June 2, 2020

Drug Enforcement Administration (DEA)
Attention: DEA Federal Register Representative/DPW
8701 Morrisette Drive
Springfield, VA 22152

RE: RIN 1117-AA61/Docket No. DEA-2181, Reopening of Comment Period in Interim Final Rule With Comment (IFC) on Electronic Prescribing for Controlled Substances

Dear DEA Staff:

Point-of-Care Partners, LLC (POCP) is pleased to provide comments on issues related to the IFC that were outlined in the April 21, 2020, *Federal Register* document. We applaud the agency for revisiting some requirements for electronic prescribing for controlled substances (EPCS). Numerous changes in technologies and the healthcare landscape have occurred since the Interim Final Rule (IFR) was issued in 2010 and they must be taken into account.

POCP is uniquely positioned to comment on DEA's requests for information and clarification as described in the April 21 document. We are a nationally recognized consulting firm in the areas of electronic prescribing (ePrescribing), including EPCS; standards and transactions to support payers, prescribers and pharmacies; specialty pharmacy automation; electronic exchange of health and administrative data among payers and providers; interoperability of electronic health records (EHRs) and other technologies, including mobile health (mHealth); and electronic medication management. POCP also provides related management and strategic consulting services in those areas to a wide range of stakeholders.

For the past 14 years, POCP has been a leader in the development of standards and transactions being adopted under the Health Insurance Portability and Accountability Act (HIPAA) and Medicare Part D, including those related to ePrescribing, EPCS, electronic prior authorization, and the real-time prescription benefit check and/or tools. We have testified frequently on standards and technology issues before the National Committee on Vital and Health Statistics (NCVHS), as well as provided technical assistance to both the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC). In fact, POCP testified on the need for EPCS at NCVHS's hearings in 2006, which helped inform the development of the DEA's IFR.

Our comments on the April 21 document fall into four categories: 1) the need for EPCS and synchronization of requirements by the federal government and states; 2) provider authentication; 3) approval of additional transactions; and 4) looking ahead to the post-COVID-19 era.

1. Synchronizing EPCS Requirements by the Federal Government and States. EPCS has slowly been gaining traction since it was allowed by the DEA beginning in 2010. According to the latest Surescripts statistics, 38% of controlled substance prescriptions are transmitted electronically. Adoption has been slow, in large part because of the DEA's complex requirements for credentialing and authentication of prescribers, some of which will be discussed below. That said, adoption will soon be trending upward

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due to two factors: the requirement that all controlled substance prescriptions for Medicare Part D beneficiaries be transmitted electronically beginning on January 1, 2021, as well as various state laws mandating EPCS. According to POCP's Regulatory Resource Center, a dozen states have some kind of EPCS mandate in place today and another 18 have passed EPCS mandates scheduled to go into effect between July 1, 2020 and January 1, 2022.

The impetus behind the state legislation is the recognition that use of EPCS can deter diversion and fraud in the fight against the opioid epidemic. As we -- and many others -- commented on the original IFR, EPCS not only improves the quality and safety of controlled substance prescribing, it is one of the most effective tools in curbing diversion and fraud. It prevents doctor shopping; providing electronic prescribing audit trails; thwarts forgeries and alterations of paper prescriptions; and eliminates the opportunity to steal paper prescription pads, which can then be used to obtain unlawful and often deadly prescription medications. This was true then and it is true today.

Despite the proven safety benefits, the patchwork of federal and state requirements concerning EPCS creates confusion in the market and leaves the door open to possible unintended diversion opportunities. Consistency is needed to ensure the most secure and efficient use of resources by law enforcement and the healthcare system.

> **Recommendation 1a:** We recommend the DEA support EPCS as a tool that furthers its core mission and develop policies that promote awareness and use of EPCS's potential to enhance drug diversion control.
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> **Recommendation 1b:** We urge the DEA to mandate a base-level utilization of EPCS nationally while enabling states to retain the ability to impose more stringent requirements. Doing so will eliminate the need for providers and technology vendors to support multiple workflows for controlled substance prescribing and better promote the safe and effective transmission of controlled substance prescriptions. In addition, patients would understand that controlled substances must be prescribed electronically in all states, regardless of whether they have Medicare coverage.
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> **Recommendation 1c:** We recommend that the DEA reopen the comment period in five years to assess and subsequently adopt new technologies that will support the agency's core mission and the changing needs of healthcare with regard to EPCS. A ten-year window for revisiting EPCS requirements is untenable in light of rapid developments that are occurring in technologies and the delivery of healthcare.

2. Prescriber authentication. The DEA's prescriber authentication requirements require a separate EHR workflow for EPCS from legend medications. Two separate workflows are viewed as burdensome by many prescribers. They also cause the prescriber to bear additional costs in order to comply. These, individually and cumulatively, have served as barriers to adoption.

As suggested in the April 21 *Federal Register* document, there are possible technology updates that would be compliant and more in sync with today's prescribing workflows. In particular are those authentication modalities that could be used with the prescriber's smart phone. Use of a smart phone in

care delivery is becoming increasingly important, and various mobile applications have burst into the healthcare mainstream in response to requirements of the 21st Century Cures Act and supporting regulations issued by the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Healthcare Information Technology (ONC).

Prescribers increasingly are using their smart phones and tablets to prescribe medications. This is true in the office and with the accelerated use of telemedicine in response to the COVID-19 crisis. (Experts believe telehealth will remain as a key diagnostic and treatment modality even after the crisis subsides.) Most telehealth platforms encompass both audio and video. It is important to note that many desktop computers do not have those capabilities. As a result, providers use their smartphones and tablets for the video visit, which are subsequently used for prescribing. With the COVID-19 crisis, video visits typically occur outside the physician's office. The DEA's original authentication and log-in requirements are not user-friendly and outside of these out-of-office workflows.

> **Recommendation 2a:** We recommend the DEA work in conjunction with federal and state agencies as well as the electronic prescribing industry to simplify prescriber authentication to reduce burden on prescribers and continue to protect the health and safety of the American public through secure and compliant controlled substance prescribing.
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> **Recommendation 2b**: We urge the DEA to approve new means of prescriber authentication compatible with smart-phone and tablet prescribing. These include the use of SMS messaging, Bluetooth and near-field communication (NFC). The latter is an advanced technology for an easy-to-use and secure multifactor authentication. When a user tries to access protected content or initiates a transaction, proximity to the NFC device offers fast secure authentication without requiring transposition of codes from a separate device. While these authentication methods are not a seamless part of the EHR electronic prescribing process today, they are much less onerous and considerably more user-friendly than the DEA's currently approved authentication methods.
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> **Recommendation 2c**: We recommend that the DEA review and modify the onboarding process. Today, the onboarding process for set up of a prescriber to receive credentials for EPCS is particularly onerous and costly. The credentialing, the logical access control and token and/or biometric set-up is a challenge. For telehealth prescribers, logical access control is not feasible as these prescribers typically do not have staff who can verify their identities. Essentially, they must resort to friends or family for this step.

3. Approval of additional transactions. The following EPCS standard transactions were not covered in the IFC. In particular, there are three transactions (described below) that are not considered to be legal by the DEA as part of the EPCS process. This situation continues to create opportunities for diversion and abuse because the prescription must "drop back to paper" when these transactions cannot be performed electronically. Putting "paper in the hands of patients" and/or faxing heightens the risk of fraud and abuse by creating the opportunity for a patient and/or others to alter quantities or number of refills or view a physician's DEA number. In addition, this back-and-forth and rework is costly and time

consuming for physicians and pharmacies, which runs counter to the Administration's desire to eliminate burden, fraud, and abuse.

The transactions are:

Electronic Refill request/response. Electronic Refill authorization requests for controlled substances are a frequent occurrence. This issue has become particularly acute because of the quantity limits on controlled substance prescriptions that many states have put in place to fight the opioid epidemic.

Allowing EPCS for refill requests would accomplish several things. First, make it easier for prescribers to leverage EHR-enabled state PDMPs, or prescription drug monitoring programs. Each PDMP lets the prescriber see what controlled substances have been filled for each patient, and potentially identify doctor shoppers and abusers. Multiple refill requests, which the prescriber also can see, could be useful information.

Second, not being able to authorize an EPCS renewal request electronically moves the process of managing these prescriptions outside of the prescriber's EHR workflow, back to paper and faxes. Vital drug allergy and drug interaction checking features of the EHR cannot take place if the renewal request is on paper, putting patient safety at risk.

Moreover, the number and frequency of refill requests (or lack of a refill request) could indicate that the patient is not taking the medication, or not taking it correctly for schedule V epilepsy agents, as an example. Researchers estimate that medication nonadherence causes some 125,000 deaths, untold disabilities, as well as 10% to 20% of hospitalizations and nursing home admissions each year. This costs the healthcare system $100 to $300 billion in avoidable healthcare expenditures. As a result, it is high on policymakers' radar. Allowing electronic refill requests for controlled substance prescriptions can help mitigate this important nationwide problem.

Prescription transfers (or forwarding). Many times, a pharmacy receives an electronic prescription for a controlled substance and cannot fill it because the medication is not in stock or the patient decides to use a different pharmacy. Instead of being able to forward the prescription electronically to another pharmacy, the patient either must go back or contact the prescriber and obtain a new prescription or the pharmacy must spend time on the phone seeking authorization for a transfer. This places administrative burden on the pharmacy, prescriber, and patient, as well as opens the door to diversion by providing a paper prescription.

Resends. Electronically transmitted prescriptions occasionally don't go through to the pharmacy and need to be resent. If a prescription transmission fails, the prescriber now has to handwrite a new prescription and notate that the original failed. This process can be a real issue for many patients, especially on weekends when the pharmacy cannot get in touch with the prescriber. It also transfers the burden on the pharmacy, prescriber, and patient, as well as opens the door to diversion by providing a paper prescription.

> **Recommendation 3a:** We recommend that the DEA allow the electronic transmission of refill authorization requests and responses, prescription transfers, and prescription resends for controlled substance prescriptions.

4. Looking ahead to the post COVID-19 environment. The novel coronavirus and its related health impacts (COVID-19) changed the way we diagnose and treat disease. This includes how and where drugs are prescribed, such as telehealth or virtual visits. The DEA as well as some states have facilitated the process by temporarily relaxing restrictions related to prescribing, such as the need for multi-state licensure and the definition of a patient-prescriber relationship, which under DEA regulations must be in place before a prescription is issued. While we cannot predict how long the COVID-19 pandemic will be in effect, its changes in how healthcare is delivered will not be going away. We must be preparing now for the future and not be caught shorthanded.

> **Recommendation 4a:** We recommend the DEA monitor its regulations related to prescribing and make plans for making permanent the temporarily relaxed restrictions that have proved effective, and analyze additional regulations that might be proved unnecessary with the experience gained during the COVID-19 crisis.

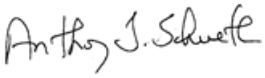
> **Recommendation 4b**: We recommend the DEA permanently allow prescribing via telehealth and permanently keep in place its relaxed restrictions on multi-state licensure for prescribing.

> **Recommendation 4c**: We recommend the DEA allow electronic prescriptions as a replacement for a print prescription when an emergency oral prescription is required. Requiring a provider to mail a prescription provides opportunities for fraud and diversion. A notation on the electronic prescription would suffice and move the industry forward with technology solutions.

Conclusion. Point-of-Care Partners is pleased to offer comments on the IFC. Please do not hesitate to ask for clarifications or additional information. You can reach me at tonys@pocp.com.

Thank you for the opportunity to comment.

Sincerely,



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