September 25, 2020

Centers for Medicare and Medicaid Services (CMS)
7500 Security Boulevard, Mail Stop C4–26–05,
Baltimore, MD 21244–1850

RE: CMS-3394-NC: Medicare Program: Electronic Prescribing of Controlled Substances; Request for Information (RFI)

Dear CMS Staff:

Point-of-Care Partners, LLC (POCP) is pleased to provide comments on issues related to the RFI, which was published in the August 4, 2020 *Federal Register*. Specifically, this RFI focuses on provisions of the SUPPORT Act's Section 2003, which requires CMS to seek input from stakeholders in advance of rulemaking related to 1) whether the agency's rulemaking should include exceptions to the SUPPORT Act's mandate that requires controlled substances prescribed under a Medicare Part D prescription drug plan or Medicare Advantage Prescription Drug Plan (MA/PD) to be electronically prescribed (electronic prescribing for controlled substances or EPCS) beginning on January 1, 2021; 2) the circumstances under which those exceptions should be made; 3) whether the agency should create penalties for non-compliance; and 4) and what those penalties should be.

POCP is uniquely positioned to comment on CMS' request for information. 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 provides related management and strategic consulting services in those areas to a wide range of stakeholders.

For the past 17 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 CMS and the Office of the National Coordinator for Health Information Technology (ONC). POCP testified on the need for EPCS at NCVHS's hearings in 2006, which helped inform the Drug Enforcement Administration's (DEA) initial rulemaking that made EPCS legal under certain circumstances.

CMS' subject RFI seeks comment on specific questions in three areas: compliance issues related to possible exceptions to the SUPPORT Act's EPCS mandate; enforcement; and penalties for non-compliance. POCP is pleased to provide our comments below.

I. Assessing compliance with EPCS requirements:

IA. What types of challenges might discourage prescribers from incorporating electronic prescribing into their normal workflows?

There are two types of workflow challenges that discourage use of EPCS. The first is the onboarding process required by the DEA. The process is complicated and expensive, factors that have discouraged practitioners who serve a minimal number of Medicare Part D patients. DEA workflow requirements also add time to the creation of an electronic prescription for controlled substances. These "extra clicks" lengthen the time needed to complete a controlled substance prescription. All of this adds to the prescriber's administrative burden and overhead, as well as creating frustration on the part of the prescriber for having to perform additional work that eats into precious patient facetime during the visit. The expense of the onboarding process, and its related extra work, serve as a barrier to EPCS adoption.

The second is the requirement by most states that prescribers check with the Prescription Drug Monitoring Program's (PDMP) database before sending a controlled substance prescription electronically to the pharmacy. This process is slowly becoming integrated into the prescriber's electronic health record and EPCS workflow. More often than not though, it is not integrated with the EPCS workflow and is disruptive, requiring the prescriber to open a different or new window, logging outside the EHR and into a PDMP portal, then searching for and selecting the patient. This adds to the time needed to create a controlled substance prescription and creates extra work and frustration—on top of those created through the EPCS process.

Prescribers generally agree with the intent of checking the PDMP to reduce duplicate prescriptions for controlled substances (especially opioids), prevent diversion and mitigate doctor shopping. However, they chafe at what is involved to do so, which serves as a barrier to EPCS adoption.

In addition to the two workflow challenges cited above, prescribers (and their EHR/ePrescribing vendors) may face challenges with keeping up and/or understanding state-specific nuances concerning EPCS transmission, as well as implementation and use of NCPDP SCRIPT version 2017071 for EPCS prescriptions. This lack of clarity could inadvertently place prescribers in a position of non-compliance if they omit required information. Another factor that could contribute to inadvertent non-compliance is lack of clarity around the waiver and appeal processes, including how they can apply for waivers and appeal a violation.

> **Recommendation 1A1**. We recommend CMS work with the DEA to streamline the onboarding process as conveyed in our June 2, 2020 comment letter. This could involve allowing new means of prescriber authentication compatible with smart-phone and tablet prescribing, such as use of SMS messaging, Bluetooth and near-field communication (NFC). 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 requiring logical access control and token and/or biometric set-up. 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.
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> **Recommendation 1A2**. Stakeholders are aware of the benefits of integrating PDMP access into the EHR EPCS workflow. ONC has conducted pilots on how this might be accomplished, such as through its Enhancing Access project. We recommend that CMS work with ONC and EHR

vendors to leverage the findings of the pilots for inclusion of PDMP checks into the EPCS workflow.

Recommendation 1A3. We also recommend that CMS and ONC consider requiring the integration of PDMP access into the EPCS workflow. This could be accomplished by requiring this functionality as part of the EHR Certification program.

Recommendation 1A4: In order to reduce providers' inadvertent non-compliance, CMS should be very specific in defining which NCPDP SCRIPT version 2017071 capabilities are expected to be used and which are out of scope. Doing so will reduce the need for pharmacies and payers to reject incomplete prescriptions. In addition, it should be easy to providers to apply for waivers and appeal violations, perhaps through links provided to EHR /ePrescribing vendors that could be communicated to providers as part of normal, ongoing communications and/or a dedicated CMS-sponsored information portal specific to EPCS/ePrescribing.

IB. How could CMS structure its EPCS policy to remove roadblocks to effective adoption of electronic prescribing for controlled substances?

As mentioned previously, the barriers to EPCS adoption as perceived by POCP are largely outside of CMS' control. There are, however, some actions CMS could take, as described in our recommendations below.

Recommendation 1B1. We recommend that CMS consider incentivizing small, solo, inner city and rural practices to help mitigate financial issues associated with EPCS adoption. Rural practices, in particular, may need financial help in broadband adoption, which is requisite for EPCS. This may have to be coordinated with the Federal Trade Commission, which already is working to improve broadband access.

Recommendation 1B2. CMS should clearly articulate how the mandate works and the parameters of the exceptions. The agency should explain for providers what fields in NCPDP SCRIPT version 2017071 are in and out of bounds in regard to the exceptions. This version of SCRIPT is likely to be new to many users and it contains much more functionality than the previous version.

Recommendation 1B3. We recommend that CMS consider training programs on the exceptions to the EPCS mandate. This could eliminate a potential barrier to adoption as well as improve compliance, as prescribers will better understand the mandate's parameters.

II. Enforcement

Any discussion of enforcement should take into account the realities of EPCS. As a matter of practice and tradition, controlled substance prescriptions account for a small proportion of total ePrescribing volume. According to Surescripts, there were 159.8 million prescriptions for controlled substances "written" electronically in 2019 out of 2.1 billion total electronic prescriptions. The small percentage of controlled substance prescriptions by comparison to the number of legend prescriptions is one reason that EPCS adoption has lagged. Most prescribers write very few controlled substance prescriptions.

POCP believes that the majority of potential compliance problems will surface in 2021 and 2022, when the Part D EPCS mandate gets off the ground. Surescripts noted that about half of all prescribers were enabled for EPCS in 2019. This suggests that those enabled for EPCS intend to use it at some point in time; otherwise, they would not go to the time and expense to do so.

The percentage of novel EPCS adopters should increase in response to the Part D mandate in 2021 and 2022 and in response to the growing number of state EPCS mandates that are in place or phasing in over the next couple of years. POCP believes that there may only be a small number of compliance issues as these prescribers get used to the EPCS Part D mandate and the technology. The majority of such issues resulting in non-compliance should iron themselves out quickly.

All of this has implications for the scope of compliance and enforcement activities. We believe non-compliance will be sporadic and limited primarily to a small group of novel users in the early days of the Part D mandate. Large-scale and complex enforcement activities (as suggested by the RFI's questions) are unlikely to be needed going forward.

Point-of-Care Partners' responses to the specific questions in the RFI are below.

IIA. What level of compliance with EPCS would be appropriate to require before levying any penalties on a non- compliant prescriber, and why? For example, should we consider adopting a percentage of prescribers' threshold that a practice must meet to be considered compliant with EPCS requirements? Should we instead consider specifying a number or percentage of a practice's patients?

We urge CMS to consider building on the enforcement program already in place for provisions of the Health Insurance Portability and Accountability Act (HIPAA). This is a phased approach that would be triggered when CMS receives a complaint indicating that a prescriber is non-compliant. The first phase would involve attempting to resolve the case by informal means, which is in line with the Department of Health and Human Services' (HHS) desire to promote voluntary compliance with HIPAA rules. Informal means may include that the potential offender can demonstrate compliance, or the entity agrees to successfully complete a corrective action plan or other agreement. This often is the end of the matter and precludes the imposition of Civil Monetary Penalties (CMPs). These are rarely levied and done so as a last resort or in the case of egregious violations that can cause harm (such as negligent and large-scale privacy breaches). We believe this approach has several benefits. First, it is a known entity, which will facilitate any compliance actions that are taken. Second, it does not create a unique, expensive or onerous enforcement process for what we believe will be non-compliance by a small number of novel EPCS users, which will diminish over time.

The RFI's questions, as reproduced above, suggest a complex and expensive process that is more appropriate for addressing a high volume of fraudulent claims. Such a process is likely to be overkill and an unnecessary use of scarce resources. Violation of the EPCS mandate is likely to involve a small number of providers for a smaller number of prescriptions, recognizing the prescriptions for controlled substances are a just a portion of the total.

> **Recommendation IIA1**. CMS should follow the enforcement protocol for violations of HIPAA, which is a phased approach. Enforcement is done on a complaint basis, and usually begins — and ends — with creating and monitoring a voluntary corrective action plan. While Civil Monetary Penalties may be imposed, this is rare.

Recommendation IIA2. We recommend that CMS conduct an education campaign on the new mandate and clearly articulate to prescribers what it is, how it works, what the exemptions are, and how enforcement will be handled. We believe this will eliminate inadvertent non-compliance and make providers comfortable with the process.

Recommendation IIA3. If CMS proceeds with an audit approach, there are two improvements to the prescribing process that would help eliminate "false positives" and problematic prescriptions. First, pharmacies should be required to accurately note the prescription origin code for the prescription. Otherwise, a prescriber could be considered to be non-compliant, when in fact, it is the pharmacy's lack of accurately noting the prescription origin code (electronic, written, telephone, facsimile, other). This can be complicated by lack of documentation of why ECPS was not followed, which could result in a non-compliant prescriber being given credit for EPCS when a valid exemption does not exist or in the prescriber being reported as non-compliant when a valid exemption exists but is unknown to the pharmacist. Secondly, since the origin code is needed to document how the EPCS prescription was received, Part D plans need to ensure that claims processing will not allow prescription origin code = zero.

Recommendation IIa4. We also recommend that CMS work with the DEA and the National Council for Prescription Drug Programs (NCPDP) to establish a list of mandated exemption codes (e.g. patient is in hospice or prescriber has an exemption) that could be used in concert with a paper controlled substance prescription, for purposes of documenting in the prescriber system and at the pharmacy the reason the prescription was not submitted electronically. Options for integrating these codified exemption codes into both workflows could be explored with NCPDP and EHR vendors but may include one or more of the following:

- **Prescriber use**: Prescribers could handwrite the exemption code(s) on the paper prescription and/or input the codes in the EHR in notes or in a new custom field.
- **Pharmacy use**: If pharmacies could find a way to add the exemption codes to the prescription claim through use of an existing field in the NCPDP telecom standard and/or a new telecom field as part of the normal NCPDP standards development process, then not only could the payers track the exemption reasons, but they also could include it on the CMS Prescription Drug Event (PDE) record for its tracking use. It should be noted, however, that it typically takes approximately 3 years for a new field to be vetted and added. But, NCPDP could recommend a temporary approach to the best course of action to expedite industry use of the exemption codes, such as through use of the NCPDP Telecom Workgroup FAQ document and/or through its normal standards development process.

Note that we do not advocate that pharmacists be the gatekeeper on evaluating the legitimacy of an exemption or requiring one be on a prescription. Instead, we suggest simply to report it if so noted. In addition, we recommend that Part D plans reject prescriptions without a prescription origin code.

IIB. What time period (or periods) should CMS use to evaluate compliance (for example, quarterly, semi-annually, annually) and how should we communicate information on performance to the prescriber to drive improvement?

Recommendation IIB1. As noted previously, we believe that compliance should be complaint driven. However, if audits are desired, they could be done according to parameters in published guidance that are informed by precedent (e.g., HIPAA enforcement rule) and by the industry.

Recommendation IIB2. We recommend that enforcement should not begin for at least 24 months after the mandate begins. This will allow time for providers to get up to speed and for CMS to identify and address unforeseen implementation and compliance issues. There is precedent for delayed enforcement, such as with the recent interoperability rules. Guidance should be clear and easily accessible to all providers, such as posting on the websites of CMS and the Department of Health and Human Services (DHHS).

III. Penalties for Noncompliance.

IIIA. What penalties, if any, would be appropriate for non-compliance with a Federal EPCS mandate?

Recommendation IIIA: We believe that CMS and DHHS should follow existing guidance for HIPAA enforcement. This lays out procedures and circumstances for imposing Civil Monetary Penalties (CMPs), the investigation process, determining penalty amounts, grounds for penalty waivers, and requirements for hearings and appeals. While fines and termination from the Medicare program may be created, they should be used as a last resort. There should be a ramp-up period if those penalties are imposed. CMS could look at other compliance programs for guidance, such as for enforcing provisions of the Health Insurance Portability and Accountability Act (HIPAA).

IIIB. How may Federal penalties affect EPCS adherence?

It is possible that the threat of non-compliance penalties will drive some providers from seeing Medicare patients. This could be devastating to America's seniors and the disabled. It is hard enough for those patients to find a provider who accepts Medicare assignment.

IIIC. What mechanism(s) should CMS use to enforce penalties among non-participating Medicare or Medicaid prescribers?

While Point-of-Care Partners staff are not attorneys, we wonder what authorities CMS could use to enforce against non-participating and Medicaid providers who would not be compliant with the EPCS mandate for Part D.

Recommendation IIIC. If enforcement actions are warranted, CMS should utilize claims data and the prescription origin code from the data received from plans. This will indicate how prescriptions are coming into pharmacies.

IIID. Are there other mechanisms CMS can use to encourage non-participating Medicare or Medicaid prescribers to use EPCS?

Many states have EPCS mandates in place or coming online in the next few years. This will help drive compliance. There may be some additional actions CMS could take to stimulate compliance. For example, CMS oversees the Medicaid program and could require Medicaid providers to use EPCS for dually eligible patients.

Are there any circumstances under which penalties should automatically be waived?

There are instances in which penalties could automatically be waived. One example is for providers who lack broadband connectivity or for those that have brought themselves into compliance before any enforcement action was taken.

How should CMS approach design and use of an appeals process for enforcement?

We suggest that an appeals process should be modeled after those for existing programs, such as enforcement of HIPAA's administrative simplification provisions.

If CMS were to impose civil money penalties, what penalty structure (including amounts) should be adopted?

We suggest that CMS look to other enforcement programs, such as for HIPAA, and input from the industry on a penalty structure and amounts.

Should any details about penalties for violations of section 2003 of the Support Act be posted publicly? What types of details should be included in information available to the public?

CMS is beginning to post information about non-compliant providers, such as with recent interoperability rules. The agency could follow that pattern, such as names and cities of provider and amounts, with EPCS non-compliance. However, given what we perceive will be a low volume of non-compliance with the mandate, such public shaming may not be effective.

Should CMS assess penalties after some interval following implementation of this requirement? If yes, what interval(s)?

We believe that enforcement should be delayed until at least January 1, 2023, or 24 months following the initial compliance date. This will give providers the chance to understand the mandate and bring themselves into compliance. Assessment of actual penalties will depend on how the enforcement process is structured. If enforcement begins with a voluntary compliance plan, imposition of penalties would begin at some point after that.

Should CMS assess penalties' severity incrementally based on repeat analyses demonstrating lack of improved compliance? If yes, please describe what type of analyses would be most effective.

We suggest looking at the structure of penalties for HIPAA enforcement. These ramp up over time as to the number of instances and severity of violations.

Should penalties be significant enough that a prescriber not eligible for a waiver or exemption would be either forced to comply with the electronic prescribing requirement for controlled substances, or stop providing such pharmacologic care across all covered classes of controlled substances? What are the implications for patients in either scenario?

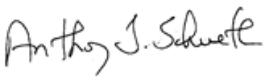
Such an approach is a very strong "stick," which may cause loss of some provider participation. This could be catastrophic for some of America's seniors and disabled, especially in rural areas and inner

cities where it often is difficult to find providers who accept Medicare assignment. Patients could be left without options and may resort to illegal means for pain control. The opioid epidemic still has not gone away and seniors and the disabled are vulnerable.

We believe that the enforcement process should use an incremental approach, such as that used for compliance with HIPAA's administrative simplification provisions.

Conclusion. Thank you for the opportunity to comment on this very important issue. Please do not hesitate to contact me for clarifications or additional information. I may be reached at tonys@pocp.com.

Sincerely,



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