AMA
AMERICAN MEDICAL ASSOCIATION

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Barbara J. Boockholdt
Chief, Regulatory Section (ODG)
U.S. Drug Enforcement Administration
Office of Diversion Control
600 Army Navy Drive
Arlington, VA 22202

Dear Ms. Boockholdt:

On behalf of the physician and medical student members of the American Medical Association (AMA), I want to thank you and your colleagues for reaching out to us and taking the time to meet with our Trustee, Jesse Ehrenfeld, MD, and our staff regarding barriers and solutions to the electronic prescription of controlled substances (EPCS). Although a number of the topics covered during this meeting were mentioned in the May 2010 AMA comments on the U.S. Drug Enforcement Administration's (DEA) interim final rule, we believe it is important to reinforce the key barriers limiting the adoption of EPCS. We have heard from many physicians that a well-designed electronic medication prescription (eRx) system adds value to their practice of medicine and supports better patient care. We believe expanding the utility of EPCS to match that of current eRx capabilities will benefit physicians and patients alike. **To accomplish greater uptake of EPCS across the nation, we urge the DEA to adopt the following solutions in its forthcoming rulemaking.**

Two-factor Authentication

While authentication through a combination of personal identification numbers (PINs), passwords, and biometrics increases the security of EPCS, it also contributes to frequent workflow disruptions and increases costs for many physicians. An AMA survey found that primary care physicians write up to 100 prescriptions per day. Other specialists usually write an average of 10 to 25 prescriptions per day. This volume of prescriptions makes compliance with two-factor authentication, particularly as a distinct process from e-prescribing of non-controlled substances onerous and a significant strain on practice workflows. Few health information technology (health IT) vendors currently support EPCS, and those that do often require physicians to purchase add-on modules or pay separate monthly service fees outside those of normal product maintenance. In speaking with many DEA-registered physicians, the AMA has

found that many methods and processes health IT vendors utilize for EPCS are not well-aligned with normal eRx workflows. In most instances, physicians must initiate an entirely new set of computer programs and windows each time they wish to use EPCS. **We believe cumbersome workflows and applications that do not take physician needs into account are the primary impediment to physician EPCS uptake and should be squarely addressed by system designers and product implementers.** The DEA requirement that biometric devices comply with Federal Information Processing Standards (FIPS) compounds this problem by limiting many user-friendly consumer electronics already found in physicians' offices from being utilized. **The AMA asks that the DEA reexamine the scope of technology that is compliant with EPCS requirements and allow for lower-cost, high-performing biometric devices (e.g., fingerprint readers on laptop computers and mobile phones) to be leveraged in two-factor authentication.**

Identity Proofing

For individual physicians in private practice, identity proofing (verifying that the authenticated user is who he/she claims to be) must occur by an authorized third party that will, after verifying the physician's identity, issue the authentication credential to the DEA registrant. The current identity proofing process is complex and must be performed for each location a physician wishes to employ EPCS. **The AMA suggests the DEA allow a physician's hospital credentialing to be used for his or her EPCS identity proofing instead of requiring a separate process for EPCS. The AMA also suggests that DEA engage with initiatives like the Administration's National Strategy for Trusted Identities in Cyberspace federated identity management program.**

Current regulations further require that, once the authentication credential has been issued to the DEA-registered physician, logical access controls must be established to verify that the authenticated user has the authority to perform the requested operation. **We do not understand the rationale for requiring two-person access controls for EPCS on top of the other requirements and recommend it be eliminated in future rulemaking.**

Audit Requirements

The current rule states that any person designated to set logical access controls is responsible for determining whether any identified auditable event represents a security incident that compromised or could have compromised the integrity of the prescription records (e.g., an unauthorized person attempting to sign or alter a prescription would be an auditable event; a pharmacist annotating a record to indicate a change to a generic version of a drug would not be). EPCS applications must run the internal audit function daily to identify any auditable events. When one occurs, the application must generate a readable report for the physician or pharmacist. If a physician or pharmacy determines that there is a potential security problem, it must be reported to the DEA within one business day. **The AMA believes the one day**

requirement for physicians to report a compromised authentication protocol is impractical. Longer reporting timeframes, such as those required for HIPAA breaches, can be used as a precedent for revising this requirement. Additionally, the DEA should consider how health IT vendors may better support the review of audit logs and reduce the need for manual review by physicians.

Meaningful Use eRx/EPCS Parity

The Centers for Medicare & Medicaid Services (CMS) Meaningful Use (MU) program currently does not universally count EPCS toward a physician's effort to meet the eRx objective. For physicians to count EPCS as part of this MU objective they must maintain a unique eRx list containing all EPCS under a separate denominator. **The AMA recommends that the DEA work with CMS to provide an <u>option</u> for physicians who wish to include their EPCS in their Stages 1 & 2 MU participation thresholds to do so without the need to maintain separate measures.** Maintaining two eRx measurements for one reporting program continues to burden physicians seeking to incorporate EPCS. We understand this may require slight adjustments to the MU attestation system; however, we believe this would be a meaningful improvement.

Prescription Drug Monitoring Programs (PDMP)

PDMPs can be an important tool for physicians to help prevent drug misuse, diversion, and overdose. Currently, most PDMPs have limited or no ability to connect with and share information to third-party applications. **The AMA urges the DEA to work with its state and federal partners to encourage the interoperability of PDMP databases, electronic health records, and other health IT products to improve the integration of data on controlled substance use into practice workflows and physicians' clinical decision-making.**

DEA Fees and EPCS Compliance Costs

Physicians often face excessive costs for complying with EPCS requirements. Many physicians— especially those in small and solo practices—face high fees associated with the extensive technical, security, and other standard requirements (e.g., costs for identity proofing, access control training and the setting of access controls, hardware, software or application purchase and maintenance, reprogramming, and audit requirements), along with workflow adjustments needed for EPCS. In addition to the costs of compliance with EPCS, there are also monthly fees levied by health IT vendors. These fees and costs pose a significant barrier to EPCS adoption. **As DEA registration fees ($731 for 3 years) are set to cover the costs of its diversion control program and a major purpose of EPCS is to lower the risk of drug diversion, the AMA urges the DEA to consider reducing registration fees for those who employ EPCS.** We believe this action will help offset some of the costs physicians face associated with EPCS compliance and could help drive greater uptake.

Clearer Guidance

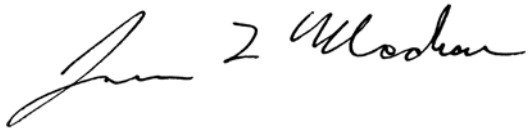
The current regulations are difficult for practicing physicians to comprehend. The procedures that registrants must follow to comply with EPCS requirements are also unclear. **As the DEA engages in new rulemaking, the AMA encourages the agency to provide clearer guidance, including examples, to help physicians understand exactly what is required of them for EPCS compliance.**

Compliant EPCS Software

The AMA supports the DEA requirement that EPCS application providers undergo a third-party audit and provide a copy of the audit report to physician registrants and the DEA. Nonetheless, currently there are nearly12 EPCS-compliant products on the market. In addition, there is no one, central location where physicians may find a list of the compliant products. **The AMA asks that the DEA maintain an up-to-date list of all EPCS-compliant products, including a clearly defined explanation of their functions and any fees associated with their purchase and maintenance.**

We appreciate the opportunity to share our views with the DEA and look forward to working with you and your colleagues at the agency to improve EPCS and remove the barriers that have prevented its widespread adoption. Should you have questions, please do not hesitate to contact Matthew Reid, Senior Health Information Technology Consultant, Federal Affairs, at matt.reid@ama-assn.org or 202-789-7419.

Sincerely,



James L. Madara, MD

cc: Jesse M. Ehrenfeld, MD, MPH