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## **DEA Interim Final Rule on Electronic Prescribing of Controlled Substances – Practitioner and Pharmacy Responsibilities**

William E. Fassett, Ph.D., R.Ph.  
Professor of Pharmacy Law & Ethics  
Washington State University - Spokane



The DEA has issued an interim final rule on e-prescribing of controlled substances, which will be published in the Federal Register on March 31, 2010. The rule, which is set forth in 21 CFR § 1311, subpart C, will take effect following a 60-day comment period and Congressional review.

The text of the rule's announcement is available at: [http://www.federalregister.gov/OFRUpload/OFRData/2010-06687\\_PI.pdf](http://www.federalregister.gov/OFRUpload/OFRData/2010-06687_PI.pdf) The actual text of the rule can be found on pages 293-334 of the document.

The following is a brief summary of responsibilities of practitioners and pharmacies under the rule.

Pharmacies will be able to process electronic prescriptions only if all the following conditions are met:

1. The pharmacy computer application must comply with the requirements of the rule; and
2. The prescription was issued in conformity with the requirements of the rule and all other requirements for prescriptions in the CSA.

All of the pharmacist's responsibilities to assure the validity of the prescription apply to e-prescriptions as well as to other prescriptions.

The practitioner's electronic signature must be verified by *two* of the following forms of authentication: (1) a biometric – something the practitioner *is* (e.g., iris scan, fingerprint), (2) a knowledge factor – something only the practitioner *knows* (e.g., password or response to a challenge question), or (3) a device separate from the computer – something the practitioner *has* (i.e., a hard token).

The rule creates two types of practitioners: individual and institutional. Depending on the category, it details specific requirements by which the practitioner receives the forms of authentication to be used in issuing e-prescriptions, as well as the responsibilities for the clinic or institution in which the practitioner issues e-prescriptions.

### Practitioners must

1. Retain sole possession of the hard token, if used, and must not share the password or biometric information with any other person, and must not allow any other person to use the token or enter the knowledge factor or ID means to sign prescriptions.
2. Notify responsible individuals within the practice or institution within 1 business day of discovery when the hard token has been lost, stolen, or compromised, or when the authorization protocol has otherwise been compromised.
3. If notified that an e-prescription was not successfully received by the intended pharmacy, insure that any replacement paper or oral prescription indicates that the order was originally transmitted to a particular pharmacy and that the transmission failed.
4. Assure that a third-party auditor or certification organization has found that his or her e-prescribing computer application meets the requirements of the rule.
5. Cease using the application if it becomes apparent or known that the application is no longer qualified under the rule or is not fully functional.
6. Notify responsible individuals of any prescriptions discovered to be issued without his or her signature or were not consistent with prescriptions he or she signed.
7. Retain responsibility to assure that prescriptions are issued only for a legitimate medical purpose while acting within the usual course of professional practice. If an agent enters data into the application prior to the practitioner's digital signing of the prescription, he or she retains responsibility for assuring that the prescription conforms to law and regulations.

Individual practitioners must obtain a two-factor authentication credential from either a government-approved credential service provider, or use a digital certificate from a certification authority that meets requirements of the Federal Bridge Certification Authority. The credential provider will assure the identity of the practitioner by requiring appropriate identity proofing information.

Prescriptions sent digitally to pharmacies will either be digitally signed, or will bear an indication via a digital certificate to have been digitally signed.

### Pharmacies must:

1. Determine that the pharmacy application has been certified by a third-party auditor or certification organization to accurately and consistently:
  - a. Import, store, and display the information required for prescriptions under 21 CFR § 1306.05(a);
  - b. Import, store, and display the indication of signing as required by the e-prescribing rule;
  - c. Import, store and display the number of refills as required by 21 CFR § 1306.22;
  - d. Import, store, and verify the practitioner's digital signature, as provided in the rule, when applicable.

2. Discontinue processing of e-prescriptions for controlled substances if the auditor or certification organization has found that the application does not function as required or no longer qualifies, or if notified that the application is not in compliance.
3. Determine which employees are authorized to enter information regarding dispensed prescriptions, and annotate or alter records of those prescriptions. Logical access controls for the application must be set so that only authorized employees are granted access.
4. When a pharmacist fills a prescription in a manner that would require a notation if the prescription were a paper prescription (under 21 CFR § 1306), the application must allow the pharmacist to make and retain such notations electronically. Prescriptions received electronically must be retained electronically.
5. When a pharmacist receives a paper or oral prescription that indicates it was originally transmitted electronically to the pharmacy, he or she must check the pharmacy's records to ensure the e-version was not received. If both prescriptions were received, one must be marked void.
6. When a pharmacist receives a paper or oral prescription indicating that it was originally e-transmitted to another pharmacy, he or she must contact that pharmacy to determine whether that pharmacy received and/or dispensed the prescription. The pharmacy that did not dispense the received prescription must mark the prescription void.
7. The pharmacist retains the corresponding responsibility to insure that all prescriptions dispensed were issued for a legitimate medical purpose in the due course of the prescriber's practice.

The rule also sets forth extensive requirements for application vendors, service providers, and for the characteristics of the applications that either transmit or receive e-prescriptions.