

E-PRESCRIPTION CONTROLLED SUBSTANCES

THE DEA WAY WEBINAR Q&A

1. Would you please clarify the issue of faxed Rx's with an e-signature. As I understood, these only could be filled if authorized application specialist or vendor has approved the transmission and receipt of Rx. Is that correct?

According to the new federal regulations, a prescription for a controlled substance transmitted via fax to a pharmacy cannot have an electronic signature, it must be manually signed by the prescriber. The DEA considers a prescription transmitted via fax to be a paper prescription transmitted via a facsimile machine. Electronic signatures for controlled substance prescriptions transmitted via fax machine are not valid.

2. If a medical resident e-scripts a controlled substance, the only way that Rx can be filled is if the suffix is tagged electronically, otherwise, it is not a valid Rx?

Correct, the DEA states that both the prescribers application must be able to transmit and the pharmacy application must be able to validate the special code assigned by an institutional practitioner to individual practitioners permitted to prescribe controlled substances using the institution's DEA registration. If the third-party auditor cannot record, store, and transmit or import, store, and display these data fields, the prescriber or pharmacy must not use the application to process electronic prescriptions for controlled substances that require this information.

3. Am I correct to understand that I need to contact my software vendor and make sure that our system has passed the audit to meet the DEA requirements? What type of documentation do I need to prove this? If I call a doctors office to see if their system has passed the audit, should they provide documentation, or is their "word" good enough?

Yes, prior to accepting controlled substance prescriptions, the pharmacy application must be audited by a third-party or outside organization that validates the ability of the application to perform all required functions as identified by the DEA.

The application provider must give a copy of the report to pharmacies that use or are considering use of the pharmacy application to allow them to determine whether the application is compliant with DEA's requirements.

The Federal Regulations in 21 CFR 1311.300 states that electronic prescription applications must make certain determinations of elements as required by section 1306.22 and these elements must be consistently and accurately recorded, stored, and transmitted. If the pharmacy application cannot consistently and accurately import, store and display these required elements; then the pharmacy applications should not process these electronic prescriptions.

As always, the applications providers for both the pharmacy programs and prescriber's programs must give a copy of the audit to all individuals requesting.

4. Can we still accept electronic scripts for NON controlled drugs that are transmitted computer to fax legally? The DEA only allows computer to computer for controlled substances but does this override the state rule that allows computer to fax for non controlled items or is this interpreted as a "more stringent law" and would apply to ALL prescriptions?

Michigan law allows the electronic transmission of non-controlled substance prescriptions from the computer of the prescriber to the fax machine of the pharmacy. The new DEA regulations are specific for the prescribing and dispensing of controlled substances.

5. Would you please give us the website for the federal register again.

http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.htm

6. Please repeat the names of some of the third party audit certification bodies.

The DEA did not provide names of auditors but indicated the following:

Application providers must obtain a third-party audit or certification to certify that each electronic prescription and pharmacy application to be used to sign, transmit, or process controlled substance prescriptions is in compliance with DEA regulations pertaining to electronic prescriptions for controlled substances.

The application may undergo a WebTrust, SysTrust, or SAS 70 audit conducted by a person qualified to conduct such an audit.

The application may undergo an audit conducted by a Certified Information System Auditor who performs compliance audits as a regular ongoing business activity.

The application may have a certification organization whose certification has been approved by DEA verify and certify that the application meets DEA's requirements.

7. *True or False – After June 1, 2010, it will still be illegal to dispense an electronic prescription for a controlled substance in Michigan because state law still prohibits this activity.

False, Michigan law allows the dispensing and prescribing of controlled substances transmitted via electronic means, the prohibition prior to June 1, 2010, was the prohibition by the DEA allowing the transmission electronically and the use of an electronic signature for controlled substances.

8. *What processes are in place to prevent a prescriber from sending an electronic substance prescription to a pharmacy that has not been certified to receive and dispense such a prescription?

It is up to each practitioner and pharmacy to validate that their application is compliant with the federal regulations. The Controlled Substance Act is unique and violations of the Act can be civil or criminal in nature, which may result in administrative, civil or criminal proceedings. Remedies under the Act can range from modification or revocation of DEA registration, to civil monetary penalties or imprisonment, depending upon the nature, scope, and extent of the violation.

9. Please provide the website for the DEA Registry.

http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.htm

10. A prescriber send us an e-script for controlled drug. How do we fill the prescription?

Do you mean how do you file the electronic prescription? All controlled substance prescriptions transmitted electronically are required to be maintained in an electronic format according to the new federal regulations. Regarding the actual filling of the prescription, you would fill it in the same manner you dispense a controlled substance prescription written on a paper form.

11. Will we be able to tell if a prescriber's application has passed a third party audit?

It is my understanding that once the pharmacy application has been audited and approved, if that application does not import, store, and display the information required to be transmitted, 21 CFR 1306, then the pharmacy application must not process the electronically transmitted prescription as the prescriber's application transmitted a prescription did was not in conformity with the requirements of the Act or did not pass the third party audit requirement. Lastly, you can always ask the prescriber for confirmation that their application has been approved by a third-party auditor.

Nothing in the Act alters the responsibilities of the practitioner and pharmacy, specified in part 1306, to ensure the validity of a controlled substance prescription.

12. I assume this applies to CIII to CV. CII prescriptions will not be able to be submitted electronically, correct?

The new regulations applies to controlled substances, schedules CII - CV.

13. Will prescribers be allowed to “electronic sign” of a CII and not a manual signature come 6/1/10 when they send prescriptions electronically?

Yes