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Everything's Going Electronic, Including Your Prescription for Vicodin (But Not Likely Anytime Soon)

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Effective June 1, 2010, physicians may write, and pharmacies may fill, electronic prescriptions for controlled substances if both the physician and pharmacy comply with the requirements of the U.S. Drug Enforcement Agency (DEA) e-prescribing interim final rule published at 75 Fed. Reg. 16235 (March 31, 2010). The DEA's interim final rule primarily affects three groups: first, makers of e-prescribing software and pharmacy electronic processing software (which the DEA refers to as the "application" and the "application providers"); second, physicians and other licensees who are authorized by the DEA to write prescriptions for controlled substances (referred to in this article as "prescribers"); and third, pharmacies filling the prescriptions. This article will focus primarily on the requirements for prescribers to prescribe controlled substances electronically, and why e-prescribing of controlled substances is not likely to be implemented soon in many prescribers' offices despite now being permitted by the DEA.

Background on the Rule
The rule addresses the goals and concerns of the DEA regarding e-prescribing of controlled substances while balancing the benefits of reduced errors and increased efficiency for prescribers by not having two "processes" for writing prescriptions (i.e., a paper process for controlled substances and an electronic process for non-controlled substances). The DEA's main concerns were that electronic prescriptions would allow for inadvertent diversion and abuse of controlled substances and that the DEA and law enforcement would not be able to prove who wrote the prescription allowing for diversion. The DEA was equally concerned that a prescriber whose DEA number was used to prescribe controlled substances would not be able to refute writing the unlawful prescription. See 75 Fed. Reg. at 16239-16240.

The DEA stressed that (1) e-prescribing is voluntary and (2) it does not replace or change any of the existing requirements with respect to prescribing controlled substances. See 75 Fed. Reg. at 16283. In addition, the rule will not supersede state law requirements with respect to e-prescribing of controlled substances, and prescribers will need to be mindful of state requirements or prohibitions on e-prescribing. It should be noted that the N.C. Board of Pharmacy currently has a regulation, 21 NCAC 46.1813, permitting electronic prescribing. The DEA noted that controlled substances currently constitute between 10 percent and 11 percent of all prescriptions written in the United States.

Identity Proofing
Identity proofing is the method for verifying that the prescriber is who he claims to be, and it was a key requirement for the DEA in allowing e-prescribing of controlled substances. See 75 Fed. Reg. at 16242, 16244-16247. Prescribers will need to obtain identity proofing at National Institute of Standards and Technology SP 800-63-1 Assurance Level 3 from certification authorities and similar credential service providers that are federally approved. This level of identity proofing can be in person or remote, which should accommodate practitioners in rural areas. The entity conducting the identity proofing will provide the two-factor authentication credential or digital certificate that the prescriber uses to "sign" his electronic prescriptions.

Identity proofing will likely be a cost that is incurred by the prescriber. In addition, the DEA expects software providers to work with entities that can provide identity proofing for their particular e-prescribing software and then recommend

to prescribers which identity proofing entities are interoperable with such software.

The interim final rule contains differences for identity proofing done at institutions, such as hospitals that are DEA registrants, as opposed to physician practices.

Access Control
Logical access control is the method of verifying that an authenticated user has the authority to perform the requested operation of prescribing a controlled substance, and it was another key element for the DEA in allowing e-prescribing of controlled substances. See 75 Fed. Reg. at 16247-16249. The interim final rule requires the prescriber (or the prescriber's office staff) to (1) check DEA and state authorities to confirm an individual's ability to prescribe controlled substances, and (2) set logical access controls to the e-prescribing software. The DEA allows for flexibility in confirming an individual's authorization to sign prescriptions: small practices could check expiration dates on DEA Certificates of Registration and state authorizations, unless there is a reason to question that the expiration dates are valid, and larger practices could check individual registrations on the DEA's website. Access controls are not required to be "set" for each prescription, but rather upon starting to use the software or the individual joining the practice and when changes need to be made. The access controls must limit who can indicate that a prescription is ready to be signed and who can sign a prescription to prescribers only. The access controls can be by name (i.e., John Doe, M.D.) or by role (i.e., DEA registrant or physician).

Two individuals will be required to enter or change logical access controls. The first person would enter data identifying those individuals authorized to sign a prescription for a controlled substance. The second person would be the prescriber, and he would use his two-factor authentication credential to approve the data that the first person entered about him. There are no requirements as to the relationship between the person entering the data and the prescriber; the DEA only requires that two individuals be involved in the setting and changing of access controls so that there is a "check" on any one person's ability to falsify information.

The interim final rule requires that access controls be revoked upon certain events, such as the DEA registration expiring, terminating, being revoked or suspended; termination from the practice or institution; or loss of the token associated with the two-factor authentication credential.
There are differences for institutions that have a DEA registration number in setting logical access controls as opposed to physician practices.

Two-Factor Authentication Protocol
A two-factor authentication protocol would be issued to the prescriber once the identity proofing is performed, and it is how the prescriber "signs" prescriptions for controlled substances. See 75 Fed. Reg. at 16249-16254. The DEA requires two out of three factors to be used to sign a prescription: one factor is "something you know" (i.e., a PIN or password), a second factor is "something you have" (i.e., a token or card), and a third factor is "something you are" (i.e., a fingerprint or iris). The DEA stated that the prescriber must retain sole possession of a hard token (if used) and must not share the password or other knowledge factor with anyone; failure to follow this requirement may provide a basis for revocation or suspension of the prescriber's DEA registration. See FAQ for Prescribing Practitioners, available at www.deadiversion.usdoj.gov/ecomm/e_rx/faq/practitioners.htm (last visited Sept. 20, 2010) (hereinafter, "FAQ for Prescribing Practitioners").

The interim final rule has certain requirements related to the security level of hard tokens to be used, the use of biometrics and the testing of software used to read biometrics. See 75 Fed. Reg. at 16250-16253. A hard token or biometric that satisfies the DEA's security requirements may prove costly for some small practices and may create challenges at larger institutions with many physicians using different types of tokens. See Comments Submitted by the American Medical Association to DEA's Interim Final Rule, dated May 26, 2010, available at www.regulations.gov (last visited Sept. 21, 2010) (hereinafter, "AMA Comments").

The rule states that prescribers will be held liable for any controlled substance prescriptions written on an authentication protocol that may have been lost or comprised or a hard token that has been lost or comprised. See 75 Fed. Reg. at 16285; AMA Comments. Furthermore, prescribers are required to notify the DEA within one business day of discovering a lost or comprised protocol.

Creating and Signing Prescriptions
The interim final rule requires that each prescription be "approved" for "signature" and "signed" by the authorized prescriber. See 75 Fed. Reg. at 16254-16259. The approval process will require the prescriber to view all of the information that would be required to appear on a paper prescription: the patient's name, drug information, refill/fill information, and the prescriber's information. The DEA agreed to delete the requirement that the patient's address be viewed; however, the patient's address will need to appear on the prescription that is digitally signed and transmitted to the pharmacy.

After the prescriber indicates that he has reviewed the information on the prescription and that the prescription is ready to be signed, the prescriber will "sign" the prescription by entering his two-factor authentication. Entering the two-factor authentication is the legal equivalent of manually signing the prescription. The software will enter a private key to digitally sign all of the information that would be in a paper prescription, and the digitally signed record must be electronically archived. Many software providers complained that requiring a "key" to indicate that the prescription has been signed will require software updates, which may take up to two years to develop and implement. See AMA Comments; Comments from Healthcare Information and Management Systems Society to DEA's Interim Final Rule, dated May 28, 2010, available at www.regulations.gov (last visited Sept. 21, 2010).

The DEA responded to concerns by affirming in the rule that staff members may enter information at the prescriber's direction prior to the prescriber reviewing and signing the prescription. However, the DEA noted that as with paper prescriptions, the prescriber is responsible if the information entered on the prescription does not comply with all legal requirements.

The DEA provided flexibility in the interim final rule for creating and signing prescriptions in response to submitted comments. First, the prescription is not required to be sent upon signing; there can be a delay, although the DEA recommends transmission occur as soon as possible after signing. Second, the prescriber's staff may add information, such as insurance information or receiving pharmacy information, after the prescriber has "signed" the prescription, but before the prescription is transmitted to the pharmacy. Third, prescribers are allowed to sign multiple prescriptions for a single patient with a single signature. However, the DEA decided not to allow prescribers to sign multiple prescriptions for multiple patients with a single signature. Fourth, the DEA permitted a supervisor's DEA number to appear on the prescription of a dependent practitioner who is permitted to sign a prescription. Fifth, there is an attestation statement that must appear on the screen for review by the prescriber prior to signing the prescription, but due to many comments received, the attestation does not need to be "acknowledged" (i.e., through a key stroke) by the prescriber. Finally, the DEA deleted the requirement that the software has a "lock out" period if there is inactivity for two minutes.

The DEA also revised the rule to allow for, but not require, public key infrastructure or digital signatures, which previously had been proposed to be permitted only in the federal healthcare system. However, to ensure security and authenticity, the DEA has specific requirements with respect to the type and security of digital signatures that may be used. See 75 Fed. Reg. at 16260-16261.

Sending the Prescription

Another area where the DEA responded to comments was with respect to transmitting the prescription. See 75 Fed. Reg. at 16263-16264. The rule allows for electronically transmitted prescriptions to be printed out after transmission for inclusion in patient records or insurance files, provided that the prescription clearly states that it is a copy, is not for dispensing purposes, and may not be manually signed. The DEA also permitted a list of prescriptions to be printed out after transmission, such as for patients, if the printed list indicates that it is only for informational purposes, and not for dispensing. The DEA prohibits a prescription for controlled substances to be transmitted if it has been printed out prior to transmission.

Furthermore, the DEA revised the regulations to allow for printing out of an electronic prescription when the transmission between the prescriber and pharmacy fails. The print out must indicate that the prescription was originally transmitted to the pharmacy, but the transmission failed, and it must be manually signed by the prescriber and transmitted as paper prescriptions would be. The DEA refused to allow for the software to fax an electronic prescription that failed during transmission. The interim final rule prohibits altering prescriptions during the transmission between the prescriber and the pharmacy, and the DEA clarified that this prohibition is limited only to the DEA-required elements found on a prescription as set forth in 21 C.F.R. Part 1306. Furthermore, the DEA clarified that pharmacies may alter a prescription (such as substituting a generic drug for a brand-name drug) after receipt if the pharmacies follow the existing requirements for altering paper prescriptions.

The recordkeeping requirements related to electronic prescriptions of controlled substances are the same as paper records: a minimum of two years. See 75 Fed. Reg. at 16261-16262. These requirements will fall primarily on pharmacies and software providers. Prescribers will not be required to maintain hard copies of their electronic prescriptions, but they should ensure that the software can retain records for two years. This means the contract between the software provider and prescriber should address transfer of records upon termination of the relationship so that the prescriber can fulfill his requirements to retain records for at least two years.

Provisions Related to E-Prescribing Software

Prescribers will need to ensure that the e-prescribing software they use has been audited or certified for compliance with the DEA's requirements. See 75 Fed. Reg. at 16269-16277. Third-party audits or certifications by an

independent organization must be done every two years or upon major changes to the software, whichever occurs first. Examples of third-party audits include WebTrust, SysTrust or SAS 70, or an auditor who is a Certified Information Systems Auditor, and certifications must be by an independent organization, such as the Certification Commission for Health Information Technology. The software provider must provide to the prescriber a copy of the report from the third-party auditor or certification body stating whether the e-prescribing software complies with the DEA's requirements and if there are any limitations on its use for controlled substances. The cost of the audits or certifications will not be direct costs on the prescriber, but rather, on the software provider (unless they are one and the same).

The software is required to generate and provide monthly logs to prescribers of all electronic prescriptions for controlled substances made in the previous month. See 75 Fed. Reg. at 16262-16263. In addition, upon request of the prescriber, the software must generate and provide a log of all electronic prescriptions for controlled substances for a specified period of time (up to two years). All logs must be sortable by patient name, particular drug, and date of issuance. In response to comments, the DEA deleted the requirement that the prescriber had to review and indicate that he had reviewed his monthly logs.

Also, the interim final rule includes requirements with respect to internal audit trails that the software must be able to create and maintain. See 75 Fed. Reg. at 16261. Software providers must run daily audits for auditable events, and provide a report to the prescriber if any events are detected. The DEA did not provide a list of "auditable events," as comments had requested; rather, the DEA stated that the events should be limited to potential security problems. This requirement directly impacts prescribers because upon the occurrence of an auditable event, the prescriber or other person authorized to set access controls will receive a report from the software provider and such person must investigate the event. If the prescriber determines that the event represents a security problem, the prescriber must notify the software provider and the DEA within one business day. See FAQ for Prescribing Practitioners. The rule lacks clarity on what constitutes an auditable event, the degree of investigation that the prescriber must conduct, and what information the prescriber must disclose to the DEA. The DEA stated that "in general, the security incidents that should be reported are those that represent successful attacks on the application or other incidents in which someone gains unauthorized access." 75 Fed. Reg. at 16261. The DEA acknowledged that there is currently no express requirement under its regulations to report suspected diversion of controlled substances to the DEA, but every prescriber has a duty to have measures in place to protect against theft and diversion of controlled substances. The DEA acknowledged it may need to provide further guidance related to reporting security incidents.

Interplay with Meaningful Use and Implementation Issues

It is important to note that compliance with the DEA's requirements for e-prescribing of controlled substances is completely voluntary. To the extent the requirements are too costly or too burdensome, the DEA stated that prescribers can continue to manually write prescriptions for controlled substances or use e-prescribing software to create the prescriptions, but print out and manually sign prescriptions for controlled substances. However, many comments stated that having two systems for prescribing served as a barrier to the adoption of electronic health records.

In addition to the inconvenience, not implementing e-prescribing for controlled substances could eventually prevent a prescriber from receiving Medicare and Medicaid financial incentives as a "meaningful user" of electronic health records and could even result in financial penalties for not achieving "meaningful use." The Medicare and Medicaid Electronic Health Record Incentive Program (EHR Incentive Program) requires the electronic transmission of prescriptions; in other words, just using the e-prescribing software to "create" the prescription, but printing out and manually signing the prescription will not count toward the number of electronic prescriptions required to achieve meaningful use. However, in the Centers for Medicare and Medicare Services (CMS) meaningful use final rule, published on July 28, 2010, 75 Fed. Reg. 44313, 44337-44338, the formula for determining whether a prescriber satisfies the 40 percent threshold for generating and transmitting prescriptions electronically excludes prescriptions that were not permitted to be written electronically as of Jan. 13, 2010. Thus, prescriptions for controlled substances are not factored in determining whether a prescriber meets the meaningful use requirements in Stage 1 of the EHR Incentive Program.

However, CMS has only issued the criteria for Stage 1 of the EHR Incentive Program; Stage 2 and Stage 3 are still to come. It is possible that CMS will include prescriptions for controlled substance in the types of prescriptions used to assess whether a prescriber meets the e-prescribing objective, and thus demonstrates meaningful use. There were some comments made to the DEA requesting it to urge CMS to delay including controlled substances in the meaningful use criteria for at least two years to allow for software developers to create and update software that meets the DEA's requirements. In addition, there were comments requesting the DEA to urge CMS not to include controlled substances in the meaningful use criteria at all due to the cost of purchasing qualified software and implementing the security measures to use the software consistent with the DEA's requirements.

Finally, prescribers need to make sure that the e-prescribing software they use includes both an audit/certification showing compliance with the DEA's requirements for e-prescribing of controlled substances and a certification as to being electronic health record technology for purposes of the EHR Incentive Program. These are two separate certification/audit requirements, and the software should comply with each before a prescriber electronically prescribes controlled substances.

Conclusion

The DEA took a major step toward "modernizing" prescription writing for controlled substances with the implementation of its e-prescribing interim final rule. However, the effects of this modernization will be slow to come, and whether e-prescribing will be utilized by the provider community (and whether with a carrot or stick from CMS) may take several years to determine.

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