Electronic Prescriptions for Controlled Substances

Michelle Ferritto, Chief
Regulatory Drafting Unit
Office of Diversion Control
Drug Enforcement Administration
Electronic Prescriptions for Controlled Substances

- Interim Final Rule with Request for Comment (75 FR 16236, March 31, 2010)
- Effective June 1, 2010
- Comment period ended June 1, 2010
Overview

- Provides practitioners with the option of signing and transmitting prescriptions for controlled substances electronically
- Permits pharmacies to receive, dispense, and archive electronic prescriptions
- Schedule II, III, IV, V controlled substances
- Electronic prescriptions for controlled substances voluntary from DEA’s perspective
- Written, manually signed, and oral prescriptions for controlled substances, where applicable, still permitted
- Electronic prescriptions for controlled substances subject to State requirements
Cooperation with Other Federal Agencies

- DEA worked closely with HHS in development of Interim Rule
- DEA also worked with NIST and GSA
Implementation of the Rule

- Prescribing practitioners: select application, identity proofing, set access controls, sign prescriptions
- Pharmacies: select application, set access controls, process prescriptions, archive prescriptions
- Application providers:
  - Evaluate application and reprogram where necessary
  - Undergo third-party audit or certification to determine whether application meets DEA’s requirements
For individual practitioners, Identity proofing conducted by credential service providers or certification authorities approved by Federal government.

Remote identity proofing permissible.

CSP or CA will issue two-factor credential.

Institutional practitioners may do this in-house, in person.

Application provider will tell practitioner what CSP or CA to work with.
Two-Factor Authentication

Credentials

- Protects practitioner from misuse of credential by insiders; also protects him from external threats because practitioner can retain control of a biometric or hard token.
- Authentication based only on knowledge factors easily subverted because they can be observed, guessed, or hacked and used without the practitioner’s knowledge.
- Two-factor – two of the following:
  - Something you know – password, PIN
  - Something you have – hard token separate from computer being accessed
  - Something you are – any biometric that meets DEA’s requirements
- Two-factor credential used only to sign prescriptions and approve access controls.
Access Controls

- Set at the practice by two people, one a registrant possessing two-factor credential.
- Limits the permission to approve and sign controlled substances prescriptions to persons whose:
  - State authorization(s) to practice and to prescribe controlled substances, where applicable, are current and in good standing.
  - DEA registration is current and in good standing.
- May be set by name or role.
Signing a Controlled Substance Prescription

- A practitioner or agent may prepare the prescription for review and signature by the practitioner.
- Practitioner accesses list of prescriptions for a single patient.
- Screen displays:
  - Date of issuance
  - Patient name
  - Drug name, strength, form, quantity prescribed, directions for use
  - Name, address, DEA registration number of practitioner
  - Other information as applicable
Signing a Controlled Substance Prescription

- On same screen, statement that completion of two-factor authentication protocol is legally signing prescription(s) and authorizing transmission to pharmacy for dispensing displayed
- Practitioner indicates those prescriptions ready to be signed
- Practitioner prompted to complete two-factor authentication protocol
- Authentication causes application to digitally sign DEA elements and archives OR
- Authentication causes practitioner’s digital certificate to digitally sign DEA elements and archive
- Information not required by DEA may be added after signature, e.g., pharmacy URL
Issues related to Transmission

- Transmission should be as soon as possible after signature, but need not be immediate.
- Prescription must remain electronic; conversion to fax NOT permitted during transmission.
- Prescription may be printed after signature if labeled “Copy only - not valid for Dispensing”.
- Information may be transferred to electronic medical records; lists of prescriptions may be printed if indicated as not for dispensing.
- Transmitted prescription may be printed for manual signature if practitioner notified that transmission failed; must indicate original was electronic, name of pharmacy, and date/time transmitted.
Pharmacy

- Sets access controls to ensure only authorized persons can annotate, alter (where permissible), delete prescriptions
- Pharmacy receives prescription, archives
- All annotations, records must be electronic
Electronic Prescription and pharmacy applications must conduct internal audits to determine whether security incidents have occurred. Automated function; generates a report for human review. If person reviewing report determines that security incident has occurred, reports incident to application provider and DEA.
Applications

- Must allow access controls (practitioner, pharmacy)
- Must require use of two-factor credential for signing (practitioner)
- Must have an internal audit trail (practitioner, pharmacy)
- Must digitally sign and archive record (practitioner, pharmacy)
- Must include all DEA-required information in prescription record (practitioner)
- Must be able to import, display, and store DEA information in record (pharmacy)
- Must be able to generate a record of controlled substance prescriptions for review (practitioner, pharmacy)
Application Audits

- Application must undergo an independent audit or certification
  - WebTrust, SysTrust, SAS 70
  - Certified Information System Auditor
  - Independent certification organization approved by DEA
- Audit/certification must determine whether application meets DEA’s requirements
- Application provider must make report available to practitioners/pharmacies using or considering use of application
- Practitioners, pharmacies may only sign or process controlled substances prescriptions using applications that have been determined to meet DEA’s requirements
Questions?