October 2, 2020

Administrator Seema Verma
U.S. Centers for Medicare &
Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma:

The College of Healthcare Information Management Executives (CHIME) is grateful for the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) *Medicare Program: Electronic Prescribing of Controlled Substances; Request for Information (RFI)* placed on display in the Federal Register on Aug. 4, 2020.

CHIME is an executive organization dedicated to serving chief information officers (CIOs), chief medical information officers (CMIOs), chief nursing information officers (CNIOs), and other senior healthcare IT leaders. With nearly 3,400 members, CHIME provides a highly interactive, trusted environment enabling senior professional and industry leaders to collaborate; exchange best practices; address professional development needs; and advocate for the effective use of information management to improve the health and healthcare in the communities they serve.

CHIME and its members have been actively engaged in fighting the opioid epidemic for several years. Through the creation of our Opioid Taskforce, CHIME members and our partners have worked together to educate healthcare leaders on the technology issues related to opioid use disorders (OUD) and substance use disorders (SUD). In addition to furthering the education around OUD/SUD, CHIME has also relished the opportunity to lend its expertise to help shape critical pieces of policy related to OUD/SUD. We appreciate the opportunity to continue doing that by providing CMS with additional information around how best to implement electronic prescribing of controlled substances (EPCS) requirements and reduce the potential burdens implementation places on providers.

We strongly support the EPCS mandate in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act. We believe this will have a meaningful impact on managing the opioid epidemic. **As part of your RFI, you posed several specific questions related to compliance, enforcement, and waivers. We have responded to your specific questions below. Common themes found throughout our responses include:**

- **CMS should work closely with the Federal Communications Commission (FCC) and other vital governmental agencies to ensure providers have access to highspeed, stable broadband. Without access to stable internet, the ability to implement and utilize EPCS is significantly hampered.**

- **Compliance and enforcement should be centered on providers' ability to access EPCS tools on a reliable basis. There should be some form of exception process built into the EPCS requirements.**
- **EPCS requirements should remain flexible as current requirements impact other crucial healthcare initiatives, including, but not limited to, the expansion of telehealth and fighting the COVID-19 pandemic.**

Compliance

1. **What types of challenges might discourage prescribers from incorporating electronic prescribing into their routine workflows? How could CMS structure its EPCS policy to remove roadblocks to the effective adoption of electronic prescribing for controlled substances?**

   Response: There are multiple challenges that providers face related to the implementation and use of an EPCS framework. Those challenges include, but are not limited to:
   - The use of multi-factor identification;
   - Cost;
   - Access to broadband;
   - The need for a patient to be physically present at the point of care;
   - Available workflows; and
   - Administrative challenges, such as providers attaining tokens.

   Many of these challenges impact prescribers in rural, underserved, and urban settings. Each individual challenge is not one that is insurmountable to a prescriber, but collectively they create the potential for non-compliance or for prescribers to cease prescribing these medications.

   In addition to the challenges listed above, there are additional challenges that impact a prescriber's ability to use telehealth. The need for patients to provide a government issued ID, prove their identity, and present in-person for their visit makes prescribing through telehealth next to impossible.

   CHIME and CMS have advocated for the expansion of telehealth, especially as the nation continues to fight the COVID-19 pandemic. With that in mind, allowing providers to prescribe controlled substances through telehealth can significantly reduce the burden placed on the healthcare continuum by requiring patients to present in person for routine follow-up or check-in appointments. Providing exceptions for telehealth visits or working to find a solution to enable telehealth in EPCS with proper, and stringent, supervision is essential to ensuring the success of telehealth and the EPCS programs.

   The costs required to meet these requirements for rural and underserved providers could push many into non-compliance or may force them to decide not to prescribe prescriptions governed by the EPCS requirements. Staffing requirements and the technology required for the implementation of EPCS are not always attainable by rural facilities. Carving out easements or exceptions for prescribers in rural areas is crucial for attaining complete utilization.

Finally, to ensure all providers see the value of EPCS, there must be a streamlined process for attaining two-factor authentication tokens. Multiple members have informed CHIME of extended wait times for these tokens. This wait means providers who have followed all of the requirements for EPCS must remain on the outside looking in as they are unable to meet the two-factor requirements. We ask you to consider including exceptions into EPCS rulemaking for providers who have followed all EPCS requirements in good faith but are hindered by administrative hurdles.

We also encourage CMS to examine the security of utilizing tokens as a form of two-factor authentication, particularly in the ambulatory setting.

2. **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?**

   Response: CHIME recommends that 100% compliance should be the goal of EPCS, with some critical exceptions in place requiring documentation of the exception taken. As stated above, several challenges face prescribers as they relate to the following EPCS requirements. Those challenges should allow for exceptions to be taken by providers, giving relief from penalties when prescribers attempt in good faith to remain in compliance.

   As it relates to requesting or attaining relief from EPCS rules, CHIME proposes allowing prescribers to document on a case-by-case basis why they were not able to follow all EPCS requirements. There are many ways this could be accomplished. **CHIME suggests a possible solution to this problem is creating a series of prescribing modifier codes, allowing prescribers to attach a code indicating, as one example, that they did not have access to broadband internet and thus could not use EPCS. These exceptions could also encompass other challenges that may make the use of EPCS challenging, such as disasters and health technology downtimes.**

   A member described a real-world scenario outlining that when they provide services to patients in the bureau of prisons (BoP) system, they do not have access to a mobile device or computer with broadband to connect to an EPCS system or meet EPCS requirements. As a result, it is not that the prescriber is not compliant with EPCS; it is that they do not have the opportunity to be compliant. In this example, having a case-by-case code that prescribers could place on their transactions allows them to flag that their non-traditional care setting caused them to be unable to meet EPCS requirements. A similar scenario arises with nursing homes and long-term care facilities, given how prescriptions are handled in those settings.

3. **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?**

   Response: CHIME recommends an annual attestation period for EPCS compliance. An annual process allows for CMS to audit any transactions that required an exception to EPCS

compliance and would place an unreasonable burden on the providers who need to attest to utilizing EPCS.

Enforcement

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

   Response: CHIME recommends CMS propose a series of appropriate corrective and education actions for providers who struggle to comply with EPCS mandates and to make those proposed actions available for public comment. CHIME does not believe penalties are an effective way to encourage compliance.

   Instead of implementing penalties, CMS should instead implement incentives for providers to meet the EPCS requirements. These incentives could include expanding the Promoting Interoperability (PI) program appropriate opiate prescribing incentives, such as query of prescription drug monitoring program (PDMP), to include the utilization of EPCS. The CY 2021 Physician Fee Schedule (PFS) proposes leaving the query of PDMP as optional. CHIME supports leaving these provisions optional for 2021 and then expanding them in CY 2022 to include optional EPCS PI incentives with them becoming permanent in CY 2023.

   If CMS were to propose enforcement penalties, we strongly encourage CMS to include an increasing scale of penalties. Those proposed penalties should not include the revocation of a provider's Conditions of Participation (CoP). We believe jeopardizing a provider's entire Medicare reimbursement is overly punitive and could hurt access to care. Instead, the increasing scale should give prescribers ample time to correct errors and return to compliance through a warning and corrective action plan process. Additionally, CMS should also ensure there are adequate resources available to assist prescribers in implementing EPCS and remaining in compliance.

   We do note, however, that at no point should a prescriber be punished multiple times for non-compliance caused by a singular issue if CMS chooses to implement penalties. For instance, if a provider makes an error with authentication or a flaw in their health IT system causes multiple instances of EPCS non-compliance, there would be the potential for multiple instances of non-compliance. Those transactions should be considered one instance of non-compliance. This allows the prescriber to fix the problems and find themselves back in compliance with the EPCS requirements without incurring potentially significant financial penalties.

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

   Response: There are several options CMS could use to encourage non-participating Medicare or Medicaid prescribers to use EPCS. They could include making EPCS mandatory in the Promoting Interoperability (PI) program and the Merit-based Incentive Program (MIPs). Other options may also include aligning the CMS EPCS penalties with similar disincentives outlined by the U.S. Drug Enforcement Agency (DEA).

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

   Response: CHIME recommends penalties be automatically waived in the following circumstances:
   - Prescriber's inability to access broadband;
   - A patient's pharmacy is not utilizing EPCS;
   - Technical barriers outside the control of the prescriber (i.e., provider's electronic health record sends the script; however, it never makes it to the pharmacy);
   - The prescriber is utilizing CMS allowable telehealth solutions;
   - EHR downtime/network failures/inaccessibility due to upgrade; or
   - The prescriber in good faith has attempted to comply with CMS EPCS requirements but is awaiting administrative requirements to be processed.

   Prescribers should also have the ability to request a waiver from requirements on a case-by-case basis, to be reviewed by CMS. EPCS requirements are vast, and having a waiver process will protect the quality of care patients can receive without administrative blockades.

4. **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?**

   Response: Barring a prescriber from providing such pharmacologic care sets a dangerous precedent and should only be used in extreme circumstances, such as criminal activity or outright fraud. We continue to assert that penalties are not the appropriate path forward for compliance and instead increased education and assistance should be made available to providers struggling to comply. Education and assistance is the proven path to successful implementations of federal guidelines and regulations.

   The revocation of a provider's ability to prescribe should also be reserved for clear cases of abuse. Providers who struggle to implement the EPCS requirements or are simply unable to comply with the requirements, such as in cases of broadband access being hindered, should not be crippled in their ability to prescribe. Revoking a provider's ability to prescribe controlled substances does nothing but eliminate an avenue for a patient to receive care if the penalty is applied too liberally. If CMS were to choose to implement penalties, CHIME implores CMS to ensure the revocation of the ability to prescribe controlled substances only be implemented as a last resort and should happen only after a series of escalating warnings and penalties. This should also come after the provider has been provided with ample education and assistance in gaining compliance.

While not included in this RFI, we did want to take the opportunity to thank the CMS for including a delay of the EPCS requirements in the draft CY 2021 PFS. Given the continued deepening of the opioid epidemic, we strongly support the EPCS mandate in the SUPPORT Act. However, we believe this extra time is invaluable in assisting providers in fighting COVID-19 and also allows CMS the opportunity to dissect each EPCS requirement to determine how best to preserve a provider's ability to care for patients, while also encouraging the use of EPCS tools. Through partnering

together to ensure no provider is left behind, we can ensure the implementation of EPCS is a success.

If you would like to speak further with CHIME or our members about how we can best work together to implement these EPCS requirements, please feel free to reach out to Andrew Tomlinson, our Director of Federal Affairs, at atomlinson@chimecentral.org.

Sincerely,

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