



FAQs: Electronic Prescriptions of Controlled Substances

The following questions and answers are intended to help you understand the impact of the federal Drug Enforcement Agency (DEA) Interim Final Rule (IFR) regarding electronic prescription of controlled substances. The DEA published its IFR "Electronic Prescriptions for Controlled Substances" on March 31, 2010, establishing rules for the type of transmission. While the ruling may legalize this type of electronic prescription, pending Congressional approval, as early as June 1, 2010, Pharmacy and EHR vendors must now develop the appropriate technological infrastructure for these communications based on the guidelines provided in the ruling.

DrFirst™, the SureScripts® provider for PrimeSuite~ePrescribe, is currently involved in a pilot program, in concert with the DEA, to overcome the substantial hurdles that still remain to allow electronic prescribing of controlled substances. As a part of this pilot program, DrFirst has successfully demonstrated the technology and capability to make the process efficient, safe, and secure.

Greenway's Vice President for Marketing, Corporate and Government Affairs, Justin Barnes, is closely monitoring developments related to this ruling and we will continue to keep you apprised of the situation. All customers attending the 2010 PrimeLeader conference, Aug. 29-Sept. 1, can expect updates on the DEA IFR and related advances. In addition, all customers will receive continuing direct messages as we learn more about assignment of a certification authority and subsequent infrastructure changes to allow electronic certification of these prescriptions.

"At this point, it does not look like electronic controlled-substance prescriptions will be included in Stage 1 Meaningful Use denominators," Barnes said. The Centers for Medicare & Medicaid Services (CMS) published its initial IFR detailing Meaningful Use criteria, including an outline of the three stages, in January 2010. To receive the maximum Medicare payments, eligible providers need to qualify under Stage 1 denominators by calendar year 2012 and hospitals by fiscal year 2013.

What Should I Do Today?

Until pharmacies have the infrastructure in place to receive certified electronic controlled substance prescriptions including network and transmission specifics, Greenway advises that you continue using your current workflow for controlled substance prescriptions.



What Is the DEA Ruling?

The DEA's IFR defines criteria for the electronic prescribing of controlled substances, including methods for certifying electronic authorization and rules regarding specifications for the actual prescription with codes verifying authorization. It is subject to congressional approval, but is expected to be approved and may be effective as early as June 1, 2010.

For additional information on the DEA IFR, see the following sites:

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

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

What Are Main Points of the Ruling?

There are four main points to criteria defined in the DEA IFR: identity proofing, access control, two-factor authentication and auditing.

- **Identity Proofing:** The ruling requires a two-step process of identity proofing to ensure separation of the duties involved in verifying the provider requesting credentials is who he or she says. A trusted third party and the prescribing physician will both be required to certify the identity of the prescriber. For private practices, an outside organization would be authorized for identity proofing. DrFirst hopes to become one of these entities. For larger organizations, identity proofing may be conducting as part of credentialing and the institution may be able to function as the trusted third party.
- **Access Control:** The application that will transmit the prescriptions is required to allow setting of access controls to ensure that only DEA-credentialed prescribers can sign electronic prescriptions for controlled substances. One person will be required to set up the control and the provider with DEA credentials must approve the access using a two-factor authentication process.
- **Two-Factor Authentication:** Two-factor authentication requires the use of both something you know and something you have. For example, a hard token (something you have) and a password (something you know) can be used in combination for authentication of the credentialed prescriber. The hard token would contain a digital certificate that is activated by the user's password.
- **Auditing:** Monthly audit logs of controlled substances are required to be generated and archived. Both pharmacies and EHR applications such as PrimeSuite~ePrescribe must maintain audit trails. In addition, methods of alerting users to potential security threats are required.



What Does the DEA Ruling Mean?

The DEA ruling effectively legalizes electronic prescription of controlled substances, pending Congressional approval, providing a framework for development of the infrastructure for these transmittals. This is a significant first step toward implementation of e-prescribing of scheduled medications. The IFR provides guidelines to allow Pharmacy and EHR vendors to develop appropriate tools and workflows for these communications; however, much work remains before practices can begin to send electronic prescriptions of this type and pharmacies are not yet ready to accept them. The ruling requires physician practice registrants to apply to federally-approved credential service providers (CSP), or certification authorities, to obtain security certificates for electronic validation of controlled substance prescriptions. No certification authority has yet been named and, without that key, the infrastructure to allow acceptance of electronic prescriptions of controlled substances by pharmacies cannot be put into place.

What Is Being Done to Make PrimeSuite~ePrescribe Ready?

DrFirst's DEA-waivered pilot program for electronic prescribing of controlled substances in western Massachusetts has been underway for several years. The specifications in the DEA's IFR evolved, in part, during this pilot program. Since DrFirst is the provider for PrimeSuite~ePrescribe, once a certification authority has been designated and questions regarding specifications for indicating authorization are answered, it should be relatively easy to adapt the workflow within DrFirst for this type of prescription. Greenway's Vice President for Government Affairs, Justin Barnes, and representatives of DrFirst are both involved in efforts at the federal level to resolve these questions.

DrFirst Questions and Answers

According to DrFirst Partner Programs Account Manager Reema Asad, "The DEA IFR allowing e-prescribing of scheduled medications establishes an important step toward the ability for practices to adopt an optimal e-prescribing workflow that includes scheduled drugs. The next step will be for the industry to meet these rules so that practices can begin to electronically prescribe controlled medications."

The following questions and answers are provided by Greenway's partner DrFirst, regarding preparation to make PrimeSuite~ePrescribe ready for electronic prescriptions of controlled substances and about the IFR in general.

When Can We Start ePrescribing for Controlled Substances?

Technically, e-prescribing of controlled substances will be legal as soon as Congress approves the interim rule, perhaps as early as June 1, 2010. However, legal does not equal possible. There is no industry-wide infrastructure currently available to send the



prescriptions through to pharmacies, nor can pharmacies accept them. We expect that the first pharmacies will be able to begin accepting electronic prescriptions of controlled-drugs in the 4th quarter of 2010 (approaching next winter).

How Will PrimeSuite~ePrescribe Use Change for Prescribing Controlled Drugs?

A user will need to obtain a hard-token security credential from a CSP (a company with federal approval to supply and validate these small pieces of hardware that provide verified credentials). Then, a second staff member within the user's office, or an authorized DrFirst employee, will approve the user and the user's certification token. DrFirst already has experience using these kinds of tokens for controlled-drug e-prescribing since we have been doing this for several years as part of a DEA-waivered pilot program in western Massachusetts. To prescribe controlled drugs with PrimeSuite~ePrescribe, very little change will be required other than inserting the hardware token into a computer's USB slot. DrFirst designed a workflow for the pilot program to display a message indicating at least one controlled-drug prescription exists on the pending list and require the user to individually select and authorize each controlled-drug prescription. Also, DrFirst will not allow controlled-drug prescriptions for more than one patient to be signed at a time. These workflow changes are requirements in the DEA's IFR.

What Is a Hard Token?

A hard token looks like a USB memory stick, but actually contains a small computer processor and, in memory, a secure digital signature that is activated by a password. The tokens themselves are very inexpensive, but registering them with a certification authority (who would often supply the tokens as part of their service) is usually more than \$100 for a 3-year license.

Are There Alternatives to the Hard Token?

The DEA, in their IFR, allows for several methods to authorize the prescription. One method uses the same type of hard token but sends the prescription in an encrypted form to the pharmacy, to be decrypted using the prescriber's public (published) key, which will only decrypt a prescription written with that prescriber's private key. There is no infrastructure to do this for ambulatory e-prescribing. The DEA also allows a biometric validation (for example, a fingerprint) to be one of two factors in an electronically credential (the other factor can be either a hard token or a password). DrFirst is not currently developing a biometric-based authentication for the first phase of controlled-drug e-prescribing.



What Are Monthly Logs and How Do They Affect Me?

The IFR requires the system generate monthly logs and archive them; however, it does not require a practice to review them. The system must also alert the practice if a potential security threat is identified. If a security threat were identified, the audit logs would be available for review.

How Do Electronic Prescriptions of Controlled Substances Differ?

The DEA's ruling requires controlled-substance e-prescriptions to include a flag indicating the prescription was authorized using two-factor authentication. It also requires a specific field for this flag, and that field does not exist in the current electronic prescription format. In addition to alerting the DEA to this issue, DrFirst has orchestrated comments regarding this field and proposed temporary alternatives to it, to originate with other vendors, standards organizations, vendor organizations, the AMA, or other specialty organizations. It is hoped that a solution will be available soon, but until it is, EHR and e-prescribing vendors, SureScripts and pharmacy software developers cannot even begin to code for transmission of this critical bit of information.

What Does Auditing Require Based on the IFR?

The IFR requires the system to provide monthly audit logs of prescribed controlled substances and to audit for security threats, such as failed logins based on invalid information. When a security threat is identified, the system must alert the practice. If a problem is determined to be a real security risk, the practice must notify the DEA.

What Is Required if a User Loses the Hard Token?

A provider can obtain a replacement from their CSP, but there would probably be a charge for this. The user or practice is also required to notify the DEA within one business day if a token is lost. We recommend users put their hard token on their key chain to increase the chance they will always know where it is.

What Is DrFirst Doing to Prepare for Electronic Prescription of Controlled Substances?

DrFirst is working in conjunction with multiple organizations to press the DEA on an interim step for transmission of the two-factor authentication flag. We are preparing necessary coding for that flag, and also screen changes to follow the workflow as outlined in the IFR. Fortunately, much of the DEA workflow was actually based on DrFirst screens used in our Massachusetts pilot program, so we do not anticipate the need for significant changes. DrFirst has already added most, if not all, of the audit capabilities required in the IFR for their separate, upcoming CCHIT certification. The company also is evaluating CSPs to find one that is stable, flexible, and cost-effective to recommend to users.



Will the Ability to e-Prescribe Controlled Substances be a Required Component for Achieving Meaningful Use of an EHR?

DrFirst cannot currently answer that question authoritatively. Clarification has been requested of the CMS. DrFirst is working with the AMA and other specialty organizations to press for an answer to this question. DrFirst is recommending that electronic prescription of controlled substances not be required for Meaningful Use, but rather that only e-prescribing of non-controlled substances be a Meaningful Use denominator. Greenway's Government Affairs division is also closely monitoring the situation and advises that electronic controlled-substance prescriptions is not likely to be included in Stage 1 Meaningful Use denominators.

For additional information on the Health Information Technology for Economic and Clinical Health (HITECH) Act, which includes Meaningful Use incentives, see <http://www.greenwaymedical.com/news/stimulus-overview/>.

For more information on Meaningful Use of an EHR, see <http://www.greenwaymedical.com/news/ehr-meaningful-use/>.