

September 29, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

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

Dear Administrator Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to provide input on the Centers for Medicare & Medicaid Services' (CMS) Request for Information (RFI) regarding electronic prescribing of controlled substances (EPCS). The RFI solicits comments on whether CMS should include exceptions to the EPCS requirements laid forth in Section 2003 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, and whether CMS should impose penalties for noncompliance.

While we do not oppose the general requirement for prescriptions for Schedule II-V controlled substances to be transmitted electronically, we are concerned with the timeline proposed for implementation as well as the potential for penalties for noncompliance within this timeline. The AHA urges CMS to approach this requirement based on a holistic view of the full range of federal regulations that require hospital IT development, upgrade, testing and end-user training, and proceed with a period of enforcement discretion and lack of penalties.



There is an inherent conflict between CMS' goal of burden reduction and the reality of the current health IT regulatory environment. Over the next several months, hospitals and health systems will require upgraded IT infrastructure to comply with, at a minimum:

- Compliance with information blocking;
- Implementation of admission/discharge/transfer notifications under the Conditions of Participation;
- Deployment of IT tools to facilitate disclosure of negotiated rates;
- Upgrades for the Promoting Interoperability Program; and
- New electronic clinical quality measurement requirements.

As noted in our [comments](#) on the CY 2021 Inpatient Prospective Payment System Proposed Rule, the AHA has significant concerns regarding EHR vendor capacity to deploy, and hospitals' and health systems' capacity to implement, such a high volume of IT system changes on a short timeline. This is especially true in light of the redirection of resources to support technology and data needs specific to the COVID-19 public health emergency. Because of this, we appreciate CMS' proposed delay of the requirement to conduct e-prescribing of Schedule II-V controlled substances using the NCPDP SCRIPT 2017071 standard to Jan. 1, 2022, as set forth in the CY 2021 Physician Fee Schedule Proposed Rule.

Indeed, further softening of enforcement is necessary, as many providers –small hospitals in particular – struggle to implement IT upgrades due to the cost and logistical barriers to working with EHR vendors. Due to U.S. Drug Enforcement Agency (DEA) requirements, the EPCS capability is often an add-on to existing EHR systems; this can result in exorbitant added costs. In addition, while many providers have experience using the required standard under the Part D program for certain e-prescriptions, newly Medicare-eligible opioid treatment programs (OTPs, which commonly prescribe and dispense controlled substances for use in medication-assisted therapy MAT) likely have not used this standard before. In fact, as CMS notes in its background on e-prescribing, there is a mismatch in EPCS capabilities nationwide: while 97% of U.S. pharmacies are capable of processing EPCS, only 49% of prescribers were capable of EPCS. Moreover, state-level requirements are sometimes at odds with national programs.

Even if the EHR contains the EPCS capability, there has been low uptake of the process in physician practice; in other words, organizations will need to engage in substantial staff training and implementation of workflow alterations. The processes necessary for EPCS as dictated by DEA requirements – including but not limited to identity proofing, two-step logical access control for permissions, two-factor authentication, and comprehensive and detailed reporting – significantly interrupt usual care protocols. While there are good reasons for these steps, they necessitate

comprehensive upgrades to EHR systems; these upgrades are not all the same, depending on the EHR vendor, and the various systems – including EHRs across different sites within the same network or other electronic information systems within a facility – are often not interoperable.

To be clear, the AHA agrees that e-prescribing is appropriate for controlled substances due to the security and data advantages it provides. However, due to the arduous nature of IT upgrades and the long list of other requirements currently heaped upon providers, **we recommend that CMS move forward with a gradual implementation timeline including a period of enforcement discretion and a lack of penalties.**

We thank you for the opportunity to comment on this RFI. If you have any questions concerning our comments, please feel free to contact me, or have a member of your team contact Caitlin Gillooley, senior associate director of policy, at cgillooley@aha.org.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis & Development