

Controlled Substance E-Rx FAQs

When does the DEA's rule go into effect permitting the electronic transmission of controlled substance prescriptions?

The rule goes into effect June 1, 2010 unless Congress delays implementation.

What schedules of controlled substances may be transmitted electronically?

Prescriptions for Schedule II, III, IV, and V medications that are transmitted electronically and in compliance with the DEA rule may be filled. 21 CFR 1306.08(b).

Does the prescriber's digital signature have to be in any particular format?

There are software requirements for digital signatures on the prescriber side, but no requirements for how this information is displayed to pharmacists. The digital signature in almost all cases will not consist of a digitized written signature.

DEA definition of digital signature: "a record created when a file is algorithmically transformed into a fixed length digest that is then encrypted using an asymmetric cryptographic private key associated with a digital certificate. The combination of the encryption and algorithm transformation ensure that the signer's identity and the integrity of the file can be confirmed."

DEA definition of electronic signature: "a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person's approval of the information contained in the message."

How can a pharmacy know whether its software application or program can be used to process electronic controlled substance prescriptions?

The Board of Pharmacy does not evaluate or approve pharmacy software applications or programs for compliance with DEA standards governing the receipt of electronic controlled substance prescriptions.

Per the new DEA rule, to meet the DEA's requirements for receipt of electronic controlled substance prescriptions, the pharmacy must determine that a third-party auditor or certification organization has found that the pharmacy's software does the following accurately and consistently:

- I. Import, store, and display the information required for prescriptions
- II. Import, store, and display the indication of signing
- III. Import, store, and display the number of refills
- IV. Import, store, and verify the practitioner's digital signature

21 CFR 1311.200(a).

Board staff recommends that pharmacies contact their software vendors to determine whether existing systems meet DEA requirements and/or whether new or modified systems are needed. Software vendors presumably are already working to obtain the necessary certifications for their systems.

Is the pharmacy responsible for determining if the software/hardware system used by a prescriber complies with DEA regulations for the transmission of electronic controlled substance prescriptions?

No, the pharmacy is responsible only for the pharmacy software application or program that it uses to receive electronic controlled substance prescriptions. This does not, of course, eliminate a pharmacist's responsibility to use sound professional judgment to assure him/herself that a controlled substance prescription was written for a legitimate medical purpose and in the ordinary course of medical practice.

What are the requirements governing annotations of electronic controlled substance prescriptions?

Any annotation required for a paper controlled substance prescription is also required for an electronic controlled substance prescription. The annotation must be retained electronically in the prescription record or linked files. 21 CFR 1311.200(f).

Does the new DEA rule have any impact on emergency verbal transmission of prescriptions for Schedule II controlled substances?

Under existing DEA rules, if a pharmacy accepts a verbal Schedule II prescription in an emergency situation and immediately reduces it to writing for dispensing, the pharmacist must receive a valid prescription from the prescriber within seven (7) days (failure to receive the prescription obligates the pharmacy to report the prescriber to the DEA). An electronic prescription may be used to fulfill this requirement, but the electronic prescription must be annotated with the original authorization and date of oral order. 21 CFR 1306.11(d)(4).

What schedules of controlled substances may be transferred and how many times may they be transferred?

DEA rules governing transfer of controlled substance prescriptions have not been changed. Accordingly, Schedule III, IV, and V prescriptions may be transferred to another pharmacy, and the transfer process may only occur once. (Pharmacies linked through a unified, central, real-time electronic database can still move Schedule III, IV, and V prescriptions between the pharmacies connected to that database an unlimited number of times during the period of prescription validity.)

Can Schedule III, IV, and V be transferred electronically?

Prescriptions may be electronically transferred between pharmacies so long as all of the other DEA requirements for a prescription are met. Prescriptions may be electronically transferred between pharmacies so long as all of the other DEA requirements for a prescription are met.

What if a pharmacy receives a paper prescription that indicates it was also transmitted electronically to that, or any other, pharmacy?

The pharmacist must check pharmacy records to see if the electronic prescription was received. If both an electronic and paper prescription were received, then the pharmacist must mark one or the other as void.

If the paper prescription indicates it was also transmitted electronically to another pharmacy, then the pharmacist must check with the pharmacy that received the electronic prescription and verify that the prescription has not been dispensed. If the electronic prescription has not been dispensed, then the pharmacy that received the electronic prescription must be notified to void it. If the electronic prescription has been dispensed, then the pharmacy receiving the paper prescription must mark it as void.

21 CFR 1311.200(g-h).

May a pharmacy transfer a controlled substance prescription originally received electronically? If so, what additional requirements are involved?

Yes. The transfer requirements are similar to those pre-dating the electronic controlled substance prescription rule:

- I. Transferring pharmacist:
 - a. Information that the prescription has been transferred must be added to the prescription record.
 - b. The name, address, and DEA registration number of the pharmacy to which the prescription was transferred must be added to the prescription record.
 - c. If a prescription is transferred electronically then the transferring pharmacist must provide:
 - i. The date of original dispensing
 - ii. The number of refills remaining and the date(s) and locations of previous refills
 - iii. The name of the pharmacist transferring the prescription
 - iv. The name, address, DEA registration number, and prescription number for each dispensing pharmacy
 1. This applies mainly to prescriptions dispensed from more than one pharmacy connected to a real-time central electronic database
 - v. The original electronic prescription data
- II. Receiving pharmacist:
 - a. There are no changes to existing rules governing the receipt of controlled substance prescriptions transferred verbally.
 - b. If a controlled substance prescription is transferred electronically, then the receiving pharmacy must create an electronic record that includes:
 - i. The date of original dispensing
 - ii. The number of refills remaining and the date(s) and locations of previous refills
 - iii. The name of the transferring pharmacist
 - iv. The name, address, DEA registration number, and prescription number for each dispensing pharmacy
 1. This applies mainly to prescriptions dispensed from more than one pharmacy connected to a real-time central electronic database
 - v. The receiving pharmacist's name
 - vi. The original electronic prescription data

21 CFR 1306.25(b).

Are electronic prescription records required to be backed-up?

Yes, pharmacy application service providers must back up files daily. Also, although it is not required, DEA recommends as a best practice that pharmacies store their back-up copies at another location to prevent the loss of the records in the event of natural disasters, fires, or system failures.

What if a pharmacy software application or program being used to receive electronic controlled substance prescriptions is found to no longer be compliant with DEA requirements?

Regardless of the source from which the compliance failure is detected (DEA, pharmacy application auditor, or the pharmacy), when a pharmacy becomes aware that a software application or program is no longer compliant with the DEA rule, it must stop using the software to receive controlled substance prescriptions electronically until such a time as the pharmacy is notified that the application is again compliant with the rule. 21 CFR 1311.200(c-d).

What happens if a pharmacy's software application is no longer supported by the developer or vendor, or a pharmacy chooses to cease using an application service provider?

The application service provider must transfer any records subject to the DEA rule to the registrant in a format that the registrant's applications are capable of retrieving, displaying, and printing in a readable format. 21 CFR 1311.304(e).

Where can I find more information about the implementation of this rule?

Drug Enforcement Administration Summary:

http://www.deadiversion.usdoj.gov/ecommm/e_rx/faq.htm

American Pharmacists Association Summary:

http://www.pharmacist.com/AM/Template.cfm?Section=Government_Affairs&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23050