

Requirements for Electronic transmission of controlled substance prescriptions:

The DEA has published interim final rules regarding the electronic transmission of prescriptions for controlled dangerous substances (CDS). Prior to the ability of a physician to transmit a CDS prescription electronically, and the pharmacy to receive the CDS prescription electronically, the following must occur:

- 1) A practitioner will be able to issue electronic controlled substance prescriptions only when the electronic prescription or electronic health record (EHR) application the practitioner is using complies with the requirements in the interim final rule.
- 2) A pharmacy will be able to process electronic controlled substance prescriptions only when the pharmacy application the pharmacy is using complies with the requirements in the interim final rule
- 3) The application provider must either hire a qualified third party to audit the application or have the application reviewed and certified by an approved certification body. The auditor or certification body will issue a report that states whether the application complies with DEA's requirements and whether there are any limitations on its use for controlled substance prescriptions. (A limited set of prescriptions require information that may need revision of the basic prescription standard before they can be reliably accommodated.) The application provider must provide a copy of the report to practitioners or pharmacies to allow them to determine whether the application is compliant.
- 4) A pharmacy cannot process electronic prescriptions for controlled substances until its pharmacy application provider obtains a third party audit or certification review that determines that the application complies with DEA's requirements and the application provider provides the audit/certification report to the pharmacy. The pharmacy may continue to use its pharmacy application to store and process information from paper or oral controlled substances prescriptions it receives, but the paper records must be retained.
- 5) Identity proofing is still required. It is critical to the security of electronic prescribing of controlled substances that authentication credentials used to sign controlled substances prescriptions are issued only to individuals whose identity has been confirmed. Individual practitioners will be required to apply to certain Federally approved credential service providers (CSPs) or certification authorities (CAs) to obtain their two-factor authentication credential or digital certificates. The CSP or CA will be required to conduct identity proofing that meets National Institute of Standards and Technology Special Publication 800-63-1 Assurance Level 3. Both in person and remote identity proofing will be acceptable. Institutional practitioners will have the option to conduct in-person identity proofing in-house as part of their routine credentialing process.

Under the interim final rule, DEA is allowing the use of two of the following – something you know (a knowledge factor), something you have (a hard token stored separately from the computer being accessed), and something you are (biometric information). The hard token, if used, must be a cryptographic device or a one-time-password device that meets Federal Information Processing Standard 140-2 Security Level 1. The practitioner will use the two-factor credential to sign the prescription; that is, using the two-factor credential will constitute the legal signature of the DEA-registered prescribing practitioner. When the credential is used, the application must digitally sign and archive at least the DEA-required information contained in the prescription.

Practitioners must have identity proofing authentication credentials to utilize the software for electronic transmission of CDS prescriptions. That is, they must have been issued an electronic token (USB device, card, etc) and a password to begin using a software system. Software vendors must provide the practitioner AND the pharmacy with certification that their system complies with the DEA rule. As of January 1, 2011, the Board of Pharmacy was not aware of ANY software system that had received compliance certification.