NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Submitted via: https://www.regulations.gov

June 19, 2020

The Honorable Timothy J. Shea
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Electronic Prescriptions for Controlled Substances Interim Final Rule - Reopening of Comment Period; Docket No. DEA–218I; RIN 1117–AA61

Dear Acting Administrator Shea:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to respond to the reopening of the comment period for the Interim Final Rule (IFR) regarding electronic prescriptions for controlled substances (EPCS). We strongly support the use of electronic prescriptions for controlled substances as an important tool to improve patient health outcomes and combat the misuse, abuse, and diversion of controlled substances.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

I. Introduction

For more than 20 years NACDS has collaborated with DEA on the development and implementation of policies and standards for EPCS. We remain committed to the use of electronic prescriptions for all medications, especially controlled substances. Our member companies have made substantial investments in technology and staff training to promote the secure, accurate, and reliable transmission and dispensing of controlled substance prescriptions for patients with legitimate medical need for these medications.

In 2015, DEA invited NACDS to meet and discuss the IFR, particularly any concerns with the IFR or modifications that we would recommend. Now, as back in 2015, our greatest concern continues to be that if DEA were to amend the IFR then we would urge DEA that such changes are not ones that would require pharmacies to alter their EPCS systems or pharmacy workflow.

NACDS members have designed their pharmacy operations and built their technology infrastructure around the specifications outlined in the EPCS IFR. Any new EPCS pharmacy mandates would require significant additional investment of resources and could take considerable time to implement.

NACDS appreciates this opportunity to reiterate our support for EPCS and to discuss the many advantages of encouraging further adoption of this valuable technology. **Considering the significant and substantial benefits of EPCS, we recommend that DEA go beyond encouraging its use, and require, rather than merely allow, EPCS in most circumstances.** Additionally, since DEA is seeking comments on any aspect of the IFR or other EPCS areas that need clarification, **NACDS recommends modifications to the requirements regarding the frequency at which third party audits must be conducted for application providers of pharmacy systems.** We have provided greater details regarding our recommendations below.

II. Significant Benefits Associated with EPCS

Chain pharmacy supports policies that promote the use of electronic prescribing to transmit prescription information between prescribers and pharmacists. Use of this technology improves safety and security in the prescribing process. EPCS is a vital component of the national effort to deter opioid abuse and diversion, as well as prevent overdoses.

Because of these benefits, adoption and utilization of electronic prescribing has continued to grow. According to the most recent data available, 2.1 billion prescriptions were issued electronically in the United States last year (accounting for 80% of all new prescriptions), of which 160 million were for controlled substances (accounting for *only 38%* of new controlled substance prescriptions).[1] Although these are promising statistics, there is room to further improve the rate of electronic prescribing, particularly with controlled substance prescriptions, which data show lag behind overall adoption of this beneficial technology.

A. EPCS Adds New Dimensions of Safety and Security

Electronic prescribing helps combat abuse and misuse of controlled substances. Electronic controlled substance prescriptions cannot be altered, cannot be copied, and are electronically trackable. Traditional paper prescriptions do not have these safeguards and can be at risk of unauthorized changes, as well as reproduction and diversion. Furthermore, the DEA IFR establishes strict security measures, such as two-factor authentication, that reduce the likelihood of fraudulent prescribing. Notably, the state of New York saw a 70% reduction in the rate of lost or stolen prescription forms after implementing its own mandatory electronic prescribing law.[2]

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[1] Surescripts' *2019 National Progress Report* is available here: https://surescripts.com/news-center/national-progress-report-2019/

[2] Remarks of Anita Murray, Deputy Director, New York State Department of Health at the Harold Rogers Prescription Drug Monitoring Program National Meeting (September 6, 2017)

B. Electronic Prescriptions Are Less Prone to Errors

According to a study conducted at a Johns Hopkins Medication outpatient pharmacy, 89% of handwritten prescriptions failed to meet best practice guidelines or were missing information that would otherwise be prompted by an electronic prescribing system. By comparison, not a single prescription in that study issued electronically contained these types of errors.[3] In fact, electronic prescribing has been shown to reduce medication errors in the ambulatory setting by as much as seven-fold.[4]

C. Electronic Prescribing Improves Patient Care and Outcomes

Electronic prescribing eliminates handwriting errors, and this technology allows prescribers to track whether the prescription was filled and how often it is refilled. This information can be extremely helpful in identifying excessive use and potential abuse of controlled substances. Electronic prescribing tools also enable clinical decision-making at the point of care. Electronic prescribing systems can be used to issue reminders about a days' supply limit for controlled substances and prompt prescribers to issue a naloxone prescription when using a high dose opioid medication for a patient at risk for an overdose.

Furthermore, when electronic prescribing is part of a healthcare provider's electronic health record system, prescriptions can be checked for interactions with patient medications, health conditions, and allergies. These processes, which are built into the electronic health record and electronic prescribing applications, enable prescribers to make better care decisions, deter abuse of controlled substances, and serve to improve patient outcomes.

D. Electronic Prescribing Improves Workflow in Healthcare Settings

Electronic prescribing reduces the administrative burden on physicians and clinical office staff responding to prescription refill authorization. Further, electronic prescribing streamlines the process of getting the prescription to the pharmacy, thereby reducing the time spent by pharmacists and prescribers on the phone.

E. Electronic Prescribing Drives Down Healthcare Costs

With electronic prescribing helping to reduce medication errors to as little as a seventh of their previous level, the associated cost savings due to improved patient outcomes and decreased

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[3] http://www.hopkinsmedicine.org/news/media/releases/researchers_find_handwritten_opioid_prescriptions_are_more_prone_to_mistakes_

[4] "Electronic Prescribing: Improving the Efficiency and Accuracy of Prescribing in the Ambulatory Care Setting"; *Perspect Health Inf Manag.;* 2014 Spring; 11 available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3995494/

patient visits are estimated to be between $140 billion and $240 billion over 10 years.[5] Substantial savings result from the decrease in adverse drug events, primarily due to reduced visits to primary care offices and emergency rooms.[6] Additionally, electronic prescribing enables the use of tools that allow for greater price transparency at the point of prescribing and enhanced formulary compliance, which further helps control healthcare spending. Electronic prescribing helps practitioners select the most appropriate treatment in order to reduce unnecessary care and costs.

III. Mandatory EPCS

Considering the numerous benefits of electronic prescribing, chain pharmacy urges the adoption of laws and policies requiring electronic prescriptions where practical. According to the *Surescripts 2019 National Progress Report*, with 13 states enacting electronic prescribing requirements in 2019, more than half of all states now require electronic prescribing for opioids, all controlled substances, or all prescriptions.

Moreover, recognizing the important role of electronic prescribing in helping to curb the opioid crisis, in 2018 Congress enacted legislation requiring controlled substances prescriptions covered under Medicare Part D to be electronically transmitted starting in 2021.[7] We encourage DEA to build upon this effort and update its regulations to require electronic prescribing for controlled substances where practicable.

NACDS urges DEA to amend the EPCS regulations to require that prescribers issue prescriptions for controlled substances in electronic format only, with exceptions where EPCS is impractical or could negatively impact patient care. NACDS understands that any such mandate must recognize circumstances in which a prescriber may not be able to issue prescriptions electronically. Therefore, NACDS recommends that DEA mandate EPCS with exceptions for prescriptions issued:

- By a veterinarian;
- When electronic prescribing is not available due to temporary technological or electrical failure;
- When a prescriber and dispenser are the same entity;
- That include elements that are not supported by the most recently implemented version of the National Council for Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT Standard;

[5] "Electronic Prescribing: Improving the Efficiency and Accuracy of Prescribing in the Ambulatory Care Setting"; *Perspect Health Inf Manag.*; 2014 Spring; 11(Spring) available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3995494/
[6] Ibid.
[7] The *Support for Patients and Communities Act* (H.R. 6) was enacted to include the *Every Prescription Conveyed Securely Act*, legislation requiring Schedule II through V controlled substances prescriptions covered under Medicare Part D to be electronically transmitted starting in 2021.

- By a practitioner for a drug that the federal Food and Drug Administration (FDA) requires the prescription to contain certain elements that are not able to be accomplished with electronic prescribing;
- By a practitioner allowing for the dispensing of a non-patient specific prescription pursuant to a standing order, approved protocol for drug therapy, or collaborative drug management or comprehensive medication management agreement, in response to a public health emergency, or other circumstances where the practitioner may issue a non-patient specific prescription;
- By a practitioner prescribing a drug under a research protocol;
- By a practitioner who has received a waiver or a renewal thereof for a specified period determined by the attorney general, not to exceed one year, from the requirement to use electronic prescribing, due to economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner; and
- By a practitioner who reasonably determines that it would be impractical for the patient to obtain a controlled substance prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition.

Moreover, because pharmacies and pharmacists do not have the ability to verify that a prescription properly falls under one of the EPCS exceptions listed above, we urge DEA to promulgate a rule clearly stating that, notwithstanding an EPCS mandate:

- pharmacists may continue to dispense medications from otherwise valid written, oral or fax prescriptions that are consistent with current laws and regulations; and
- DEA does not expect pharmacists and pharmacies to verify that an exception to the EPCS mandate exists.

IV. Modifying Third Party Audits or Certification Requirements for Pharmacy Applications

In response to DEA's request for comments on the need for clarification of the IFR or related EPCS guidance, NACDS asks DEA to consider a minor, but extremely helpful, modification to 21 CFR § 1311.300 - *Application provider requirements - Third-party audits or certifications*. NACDS members have made substantial technological investments to confirm that their EPCS applications comply with the IFR and any subsequent DEA guidance. As long-standing supporters of EPCS, NACDS members are diligent about ensuring that any modifications to their EPCS pharmacy software comply with standards for third-party audits and certifications.

We respectfully request DEA to reevaluate subparagraph (2) of the rule quoted below, and delete the text as indicated, which is unnecessary based upon the established business practices of NACDS members and pharmacy application vendors:

> § 1311.300 Application provider requirements- Third-party audits or certifications.
> (a) Except as provided in paragraph (e) of this section, the application provider of an electronic prescription application or a pharmacy application must have a third-party audit of the application that determines that the application meets the requirements of this part at each of the following times:
> (1) Before the application may be used to create, sign, transmit, or process controlled substance prescriptions.
> (2) Whenever a functionality related to controlled substance prescription requirements is altered ~~or every two years, whichever occurs first~~.

In today's environment, technology changes very rapidly. NACDS members are committed to using the most current pharmacy software applications to improve electronic prescribing functionality and security, especially for controlled substances. Consequently, NACDS member companies often may conduct third-party audits or certifications more frequently than every two years due to other pharmacy software updates, including upgrading to newer versions of CMS-mandated electronic prescribing technology standards (i.e., the NCPDP "SCRIPT standard"). Often, the CMS-mandated technology standard upgrade timelines do not align with other already scheduled pharmacy application upgrades and with the biennial third-party audit schedule. This results in pharmacy applications having to undergo unnecessarily redundant, costly, and frequent third-party audits. Removing the reference to conducting audits "*every two years*" streamlines the focus and reduces unnecessary administrative burdens, while also maximizing resource utilization for the compliance efforts of NACDS members and likely other pharmacies.

V. Conclusion

NACDS thanks DEA for this opportunity to comment on the reopening of the IFR for EPCS. We would welcome the opportunity to further discuss the outlined policy priorities and recommendations. If you have any questions, please do not hesitate to contact Kevin Nicholson, R.Ph., J.D., Vice President, Public Policy and Regulatory Affairs at knicholson@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer