

COMPLIANCE ALERT 10-23

DEA Interim Rule Allows E-Prescribing for Controlled Substances

The March 31, 2010 Federal Register announced the Drug Enforcement Administration's (DEA) revision of its regulations that will allow practitioners the option of writing prescriptions for controlled substances electronically. The regulations also allows pharmacies to receive, dispense, and archive the electronic prescriptions. The rule is scheduled to take effect June 1, 2010 and any written comments on the Interim Rule need to be submitted by that date.

In announcing the Interim Rule, the DEA is augmenting the requirements of the HITECH Act. The DEA feels the changes will streamline the prescribing process, reduce the numbers of errors made because of illegible handwriting, and further the integration of comprehensive healthcare into the medical record.

For any Electronic Health Record (EHR) system to utilize electronic prescribing of controlled substances:

- Only DEA registrants can sign controlled substance electronic prescriptions.
- Identify Theft of the registrants must be carefully protected.
- Method used to authenticate a prescriber to the prescribing electronic system must ensure that the practitioner cannot repudiate the prescription.
- Prescription records must be reliable enough to be used in legal actions.
- Security systems used by electronic prescription application must prevent, to the greatest extent, the possibility of insider alteration of the prescriptions

The proposed rule requires that practitioners be required to undergo in-person identity-proofing with DEA-registered Hospitals, State Licensing Boards, or law enforcement agencies. The record of the identify-proofing would then be sent to the electronic prescribing application provider to allow the setting of access controls so that only approved practitioners could sign the e-prescriptions. The Interim Rule continues to support the importance of identity proofing DEA registrants and fine-tunes some of the requirements.

The Interim Rule discusses in depth requirements for EHR set up, creating and signing for electronic controlled substance prescriptions, and issuing paper prescriptions. Implementers and providers of EHR applications should be queried as to their familiarity with the technological requirements listed in the Interim Rule.

Source: Federal Register. March 31, 2010, 75, 61, 16236-16318

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