



Via Electronic Submission to: www.regulations.gov

June 22, 2020

Scott A. Brinks
Diversion Control Division
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, VA 22152

Re: RIN 1117-AA61/Docket No. DEA-218I, Electronic Prescriptions for Controlled Substances, Interim Final Rule; reopening of comment period

Dear Mr. Brinks:

The American Pharmacists Association (APhA) is pleased to submit our comments to the Drug Enforcement Administration (DEA) during the reopening of the comment period on DEA's Interim Final Rule (IFR) on Electronic Prescriptions for Controlled Substances (EPCS), published in the Federal Register on April 21, 2020 (85 FR 22018). Founded in 1852, APhA represents pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA appreciates DEA's efforts to clarify issues related to electronic prescribing for controlled substances. In addition to our June 1, 2010 joint comments¹ with the American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, and National Community Pharmacists Association, APhA offers the following comments on the IFR:

Outstanding EPCS Issues and DEA's Need for Additional Comments

¹ American Pharmacists Association, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, and National Community Pharmacists Association. Comments to DEA on Docket No. DEA-218I, Electronic Prescriptions for Controlled Substances, Interim Final Rule with Request for Comment. June 1, 2010, available at: <https://www.regulations.gov/document?D=DEA-2010-0010-0091>

Question 1

DEA currently requires that the authentication credential be two-factor to protect the practitioner from internal misuse, as well as external threats. Is there an alternative to two-factor authentication that would provide an equally safe, secure, and closed system for electronic prescribing of controlled substances while better encouraging adoption of EPCS? Are practitioners using universal second factor authentication (U2F)?

Comments

APhA agrees with the Pharmacy Health Information Technology (HIT) Collaborative’s comments stating “EPCS two-factor authentication (2FA) agents need to be interoperable with other systems, especially pharmacy systems, to be successful, and particularly if a prescriber is practicing in more than one care setting. EPCS should also require vendors to make authentication sharable and transferrable with other systems, which would enhance interoperability. Currently, prescriber adoption (including at long-term post-acute care settings) of EPCS is not where it needs to be. Adoption has been slow for various reasons. Reasons for slow adoption include, not all systems are interoperable; some technologies used are cumbersome; some health care settings are having difficulty integrating EPCS software with outpatient practitioners’ clinics and hospital systems; challenges with integrating EPCS to prescription drug monitoring systems; and there are still technical issues with 2FA.”

APhA agrees with the Pharmacy HIT Collaborative’s recommendation to move toward U2F: “Although 2FA is secure, it is an older technology and can break access with other services. The Collaborative would encourage the DEA to move toward U2F security key, particularly if using a mobile device. U2F is the new security standard, is interoperable, and is more secure than the current 2FA. FIDO certified U2F should be used.”

APhA notes that some community pharmacies lack the electronic prescribing software/systems to perform two-factor authentication. Members point out that no funds were allocated to pharmacies to support necessary technology adoption and implementation, although they were provided for adoption of EHR by other providers.² As a result, the financial burden to implement these systems falls on the pharmacies.

Question 6 – Security Incidents

The IFR requires that security events—auditable events that compromise or could compromise the integrity of the prescription records of an electronic prescription application—be reported to both the application’s provider and DEA within one business day. DEA is seeking comment from EPCS application users on whether they have experienced a security incident and, if so, whether they have experienced any difficulties reporting it.

² The Health Information Technology for Economic and Clinical Health (HITECH) Act (part of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5)), has specific meaningful use of electronic health records (EHR) criteria, and incentivizes the use of EHRs through financial payments.

Comments

APhA is not aware of members who receive EPCS and dispense controlled substances to patients who have experienced security incidents.

Question 7 – EPCS Implementation Issues

DEA is generally seeking comment on any aspects of the IFR or other EPCS areas where further clarification would be helpful.

- *What types of issues have registrants encountered during the adoption and implementation of EPCS into their workflow, particularly where a prescriber uses an electronic health record (electronic medical record)?*

Comments

APhA members reported that 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).

1) DEA should provide additional clarification on transferring C-II prescriptions

The major concern that APhA members identify is lack of clarity on pharmacists' ability to transfer unfilled C-II electronic prescriptions from one pharmacy to another, and the requirements that must be met to do so. This occurs specifically in the context of electronic prescriptions for ADHD medications, among others. There are instances where a C-II 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.

APhA notes that DEA regulations do not specifically allow for the transfer of unfilled C-II prescriptions in any form, and only specifically allow for the transfer of original information from schedule III-V prescriptions in any form for purposes of refill only.³ However, DEA has indicated its current policy in a letter to a stakeholder⁴ that any unfilled EPCS for a schedule II-V controlled substance may be transferred to another pharmacy. APhA requests that DEA issue guidance and/or codify this schedule II-V EPCS transfer policy in its regulations so the policy is clear and unambiguous.

³ See 21 CFR §1306.25

⁴ DEA. Letter to the National Association of Chain Drug Stores. October 6, 2017, available at: https://cdn.ymaws.com/www.ascp.com/resource/resmgr/files/DEA_Redirection_Issue.pdf

2) Third-party audits or certifications

Pharmacies are subjected to numerous audits that significantly impact operations and patient care delivery. Because there are appropriate and adequate checks and balances in place, APhA believes that third-party audits or certifications should be done when there is a significant event that may impact functionality. APhA supports the Pharmacy HIT Collaborative's recommended change to 21 CFR §1311.300(a)(2) Application provider requirements - Third-party audits or certifications. (a)(2) currently says: "Whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first." The change would amend (a)(2) to read: Whenever a functionality related to controlled substance prescription requirements is altered.

- ***What types of devices are currently being used to create, sign, transmit, and process controlled substances electronically? For example, are practitioners using iOS or Android mobile devices, Chromebooks, Windows Laptop/Desktops, Mac OS, or others?***

Comments

APhA members report using a wide variety of devices to create, sign, transmit, and process controlled substance prescriptions electronically, including both iOS and Android mobile devices, Windows laptops and desktops, and Mac OS. As the Pharmacy HIT Collaborative notes in its comments, "it should not matter what system or communication device (e.g., cellphone, laptop, etc.) is being used, as long as all systems recognize the prescriber."

Question 9 – Transmission Failure

As DEA notes in the Federal Register notice, if the practitioner is informed that the prescription's transmission has failed, he or she may provide a paper or oral (where permitted) prescription as a replacement (including a manually signed printout of the electronic prescription), but must ensure that the replacement prescription indicates that the prescription was originally issued electronically but that transmission failed. Before filling such a replacement prescription, a pharmacist must check his or her records to ensure that the electronic prescription was not already received and filled. If it was, the replacement prescription must be marked void. In this manner, the IFR seeks to ensure that electronic prescriptions will not be filled twice.

Previous commenters have expressed concern regarding failed transmissions of electronic prescriptions. DEA is seeking comment in response to the following questions:

- ***Have any entities experienced failed transmissions (e.g., an EPCS being sent to the wrong pharmacy, an incorrectly filled out EPCS, an EPCS fails to send, the pharmacy does not have the prescribed controlled substance in stock, or the pharmacy rejects the EPCS)?***

Comments

1) EPCS Transmission to the Wrong Pharmacy

APhA members report numerous instances of EPCS being sent to the wrong pharmacy. In these cases, the pharmacist must contact the prescriber to alert him/her to the error. The prescriber must then cancel the EPCS that was sent to the wrong pharmacy and reissue and transmit the prescription to the correct pharmacy. APhA is concerned about the existence of potential duplicate prescriptions if the prescriber fails to cancel the original EPCS.

2) Incorrectly filled out EPCS

There are also instances where an EPCS is incorrectly filled out. In this case, the pharmacist must contact the prescriber to ask him/her to correct the error(s). APhA members report that it can be very time consuming for the pharmacist to have to track down the prescriber, especially when the prescriber is out of the office or the office is closed. However, as one APhA member stated: “This is what pharmacists have always done to ensure patient access to their medications.”

3) Controlled Substance Not in Stock

APhA members report instances where their pharmacies did not have the prescribed controlled substance in stock. In that case, the pharmacists were able to place an order for next day delivery to the pharmacy, at which time the controlled substance was dispensed to the patient.

- *If any failed transmissions have occurred, what alternative means of submitting the prescription to the pharmacy have been used?*

Comments

APhA members report instances of failed EPCS prescriptions. One APhA member explained that if there was an error in the EPCS, it would not come into their pharmacy’s e-system but would be transmitted to the pharmacy via fax instead. Similarly, an APhA member in a hospice pharmacy reported that if an EPCS failed, the pharmacist requested a faxed prescription from the prescriber. These faxed prescriptions posed problems, however, because they were then subject to state standards for written controlled substance prescriptions.

Conclusion

APhA appreciates DEA’s efforts to clarify issues related to electronic prescribing of controlled substances and appreciates the opportunity to provide comments on this important issue. If you have any questions or require additional information, please contact Karin Bolte, Director, Health Policy, at kbolte@aphanet.org or by phone at (301) 648-0673.

Sincerely,

A handwritten signature in cursive script that reads "Ilisa BG Bernstein". The signature is written in black ink and is positioned below the word "Sincerely,".

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