EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

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October 5, 2020

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma,

On behalf of the nearly 30 member companies of the Electronic Health Record (EHR) Association, we are pleased to offer our comments on the Centers for Medicare and Medicaid Services' (CMS) request for information on the Medicare Program: Electronic Prescribing of Controlled Substances, which was published in the Federal Register on August 4, 2020.

The EHR Association's member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our core objectives focus on collaborative efforts to accelerate health information and technology adoption, advance information exchange between interoperable systems, and improve the quality and efficiency of care through the use of these important technologies.

The adoption of electronic prescribing of controlled substances (EPCS) has been largely successful in recent years -- and particularly in the geographies where it is mandated. However, because EPCS comes with an added cost, additional security requirements, and requires changes to prescribing workflows, adoption figures are not where they could be. We appreciate CMS' continued efforts to identify and address barriers to more widespread adoption.

Our detailed responses to CMS' specific questions follow. Thank you for this opportunity to share the perspective of our members. We look forward to continuing to work with CMS and other stakeholders to advance widespread adoption of EPCS and minimize clinician burden.

Sincerely,

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Chair, EHR Association
Cerner Corporation

David J. Bucciferro
Vice Chair, EHR Association
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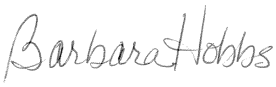
HIMSS EHR Association Executive Committee



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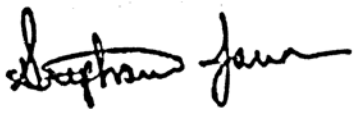

Stephanie Jamison
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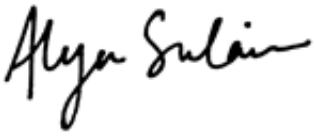

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About the HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org

Electronic Health Record Association
Comments on the Medicare Program:
Electronic Prescribing of Controlled Substances
Request for Information

EPCS Compliance Assessments

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

Today, most EHR systems offer the ability to incorporate EPCS capabilities directly into standard provider workflows. In our experience, the most significant barrier to adoption of EPCS amongst provider organizations is the ongoing administrative burden it places on them as a result of the requirements finalized in DEA's 2010 Interim Final Rule. The cost and effort associated with understanding and implementing the processes and technical solutions required to comply with DEA's strict rules for identity proofing can be prohibitive for small or rural practices, as well as large integrated health systems.

While most EHR systems are able to incorporate EPCS capabilities into provider workflows, some prescribers still find EPCS adoption and utilization challenging because of rules that have been defined by the DEA. For example, as is widely known, some prescribers have expressed frustration that DEA regulations require them to submit EPCS orders themselves without the option to delegate to another member of the care team. Prescribers also find multifactor authentication frustrating because it is disruptive to their ordering workflow, especially when they may have already been asked to authenticate twice with multiple factors in a single encounter: once to access their workstation, and again to log into their EHR.

Secondary challenges that may affect prescriber adoption include concern about meeting sometimes ill-defined or confusing quality measure standards that draw data from controlled substance prescribing practices. Alignment of state and federal mandates and expectations regarding prescribing schedules would help alleviate other challenges, as well, as there are sometimes subtle and sometimes more dramatic differences in what is allowable from state to state. This can present difficulties to organizations serving patients across state lines.

The EHR Association recommends that CMS collaborate with DEA to expedite the modernization of its EPCS requirements, which were first promulgated more than ten years ago. We also encourage CMS to partner with DEA to develop and promote programs designed to educate providers on their regulatory obligations when adopting tools to electronically prescribe controlled substances. CMS and DEA could

accomplish this by creating compliance guides and toolkits that make EPCS adoption easier through clarification of complex regulatory requirements.

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 oppose CMS assessing compliance with the EPCS requirement by measuring the percentage of prescribers using EPCS or the percentage of controlled substance prescriptions submitted electronically against an arbitrary threshold. Establishing a threshold requirement would not adequately account for systematic differences across provider organizations that will significantly impact the rate of controlled substance prescriptions ordered electronically. For example, small or rural practices may face constraints in internet connectivity, financial resources, or in the technological capabilities of nearby dispensing pharmacies that inhibit their ability to electronically prescribe controlled substances at the same rate as non-rural or larger organizations.

Instead, CMS should implement an exception-based compliance assessment framework that describes clear situations or scenarios in which EPCS is considered infeasible or inappropriate. Provider organizations should then be given the flexibility to leverage those exceptions to the EPCS requirement in any case that is appropriate, without fear of being "deemed non-compliant" for failing to meet an arbitrary percentage-based threshold.

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?

CMS should do everything possible to encourage and support the mandated use of EPCS, including working with provider stakeholders to identify reporting and accountability mechanisms that they would feel comfortable with. While we note our concerns about threshold-related measurement above, we do believe CMS should explore other ways that reporting programs could encourage adoption and use of EPCS functionality, which is beneficial to patients. Semi-annual or annual reporting would be reasonable, though we encourage CMS to harmonize any reporting expectations with what is required by the states in their own oversight of controlled substance prescribing.

EPCS Waivers

A prescription issued when the practitioner and dispensing pharmacy are the same entity. We seek comments on whether this exception is necessary, and how these claims may be identified.

We support the adoption of such an exception. Today, many healthcare organizations have integrated dispensing pharmacies so that a patient can receive care and pick up prescribed medications during the

same encounter or visit. Organizations that both deliver care and dispense prescription medications often share a single patient record by nature of having access to the same EHR system within their organization. Having access to a single, shared patient record enables a closed-loop prescribing and dispensing workflow for medications, which eliminates the need to use an NCPDP interface to prescribe controlled substances. It also carries a range of benefits associated with patient safety, workflow efficiency, and health IT performance.

Adopting an exception for when the practitioner and dispensing pharmacy are part of the same legal entity would preserve these benefits, and aligns with CMS' existing policy for electronic prescribing and regulations at 42 CFR 423.160.

A prescription issued that cannot be transmitted electronically under the most recently adopted version of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard. We believe that the current adopted standard NCPDP SCRIPT version 2017071 allows for most electronic prescribing transmissions. We seek comment on this assumption and on any specific circumstances in which a prescription for a controlled substance could not be transmitted electronically under this standard.

NCPDP SCRIPT version 2017071 may cover the majority of practices but not all. We are aware of concerns with this standard arising from character limits, information missing, connectivity, and special characters in names.

We recommend CMS adopt an exception to the requirement to use NCPDP SCRIPT 2017071 standards to electronically prescribe controlled substances in cases where technical limitations of the standard prevent electronic transmission of the prescription.