AMA
AMERICAN MEDICAL ASSOCIATION

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Demetrios Kouzoukas
Principal Deputy Administrator for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code CMS–3394–NC. Medicare Program; Electronic Prescribing of Controlled Substances; Request for Information.

Dear Principal Deputy Administrator Kouzoukas:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the Request for Information (RFI) regarding Electronic Prescribing of Controlled Substances (EPCS), published in the *Federal Register* on August 4, 2020 (85 Fed. Reg. 47151).

The Support for Patients and Communities Act included a requirement that Medicare Part D prescriptions for controlled substances be electronically prescribed and that the U.S. Drug Enforcement Administration (DEA) update its EPCS regulations pertaining to the biometric component of two-factor authentication. The current DEA requirements for multifactor authentication have been a significant hurdle to the greater adoption of EPCS. In particular, the rigid and burdensome requirements for biometrics included in the 2010 regulations preclude physicians from deploying user-friendly devices already found in their practices to satisfy these DEA requirements. Instead of using laptop computers and smartphones with fingerprint scanners, facial recognition, or other biometric technology, they must utilize separate biometric technology that has been reviewed by the DEA or a DEA-approved certifying organization for specific compliance with EPCS requirements. The biometric scanners found on consumer devices commonly employed in medical practices are used for secure access to other sensitive information, like banking and electronic health records, but typically do not comport with the EPCS rules.

The regulations further require that the biometric device either be co-located with or built into the computer that is being used for EPCS. This rule has led to the development of a niche market for EPCS products that are certified to comply with DEA regulations. The fingerprint reader or facial scanner on a smartphone could not be used by a physician for EPCS because, even if it had been reviewed by the DEA, the smartphone would be separate from and work independently of the EPCS software and hardware being used in the practice. The existence of this niche market allows health information technology (IT) vendors to charge high prices to physician practices to add the technology needed for EPCS and, even after assuming these costs, EPCS technology is still likely to disrupt workflows because it is not integrated with physicians' other systems.

The COVID-19 public health emergency has further exacerbated problems that physicians were facing in attempting to adopt EPCS for their practices. Quarantine and social distancing guidance led many physicians to work from their homes or in alternative locations away from the technology in their regular medical offices. Whereas many physicians could have successfully used widely available consumer devices in their homes or other sites to provide telehealth services, access their electronic health records, and prescribe non-controlled medications, this DEA rule would have prevented them from using these devices for EPCS.

Several months ago, to facilitate the needed update to the EPCS regulations, the DEA reopened the comment period on its 2010 EPCS interim final rule. This was a critical step forward that was very encouraging to the physician community. 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.

To encourage EPCS adoption by physician practices, the AMA recommends that CMS encourage the DEA to expedite its revisions of the EPCS requirements. Once these revisions are finalized, CMS should work with the health IT companies that develop and market electronic health record systems for physicians to ensure that EPCS systems that comply with the revised DEA regulations will be simple and inexpensive for medical practices to adopt. A high priority will be to ensure that new EPCS systems work well with other health IT in medical practices and does not disrupt practice workflows.

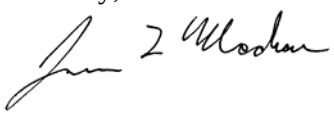
There should be no penalties for noncompliance with the EPCS requirement. CMS should work to support and encourage EPCS adoption and not take a punitive approach.

Similar to the low volume threshold in the CMS Quality Payment Program, the AMA recommends that DEA-registered physicians who prescribe controlled substances to fewer than 200 unique Medicare patients annually should be exempt from the requirement to use EPCS for Medicare Part D prescriptions. Clinicians who do not provide Medicare Part B services but prescribe Part D prescription drugs, such as dentists, should also be exempt. In addition, physicians who practice in facilities, such as hospital emergency departments, where they may have little or no influence over health IT decisions, should be exempt from this requirement.

Finally, it is important to recognize that medical practices are still reeling from the effects of the COVID-19 public health emergency and are likely to continue to suffer economic hardship for the foreseeable future. It is difficult to predict when medical practice workflows, staffing, and financial resources will be sufficiently stable for many of them to consider adding EPCS capabilities. It is not possible for us to identify now the variety of practice circumstances that might create hardships for practices in complying with the EPCS requirement. **The AMA strongly recommends that CMS develop procedures that will allow any practice that is facing such a hardship to easily request a waiver from the requirement at the appropriate time.**

We thank you for the opportunity to provide input on this RFI and for your consideration of our recommendations. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



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