

## Chapter 5

p. 220 2<sup>nd</sup> full paragraph

Regarding whether a pharmacist can correct a written C-II prescription with the verification of the prescriber. The DEA has changed its website to reflect that pharmacists should follow state law or policy regarding whether corrections can be made to a written C-II prescription until it issues a regulation.

(<http://www.deadiversion.usdoj.gov/faq/general.htm#rx-7>)

p. 223 Return of Controlled Substances to Pharmacies for Disposal

In 2010 Congress passed the Secure and Responsible Drug Disposal Act of 2010. This law permits an ultimate user who has lawfully obtained the controlled substance to deliver it to another person for disposal if the person receiving the controlled substance is authorized to engage in its disposal and the disposal takes place pursuant to regulations implemented by the DEA. The DEA is required to enact regulations to implement this law. Until such time pharmacies may not accept controlled substances from a non-registrant.

**Replace the subsection “Electronic Transmission Prescriptions” on pp. 230 to 231 with the following:**

*Electronic Transmission Prescriptions*

After years of waiting and anticipation by practitioners the DEA has authorized the electronic transmission of controlled substance prescriptions. The Agency issued proposed regulations in June 2008 (73 Fed. Reg. 36721) and interim final regulations (IFR) on March 31, 2010 (75 Fed. Reg. 16236). The IFR permits, not requires, the e-prescribing and dispensing of controlled substances in schedules II –V. Pharmacists, however, must refer to their state laws and regulations as to whether electronic controlled substance prescriptions are permitted in their state, and if so, whether to the same extent as the federal regulations. In the IFR the DEA amended many of the requirements contained in the proposed regulation primarily because of comments from pharmacy and prescriber stakeholders.

In its discussion in the preamble to the regulations, the DEA makes it very clear that the regulations were structured with two primary concerns in mind. First, security, such that only authorized persons have access to the electronic system, and that only the authorized persons are actually using the system. Second, accountability for law enforcement purposes, such that a prescription cannot be repudiated and that violators of the law can be readily identified. The DEA's concerns are very valid considering that an electronic prescription between a pharmacy and a practitioner is generally routed between three to five intermediaries, creating several external and internal opportunities for fraud and diversion to occur. Moreover, electronic prescriptions do not provide evidence of forgery and alteration like paper prescriptions, thus making detection by pharmacies almost impossible. Without adequate controls and requirements, pinpointing

accountability for fraud and diversion would be most difficult, since every party in the process would blame someone else. Thus, the regulations establish several specific standards and requirements for application service providers (the entity that controls the software and server programs), for prescribers and for pharmacies. The following discussion will provide a general highlight of many of these standards and requirements.

**Prescriber Requirements.** In order to ensure that only authorized persons have access to an e-prescribing system, the regulations require that prescribers must undergo identity proofing, meaning that they must establish identity, either in person or remotely, with a federally authorized credential service provider (CSP) or certification authority (CA). Once identity is proven, the prescriber will be provided an authentication credential or a digital certificate. Institutional practitioners have the authority to conduct in-person identity proofing of individual practitioners authorized to utilize the institution's DEA registration.

Establishing identity and obtaining a credential or certificate is not in itself, however, enough to allow a prescriber access to an e-prescription system. Access to the system first requires a person other than the prescriber (for example a nurse) to enter information into the system verifying that the prescriber has a valid DEA registration, state authorization to practice, and when required, state controlled substance authorization. Once this verification has been completed, another person, who must be a DEA registrant, must approve the information entered and grant the prescriber access.

Once these steps are completed the prescriber is authorized to sign and transmit controlled substances electronically, but must use a two-factor authentication method.

The IFR allows prescribers to select two of three authentication factors for this purpose that will act as digitally signing the prescription including: (1) Something you know, such as a password or pin number; or (2) Something you have, a hard token separate from the computer such as a PDA, cell phone, or flash drive; or (3) Something you are (biometrics). (The option to use biometrics was added in the IFR in response to comments to the proposed regulation.)

When a prescriber is ready to sign the prescriptions, a review screen containing a list of the prescriptions for approval will appear and the prescriber will then incorporate the two-factor authentication method to sign and ultimately transmit the prescriptions. An attestation will appear on the review screen prior to the prescriber authorizing the prescription that use of the two-factor authentication approves (signs) the prescription. (The two-factor authentication is synonymous with signing.) Alternately if the prescriber has a digital certificate and is transmitting the prescriptions directly to the pharmacy without using an intermediary, the prescriber can digitally sign the prescriptions using public key infrastructure (PKI)/digital signatures.

An agent of the prescriber may enter the appropriate prescription information into the system for later approval and authentication by the prescriber. However, an agent cannot have access to the two-factor authentication to sign the prescriptions. The prescription ultimately transmitted to the pharmacy must contain all of the information required on paper prescriptions. The patient's address, however, is not required to appear on the review screen that the prescriber sees when approving and digitally signing the prescription, but instead may be added after the prescriber signs and before transmission. Once the two-factor authentication is completed, the digitally signed record is

electronically archived prior to transmission thus allowing the prescriber's staff to add information not required by DEA regulations such as pharmacy URLs. The prescriber is permitted to simultaneously sign multiple prescriptions for a single patient, but not for multiple patients. The content of the required information on the prescription must not be altered during transmission between the prescriber and the pharmacy.

Prescribers must generate a log of all controlled substances prescribed electronically, but unlike the requirement in the proposed rule prescribers are not required to review and confirm the log. The IFR, unlike the proposed rule, allows prescribers to print copies of electronic prescriptions. The printed prescription must clearly be marked as a copy and cannot be used as a hard copy prescription in the event transmission fails and cannot be used to satisfy the recordkeeping requirements.

**Pharmacy Requirements.** The IFR clarified many of the requirements for pharmacies contained in the proposed regulation. When the electronic prescription is transmitted to the pharmacy, the first recipient of the e-prescription (either the pharmacy or its application service provider (ASP) if it uses one) must digitally sign, and the pharmacy must archive the e-prescription. If a prescription transmission fails the prescriber may write a copy of the transmitted prescription and sign it. The prescription must indicate that it was originally transmitted to a specific pharmacy and that the transmission failed. The pharmacy must check to ensure that the electronic prescription was not received or dispensed before it dispenses the paper prescription. Similarly, if a pharmacist receives a paper or oral prescription that it indicates it was originally transmitted electronically to another pharmacy, the pharmacist must check with that pharmacy to determine whether

the prescription was received and dispensed. If the pharmacy that received the original electronic prescription had not dispensed the prescription it must void it. If the original electronic prescription was dispensed, the pharmacy with the paper prescription must void it.

A pharmacy may make changes to the electronic prescription after receipt in the same manner that it may make changes to paper controlled substance prescriptions. The pharmacy application system must document any such changes, in addition to documenting prescription receipt, annotation or deletion. In addition the pharmacy, as well as all parties involved in the electronic transmission process, must maintain a daily internal audit trail that compiles a list of auditable events. Auditable events are those that indicate a potential security problem. For example, the DEA points out that an unauthorized person attempting to sign or alter a prescription is an auditable event. However, a pharmacist annotating the prescription to indicate a change to a generic drug would not be. (The proposed rule would have required pharmacies to document every instance in which a prescription was opened or viewed.)

Pharmacies must back-up all electronic prescription records daily. The proposed regulation would have required the back-up records be kept at an offsite location. The IFR removed this requirement, however the DEA recommends that pharmacies do so. All related records to an electronic prescription must be maintained by the pharmacy for two years, the same as for paper prescriptions. (The proposed rule would have required five years).

Electronic prescriptions may be electronically transferred between pharmacies subject to the same requirements as if the transfer was by paper or oral. The transferring

pharmacist must provide with the electronic transfer all the information that the recipient pharmacist must transcribe if the prescription was transferred orally.

Pharmacies, as well as prescribers, must only use electronic prescription systems that meet all DEA requirements. The DEA will not personally audit or approve these systems. Instead the systems must be audited by a third-party for compliance every two years, or whenever the system is altered in a way that could affect the functionality of the system. The requirements of a third-party audit apply to the application service provider. Pharmacies and prescribers are not responsible for these audits unless they use their own application.