



Via Electronic Submission to: www.regulations.gov

January 18, 2022

Scott A. Brinks
Regulatory Drafting and Policy Support Section
Diversion Control Division
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, VA 22152

Re: RIN 1117-AB64/Docket No. DEA-637, Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances Between Pharmacies for Initial Filling

Dear Mr. Brinks:

The American Pharmacists Association (APhA) is pleased to submit our comments to the Drug Enforcement Administration (DEA) on the Notice of proposed rulemaking (NPRM) on the “Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances Between Pharmacies for Initial Filling,” published in the Federal Register on November 19, 2021 (86 FR 64881). Founded in 1852, APhA is the largest association of pharmacists in the United States representing the entire pharmacy profession. APhA members practice in community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA members report that receiving electronic prescriptions for controlled substances (EPCS) has improved the workflow at their pharmacies. EPCS can reduce prescribing errors, eliminate difficulties reading prescribers’ handwriting, prevent diversion by eliminating lost, forged, and/or altered paper prescriptions, and be included as part of the integrated electronic health record (EHR). APhA agrees with DEA that patients prescribed controlled substances electronically should have the same ability as patients issued paper controlled substance prescriptions to choose an alternate pharmacy if the first pharmacy is unable to fill a prescription.¹

¹ 86 FR 64881, p. 64882.

Benefits of the NPRM from a Patient Care Standpoint

From a patient care standpoint, APhA supports DEA’s proposal to allow the transfer of electronic prescriptions for Schedule II-V controlled substances between pharmacies for initial filling. APhA had asked DEA for clarity on this issue in our June 22, 2020 comments to the agency on RIN 1117-AA61/Docket No. DEA-218I, Electronic Prescriptions for Controlled Substances, Interim Final Rule with Request for Comment.² There are instances where a Schedule II-V prescription is received, opened, and processed at a pharmacy but dispensing may not occur at that pharmacy. The change in dispensing pharmacy may be due to patient preference of where to pick-up their prescription, the medication being out of stock, formulary/insurance coverage determinations, or other issues. This NPRM is designed to address this issue.

As examples of the benefits of this NPRM from a patient care perspective, APhA members reported that this proposal would help patients to more seamlessly secure access to buprenorphine for the treatment of opioid use disorder, as many pharmacies do not currently carry buprenorphine. Another member reported that allowing the transfer of Schedule II-V controlled substances for purposes of initial filling would be helpful for those patients filling a prescription for a stimulant medication, since there are many stimulant products available, and pharmacies may not have the particular prescribed medication in stock. Allowing the prescription to be transferred to another pharmacy would eliminate the need for the prescriber to be contacted and avoid delays in patients receiving their medication.

Concerns about Implementation of EPCS Transfers Between Pharmacies for Initial Filling

From a practical implementation standpoint, APhA is concerned that pharmacies might not be able to transfer EPCS to another pharmacy for initial filling. APhA members reported that the NPRM’s requirement that the prescription remain in its electronic form would prevent some pharmacies from being able to transfer the EPCS. While the technical ability to transfer EPCS between pharmacies became available with NCPDP’s SCRIPT version 2017071, many pharmacy vendors have not implemented this functionality. As a result, many pharmacies are not able to transfer EPCS. While pharmacies in the same chain might be able to electronically transfer to another pharmacy in the chain because they share a common database, independent community pharmacies are not linked in this manner.

² American Pharmacists Association. Comments to DEA on Docket No. DEA-218I, Electronic Prescriptions for Controlled Substances, Interim Final Rule with Request for Comment. June 22, 2020, available at: https://aphanet.pharmacist.com/sites/default/files/APhA_Comments_to_DEA_on_EPCS.pdf

For this reason, APhA believes that it is important for DEA to allow but not require the transfer of EPCS between pharmacies for initial filling. To address technological limitations, APhA recommends that DEA allow pharmacies to transfer an EPCS to another pharmacy via phone or fax.

Comments on the Cost of the NPRM

APhA notes that while DEA estimates overall health system cost savings from this proposal of \$22 million,³ pharmacies bear the brunt of the total estimated costs. DEA estimates that it will cost pharmacies 6 minutes/\$7.33 per transfer,⁴ for a total annual cost of \$91,625,000.⁵ These costs – both in financial terms and pharmacists’ time – are significant, especially in a busy pharmacy setting where every minute counts.

In addition, while DEA recognizes that pharmacies would incur system and implementation expenses, including modifying software configurations, updating business processes, and training personnel, the agency does not factor these costs into the cost of this proposal. APhA respectfully requests that DEA take steps to lessen the burden of this proposal on pharmacies and pharmacists. For example, DEA could streamline the documentation process. The agency could also work with pharmacies to ensure that everyone has the proper software to implement the transfer functionality, perhaps by providing grants for software upgrades. Finally, DEA could meet with pharmacy owners and corporations to discuss ways to improve implementation in a way that allays the time concerns of pharmacists.

Conclusion

While APhA supports DEA’s proposal to allow the transfer of EPCS between pharmacies for initial filling from a patient care perspective, we have concerns about the feasibility of implementing this proposal and the increased burden on pharmacies and pharmacists – in terms of both time and money. For this reason, APhA urges DEA to allow – but not require -- the transfer of EPCS between pharmacies for initial filling and to take steps to reduce the burden of this proposal on pharmacies and pharmacists.

³ 86 FR 64881, p. 64883.

⁴ Id. at p. 64889.

⁵ Id. at p. 64899.



Thank you for your attention to our concerns. If you have any questions or require additional information, please contact Karin Bolte, Director, Health Policy, at kbolte@aphanet.org or by phone at (202) 558-2727.

Sincerely,

A handwritten signature in black ink that reads 'Ilisa BG Bernstein'. The signature is written in a cursive style with a horizontal line at the end.

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs