

REQUIREMENTS FOR E-PRESCRIBING OF CONTROLLED SUBSTANCES

The Drug Enforcement Agency (DEA) has issued an interim final rule (IFR) which spells out the criteria for e-prescribing of controlled substances. Although this information was released a year ago, some questions remain about its implementation. This article will, hopefully, provide the information needed for use of e-prescribing for controlled substances.

As stated in an NABP bulletin of December, 2010, "DEA's Interim Final Rule on e-prescribing, formally allows (but does not mandate) electronic prescribing of Schedule II through V controlled substances, and provides the regulations by which this e-prescribing will be governed." Alabama rules, written August of 2006 state, at the time that the Drug Enforcement Agency "has adopted applicable regulations, all prescriptions for controlled substances must comply with the provisions of any such regulation or any later amendments or changes thereto." Consequently, Alabama pharmacists may process schedule II through V prescriptions using e-prescribing.

The software used by the prescriber and the software used by the pharmacy must be audited by a third party, and that third party must be approved by the DEA. In the situation where the prescription has been digitally signed by the prescriber using his or her private cryptographic key, the pharmacy software must be able to apply the prescriber's public key to confirm that the prescription was, in fact, signed. In this instance, the software must check to verify that the prescriber's digital certificate is still valid and has not been revoked. Otherwise, the software must be able to read and/or display the transmitted flag indicating that the prescription was signed. The software must retain the full DEA number of the prescriber. On receipt of a controlled-substance e-prescription, the software must digitally sign the prescription (this may also be done by the last intermediary, such as the final intermediary for a pharmacy chain). The digitally signed prescription must then be archived by the software. This archived version may be used in audits. The pharmacy software must have logical access controls that restrict access by name or role. The software must store all applicable dispensing information, such as the number of units dispensed. It must also have an internal audit trail, and must perform automated internal audits and provide reports of incidents to the pharmacist. All records must be backed up daily and stored for a minimum of 2 years. (<http://www.uspharmacist.com/content/d/techrx/c/41437/>; Technology Support for Pain Management: e-Prescribing Controlled Substances)

The prescriber must be credentialed. There are three possible authentication credentials available: 1) a password or response to a challenge question, 2) a biometric such as a fingerprint or iris scan, and 3) a hard token such as a cryptographic module. The prescriber must use two of these three credentials. The act of applying the two credentials ensures the legal electronic signature on the prescription. The software should not permit the transmission of the controlled e-prescription unless the prescription is properly signed by a credentialed prescriber using the two-factor system.

For further information go to: http://www.dea.gov/diversion/usdoj.gov/e-comm/e_rx/faq/pharmacies.htm

With a certified e-prescribing application, providers first complete an identity proofing process that matches their practice license information with a valid DEA identification number. This activity is conducted remotely or face to face via a credentialing service provider or certification authority approved by the federal government. Providers then log on to the e-prescribing system with two-factor authentication, utilizing at least 2-of-3 devices that include a security

token, unique password or biometric scan. Finally, the prescriber creates the e-prescription using the e-prescribing of controlled substances (EPCS) system and securely sends it to the pharmacy via a third-party transaction processing vendor.

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When a prescriber submits an order, the system can automatically send an email, text or voice message to the individual confirming the order and pharmacy destination of choice.

<http://drugstorenews.com/article/e-prescribing-controlled-substances-next-generation-medication-ordering-4/24/14> E-prescribing of controlled substances: The next generation of medication ordering.