

October 5, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8013
Baltimore, MD 21244-8010

Re: CMS-3394-NC

**Re: Medicare Program: Electronic Prescribing of Controlled Substances;
Request for Information (RFI)**

Dear Administrator Verma:

On behalf of our 42,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on a request for information (RFI) on how the Centers for Medicare & Medicaid Services (CMS) should implement a provision included in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act that requires there to be electronic prescribing under Medicare Part D for Schedule II, III, IV, or V controlled substances beginning in 2021. We note that in the Calendar Year (CY) 2021 Physician Fee Schedule (PFS) and Quality Payment Program (QPP) proposed rule, CMS delays this requirement to 2022, mostly due to the challenges that the health care practitioner community is currently facing responding to the novel coronavirus (COVID-19) public health emergency (PHE).¹ ACEP supports that proposal.

In this RFI, CMS seeks comments on three issues related to the implementation of the electronic prescribing for controlled substances (ECPS) requirement: 1) compliance with the requirement; 2) enforcement and penalties; and 3) exceptions. CMS also references the Drug Enforcement Administration's (DEA) policies. The DEA recently reopened the Electronic Prescriptions for Controlled Substances Interim Final Rule (IRF) for comments.² ACEP appreciated the opportunity to comment on this regulation³, as a lot

¹ Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule, 85 Fed. Reg. 50258- 50261 (August 17, 2020).

² Drug Enforcement Administration. Docket No. DEA-218I. "Electronic Prescriptions for Controlled Substances." https://www.deadiversion.usdoj.gov/fed_regs/rules/2020/fr0421_3.htm.

³ ACEP's comments on the DEA IFC can be found at: <https://www.acep.org/globalassets/new-pdfs/advocacy/acep-response-to-dea-electronic-prescribing-interim-final-rule.pdf>.

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has changed since the IRF was first released ten years ago. Going forward, we believe it is important for the DEA and CMS to work together in order to ensure that the final implementation timeline adopted by CMS for Medicare prescriptions takes into account the DEA's timeframe for implementing new regulations. Sufficient time will need to be allotted between the DEA issuance of revised regulations and the imposition of new Medicare requirements for vendors to update their products to comply with the new DEA requirements and for medical practices to acquire and transition to the new technology.

Compliance

CMS requests comments on what challenges might discourage prescribers from incorporating electronic prescribing into their normal workflows. As emergency physicians, many of us experience hurdles getting registered and implementing EPCS into our workflows. In most cases, we are using an institution-approved application from a credential service providers (CSP) installed on our smartphone for two-factor authentication. The health care practitioner's credentials (government issued ID or hospital ID) are reviewed in-person with an authorized representative from the institution's IT or human resources (HR) departments, and credentials are assigned for the CSP app and further tied to the electronic health record (EHR). So long as that practitioner has the same phone, they will be able to generate a token (updated every 30 seconds) to serve as a second factor for authentication (the first factor being their EHR login and password).

This process can be burdensome and time-consuming. For example, when we purchase a new smartphone, we are required to visit the credentialing office and obtain a new helpdesk ticket and a new credentialing of the CSP app. Then, that credential must be tied to the EHR for two-factor authentication for EPCS. Further, if we lose a smartphone, we have to re-enroll—and since that process takes time and an in-person office visit, often we cannot e-prescribe for days to weeks afterwards.

Mandating additional forms of identification and authentication could also disrupt workflows. Biometric identification, if implemented properly, is a safe, secure, and closed system that would do more to encourage EPCS. However, we find that third-party fingerprint scanners or in-app facial recognition algorithms are cumbersome to set up and seem prone to mis-reads and frequent failures to recognize the credentialed user. These third-party biometric solutions generally seem less convenient than system-level smartphone biometric authentication.

In all, most prescribing for institutional practitioners occurs via an EHR. Such applications are already required to comply with sufficient security standards without being overly burdensome to practitioners. As interoperability increases and Health Information Exchanges proliferate, prescriptions issued via EHR (whether on paper or e-prescribed) are increasingly accessible to other clinicians caring for a given patient, and EHR prescription logs can be readily shared with a state's prescription drug monitoring program (PDMP); an EPCS requirement does not necessarily improve visibility or PDMP contributions.

E-prescriptions transmitted via EHRs should be considered the most reliable and least likely to be subject to misuse. As such, additional barriers to use, such a two-factor authentication with each use may at times be unnecessary and perhaps superfluous in these settings. Overly burdensome security procedures create a barrier to the adoption of EHRs and other health IT platforms, or a disincentive to prescribe the most medically appropriate drug for a patient.

CMS also request comments on what level of compliance with EPCS would be appropriate to require before levying any penalties on a non-compliant prescriber. As described below, ACEP opposes penalties for non-compliance and requests that emergency physicians be excluded from the requirement in certain cases.

Enforcement/Penalties

Although the SUPPORT Act provides the authority to the Secretary of the Department of Health and Human Services (HHS) to enforce and specify appropriate penalties for non-compliance with the EPCS requirements, ACEP strongly recommends that CMS not implement any penalties, especially initially as the requirement is phased in. If CMS does decide to levy penalties, it should restrict penalties to outlier prescribers who knowingly and repeatedly do not comply with the requirement to the detriment of the patients they serve.

Exceptions

ACEP believes that as CMS implements the EPCS requirement, it must take into account factors that are unique to emergency medicine and create exceptions accordingly. The SUPPORT Act specifies some circumstances under which the HHS Secretary may waive the electronic prescribing requirement with respect to controlled substances that are covered Part D drugs and also permits HHS to develop other appropriate exceptions. One specific exclusion included in the SUPPORT Act are cases where the prescriber reasonably determines it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and the delay would adversely impact the individual's medical condition. This specific exclusion applies regularly to patients who seek treatment in emergency departments (EDs).

The majority of ED visits fall outside of “business hours,” and some of our patients are not familiar with a regular pharmacy. Thus, many e-prescriptions are prone to “failure” - meaning, the pharmacy hours are not convenient for the patient, or the prescribed drug may not be in stock. This usually requires the patient to return to the ED or call the prescriber to cancel the original prescription and re-issue it to a new pharmacy. If the original prescriber's ED shift has ended, a new prescriber must be recruited, which either prompts a new and avoidable ED visit, or pulls a clinician away from current emergency patients. Emergency physicians especially may have trouble electronically prescribing controlled substances in rural areas. In some areas of the country, there are no 24-hour pharmacies. Pharmacy hours can change frequently and getting even non-controlled prescriptions to an open pharmacy that the patient can use is problematic after business hours.

Despite the widespread adoption of EHRs in recent years, “EHR downtime” is still a regular phenomenon, where system upgrades and maintenance are performed and clinical work is carried out on paper – including charting, lab requisitions, and prescribing. Emergency physicians work 24/7 and so are more susceptible to experiencing downtime than other prescribers and would benefit from the option to write paper prescriptions.

In addition, we have had issues getting buprenorphine prescriptions filled through electronic prescribing. Many pharmacies do not carry buprenorphine, and others carry a limited supply of certain buprenorphine products (particularly of the generics). Thus, emergency physicians are constantly having to re-route e-prescriptions, creating a huge administrative burden and discouraging physicians who otherwise want to prescribe buprenorphine from doing so.

Further, we believe that in some cases, patients have a better chance of filling a prescription if they have a paper prescription in hand. Sometimes, patients who are electronically prescribed a controlled substance show up at the wrong pharmacy and it extremely difficult and burdensome for us to get the prescription transferred.

Therefore, we ask that CMS create an exception for emergency physicians in cases where they feel, in their clinical judgment, that issuing an electronic prescription for a controlled substance would be logistically challenging and/or decrease the likelihood that their patient will actually get their prescription filled.

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,

A handwritten signature in black ink that reads "William P. Jaquis". The signature is written in a cursive, flowing style.

William P. Jaquis, MD, MSHQS, FACEP
ACEP President