additional costs to the transferring and receiving pharmacies. However, a pharmacy is expected to participate in transfers of EPCS based on its own analysis of benefits and costs. While only costs were quantified, benefits to pharmacies may include customer retention, increased customer traffic, increased customer loyalty, good will, etc., leading to increased sales over time. DEA estimates each transfer of EPCS will cost \$2.92 and \$4.38 for the transferring and receiving pharmacies, respectively.<sup>34</sup> Since pharmacies are likely to transfer and receive, an average was taken to determine the typical cost per EPCS transfer for a pharmacy. The average cost is \$3.65 per transfer.<sup>35</sup> Applying this total to the estimated maximum number of transfers of 13.7 million per year results in a maximum total net cost, to all pharmacies combined, of \$50,005,000 annually.<sup>36</sup> As noted above, this \$50 million

estimate does not reflect the costs that are mandated by this rule, as this rule by its terms does not require pharmacies either to transfer EPCS or receive EPCS, but it does reflect the estimated cost of doing business for pharmacies that choose to transfer EPCS or receive EPCS under this rule.

In the Regulatory Flexibility Act analysis below, DEA compared the estimated cost of this rule to the annual revenues of the smallest of small pharmacy firms, those with less than \$100,000 in annual revenue. The estimated cost of this rule is \$9 annually for the 666 smallest of small pharmacies.<sup>37</sup> The average cost per firm of \$9 equates to 0.01745 percent of average receipt per firm of \$51,565.<sup>38</sup> DEA anticipates this rule will not have a significant economic impact for the smallest of small pharmacies; and therefore, this rule will also not have a significant economic impact for larger pharmacies. Additionally, as noted in the analysis, 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. As discussed above, these costs are not being mandated by this rule, but would be voluntarily borne by the various pharmacies in order to improve or expand their abilities for transferring EPCS.

#### Other Comments

*Comments.* One commenter recommended that EPCS transmitted to one pharmacy and dispensed at another pharmacy should not be considered transferred prescriptions if the pharmacy that received the prescription and the pharmacy that dispensed the prescription are both owned by the same entity and share the same integrated information technology (IT) system.

*DEA Response.* The CSA and DEA regulations require each registrant to maintain complete and accurate records of controlled substances.<sup>39</sup> Each pharmacy, not the entity who owns the pharmacy, is a DEA registrant and is therefore, subject to DEA's recordkeeping requirements. Consequently, a prescription that is received at one pharmacy and dispensed at a different pharmacy is a transferred prescription because the transaction is occurring between two different DEA registrants, even if they

are owned by the same entity and share an integrated IT system.

*Comments.* One commenter recommended that DEA require a pharmacy transferring EPCS to verify that the pharmacy receiving the transferred prescription will be able to dispense the prescription's full quantity prior to transferring the prescription to that receiving pharmacy.

*DEA Response.* This rule provides for transfers of EPCS at the request of the patient. Although DEA suggests that the transferring pharmacy or the patient verify, prior to the transfer, that the receiving pharmacy is able to fill the transferred prescription, DEA is not requiring pharmacies to do so.

*Comments.* One commenter stated that the prescribing practitioner should receive an automatic notification when a controlled substance prescription that they issued is transferred.

*DEA Response.* DEA does not believe that it is necessary to require pharmacies to notify practitioners when an electronic controlled substance prescription that they issued is transferred. DEA believes this would be unnecessarily burdensome to pharmacies.

*Comments.* One commenter asked that DEA expand exceptions to the definition of "online pharmacy" to clarify that using the internet to transfer prescription information between pharmacies does not render a pharmacy an "online pharmacy."

*DEA Response.* DEA does not believe further clarification is necessary. The definition of an online pharmacy contains ten exceptions, which include a DEA-registered pharmacy whose dispensing of controlled substances via the internet consists solely of filling prescriptions that were electronically prescribed in a manner otherwise consistent with DEA regulations and the CSA.<sup>40</sup>

*Comments.* One commenter recommended that DEA work with State prescription drug monitoring programs (PDMPs) to require pharmacies receiving transferred EPCS to report the transfers to the PDMP. The commenter stated that prescribers should be able to easily identify transferred prescriptions when searching a PDMP database.

*DEA Response.* PDMP reporting is beyond the scope of this rule and DEA's authority, as PDMPs are regulated by the States.

*Comments.* One commenter suggested that DEA should preempt any State requirements for transferring EPCS that exceed the requirements established by DEA.

<sup>33</sup> The numbers have been updated since the NPRM with 2021 data. See the Executive Order 12866 section below under Regulatory Analyses for the detailed analysis.

<sup>34</sup> Id.

<sup>35</sup> The numbers have been updated since the NPRM with 2021 data. See the Regulatory Flexibility Act section below under Regulatory Analyses for the detailed analysis.

<sup>36</sup> Id.

<sup>37</sup> Id.

<sup>38</sup> Id.

<sup>39</sup> 21 U.S.C. 827 and 21 CFR 1304.21(a).

<sup>40</sup> See 21 CFR 1300.04(h)(9).

**DEA Response.** DEA generally will not preempt any State laws or regulations related to dispensing controlled substances,<sup>41</sup> including the transfer of EPCS between pharmacies for initial dispensing.

**Comments.** One commenter recommended that DEA revise the language in the proposed 21 CFR 1306.08(g), which states that EPCS transfers for initial dispensing are permissible only if allowable under existing State or other applicable law. The commenter stated that, as currently written, a State would have to enact a law to expressly allow this activity. The commenter recommended replacing “only if allowable under existing State or other applicable law” with “unless prohibited by existing State or other applicable law.”

**DEA Response.** DEA understands the commenter’s concern. However, DEA is not amending this language at this time. The regulations for the transfer of EPCS between pharmacies for initial dispensing were written to parallel those for the transfer of prescription information for refill dispensing, as well as those for prescriptions in general. DEA notes that the phrase, “only if allowable under existing State or other applicable law,” is included in several provisions in 21 CFR part 1306.<sup>42</sup>

**Comments.** One commenter recommended that DEA use the term “forward” instead of “transfer” when referring to the transfer of prescription information for initial dispensing. The commenter was concerned that the transfer of prescription information for initial dispensing would be confused with the transfer of prescription information for refill dispensing outlined in 21 CFR 1306.25. The commenter noted that while schedule II controlled substance prescriptions cannot be transferred for refill dispensing because refills are not permitted, this rule, if promulgated, will allow the transfer of schedule II controlled substance prescriptions between pharmacies for initial dispensing.

**DEA Response.** DEA understands the commenter’s concern and preference for differentiating between prescriptions transferred for initial dispensing and those transferred for refill dispensing. However, DEA uses “transfer” to refer to the exchange of prescription information between pharmacies for both initial and refill dispensing. Therefore, this final rule continues to use the term “transfer.”

## Out of Scope

Five comments were outside the scope of this rule. Three commenters asked DEA to also allow controlled substance prescriptions prescribed orally and via facsimile to be transferred between pharmacies for initial dispensing. This is beyond the scope of this rule which only addresses the one-time transfer of EPCS between pharmacies for initial dispensing. One commenter disagreed with health insurance entities requiring prior authorization for medications currently being prescribed and those prescribed to treat chronic illnesses. The commenter also stated that after patients have been prescribed medications to treat chronic illnesses for an extended period of time, the prescriptions should be allowed to be refilled without requiring patients to revisit the prescribing practitioner or requiring the practitioner to issue new prescriptions. Additionally, the commenter stated that practitioners should be allowed to prescribe stimulants for less than a 30-day supply. One commenter wanted medications used to treat attention-deficit/hyperactivity disorder removed from the controlled substances lists. These comments are beyond the scope of this rulemaking and therefore are not addressed.

## Summary of Changes From the NPRM

DEA is finalizing the proposed regulatory text with modifications to address concerns brought forth by commenters. The final rule adds “upon request from the patient,” to the proposed text in 21 CFR 1306.08(e) to clarify that prescription transfers must be requested by the patient. Further, a new sentence is also added to 21 CFR 1306.08(e) to clarify that, when a prescription for a schedule III, IV, or V controlled substance issued with authorized refills is transferred, the authorized refills are transferred with the original prescription.

Additionally, a new paragraph is added to 21 CFR 1306.08(f) to state that a transferring or receiving pharmacy’s prescription processing software, if capable, is permitted to capture the information required from the electronic prescription and automatically populate the corresponding data fields to document the transfer of prescriptions between pharmacies. The new paragraph also states that the transferring or receiving pharmacist, as applicable, must ensure that the populated information is complete and accurate.

## Summary of the Final Rule

DEA is amending its regulations to allow, upon request from the patient, the transfer of EPCS between registered retail pharmacies for initial filling on a one-time basis only. The final rule explicitly states that an electronic prescription for a controlled substance in schedule II–V may be transferred between retail pharmacies for initial filling on a one-time basis only, upon request from the patient, and clarifies that any authorized refills included on a prescription for a schedule III, IV, or V controlled substance are transferred with the original prescription. The final rule specifies the following requirements that must be met when EPCS are transferred between pharmacies for initial dispensing. The prescription must be transferred in its electronic form and may not be converted to another form (e.g., paper, facsimile) for transmission. The information required to be on a controlled substance prescription pursuant to 21 CFR part 1306 must be unaltered during the transmission. The transfer must be communicated between two licensed pharmacists. The final rule also stipulates that the transfer of EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law.

The final rule describes the documentation requirements for pharmacies transferring EPCS for initial filling. A pharmacist transferring an electronic controlled substance prescription 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. Similarly, the pharmacist receiving the transferred prescription 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. In lieu of manual data entry, the transferring or receiving pharmacy’s prescription processing software may, if capable, capture the aforementioned required information from the electronic prescription and automatically populate the corresponding data fields to document the transfer. However, the transferring or receiving pharmacist, as applicable, must ensure that the

<sup>41</sup> See 21 U.S.C. 903.

<sup>42</sup> See 21 CFR 1306.12(b)(1)(iv) and (v) and 1306.25(e).



populated information is complete and accurate. The final rule requires the electronic records documenting EPCS transfers to be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the prescription and the pharmacy receiving and filling the prescription.<sup>43</sup> The existing requirements for all prescriptions, as outlined in 21 CFR part 1306, Prescriptions, and the requirements for prescribing and pharmacy applications, as outlined in 21 CFR part 1311, Requirements for Electronic Orders and Prescriptions, remain unchanged in this final rule.

### Regulatory Analyses

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

This final 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. The Office of Management and Budget (OMB) has determined that this rule is not a “significant regulatory action” under E.O. 12866, section 3(f).

### Analysis of Benefits and Costs

DEA is amending its regulations to allow the transfer of electronic prescriptions for schedule II–V controlled substances between registered retail pharmacies for initial dispensing, upon request from the patient, on a one-time basis only. This amendment specifies the procedure that must be followed and the information that must be documented when transferring EPCS between DEA-registered retail pharmacies. As described below, DEA estimates the annual cost savings of this rule is \$29 million.<sup>44</sup>

The final rule specifies that: the transfer must be communicated directly between two licensed pharmacists; the prescription must be transferred in its electronic form and may not be converted to another form (e.g., facsimile) for transmission; the required

prescription information must be unaltered during the transmission; and the transfer of EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law. 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 was transferred, the name of the pharmacist receiving the transfer, the name of the transferring pharmacist, and the date of the transfer. Similarly, the pharmacist receiving the transferred prescription 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, the final rule requires that the electronic records documenting the transfer 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 DEA regulations previously did not permit the transfer of schedule II–V EPCS from one retail pharmacy to another retail pharmacy for initial filling, DEA anticipates the ability to transfer EPCS under this final rule will affect the following parties: the first (transferring) pharmacy, patient, prescriber, and second (receiving) pharmacy. To quantify the economic impact of this 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>45</sup> DEA notes, however, that nothing in this rule mandates that pharmacies must transfer EPCS, or must receive EPCS; so, the economic analysis addresses the estimated costs and cost savings in instances where the transferring and receiving pharmacies agree to engage in such transfers under the terms of this rule.

### 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 EPCS it cannot fill under current practices (prior to the final rule) versus the final rule. The term “current” is used in the

analysis to mean prior to the implementation of this final rule. 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.

1. The first (transferring) pharmacy contacts the patient to inform the patient that it is unable to fill the prescription.

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

3. The patient receives the call from the first pharmacy notifying the patient that it is unable to fill the prescription.

4. The patient contacts the prescriber and requests a new prescription.

5. The prescriber’s secretary or administrative personnel receives the phone call from the patient.

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

7. The alternate pharmacy receives and fills the EPCS.

8. The patient receives the filled prescription from the alternate pharmacy.

By contrast, the anticipated activities for each of the affected parties under the final rule and the economic impact are described below.

1. The first (transferring) pharmacy contacts the patient to inform them that it is unable to fill the prescription. DEA assumes the duration of the call to the patient is the same under the current and final rule scenarios, and therefore, there is no impact on the transferring pharmacy.

2. The patient receives a call from the transferring pharmacy notifying the patient that it is unable to fill the prescription; the patient requests that the prescription be transferred to an alternate (receiving) pharmacy. DEA assumes the duration of the call from the transferring pharmacy is the same under current and final rule scenarios. Therefore, there is no impact to the patient.

3. The patient (nor the transferring or receiving pharmacy) does not need to contact the prescriber to request a new prescription under the final rule. Therefore, there are cost savings for the patient from not contacting the prescriber.

4. The prescriber does not receive a call from the patient. Therefore, there are cost savings for the prescriber.

<sup>43</sup> 21 CFR 1304.06(g).

<sup>44</sup> This analysis has been updated since the NPRM with the latest available data.

<sup>45</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.



5. The prescriber does not need to issue a new EPCS. Therefore, there are cost savings for the prescriber.

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

7. The alternate (receiving) pharmacy receives the transfer and fills the transferred EPCS (including being contacted by the transferring pharmacy, exchanging information, and recording

the required information regarding transfer). DEA anticipates there will be additional costs related to being contacted by the transferring pharmacy and exchanging information. Therefore, there is an additional cost to the receiving pharmacy to transfer a prescription, but the receiving pharmacy also obtains full reimbursement for the cost of filling the prescription.

8. The patient receives the filled prescription from the alternate (receiving) pharmacy. DEA assumes the burden is the same under the current and final rule scenarios, and therefore, there is no impact on the patient. Note that there may be a burden for the

patient in needing to travel to a different pharmacy, but that is a cost that arises in every case where the patient must go to a different pharmacy than expected because the first pharmacy is unable to fill the prescription. There is no difference under this rule in the patient's burden in traveling to a different pharmacy, whether the EPCS is transferred under this rule, or the prescriber sends a new EPCS to the second pharmacy, or the patient takes a paper prescription to the second pharmacy.

Table 1 summarizes the activity scenarios under current practices (prior to the final rule) and final rule and the anticipated economic impact.

TABLE 1—PERSONS AND ACTIVITIES, CURRENT VS. FINAL RULE

Persons	Change in activity		Economic impact
	Current	Final Rule	
First or Transferring Pharmacy.	First pharmacy contacts patient to inform that they are unable to fill the prescription. Note action taken ( <i>i.e.</i> , void, cancel, etc.), as needed.	Transferring pharmacy contacts patient to inform that it is unable to fill the prescription. Transfer prescription. "Transfer" includes: contacting the receiving pharmacy, exchanging information, and recording the required information regarding transfer.	Assume duration of call/contact is same ==> no impact. Additional cost to transfer vs. noting action taken.
Patient .....	Receive call from pharmacy that it is unable to fill the prescription.	Receive call from pharmacy that it is unable to fill the prescription, request transfer of the prescription to an alternate (receiving) pharmacy.	Assume duration of call/contact is same ==> no impact.
Prescriber .....	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.
	Receive call from patient. (prescriber's secretary).	N/A .....	Cost savings.
Second (Receiving) Pharmacy.	Cancel prescription sent to first pharmacy and issue new prescription at second (receiving) pharmacy.	N/A .....	Cost savings.
	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, but the receiving pharmacy gets full reimbursement for filling prescription.

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. Occupation codes 29–1051 Pharmacists, 00–0000 All Occupations, and 43–6013 Medical Secretaries and Administrative Assistants are used as best representations of first (transferring) and second (receiving) pharmacists, patient, and prescriber's secretary, respectively. DEA estimates the best representation for prescribers are the occupation codes

29–1215 Family Medicine Physicians, 29–1171 Nurse Practitioners, and 29–1071 Physician Assistants for practitioner, nurse practitioner, and physician assistant prescribers, respectively. The occupation code 29–1215 Family Medicine Physicians was chosen to represent practitioners as DEA estimates that it best represents the typical prescribing practitioner.

DEA estimates the median hourly wages for the first (transferring) and second (receiving) pharmacist, patient, prescriber's secretary, and prescriber are \$61.81, \$22.00, \$18.01, and \$99.18,

respectively.<sup>46 47</sup> Additionally, BLS reports that average benefits for private industry is 29.5 percent of total compensation. The 29.5 percent of total compensation equates to 41.8 percent (29.5 percent/70.5 percent) load on

<sup>46</sup> BLS, May 2021 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).

<sup>47</sup> The prescriber median hourly wage is a weighted average of the hourly wages of the occupation codes 29–1215 Family Medicine Physicians, 29–1171 Nurse Practitioners, and 29–1071 Physician Assistants, with the weights based on 1,368,536 Practitioner, 331,410 Nurse Practitioner, and 143,725 Physician Assistant active DEA registrations on 6/10/2022.

wages and salaries.<sup>48</sup> The load of 41.8 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 weighted average prescriber are \$87.65, \$31.20, \$25.54,

and \$140.64, respectively. Table 2 summarizes the calculation for the loaded hourly wages for each of the affected persons.

TABLE 2—LOADED HOURLY WAGES

Affected persons	Occupation code	Occupation code description	Median hourly wage	Loaded hourly median wage
Patient .....	00–0000	All Occupations .....	\$22.00	\$31.20
Pharmacist .....	29–1051	Pharmacists .....	61.81	87.65
Medical secretary .....	43–6013	Medical Secretaries and Administrative Assistants.	18.01	25.54
Prescriber .....	.....	Prescriber (Weighted Average) .....	99.18	140.64

The below sections describe the calculation conducted to quantify the economic impact associated with the changes in activities under the current and final rule 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 \$87.65. Multiplying the loaded hourly rate of \$87.65 by 0.05 (3/60) hours results in a cost of \$4.38. Under the final 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 final rule, resulting in the same cost of \$4.38. Therefore, there is no economic impact to the transferring pharmacy associated with this activity under the final 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 \$87.65. Multiplying the loaded hourly rate of \$87.65 by 0.0167 (1/60) hours results in a cost of \$1.46. Under the final 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 \$87.65. Multiplying the loaded hourly rate of \$87.65 multiplied by 0.05 (3/60) hours results in a cost of \$4.38. Therefore, the net cost to the transferring pharmacy under the final rule is \$2.92 (\$4.38–\$1.46) per transfer.

3. Under current practices, the patient first receives a call from the pharmacist who informs him/her that his/her 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 \$31.20. Multiplying the loaded hourly rate of \$31.20 multiplied by 0.05 (3/60) hours results in a cost of \$1.56 to the patient. Under the final rule, this activity does not change. With transfers of EPCS, the pharmacist must still contact the patient. Thus, under the final rule, the patient also receives a call from the pharmacist. Estimating three minutes for the call, there is still a cost of \$1.56 to the patient. Therefore, there is no economic impact to the patient associated with this activity under the final 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 \$31.20. Multiplying the loaded hourly rate of \$31.20 by 0.083 (5/60) hours results in a cost of \$2.60. Under the final 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 final rule results in a

cost savings to the patient of \$2.60 per transfer.

5. 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 \$25.54. Multiplying the loaded hourly rate of \$25.54 by 0.083 (5/60) hours results in a cost of \$2.13. Under the final rule, the patient no longer needs to contact the prescriber; thus, this interaction will not occur. Therefore, this activity under the final rule results in a cost savings to the prescriber of \$2.13 per transfer.

6. 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 \$140.64. Multiplying the loaded hourly rate of \$140.64 by 0.03 (2/60) hours results in a cost of \$4.69. Under the final rule, the prescriber does not need to issue a new prescription; the original prescription is simply transferred to the receiving pharmacy. Therefore, this activity under the final rule results in a cost savings to the prescriber of \$4.69 per transfer.

7. 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 \$87.65. Multiplying the loaded hourly rate of \$87.65 by 0.25 (15/60) hours results in a cost of \$21.91. Under the final rule, DEA also estimates the receiving pharmacist still conducts this activity at the same loaded labor

<sup>48</sup> BLS, "Employer Costs for Employee Compensation—December 2021" (ECEC).

rate and time duration, resulting in a cost of \$21.91. However, under the final 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 \$87.65. Multiplying the loaded hourly rate of \$87.65 by 0.05 (3/60) hours results in a cost of \$4.38. Therefore, this activity under the final rule results in a cost to the receiving pharmacy of \$4.38 per transfer, but the receiving pharmacy would get the full

reimbursement for filling the prescription.

8. Under current practices, DEA assumes that the patient is informed that the first pharmacy is unable to fill the prescription prior to traveling 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 \$31.20. Multiplying the loaded hourly rate of \$31.20 by 0.33 (20/60) hours results in a cost of \$10.40. Under the final rule, DEA also assumes that the

patient is informed that the first pharmacy is unable to fill the prescription prior to traveling 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 final rule, there is still a cost of \$10.40 to the patient. Therefore, there is no economic impact to the patient associated with this activity under the final rule.

As shown by Table 3, the final rule results in a total cost of \$8.76 and a total cost savings of \$10.88 per transfer. This results in an overall net cost savings of \$2.12 per transfer.

TABLE 3—COST/COST SAVINGS CALCULATION, CURRENT VS. FINAL RULE

Person/activity	Current		Final rule		Costs/(cost savings) (\$)
	Estimated time (minutes)	Cost, current (\$)	Estimated time (minutes)	Cost, final rule (\$)	
Transferring pharmacist:					
1. Contact patient .....	3	4.38	3	4.38	.....
2.a. Void/transfer prescription .....	1	1.46	.....	.....	(1.46)
2.b. Transfer prescription .....	.....	.....	3	4.38	4.38
Patient:					
3. Receive call from pharmacist .....	3	1.56	3	1.56	.....
4. Contact prescriber .....	5	2.60	.....	.....	(2.60)
5. Received filled prescription .....	20	10.40	20	10.40	.....
Prescriber:					
6. Receive call from patient (secretary) .....	5	2.13	.....	.....	(2.13)
7. Issue new prescription (prescriber) .....	2	4.69	.....	.....	(4.69)
Receiving pharmacist:					
8.a. Receive prescription and fill .....	15	21.91	15	21.91	.....
8.b. Receive and record transfer info .....	.....	.....	3	4.38	4.38
Total Costs .....	.....	.....	.....	.....	8.76
Total Cost Savings .....	.....	.....	.....	.....	(10.88)
Net Cost Savings .....	.....	.....	.....	.....	(2.12)

#### Estimated Number of Transfers

As mentioned earlier, in order to calculate the total cost savings, DEA applied the \$2.12 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 for the analysis period, the first five years after the rule goes into effect, and applying an estimated percentage of EPCS that will be transferred.<sup>49</sup>

Surescripts' National Progress Reports for 2019, 2020, and 2021 form the basis for estimating the number of EPCS for the five-year analysis period.<sup>50</sup> The reports indicate that the rate of electronic prescribing for non-controlled substances (E-RX) was 76, 83, 86, 89, and 97 percent in 2017, 2018, 2019, 2020, and 2021, respectively.<sup>51</sup> Additionally, the reports indicate that the rate of EPCS is rising rapidly; the rate was 17, 26, 38, 58, and 73 percent in 2017, 2018, 2019, 2020, and 2021, respectively.<sup>52</sup> Furthermore, there were

65, 96.8, 134.2, 203.6, and 256.9 million EPCS filled in 2017, 2018, 2019, 2020, and 2021, respectively.<sup>53</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, 351.0, and 351.9 million in 2017, 2018, 2019, 2020, and 2021, respectively. Table 4 summarizes the data provided by the reports and the estimated total prescriptions for controlled substances for years 2017–2021.

<sup>49</sup> Due to the rapidly evolving industry and regulatory conditions, the analysis period is five years.

<sup>50</sup> Surescripts, "2019 National Progress Report" for 2017 data, "2020 National Progress Report" for 2018–2020 data, and "2021 National Progress Report" for 2018–2021 data.

<sup>51</sup> Ibid.

<sup>52</sup> Ibid.

<sup>53</sup> Ibid.

TABLE 4—ESTIMATED TOTAL PRESCRIPTIONS FOR CONTROLLED SUBSTANCES  
[2017–2021]

	2017	2018	2019	2020	2021
<i>Non-Controlled Substances:</i>					
Rate of E–Rx (%) .....	76	83	86	89	97
<i>Controlled Substances:</i>					
Total Rx, E and non-E (millions of Rx) .....	382.4	372.3	353.2	351.0	351.9
Rate of EPCS (%) .....	17	26	38	58	73
Total EPCS (millions of Rx) .....	65.0	96.8	134.2	203.6	256.9

As shown in Table 4, the estimated total prescriptions for controlled substances decreased from 382.4 million in 2017 to 351.9 million in 2021. For the purposes of this analysis, DEA estimates the total number of controlled substances prescriptions will stay constant at 351.9 million per year for the five-year analysis period.

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 year one due to a CMS December 2020 rule, which requires electronic prescribing for all controlled substances (with some exceptions) covered under Medicare Part D.<sup>54</sup> The 2021 rate of electronic prescriptions for non-controlled substances was 97 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 97 percent and the rate of electronic prescribing for controlled substances will be 97 percent for the analysis period. Multiplying the estimated total number of controlled substance prescriptions, 351.9 million per year, by the estimated rate of EPCS of 97 percent, the estimated total EPCS is 341.3 million per year for the analysis period, the first five years after the rule goes into effect.

CMS estimates that as much as four percent of electronic prescriptions for non-controlled substances in 2019 were transfers.<sup>55</sup> Applying the four percent transfer rate to the total EPCS prescriptions, DEA estimates the number of transfers is 13.7 million per year for each of the first five years.

#### Total Cost Savings

In order to calculate the total cost savings, DEA applied the \$2.12 net cost savings per transaction to the estimated 13.7 million transfers, resulting in a total annual net cost savings of \$29.0 million over the five-year analysis period. The net present value (NPV) of the cost savings is \$132.8 million at three percent discount rate and \$118.9 million at seven percent discount rate. The annualized cost savings from year one to year five is \$29.0 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 .....	\$132.8	\$118.9
Annualized Cost Savings .....	29.0	29.0

#### *Executive Order 12988, Civil Justice Reform*

This final 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 final rule does not have federalism implications warranting the application of E.O. 13132. The final 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 final 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 rule on small entities. DEA's evaluation of economic impact by size category indicates that the rule will not 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 final rule and estimates that it will have minimal economic impact on affected entities, including small businesses, nonprofit organizations, and small governmental jurisdictions.

DEA is amending its regulations to allow the transfer of electronic prescriptions for schedules II–V controlled substances between registered retail pharmacies for initial dispensing, upon request from the patient, on a one-time basis only. This amendment specifies the procedure that must be followed and the information that must be documented when transferring EPCS between DEA-registered retail pharmacies.

The final rule specifies that: the transfer must be communicated directly between two licensed pharmacists; the prescription must be transferred in its electronic form and may not be converted to another form (e.g., facsimile) for transmission; the required prescription information must be unaltered during the transmission; and the transfer of EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law. 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

<sup>54</sup> 85 FR 84472 (Dec. 28, 2020).

<sup>55</sup> Conference call between CMS and DEA, January 2021. CMS's estimate is a "high" estimate and "four percent" is considered the maximum percent of electronic prescriptions that are transfers.

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 pharmacist receiving the transferred prescription 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, the final rule requires that the electronic records documenting the transfer 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.

DEA anticipates this final 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 this final rule. There may be other small entities under Small Business Administration size standards in other NAICS code industries affected by this final 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.

CMS estimates that as much as four percent of electronic prescriptions for non-controlled substances in 2019 were transfers.<sup>56</sup> DEA assumes, for the purposes of this analysis, that 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 will be affected by this final rule.

In order to determine whether the final rule will result in a significant impact on the affected 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 \$2.92 (the cost of transferring the

prescription, \$4.38 (2.b.), minus the cost of updating the prescription record to note that the prescription was not filled, \$1.46 (2.a.)). The cost to the receiving pharmacy is \$4.38 (8.b.) per transfer. Each transfer affects two different pharmacies, the transferring and receiving pharmacies. Since pharmacies are likely to transfer and receive, an average was taken to determine the typical cost per transfer for a pharmacy. The average cost is \$3.65 ((\$2.92 + \$4.38)/2) per transfer. Also, from Table 3, the total cost savings to a prescriber (office of physician or hospital) is \$6.82, the sum of the cost savings from not receiving a call from the patient \$2.13 (6.) and the cost savings from not issuing a new prescription \$4.69 (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 13.7 million per year. Multiplying the average net cost of \$3.65 per transfer for pharmacies by 13.7 million transfers, the estimated total cost of transfers to all pharmacies is \$50,005,000 per year. Multiplying the cost saving of \$6.82 per transfer for prescribers (office of physician or hospital) by 13.7 million

transfers, the estimated total cost saving to all prescribers is \$93,434,000 per year.

The U.S. Census Bureau's Statistics of U.S. Businesses (SUSB) is an annual series that provides national and subnational data on the distribution of economic data by enterprise size and industry. SUSB data includes the number of firms at various size ranges. For the purposes of this analysis, the term "firm" as defined in the SUSB is used interchangeably with "entity" as defined in the RFA. Based on SUSB data, there are 19,234, 161,286, and 2,560 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>57</sup> Furthermore, the total receipts for all firms, including all size ranges, are \$282 billion, \$474 billion, and \$997 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>58</sup> Table 7 summarizes the SUSB data and provides receipt values without rounding.

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 ...	19,234	281,653,229
621111 .....	Offices of Physicians (except Mental Health Specialists) .....	All size ranges ...	161,286	473,954,346
622110 .....	General Medical and Surgical Hospitals .....	All size ranges ...	2,560	997,368,727

<sup>56</sup> Conference call between CMS and DEA, January 2021. CMS's estimate is a "high" estimate and "four percent" is considered the maximum percent of electronic prescriptions that are transfers.

<sup>57</sup> SUSB, 2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size, U.S., 6-digit NAICS, <https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html> (<https://www2.census.gov/programs-surveys/susb/>

[tables/2017/us\\_6digitnaics\\_rcptsize\\_2017.xlsx](https://www2.census.gov/programs-surveys/susb/tables/2017/us_6digitnaics_rcptsize_2017.xlsx)). (Accessed June 8, 2022.) 2017 data by enterprise receipt size is the latest available.

<sup>58</sup> Ibid.

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 666 firms with receipts under \$100,000, and their combined receipts is \$34,342,000. Dividing \$34,342,000 by 666 results in an average receipt of \$51,565 per firm. Performing the same calculation for all three industries, the average receipt per firm is \$51,565, \$50,554, and \$259,478 for the smallest size category in

446110—Pharmacies and Drug 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	666	34,342	51,565
621111 .....	Offices of Physicians (except Mental Health Specialists) .....	<100,000	14,302	723,029	50,554
622110 .....	General Medical and Surgical Hospitals .....	100,000–* 499,999	23	5,968	259,478

\* “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 666 firms with receipts under \$100,000 in 446110—Pharmacies and Drug Stores industry sector is \$34,342,000. This is 0.0121930 percent of total receipt of \$281,653,229,000 for all size ranges. Allocating 0.0121930 percent of total cost to pharmacies of \$50,005,000 to the 666 firms, the

average cost per firm is \$9.<sup>59</sup> Dividing the average cost per firm of \$9 by the average receipt per firm of \$51,565, the average cost per firm is 0.01745 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 is 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 0.01745 percent, 0.01978 percent, and 0.00925 percent for 446110—Pharmacies and Drug 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	666	0.012193	6,097	9	0.01745
621111 .....	Offices of Physicians (except Mental Health Specialists) .....	<100,000	14,302	0.152552	142,536	10	*(0.01978)
622110 .....	General Medical and Surgical Hospitals .....	100,000–499,999	23	0.000598	559	24	*(0.00925)

\* Cost savings.

In conclusion, the average cost or cost savings per firm as percent of receipt of 0.01745 percent, 0.01978 percent, and 0.00925 percent are not significant economic impacts. Therefore, DEA concludes this final rule will not have a significant economic impact on a substantial number of small entities.

#### 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 final

rule will 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 rule and has submitted this collection request to the Office of Management and Budget (OMB) for review and approval.<sup>60</sup> This final rule establishes the 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

<sup>59</sup> (\$50,005,000 x 0.0121930 percent)/666 = \$9.

<sup>60</sup> 44 U.S.C. 3501 *et seq.*

obtained at <https://www.reginfo.gov/public/do/PRAMain>.

#### A. Collections of Information Associated With the 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:** 1117–0061.

**DEA Form Number:** N/A.

DEA is creating a new collection of information by requiring pharmacies to create and maintain certain records relating to the transfer of unfilled EPCS between pharmacies for initial filling. The rule requires the transferring pharmacy to note in the electronic prescription record that the prescription was transferred. The transferring pharmacy is also 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 requires 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 required 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.

If you need additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 776–2265.

Any additional comments on this collection of information may be sent in writing 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.

#### Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

#### Signing Authority

This document of the Drug Enforcement Administration was signed on July 20, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

#### List of Subjects 21 CFR Part 1306

Drug traffic control, Prescription drugs.

For the reasons stated in the preamble, DEA amends 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, 829a, 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, upon request from the patient, on a one-time basis only. If the transferred prescription is for a controlled substance in Schedule III, IV, or V and includes authorized refills, the refills are transferred with the initial prescription to the pharmacy receiving the transfer.

(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 this part 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.

(6) In lieu of manual data entry, the transferring or receiving pharmacy’s prescription processing software may, if capable, capture the information required, as outlined in this paragraph (f), from the electronic prescription and automatically populate the corresponding data fields to document the transfer of an electronic controlled substance prescription between pharmacies. The transferring or receiving pharmacist, as applicable, must ensure that the populated information is complete and accurate.

(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 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.

**Scott Brinks,**

*Federal Register Liaison Officer, Drug Enforcement Administration.*

[FR Doc. 2023–15847 Filed 7–26–23; 8:45 am]

**BILLING CODE 4410–09–P**

## LIBRARY OF CONGRESS

### Copyright Office

#### 37 CFR Parts 222 and 235

[Docket No. 2023–4]

#### Copyright Claims Board: Agreement-Based Counterclaims

**AGENCY:** U.S. Copyright Office, Library of Congress.

**ACTION:** Final rule.

**SUMMARY:** Pursuant to the Copyright Alternative in Small-Claims Enforcement Act, the U.S. Copyright Office is adopting as final a May 3, 2023, proposed rule governing the filing of agreement-based counterclaims and related discovery requirements in Copyright Claims Board proceedings.

**DATES:** Effective August 28, 2023.

**FOR FURTHER INFORMATION CONTACT:** Rhea Efthimiadis, Assistant to the General Counsel, by email at [meft@copyright.gov](mailto:meft@copyright.gov) or telephone at (202) 707–8350.

**SUPPLEMENTARY INFORMATION:** The Copyright Alternative in Small-Claims Enforcement Act of 2020 (the “CASE Act”) <sup>1</sup> directed the Copyright Office to establish the Copyright Claims Board (the “CCB”), an alternative and voluntary forum for parties seeking to resolve certain copyright-related disputes that have a total monetary value of \$30,000 or less. After receiving and considering comments from the public, the Office published final rules addressing various aspects of CCB proceedings. <sup>2</sup> On June 16, 2022, the CCB began receiving claims.

On May 3, 2023, the Office published a notice of proposed rulemaking (“NPRM”) seeking public comment on a proposed rule addressing the filing of agreement-based counterclaims and related discovery requirements in the CCB. <sup>3</sup> The proposed regulations set out the requirements for the content of such counterclaims and any responses to them. <sup>4</sup> The Office also proposed standard interrogatories and standard requests for the production of documents for use in connection with such counterclaims. <sup>5</sup>

The Office received one comment that addressed the proposed rulemaking, but did not recommend any changes to the proposed regulatory text. <sup>6</sup> The Copyright Alliance’s comment stated that “[a]t this time, we have no substantive objections to the Office’s proposal to add regulations specifically governing agreement-based counterclaims,” <sup>7</sup> but requested “the opportunity to comment further on the rules established in this notice of proposed rulemaking as well as the other regulations governing the CCB once there is more qualitative and quantitative data to consider.” <sup>8</sup> The Copyright Alliance “reiterate[d] the importance of ensuring that the rules and regulations do not become so cumbersome and complex such that they make the CCB inaccessible to pro se litigants, who comprise a significant portion of the system’s users, and whom the statute was designed to accommodate.” <sup>9</sup>

The Office appreciates these comments and will take them under advisement. Because the Office did not receive any comments recommending changes to the proposed rule, it adopts the rule as final.

#### List of Subjects in 37 CFR Parts 222, 225

Claims, Copyright.

#### Final Regulations

For the reasons stated in the preamble, the U.S. Copyright Office

2022) (active proceedings final rule); 87 FR 36060 (June 15, 2022) (active proceedings correction). The Office sought public comments prior to the adoption of these final rules. *See, e.g.,* 86 FR 74394 (Dec. 30, 2021); 86 FR 53897 (Sept. 29, 2021); 86 FR 69890 (Dec. 8, 2021).

<sup>3</sup> 88 FR 27845 (May 3, 2023).

<sup>4</sup> 88 FR 27845, 27846–47.

<sup>5</sup> 88 FR 27845, 27846–48.

<sup>6</sup> *See* Copyright Alliance Comments. The Office received a second comment, which addressed songwriter-related royalty claims that are outside of the scope of this rulemaking. *See* Timothy Gilmore Comments at 1.

<sup>7</sup> Copyright Alliance Comments at 1.

<sup>8</sup> Copyright Alliance Comments at 1–2.

<sup>9</sup> Copyright Alliance Comments at 2.

amends 37 CFR parts 222 and 225 as follows:

#### PART 222—PROCEEDINGS

■ 1. The authority citation for part 222 continues to read as follows:

**Authority:** 17 U.S.C. 702, 1510.

■ 2. Amend § 222.9 as follows:

■ a. Redesignate paragraphs (c)(6) through (8) as paragraphs (c)(7) through (9), respectively.

■ b. Add paragraph (c)(6) as follows:

##### § 222.9 Counterclaim.

\* \* \* \* \*

(c) \* \* \*

(6) For a counterclaim arising under an agreement asserted under paragraph (c)(2)(iv) of this section—

(i) A description of the agreement that the counterclaim is based upon;

(ii) A brief statement describing how the agreement pertains to the same transaction or occurrence that is the subject of the infringement claim against the counterclaimant; and

(iii) A brief statement describing how the agreement could affect the relief awarded to the claimant;

\* \* \* \* \*

■ 3. Amend § 222.10 as follows:

■ a. Redesignate paragraph (b)(6) as paragraph (b)(7).

■ b. Add paragraph (b)(6) as follows:

##### § 222.10 Response to counterclaim.

\* \* \* \* \*

(b) \* \* \*

(6) For counterclaims arising under an agreement, as set forth in 37 CFR 222.9(c)(2)(iv), a statement describing in detail the dispute regarding the contractual counterclaim, including any defenses as well as an explanation of why the counterclaim respondent believes the counterclaimant’s position regarding the agreement lacks merit; and

\* \* \* \* \*

#### PART 225—DISCOVERY

■ 4. The authority citation for part 225 continues to read as follows:

**Authority:** 17 U.S.C. 702, 1510.

■ 5. Amend § 225.2 as follows:

■ a. Redesignate paragraph (f) as paragraph (h).

■ b. Add paragraphs (f) and (g) as follows:

##### § 225.2 Standard interrogatories.

\* \* \* \* \*

(f) *For a counterclaimant asserting a counterclaim arising under an agreement.* In addition to the information in paragraph (a) of this section, the *standard interrogatories* for

<sup>1</sup> Public Law 116–260, sec. 212, 134 Stat. 1182, 2176 (2020).

<sup>2</sup> 87 FR 20707 (Apr. 8, 2022) (law student representation final rule); 87 FR 12861 (Mar. 8, 2022) (initial proceedings partial final rule); 87 FR 16989 (Mar. 25, 2022) (initial proceedings final rule); 87 FR 24056 (Apr. 22, 2022) (initial proceedings correction); 87 FR 30060 (May 17,