



DEA proposes rules to allow e-prescribing of controlled substances

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The Drug Enforcement Administration has proposed rules to allow e-prescribing of controlled substances, such as painkillers and stimulants, and will accept public comments until Sept. 25.

The proposed rules, as explained in a 62-page Federal Register notice today, require doctors to use two forms of identification for each transmission of e-prescriptions for controlled substances in addition to an annual audit of each system by a certified public accountancy.

Under current rules, doctors may use e-prescribing for most prescriptions but must sign a written prescription for Schedule II controlled substances, such as Nembutal, OxyContin and opium. The DEA rule, if it becomes final, would allow doctors to use the same system for generating and transmitting all prescriptions.

The rules call for doctors and other prescribers to have their identity verified in person at a DEA-registered hospital that has granted the doctor privileges to practice at the hospital, a state professional or licensing board, or a state or local law enforcement agency.

With their identity verified, doctors could e-prescribe by using two-factor authentication, which means using a password in addition to a device in the doctor's possession that "could be a [personal digital assistant], a cell phone, a smart card, a thumb drive, or multifactor one-time password token," the proposed rules state.

The standard software protocol for transmitting prescriptions to pharmacies, known as NCPDP SCRIPT, would have to be modified to allow a digital signature on e-prescriptions, the rules state.

E-prescribing systems in use by doctors, pharmacies and intermediaries would have to support two-factor authentication and implement strong security so there would be virtually no possibility that the e-prescription could be diverted or altered. If a diversion occurred, it would have to be possible to identify the perpetrator and exonerate the doctor who wrote a legitimate prescription.

"In the absence of appropriate controls, allowing electronic prescriptions for controlled substances could exacerbate the already increasing problem of...controlled substance abuse," the draft rules state.

"The publication of this proposed rule is an important step toward making electronic prescribing an option for practitioners who prescribe controlled substances," said Joseph Rannazzisi, deputy assistant DEA administrator of the Office of Diversion Control. "Our goal is to put in place an electronic prescribing system that is efficient, medically beneficial to patients and prescribers, and provides security from hackers and others who might seek to engage in fraudulent prescribing activities."

E-prescribing advocates had little to say about the rule because they were analyzing it. "The rule is highly technical, and because the devil is always in the details, I will review it thoroughly with this in mind: We need to lift barriers to widespread adoption of e-prescribing, not create new ones," said Sen. Sheldon Whitehouse (D-R.I.), who has pushed DEA to issue such a rule.

Doctors at federal health care facilities, such as those run by the Defense and Veterans Affairs departments, could use their federal identity cards to access prescribing systems and would not need additional identity proofing, DEA wrote.

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