E-Rx of Controlled Medications
Frequently Asked Questions

DEA Ruling

What is the DEA Ruling?

The United States Drug Enforcement Administration (DEA) recently released an Interim Final Rule (IFR) that defines criteria for the electronic prescribing of controlled substances. It is subject to congressional approval, but is expected to be approved and may be effective as early as June 1, 2010.

What are the main points of the criteria?

Identity Proofing - Will require a two-step process based on separation of duties. For example, for providers in a private practice, identity proofing will be done by an authorized third party. For large institutions, identity proofing may be conducted as part of the credentialing process and the institution can act as a trusted third party on behalf of the physician.

Access Control - Once authentication is complete, the e-prescribing application must allow setting of logical access controls to ensure that only prescribers with a DEA credential are allowed to sign controlled substances. Access controls must be handled by two people; one person will setup logical access (to the capability) and a practitioner with the DEA credential must approve access using two-factor authentication before it becomes active for the provider.

Two-Factor Authentication – Two-factor authentication requires use of two of the following: something you know, something you have, something you are. For example, Biometrics (something you are) or hard tokens (something you have) may be used in combination with passwords (something you know). Prescribers will need to use this two-factor authentication to sign all controlled substance prescriptions. Additionally, two-factor authentication will be required when granting access to other e-prescribing DEA registrants.

Audit requirements - Monthly logs of controlled substances must be generated, archived and the logs must be provided to the practitioner. Both pharmacies and physician applications must maintain audit trails. Additionally audit trail and alerts are required to recognize and alert individual for potential security threats.

Is product certification required for electronic prescribing of controlled substances?

Yes, it will be required.

Is my Allscripts EHR or ePrescribe application certified?

No: certification is not possible at this time. All e-prescribing applications must undergo an independent audit or certification. While audit organizations such as WebTrust, SysTrust, SAS 70, have been identified, independent certification organizations have not yet been named by the DEA.

When will my EHR become certified?

Allscripts is engaged in engineering work to incorporate new standards and requirements into our software. There are common architecture components for security and the transmission of the prescription that will be leveraged across all our e-prescribing products. Additionally, there are application workflow requirements specific to each product. These will be delivered and communicated according to each product's respective roadmap. Further, transmission standards will be developed to support the enhanced security requirements that have been defined for electronic prescribing of controlled substances. These industry components must be aligned prior to certification. Allscripts is working closely with our industry partners and other stakeholders to deliver this new technology as quickly as possible.

Once my Allscripts EHR (or ePrescribe) application is certified, can I start e-prescribing controlled medications?

Yes. However, in addition to necessary application requirements, pharmacy software vendors will need to adapt their systems to accommodate incoming controlled substance e-prescriptions. Therefore, there is also a dependency on the pharmacy and pharmacy system capabilities and readiness for meeting the DEA requirements.

How will this affect e-prescribing measures for Meaningful Use?

The Office of the National Coordinator for Health Information Technology (ONC) has not defined whether or not the electronic transmission of controlled medications would be included in denominator criteria for Stage 1. Allscripts is submitting comments to the DEA and ONC that electronic prescribing of controlled medications should not be included in Stage 1 meaningful use report criteria. In addition, e-Rx of controlled substances is still not legal in some states, such as New York, so could not be required as part of Meaningful Use those states.

Will Misys EMR be enhanced to meet the necessary criteria?

No. Misys EMR development is focused on patient safety and regulatory changes. While federal regulation will soon permit the electronic prescribing of controlled medications it is not a requirement. Application support to electronically transmit a controlled substance prescription is optional; written, manually signed, and oral prescriptions of controlled substances, where applicable, are still permitted.

Where can I find additional information?

You can visit www.allscripts.com/thetimeisnow for a frequently asked questions document. In addition, the DEA has made additional documents available at the links listed below.

DEA Summary of IFR -- http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.htm

General Questions and Answers -- http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/faq.htm