April 10, 2018

The Honorable John Martin  
Assistant Administrator  
Diversion Control Division  
U.S. Drug Enforcement Administration  
8701 Morrissette Drive  
Springfield, VA 22152

Dear Assistant Administrator Martin:

On behalf of the over 20,000 physician, resident and student members of the Medical Society of the State of New York, we are writing to you to request that the DEA act to reduce some of the hassles and extensive costs associated with implementing e-prescribing in their practices. In particular, we are concerned with the continuing hassles associated with the “two-factor” identification process the DEA requires for e-prescribing for controlled substances. As noted below, we are urging changes to expand the technology that can meet existing two factor identification requirements as well as expanding the ways by which a physician’s identity may be proved for locations where they may e-prescribe controlled substances.

As you may know, New York was the first state in the country to require that most prescriptions, including for controlled substances, be submitted electronically. However, the requirements for e-prescribing systems to meet DEA standards have greatly increased the costs and the complexity of adopting and implementing e-prescribing systems. With very few exceptions, physicians have no choice but to absorb these significant costs charged by Health IT vendors in order to comply with the law, and existing regulations add unnecessary administrative hassles that take time away from delivering patient care.

First, we request that the DEA expand the technology that can meet the biometric component of multifactor authentication. The requirement for multifactor authentication increases e-prescribing security but, as was noted in the March 28, 2018 AMA letter to you, 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 requirements. Instead of using laptop computers and smartphones with fingerprint scanners, they must utilize separate biometric technology that has been reviewed by the DEA or a DEA-approved certifying organization for specific compliance with e-prescribing requirements. These requirements state that the “biometric subsystem must operate at a false match rate of 0.001 or lower.” For example, while Apple products have a very low error rate, they are not low enough to meet this standard and therefore cannot be used for e-prescribing. The biometric fingerprint scanners found on the consumer devices commonly found in medical practices are used for secure access to other sensitive information, like banking and medical records, but typically do not comport with rigid rules for e-prescribing. This distinction makes no sense.
The existing regulations further require that the biometric device either be co-located with or built into the computer that is being used for e-prescribing. As a result, the fingerprint reader on a smartphone commonly used by physicians cannot be used by a physician for e-prescribing because, even if it had been reviewed by the DEA, the smartphone would be separate from and work independently of the e-prescribing software and hardware being used in the practice. These additional requirements give Health IT vendors the opportunity to charge exorbitant prices to physician practices to add the technology they need for e-prescribing, even as this additional technology still disrupts physician workflows because it is not integrated with physicians’ other systems.

As the prescribing of controlled substances is often essential for many physicians based upon the types of patients they regularly treat, the hassles associated with two-factor authentication causes a significant strain on practice workflow. In most instances, physicians must initiate an entirely new set of computer programs and windows each time they use e-prescribing. Separate workflows and authentication requirements for electronic health records (EHRs), prescription drug monitoring programs, and e-prescribing should be addressed by the DEA in concert with health IT designers and implementers.

Second, we urge an expansion in the methods by which a physician’s identity may be proved with regard to the e-prescribing of controlled substances. The identity proofing standards in the current e-prescribing regulations present additional hassles, as they require that an authorized third party verify the physician’s identity and then issue the authentication credential to the DEA registrant. The current identity proofing process is complex and must be performed for each location where a physician may issue an e-prescription for a controlled substance. As was suggested by the AMA in its March 28 letter, the DEA should permit a physician’s hospital credentialing to be used for his or her e-prescribing identity proofing instead of requiring a separate process for e-prescribing. Acknowledging a physician’s hospital privileges as proof of their identity for e-prescribing is one method to reduce the burden and cost on physicians.

Thank you for your consideration of these recommended updates to the regulations for e-prescribing controlled substances. In summary, we are cognizant of the security concerns that led to such detailed regulations. However, we believe there are ways to provide appropriate flexibility to reduce some of these hassles and costs even as the goals of the e-prescribing regulations are still being met. We would be happy to meet with you to discuss these recommendations in greater detail.

Sincerely,

THOMAS J. MADEJSKI, MD, FACP
President