May 26, 2010

Michele M. Leonhart
Deputy Administrator
Drug Enforcement Administration
DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, Virginia 22152

Re: The Drug Enforcement Administration interim final rule on *the Electronic Prescriptions for Controlled Substances*, 21 CFR Parts 1300, 1304, et al. (March 31, 2010). Docket No. DEA—218.

Dear Deputy Administrator Leonhart:

The American Medical Association (AMA) along with the undersigned organizations appreciate the opportunity to provide comments on the Drug Enforcement Administration's (DEA) interim final rule (IFR) on electronic prescriptions for controlled substances. The DEA has put forth a process for enabling the electronic prescribing (e-prescribing) of controlled substances that supplements, but does not replace, existing prescribing and dispensing requirements established by the Controlled Substances Act (CSA) and DEA regulations. Automating our current paper-based prescription process will create a safer prescribing environment by eliminating errors due to illegible handwritten prescriptions, providing physicians with drug interaction information at the point of care, and creating electronic audit trails of prescriptions for tracking purposes. In order to encourage widespread adoption of e-prescribing, the electronic process and system should be practical, functional, secure, as well as affordable for physicians.

While we appreciate that the DEA considered many of our comments, which we provided on September 25, 2008, in response to the DEA's proposed rule on e-prescriptions for controlled substances, we are concerned with some of the remaining stringent requirements specified in the IFR, including the two-factor authentication process and notice requirements. While we believe many physicians want to prescribe all prescriptions electronically, we also appreciate that the DEA has not mandated physicians prescribe controlled substances electronically. For physicians who prescribe or plan to prescribe electronically, to the extent they can use a single process, we believe this will speed adoption of e-prescribing. If physicians are forced to implement two separate, distinct electronic workflows for e-prescribing (one for controlled substances and another for non-controlled substances), we will face challenges with accelerating widespread e-prescribing use of controlled substances. We also believe that now that e-prescribing for controlled substances is permitted, that it is important that CMS retain flexibility in the new electronic health record (EHR) incentive program to allow physicians to select the method for prescribing controlled substances that best meets their needs and which retains the best access to care for their patients.

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 (e.g., authorized prescribing physician). The DEA is requiring physicians to apply to certain federally approved

credential service providers (CSPs) or certification authorities (CAs) to obtain their authentication credentials or digital certificates. These CSPs or CAs will be required to conduct identity proofing at National Institute of Standards and Technology (NIST) SP 800-63-1 Assurance Level 3, which allows either in-person or remote identity proofing. Once a federally approved CSP or CA has verified the identity of the physician, the CSP or CA will issue the necessary authentication credential. **We support the DEA's revision of the proposed rule to allow either in-person or remote identity proofing.** We also appreciate the DEA's revision that allows physicians with multiple DEA numbers to use a single two-factor authentication credential per physician. We continue to strongly urge the DEA to reconsider the current requirement that physicians, who prescribe in multiple states, as well as locum tenens physicians, obtain a separate DEA number per state. If the DEA were to make DEA numbers less accessible to non-DEA registrants and the public, such stringent, costly controls would not be necessary. **We recommend the issuance of one federal DEA number that would be physician specific and not site-specific in order to reduce the unnecessary burdens and costs on physicians for maintaining multiple DEA numbers.**

Access Controls

The IFR indicates that once the authentication credential is issued to the physician, logical access controls must be set (e.g., verifying that the authenticated user has the authority to perform the requested operation). Under the IFR, entering or changing access control must be handled by at least two people within a practice, one of whom must be registered with the DEA (e.g., DEA authorized prescriber). In other words, the validation process needs to be a two person step—someone other than the prescriber needs to authenticate the prescriber. Logical access controls may be by user or role-based; that is, the electronic prescription application may allow permissions to be assigned to individual users or it may associate permissions with particular roles (e.g., physician, nurse), then assign each individual to the appropriate role. We fail to see the rationale for requiring two person access control for e-prescribing of controlled substances given that there are no assurances that this requirement will actually reduce prescription forgery, fraud, theft, and other-related crimes to drug diversion. **We urge the DEA to recommend but not require the use of two-person access controls.**

Two-Factor Authentication

Authentication is information (e.g., PINs, passwords, biometrics) that is used to verify a person's identity for security purposes. For example, ATMs use two-factor authentication—something you know (a personal identification number (PIN)) and something you have (bank card). According to the IFR, e-prescribers for controlled substances would have to prove their identities by using two out of three factors: something you know (e.g., passwords), something you have (e.g., hard token stored separately from the computer being accessed), or something you are (e.g., biometrics such as a fingerprint or iris scan). The DEA is allowing the use of a biometric as a substitute for a hard token or a password. If a biometric is used it may be stored on a computer, a hard token, or a biometric reader. If a hard token is used, it must be a cryptographic device or a one-time-password device that meets Federal Information Processing Standard 140-2 Security Level 1, and it must be stored on a device that is separate from the computer in use (e.g., smart card). The DEA should provide greater flexibility to meet the two-factor authentication requirement. **While we appreciate the DEA's revision of the proposed rule to no longer require one of the factors to be a hard token, we remain concerned that this two-factor authentication process is unworkable in most practices.**

An AMA survey indicated that primary care physicians wrote up to 100 prescriptions per day. Specialists usually write an average of 10 to 25 prescriptions per day. Given the sheer volume of prescription activity, requiring a physician, especially a high volume prescriber, to comply with a two-factor authentication process, a separate, distinct process from e-prescribing of non-controlled substances, is onerous and will significantly affect practice workflows. In addition, in order for hard tokens or biometrics to work, the computer to which it is authenticating must be properly configured. The technological complexities and costs associated with these adjustments, especially for smaller practices, are significant. Moreover, hospitals and other settings outside the physicians' practice must also be configured to accept hard tokens and biometrics and most of these settings prohibit the connection of foreign devices to their systems due to security concerns. **We believe the DEA's two-factor authentication requirement will detract significantly from the workability of an e-prescribing system for controlled substances and would deter physicians from using the system.**

Public Key Infrastructure (PKI) and Digital Certificates

PKI is a set of hardware, software, people, policies, and procedures needed to create, manage, distribute, use, store, and revoke digital certificates. A digital certificate is an authorized digital identity that contains certain information used to verify that the owner sending a message is who he/she claims to be, and to provide the receiver with the means to encode a reply. **We support the DEA's decision to allow a physician to use his/her own digital certificate to sign e-prescriptions for controlled substances.** If the physician and his/her e-prescribing application provider wish to do so, the two-factor authentication credential can be a digital certificate specific to the physician that the physician obtains from a CA that is cross-certified with the Federal Bridge Certification Authority at the basic assurance level.

Signature and Transmission Requirements

Many physicians prefer to sign prescriptions before their office staff add pharmacy or insurance information. Physicians should have flexibility in issuing and transmitting electronic prescriptions. **We support the DEA's decision to not require the signing and transmission of a controlled substance e-prescription to occur at the same time.**

There are also situations which call for the printing of a controlled substance prescription after it has been electronically transmitted to a pharmacy. For example, a physician may be audited by a health care payer and contractually required to furnish medical records, including prescriptions for controlled substances. Technical glitches and system failures occur that will require the reprinting or resending of a prescription to a pharmacy. **The DEA's decision to only allow the printing of a transmitted electronic prescription if the printed prescription is clearly marked as a copy not for dispensing is too stringent. We strongly urge the DEA to allow the printing of a transmitted electronic prescription so long as the prescriber provides documentation or an annotation to the prescription explaining the reason for the resend (e.g., transmission failure).**

In the IFR the DEA indicates that, because the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard does not currently contain a field for the signature of a prescription that the DEA proposed, the prescription data transmitted to the pharmacy must include an indication that the practitioners signed the prescription. It is our understanding that in order to facilitate the requirements in the IFR, the NCPDP is developing an interim solution that will be available for use in the MMA-named SCRIPT version 8.1. This solution will also be available for version 10.6, which is still awaiting published HHS regulations. HHS has adopted version

8.1 of the SCRIPT Standard for the Medicare e-prescribing program and versions 8.1 and 10.6 for the purposes of the EHR incentive program. NCPDP is also evaluating whether a longer term solution is needed. The process for making changes to standards is quite lengthy due to the regulatory process required. Also, we have learned that the DEA sent a letter to all physicians indicating e-prescribing for controlled substances will be permitted June 1, 2010. While the letter indicates that systems must comply, it does not require that: the workflow be examined; prescribers must be authenticated; software of vendors, clearinghouses, and pharmacies must be updated, installed, and certified; and trading partners must prepare for exchanging transactions. **Also, while the DEA does not require physicians to electronically prescribe controlled substances, we are concerned about how this will dovetail with the standards adopted by HHS for e-prescribing in the Medicare e-prescribing incentive program and the new EHR incentive program now that controlled substances can be prescribed electronically. We urge the DEA to work with us on future communications on e-prescribing of controlled substances so that we may provide helpful feedback.**

Monthly Electronic Prescription Logs

The DEA requires the e-prescribing application for controlled substances to perform several required functions including: automatically providing the physician with a monthly log of the physician's e-prescribing of controlled substances; upon a physician's request, providing a log of the physician's e-prescribing of controlled substances for a particular time period; providing a log that covers up to a minimum of two years of prior e-prescribing of controlled substances; and providing a log for particular patients or drugs. **The IFR does not require the physician to review the logs or indicate his/her review of the logs. We strongly support the DEA's decision to eliminate the requirement that the physician review or indicate his/her review of monthly prescription logs.**

Audit Requirements

The IFR 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). The e-prescribing 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, they must report it to the DEA within one business day. The IFR also indicates that although physicians are not expressly required under the DEA regulations to report suspected diversion of controlled substances to the DEA, all DEA registrants have a duty to provide effective controls and procedures to guard against theft and diversion of controlled substances. The DEA expects physicians to ensure that information regarding potential diversion is provided to law enforcement authorities, where circumstances so warrant. **Although the DEA requires the electronic prescription applications to run the internal audit function daily to identify any auditable events, we recommend that the DEA clarify that physicians are not required to review audit reports on a daily basis.**

Liability Concerns

We remain extremely concerned with a provision in the IFR that indicates that physicians will be held responsible for any controlled substance prescriptions written using an

authentication protocol that may have been/has been compromised, or a hard token if the hard token is lost, stolen, or compromised. We strongly believe that this additional legal burden imposed on physicians will act as a disincentive for physicians to e-prescribe controlled substances given that they can be held liable for unforeseeable actions resulting from a lost or stolen smart card, cell-phone, or PDA. We also believe that the one business day time limit for reporting purposes is not practical. **We strongly recommend that the time frame for reporting a compromised authentication protocol or a lost, stolen, or compromised hard token be extended to two business days, and that the following sentence be removed from § 1311.102 of the final rule, "A practitioner who fails to comply with this provision may be held responsible for any controlled substance prescriptions written using his two-factor authentication credential."**

Recordkeeping

The IFR requires records related to that prescription to be retained electronically for two years from the date of their creation or receipt. This record retention requirement does not preempt any longer period of retention which may be required now or in the future, by any other Federal or State law or regulation, applicable to physicians. **We support the abbreviated recordkeeping requirement, and the DEA's requirement that electronic prescription applications provide a log that covers up to a minimum of two years of prior e-prescribing of controlled substances to prescribing physicians, and additional logs for particular time periods, patients, or drugs, upon a physician's request.**

Cost Impact of Security Measures and Requirements

We are disappointed that the DEA did not extensively assess the hard dollar costs, especially for small and solo physician practices, associated with the extensive technical, security, and other standards requirements (i.e., 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 e-prescribing controlled substances. **We strongly recommend that the DEA fully assess the actual purchasing, implementing, and upgrading costs of compliant e-prescribing applications and their availability in the marketplace.**

Electronic Prescription Application Requirements

We support the DEA's requirement that e-prescribing application providers undergo a third-party audit and that the application provider must provide a copy of the audit report to physicians and the DEA that will inform them whether the application is compliant. **We urge the DEA to post on its website a list of compliant e-prescribing applications and EHRs that include compliant**
e-prescribing applications so that physicians are fully aware of which applications and EHR systems are compliant with the DEA's rule.

Administration of Medications in Long Term Care Facilities

We continue to hear about unacceptable delays in dispensing urgently needed drugs to patients in long-term care facilities. We urge the DEA to establish an advisory panel comprised of key stakeholders, including physicians, to develop a process for the prescribing of controlled substances, including e-prescriptions, that addresses the unique requirements and needs found in the long-term care prescribing process.

Meaningful Use EHR Incentive Program Requirements and MIPPA E-Prescribing Penalties

Given the amount of time needed for physicians to purchase and implement the electronic prescription application and protocols for controlled substances, **we strongly urge the DEA to recommend to the Centers for Medicare & Medicaid Services (CMS) that CMS provide as much flexibility as possible so that physicians are eligible for e-prescribing and EHR incentive programs, regardless of whether they choose to e-prescribe controlled substances in accordance with the DEA's final rule and requirements.**

Given the complexity, costs, and liability concerns associated with the DEA's IFR, physicians may be reluctant to adopt e-prescribing for controlled substances. **We, therefore, further urge the DEA to recommend that CMS use discretionary authority as provided under the "Medicare Improvements for Patients and Providers Act of 2008" (MIPPA) (P.L. 110-275) to exempt the e-prescribing of controlled substances from any assessment of penalties against physicians who choose not to e-prescribe controlled substances.**

We appreciate the opportunity to comment on the DEA's IFR and look forward to working with the DEA to ensure that the e-prescribing process and system for controlled substances accelerates widespread adoption and use of e-prescribing and EHRs. Should you have questions about these comments, they can be directed to Mari Savickis at mari.savickis@ama-assn.org or 202-789-7414.

Sincerely,

AMDA-Dedicated to Long Term Care Medicine
American Academy of Child and Adolescent Psychiatry
American Academy of Dermatology Association
American Academy of Family Physicians
American Academy of Neurology Professional Association
American Academy of Otolaryngology - Head and Neck Surgery
American Association of Neurological Surgeons
American College of Cardiology
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American College of Physicians
American College of Radiation Oncology
American College of Surgeons
American Gastroenterological Association
American Geriatrics Society
American Medical Association
American Osteopathic Academy of Orthopedics
American Osteopathic Association
American Psychiatric Association
American Society for Radiation Oncology
American Society of Addiction Medicine
American Society of Anesthesiologists
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology
American Society of Hematology
American Society of Plastic Surgeons

American Urological Association
Association of American Medical Colleges
Congress of Neurological Surgeons
Heart Rhythm Society
Infectious Diseases Society of America
Medical Group Management Association
Society of Hospital Medicine