

DEA's New Proposed Regulations For E-Prescribing

Thursday, Jul 17, 2008 --- The Drug Enforcement Administration (DEA) published in the June 27, 2008, Federal Register proposed rules for Electronic Prescriptions for Controlled Substances (the "Proposed Regulations").

The Proposed Regulations provide licensed prescribers and pharmacies a way to electronically write, receive, deliver and archive prescriptions for controlled substances.

Currently, controlled substances may not be prescribed electronically. The DEA is currently soliciting comments on the Proposed Regulations, which must be either postmarked or delivered electronically on or before Sep. 25, 2008.

History And Background

While the DEA has issued regulations concerning signature, transmission and retention of records for Schedule I and II drugs (as of April 1, 2005), because of safety and concerns about illegal drug diversions, the DEA has been reluctant to do the same for Schedule III and higher controlled substances.

However, with the passage of the Medicare Prescription Drug, Improvement, and Modernization Act in 2003, which required transmission of Medicare Part D prescription drug information according to standards set by the Department of Health and Human Services (HHS), HHS issued and revised a final rule regarding electronic transmission of Medicare Part D prescription drug information on November 7, 2005, and June 23, 2006, respectively ("HHS Final Rule").

The HHS Final Rule, however, was limited in that it only set forth standards for transmission of electronic prescriptions for Medicare Part D drugs, with a focus on security of patient information.

The HHS Final Rule did not include rules for electronic writing, receipt, delivery and archiving of controlled substances information. Accordingly, the Proposed Regulations are intended to fill this gap in keeping with HHS' larger objective of encouraging physicians to electronically prescribe as a way to reduce medication errors.

The Controlled Substances Act and Controlled Substances Import Act each mandated the DEA to: (1) ensure an adequate supply of controlled substances for legitimate uses; and (2) deter diversion of controlled

substances into illegal markets.

With 8.3% of the U.S. population aged 12 and older (20.4 million Americans) classified as substance dependent, the DEA has focused the Proposed Regulations on safety issues associated with prescription dispensing as well as illegal sales, rather than electronic security (such as encryption levels).

The Proposed Regulations

In the Proposed Regulations, the DEA notes that more than 110 service providers exist for issuing electronic prescriptions and 20 service providers exist for receiving electronic prescriptions.

The DEA proposes to adopt a standard format for prescriptions of controlled substances to reduce communication problems that would occur if each prescriber chose a different format for their prescriptions that might be offered by the various service providers.

The DEA also addresses the following in the Proposed Regulations:

Verifying a valid license to prescribe the controlled substance;

Limiting signatures to authorized persons;

Security issues relating to stolen passwords or IDs;

Unauthorized access by hackers; tracking prescriptions and preventing people from modifying electronic prescriptions; and

Compliance with existing DEA regulations.

The Proposed Regulations provide two options for electronic prescriptions for controlled substances: (1) electronically signed prescriptions with security controls; and (2) modified digitally signed prescriptions.

Under both options, the Proposed Regulations mandate three types of requirements to protect against improper use of the system: (1) identity proofing; (2) authentication; and (3) other requirements.

Identity Proofing

Identity proofing requires prescription service providers to have a document from an authorized entity that conducts an in-person identity verification of the prescriber before allowing for electronic prescriptions of controlled substances, including the checking of state licenses and DEA registration.

The DEA proposes that the following three types of entities be authorized to handle identity verification:

A hospital credentialing office (or other similar privilege-granting entity within

a DEA-licensed hospital);

A state professional licensing board or controlled substances authority; or

State or local law enforcement. The DEA deliberately intended to separate the authority to provide identity proofing from the service provider to reduce the risk of fraud.

Authentication

Access to the electronic prescription system must meet the standards for "Level 4" authentication. Level 4 authentication requires that "two-factor authentication" be utilized to access the system, by either storing one factor in the form of a cryptographic key on a hard token or use of a multi-factor one-time password token.

Thus, prescribers utilizing the electronic prescription system must enter a password or biometric (such as a fingerprint) to activate an authentication key, which provides a random access number, or a device that provides for a single use of the system.

In addition, the Proposed Regulations, if adopted, would require electronic prescription systems to provide for:

Annual audits of the system's security by an independent third-party;

Automatic lock-out after 2 minutes of idle time;

Inclusion of all DEA required elements used for paper prescriptions;

Informing the prescriber which prescriptions require signature when more than one prescription is prepared and requiring the prescriber to agree to the prescriber's understanding of the electronic signature;

Immediate transmission upon signature including noting that the prescription was signed;

Generation of monthly logs;

Digital signature requirements for the first recipient and first pharmacy signature;

Validation of the prescriber's DEA registration;

Creation and retention of an audit trail and auditable events, including storage of DEA data in the pharmacy system;

Backup systems of records at another location;

Maintenance of the prescription in electronic form throughout the

transmission process (no conversion to paper form during transmission; no transmission if printed and no printing if transmitted; and no conversion to facsimile if prescription is not deliverable);

Limiting access so that only authorized prescribers may sign and authenticate to the system prior to signing;

Preventing alteration of the prescription content except for formatting; and

Storing electronic prescription records electronically.

Other Requirements

Other requirements mandated by the Proposed Regulations, if adopted, include:

Requiring separate passwords/keys for prescribers with more than one DEA registration;

Requiring sole possession of a hard token by the prescriber – a prescriber that loses or compromises the token is required to notify the service provider within 12 hours of discovery, or be held responsible for any prescriptions written using the compromised token; and

Requiring pharmacists and prescribers to notify the DEA and the service provider of security incidents or any problems identified in the logs regarding fraudulent or altered electronic prescriptions.

Implementation Concerns

The inability to prescribe controlled substances electronically is one barrier to widespread adoption of electronic prescribing technology.

Currently, prescribers who desire to adopt electronic prescribing technology must be prepared to maintain two different systems—an electronic prescribing system for non-controlled substances and a paper system for controlled substances.

As a result, some prescribers may forego the expected benefits of electronic prescribing technology, such as increased accuracy and reduced medication error, to avoid managing two systems in parallel.

Nevertheless, with the increased availability of electronic prescribing technology because of Medicare Part D prescription drug benefits and Centers for Medicare and Medicaid Services (CMS) donation guidelines, it is anticipated that prescribers will increasingly migrate to electronic prescribing technology.

The newly introduced DEA Proposed Regulations, when finalized, should facilitate broader adoption of electronic prescribing while continuing to

prevent diversion and abuse of controlled substances.

Some risks a prescriber might consider if implementing an electronic prescribing system for either non-controlled substances or controlled substances once final regulations are adopted include:

Risks associated with permitting a service provider to perform remote support functions and recordkeeping;

Hacking and other unauthorized access;

Intentional or inadvertent acts by office staff and by intermediaries; and

Malicious acts by unauthorized persons.

In most cases, the prescriber will not have the capability to assess such risks without relying on service provider disclosures and assessments.

These risks, however, are not necessarily greater than or different from considerations that should be evaluated when adopting any electronic record system, particularly systems that have a health information exchange component.

Indeed, many posit that electronic record systems are actually more secure than paper-based systems for a number of reasons, the least of which is the ability to track access and disclosures.

Another issue that may pose implementation concerns includes the costs associated with adoption of the proper hardware and software in order to facilitate the electronic prescribing of controlled substances.

Although the Proposed Regulations attempt to address cost issues, the actual cost will likely vary depending on several factors, including the complexity of the prescriber's practice, adoption of electronic health records and the level of existing electronic prescription systems.

Conclusion

The Proposed Regulations, once adopted in final form, should advance the adoption of electronic prescribing systems and electronic health records with electronic prescribing functionality by eliminating the need for prescribers to maintain a separate system for controlled substance prescriptions.

At the moment, however, prescribers, electronic health record and e-prescribing vendors, as well as pharmacies, pharmacy benefit managers and others involved in the flow of prescription ordering and delivery should evaluate the implications of the Proposed Regulations, including the degree to which they could be implemented on a cost-effective basis and then used to facilitate prescription delivery, and then consider providing public comments prior to the September 25, 2008 deadline.

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