



Health Law Alert

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Drug Enforcement Administration proposes e-prescribing regulations for controlled substances

DEA seeks comment to the proposed regulations by September 25, 2008

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The long-awaited Drug Enforcement Administration (DEA) proposed regulations for the electronic prescribing of controlled substances were published on June 27, 2008. They have been in the making for the past nine years. The proposed regulations affect four distinct industries: pharmacy, software developers and vendors, hospitals, and physicians.

Since the pronouncement in the Medicare Modernization Act (MMA; Public Law 108-173) of the federal government's goal for the rapid adoption of e-prescribing, a number of governmental initiatives have been implemented, including exceptions to and safe harbors under the Stark Law and Anti-Kickback Statute (to see *Health Law Alert* dated 10/5/06, [click here](#)) to promote donations to providers using electronic-prescribing software, and the issuance of final e-prescribing standards for the Medicare Prescription Drug Program (to see *Health Law Alert* dated 4/16/08, [click here](#)).

Despite these efforts, e-prescribing adoption has been slower than anticipated, partly due to the fact that 20-25 percent of all prescribed medications are controlled substances, which presently cannot legally be prescribed electronically. This prohibition has been a barrier for physicians who heartily embrace electronic prescribing but prescribe a significant amount of controlled substances.

Industry pressure on the DEA to adopt regulations to enable electronic prescribing of controlled substances has resulted in the published proposed regulations. The regulations are lengthy and cumbersome, and industry analysts are voicing disappointment in the proposed regulations due to their burdensome requirements.

The proposed regulations outline specific requirements for pharmacies, software vendors and service providers, hospitals, and physicians pursuant to the Comprehensive Drug Abuse Prevention and Control Act (CSA) and the Controlled Substances Import and Export Act (21 U.S.C. 801-971), as amended. The proposed regulations state in numerous places that, although the DEA supports the adoption of electronic prescriptions for controlled substances, it must be in a manner that will minimize the risk of drug diversion. The cited reason for this concern is the fact that national studies, including the National Survey on Drug Use and Health (NSDUH), estimate that 20.4 million Americans have been classified with substance dependence or abuse and that more than 20 percent of people aged 12 or older have used psychotherapeutic drugs non-medically in their lifetimes. Further, it is estimated that 33 million Americans have used prescription painkillers for non-medical reasons in their lifetimes, and controlled substances represent 66 percent of the estimated hospital emergency department visits nationally. Correspondingly, prevention of drug diversion activities by the DEA and state drug-diversion units has increased. Accordingly, the DEA insists that the electronic prescribing of controlled substances must have sufficient safeguards to prevent any further contributions to the drug diversion problem in the United States.

DEA's requirements are detailed and potentially cumbersome; [click here](#) for a summary.

DEA has requested comment on specific sections of the proposed regulations. These include:

- DEA's assessment of risk for the six categories of harm for the electronic prescribing of controlled substances.
- Whether in-person identity-proofing requirements consistent with, but not equivalent to, Level 3 are sufficient to address the DEA's concerns, or whether more stringent requirements, such as those imposed under Level 4, are necessary.
- Whether authentication protocol requirements, use of a hard token, and two-factor authentication meeting the requirements of Level 4 are sufficient to address the DEA's concerns, or whether a more stringent requirement, such as those imposed in a public key infrastructure system, are necessary.
- The requirements for in-person identity-proofing of practitioners, and the effect on practitioners, particularly those practicing at multiple locations.
- Alternatives to in-person identity-proofing.
- The current industry practices used to "sign" electronic prescriptions for non-controlled substances, and whether and how such practices present risks for non-controlled substance prescription forgery, fraud, and other related crimes.
- The extent to which service providers and intermediaries store electronic records of uncontrolled substance prescriptions.

DEA states in the proposed regulations that the requirements: "will protect both practitioners and pharmacies by ensuring that they can meet their legal obligations and lessen the threat of someone misusing their authorities to divert controlled substances. DEA emphasizes that its electronic prescription requirements do not alter the responsibilities of the practitioner and pharmacy in regard to controlled substance prescriptions."

The DEA has regulatory oversight over pharmacies and physicians prescribing controlled substances. Responsibility for a violation of the regulations, once adopted, will rest on pharmacies and prescribers. Therefore, it is important for those industries that will be affected by the final regulations to provide comment to DEA as requested, to have meaningful dialog about a practical and non-burdensome regulatory system that meets the needs of both industry and the government.

For additional information on this issue or other matters involving health information technology, please contact Linn Foster Freedman at lfreedman@nixonpeabody.com or 401-454-1108.

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