



**NIST NCPDP Analysis –
Electronic Prescribing of Controlled Substances using SCRIPT
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A. Introduction

The goal of this document is to provide a high-level overview of the prescribing of controlled substances using NCPDP SCRIPT, including remaining industry challenges with regard to the SCRIPT standard or other factors including security.

Document sections:

Background. Background of events supporting electronic controlled substance prescribing.

The EPCS Interim Rule. Overview of the DEA interim rule on electronic prescribing of controlled substances.

AHRQ Pilot. Overview of the findings of an AHRQ-led pilot of electronic controlled substance prescribing.

Remaining Challenges. Other challenges to adoption of electronic controlled substance prescribing.

B. Background

The adoption of electronic prescribing has been somewhat hindered due to the unique challenges surrounding controlled substances. The DEA is focused on preventing diversion and counterfeit of these medications and has published an interim final rule (IFR) that will allow the electronic prescribing of controlled substances (EPCS). The IFR was effective June 10, 2010 and according to the DEA Office of Diversion Control:

“The rule revises DEA regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. These regulations are an addition to, not a replacement of, the existing rules. The regulations provide pharmacies, hospitals, and practitioners with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances.”

The industry is working towards ways of implementing EPCS in compliance with the IFR while waiting for the final rule. According to the DEA’s office of diversion control, as of December 2007 (the latest year data is available) controlled substances represented approximately 11% of all prescriptions and 90% of prescribers write prescriptions for controlled substances.

C. The EPCS Interim Final Rule

The IFR does allow practitioners to sign and transmit prescriptions for controlled substances electronically. It also allows for pharmacies to receive, dispense and archive electronic prescriptions. This is a voluntary program that include schedule II-V controlled substances and does not replace written, manually signed or oral prescriptions for controlled substances. Both versions of NCPDP SCRIPT (8.1 and 10.6) that are allowed for use under MMA support the requirements of the IFR.

The IFR addresses DEA Security Safeguards which includes Identify Proofing, Access Control, Two Factor Authentication, Secure Network and Digital Signature.

Identity Proofing is specifically for prescribers and is most likely done by a third party. It is a way for the user to prove that they are who they say they are. It can be done remotely, or face-to-face. Once complete, the prescriber receives a credential that authenticates each electronic prescription for a controlled substance. It also enables two-factor authentication for each prescription written.

Access Control applies to prescribers and pharmacists. It is designed to ensure that only designated individuals manage software permissions and that appropriate prescribers and pharmacy staff only use the application for EPCS.

Two Factor Authentication is used to prove that the prescriber is authorized to digitally sign an EPCS. The two factors include a combination of:

- Something you have (hard token)
- Something you know (password, PIN)
- Something you are (biometric)

This is one of the key burdens as prescribers are somewhat resistant to carrying yet another device, such as a token, and not all mobile technologies can support biometrics. One care system has found a way for the prescriber's mobile device to also function as a token, so that prescribers can respond to patient care needs regardless of their physical location.

A *Secure Network* is provided by an aggregator (i.e. Emdeon eRxNetwork or Surescripts). The IFR allows for two options for securely transmitting an authenticated EPCS. One option is end-to-end PKI which is digitally signed with the prescriber's digital certificate. The pharmacy is required to verify the signature using the prescriber's public key. The second option is the inclusion of a flag on the EPCS that designates the prescription has been sent by a DEA registrant using two-factor authentication. The pharmacy or last intermediary must digitally sign the transaction.

Digital Signatures require that the prescription be signed at its origin. If cryptokeys are being used, the prescription must be signed with the user's digital signature. If using two-factor authentication other than cryptokey, then the prescription must be signed with the vendor's digital signature, which proves that two-factor authentication was used. If the prescription is being sent including the flag designating two-factor authentication, then the prescription must be signed at the pharmacy, either by the pharmacy or the last intermediary.

While the industry is still waiting for a final rule from the DEA, it is important to consider any state-specific restrictions. State laws must allow for EPCS; according to a presentation given by Rick Sage, Vice President of Clinical Services at Emdeon during the 2011 NCPDP Annual Conference, 18 states currently do not permit EPCS.

D. AHRQ Pilot

In a presentation also given at the 2011 NCPDP Annual Conference, Stephen J. Kelleher, Jr., MHA, FACHE of the MA Department of Public Health Drug Control Program gave an update on the AHRQ pilot program Enabling E-Prescribing and Enhanced Management of Controlled Medications. A number of entities were involved with this pilot, including:

- MA Department of Public Health, Drug Control Program
- DrFirst, Inc., Rockville, MD
- Emdeon eRxNetwork, Fort Worth, TX
- Brandeis University, Heller School for Social Policy and Management
- Berkshire Health Systems, Inc.
- U. S. Department of Justice, Drug Enforcement Administration

The scope of the pilot was two-fold. First was to encourage the expansion, adoption and diffusion of e-prescribing, to improve medication management by ambulatory care clinicians at the point-of-care. The second was to test and demonstrate the safety, security, quality and effectiveness of electronic transmission of prescriptions for federally controlled medications in the ambulatory care setting.

Among the key observations from the pilot was that having a significant number of pharmacies in a given area prepared to accept EPCS increased provider adoption. The study also showed that providers using EPCS had high operational satisfaction, improved EHR accessibility and productivity.

E. Remaining Challenges

In addition to the technical challenges associated with adoption of EPCS, implementers face increased auditing and administrative requirements included in the interim final rule. How to meet these requirements, however, is not well understood by all. Given the DEA's emphasis on management and audit related to controlled substances, the American Institute of Certified Public Accountants (AICPA) is developing audit guidelines. In addition, the DEA is expected to publish guidelines related to certification organizations.

Finally, the publication of a Final Rule is critical in increasing adoption of EPCS. Without this, the industry will be hesitant to move forward with a costly implementation. There is much work that needs to be done, including programming for provider and pharmacy systems, deployment of additional technologies to support two-factor authentication, intermediary certification, engagement of auditing firms, education of all stakeholders, and modification of state laws.