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 2181: Reopened Electronic Prescriptions for Controlled Substances; Interim Final Rule

Dear Mr. Brinks:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we are pleased to submit comments regarding RIN 1117-AA61/Docket No. DEA 2181: Electronic Prescriptions for Controlled Substances; Interim Final Rule (IFR).

The Collaborative has been involved with the federal agencies, including the Drug Enforcement Administration (DEA), regarding the use of technology in providing health care and developing the national health information technology (HIT) framework since 2010. The Collaborative is committed to furthering and improving the electronic exchange of health care information.

Pharmacists provide essential services to patients and are users of health IT, particularly, e-prescription (eRx) and electronic medical record (EMR)/electronic health record (EHR) systems. The Collaborative supports the use of these systems, which are important to pharmacists in working with other health care providers to provide needed medications and transmit patient information related to overall patient care, transitions of care, immunization (historical and administered), immunization registry reporting, medication lists, medication allergies, allergy reactions, patient problem lists, smoking status, reporting to public health agencies, clinical decision support services/knowledge artifacts, drug formulary checking, and electronic prescribing.

The following are our comments on a few of the outstanding electronic prescriptions for controlled substances (EPCS) issues posed by DEA regarding RIN 1117-AA61/Docket No. DEA 2181: Electronic Prescriptions for Controlled Substances.
The electronic prescriptions for controlled substances (EPCS) rule focuses on ambulatory care settings. With the reopening of the EPCS rule, the Collaborative believes the DEA should address other types of settings (e.g., long-term care facilities, hospitals, clinics) and the requirements at a higher level of authorizing agent where the use of EPCS can reduce prescribing errors, increase efficiency, prevent diversion, be part of the integrated electronic health record, and help save on health care costs. Additionally, with the onset of the COVID-19 pandemic and the potential for future pandemics or national emergencies, it is clear that technology should be leveraged and used as much as possible. The current pandemic has shown several vulnerabilities within the health care system, which EPCS could assist in resolving issues related to medication administration. The goal of reopening this rule needs to ensure EPCS is as secure as paper prescriptions, improves usability, and that any barrier to adopting and using EPCS is removed.

**Outstanding EPCS Issues for Additional Comments**

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 substance while better encouraging adoption of EPCS? Are practitioners using universal second factor authentication (U2F)? Are practitioners using cellular phones as a hard token, or as part of two-factor authentication? Is short messaging service (SMS) being used as one of the authentication factors used for signing controlled substance prescriptions?

**Comment**

The Collaborative believes 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.

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.

Some prescribers report needing to use SMS, especially when new controlled substance prescriptions are needed during non-business hours when patients are transferred to post-acute facilities. SMS is challenging for prescribers at that time and not as secure.

The Collaborative also recommends that DEA allow long-term care facilities to assign a designated agent nurse to transmit Schedule III-V orders. This will help alleviate some of the burden of orders not reaching the pharmacy in a timely manner.

2. DEA is seeking comment on the approach to identity proofing and whether clarification of the language regarding credential service provider (CSP) approval would be helpful.

Comment

The Collaborative believes clarifying language regarding CSP approval is needed and that the process needs to be standardized, especially if these guidelines are to be applied for use outside of government IT systems to implement EPCS. Although the IFR requires using Assurance Level 3 of the NIST SP 800-63-1, “Electronic Authentication Guideline,” these guidelines define technical requirements for federal agencies implementing digital identity services; they’re not standards, as the National Institute of Standards and Technology (NIST) notes. The guidelines cover identity proofing and authentication of those interacting with government IT systems over open networks, not those interacting with EPCS outside of government IT systems.²

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

Comment

As noted previously, the Collaborative believes EPCS 2FA authentication agents and systems need to be interoperable with other systems, including pharmacy systems, to be successful, and particularly if a prescriber is practicing in more than one care setting. 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.

EHR applications that adopt EPCS systems need to able to do audits. EPCS audits should be stricter not less strict than manual audits and produce an audit trail. This is critical for preventing the diversion of controlled substances.

An additional concern is that hospitals use different EHR solutions than post-acute care facilities. If EPCS is used from the hospital to the post-acute care facility’s

² [https://pages.nist.gov/800-63-3/](https://pages.nist.gov/800-63-3/)
pharmacy, there generally is no record of the EPCS to the post-acute care’s EHR, as this would need a separate EHR account for each post-acute care facility.

The Collaborative supports the comment letter being submitted by the National Council for Prescription Drug Programs (NCPDP), especially the section that discusses incorporating NCPDP’s RxRenewal Request and RxRenewal Response for use in EPCS and the suggested change to §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.

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The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members, including those in pharmacy education and accreditation. The Collaborative’s membership is composed of the key national pharmacy associations involved in health information technology (HIT), the National Council of Prescription Drug Programs, and 14 associate members encompassing e-prescribing, health information networks, transaction processing networks, pharmacy companies, system vendors, pharmaceutical manufacturers, and other organizations that support pharmacists’ services.

As the leading authority in pharmacy health information technology, the Pharmacy HIT Collaborative’s vision and mission are to ensure the U.S. health IT infrastructure better enables pharmacists to optimize person-centered care. Supporting and advancing the use, usability, and interoperability of health IT by pharmacists for person-centered care, the Collaborative identifies and voices the health IT needs of pharmacists; promotes awareness of functionality and pharmacists’ use of health IT; provides resources, guidance, and support for the adoption and implementation of standards driven health IT; and guides health IT standards development to address pharmacists’ needs. For additional information, visit www.pharmacyhit.org.

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On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the RIN 1117-AA61/Docket No. DEA 2181: Electronic Prescriptions for Controlled Substances.

For more information, contact Shelly Spiro, executive director, Pharmacy HIT Collaborative, at shelly@pharmacyhit.org.

Respectfully submitted,

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