Electronic Prescriptions for Controlled Substances
What Happens in Vegas, Stays in Vegas

What happens electronic, stays electronic
Federal Register Publication

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

- Practitioners have the option of signing and transmitting prescriptions for controlled substances electronically
- Permits pharmacies to receive, dispense, and archive electronic prescriptions
- CII-V prescriptions permissible
Overview

• Electronic prescriptions for controlled substances are voluntary from DEA’s perspective

• Written, manually signed, and oral prescriptions for controlled substances, where applicable, still permitted
Who is Affected

- Application providers that develop, sell, and host electronic prescription applications and pharmacy applications
- DEA-registered practitioners who want to sign and transmit controlled substances prescriptions electronically
- DEA-registered pharmacies that want to process electronic prescriptions for controlled substances
How are they Affected

• Application providers: undergo third-party audit or certification to determine whether application meets requirements

• Prescribing practitioners: select application, identity proofing, set access controls, sign prescriptions

• Pharmacies: select application, set access controls, process prescriptions, archive prescriptions
Application Providers

• Prior to use for controlled substances prescriptions must undergo independent audit or certification
  - WebTrust, SysTrust, SAS 70
  - Certified Information System Auditor
  - Independent certification organization approved by DEA

• Audit/certification must be conducted:
  - Before used to create, sign, transmit or process prescriptions
  - Whenever functionality related to controlled substance prescription requirements is altered or every two years, whichever comes first

• Audit/certification must determine whether application meets DEA’s requirements

• Auditor issues report to application provider
Auditors/Certifiers

- WebTrust, SysTrust, and SAS 70 audits are common in information technology arena; conducted by accounting firms and others
- Certification organizations whose certification process has been approved by DEA
- One organization exists that works with HHS, but more are coming
- DEA would announce such approvals through notice published in the Federal Register and posted on website
What this Means

- Practitioners and pharmacies can only use applications that meet DEA’s requirements to handle controlled substances prescriptions.
- The audit/certification report states whether the application meets DEA’s requirements.
- Application providers must provide audit/certification reports to DEA upon request.
Identity Proofing

• The process by which a credential service provider or certification authority validates sufficient information to uniquely identify a person

• Necessary to verify that a person is who he claims to be
How it Works

• Identity proofing conducted by credential service providers or certification authorities approved by Federal government.

• Prescribing practitioners must undergo identity proofing (21 CFR 1311.105).

• Application provider will tell practitioner what organization to work with.

• Remote identity proofing permissible.

• Institutional practitioners can use this method or a slightly different method specific to their needs (21 CFR 1311.110).
Identity proofing does not verify State authorization to practice, State authorization to dispense controlled substances, or DEA registration.

Those are verified as part of access controls.
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
- List 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 is legally signing prescription and authorizing transmission to pharmacy for dispensing displayed

• Practitioner indicates those prescriptions ready to be signed

• Practitioner prompted to complete two-factor authentication protocol

• Completion of two-factor authentication protocol is legal signature
What Happens When Practitioner Uses Credential

• Authentication causes application to digitally sign DEA elements and archives OR

• Authentication causes practitioner’s digital certificate to digitally sign DEA elements and archive

• This archived prescription can be compared to the prescription archived at the pharmacy
  • Prescription at pharmacy could differ from prescription at practitioner
  • Prescription at pharmacy could be same as prescription at practitioner
Transmission

• Prescription must be transmitted as soon as possible after signature
• Prescription must remain electronic; conversion to fax NOT permitted
• Prescription may be printed after signature so long as labeled “Copy only - not valid 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
Two-Factor Authentication

• After identity verified, practitioner will be issued two-factor authentication credential

• Protects practitioner from misuse of credential and from external threats

• Two-factors – two of the following:
  o Something you know – password, PIN
  o Something you have – separate hard token
  o Something you are – a biometric
Two-Factor Authentication

- Persons prescribing controlled substances have two factors
- Hard token could be a USB device, a smart card, PDA, cell phone, one-time password device
- Any biometric that meets DEA’s requirements is acceptable
What’s NOT Acceptable

• The use of a handwritten signature which has been scanned and is then affixed to a prescription

• The use of a user name and password

• The use of a biometric or hard token by itself

• Sending the user a message over a cell phone that the user then enters into the computer
Pharmacy Overview

- Application provider makes audit or certification report available to pharmacy
- Pharmacies may only process electronic prescriptions using applications determined to meet DEA’s requirements
- Pharmacy receives prescription, archives all records for two years
Pharmacy Access Controls

• Ensure that only individuals authorized to enter information regarding dispensing and annotate or alter (where permissible) prescription information are allowed to do so.

• Pharmacy sets access controls to ensure only authorized persons can annotate, alter (where permissible), delete prescriptions.
Receipt of Prescriptions

- Pharmacy receives prescription which has been digitally signed by last intermediary OR
- Pharmacy receives prescriptions and digitally signs upon receipt
- Pharmacy receives prescription signed with practitioner’s digital certificate
Pharmacy Annotations, Records

- All annotations must be electronic
- Prescriptions can be retrieved by practitioner name, patient name, drug name, date dispensed; sortable
- Pharmacy records must be backed up daily
- All records must be retained electronically
Disposal of Controlled Substances
Safe Disposal Act of 2009

- **House Resolution 1191**
  - Introduced on 2/25/2009 by Rep Inslee (WA)
  - Amend the CSA to allow states to operate disposal programs
  - Direct the Attorney General to create 5 models for implementation

- **Companion Senate Bill 1336**
  - Introduced on 6/24/2009 by Sen Murray (WA)
Secure and Responsible Drug Disposal Act of 2009

• House Resolution 1359
  • Introduced on 3/5/2009 by Rep. Stupak (MI)
  • Amend the CSA to permit ultimate user to deliver drugs for destruction
  • Grants the Attorney General discretion to promulgate regulations

• Companion Senate Bill 1292
  • Introduced on 6/18/2009 by Sen Klobuchar (MN) and Sen Grassley (IA)
Disposal ANPRM

- ANPRM Published on 1/21/09 in the Federal Register
- Entitled “Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration”
- Seeking options for the safe and responsible disposal of patient owned controlled substances consistent with CSA
• Comment period ended 3/23/2009
  • 158 comments received
• Major issues identified by commenters
  • There is a problem with left-over controlled substances.
  • No consistent national policy
  • Recognition of CSA and regulations as barrier
  • Funding – who pays?
  • Billing/Prescribing practices, 30-day supply or more
General Statements

• If no procedure to currently allow, CSA should be amended

• Disposal alternatives should be environmentally safe, easy to use, and cost effective

• Reverse Distributors should be permitted to accept cs from ultimate users

• Pharmacies are the best drop off locations for most ultimate users
Disposal – Comments

General Statements

• DEA should establish local contacts assigned to address pharmaceutical collection and disposal issues.

• Need for widespread information campaigns on environmentally safe disposal of unused and unwanted pharmaceuticals.

• Manufacturers should bear the bulk of the costs.
National Take Back Initiative

- September 25, 2010 is proposed collection date
- National program coordinated by DEA with law enforcement officials
- Collection by state/local law enforcement officers from ultimate users
- Destruction by DEA
Rulemaking
CMEA Retail Provisions

• IFR published on 9/26/2006

• Implemented retail provisions of CMEA relating to logbooks, sales and purchase limits, placement, packaging, self-certification, etc.

• Draft circulating within DEA
Removal of Thresholds

• Related to CMEA assessment of annual need
• NPRM published 11/20/2007
• Removes thresholds for importation, exportation, and domestic distributions of PSE and PPA
• Cleared to publish
Dispensing to Residents of LTCFs

- Solicitation of Information
- Request information relative to chart orders, agent of a practitioner, controlled substance registration, etc.
- Drafting – review by DOJ components
Changes to a CII Prescription

- NPRM being drafted
- Establish by regulation what information a pharmacist may change on a schedule II prescription with physician authorization
- Circulating within DEA for review
DEA Diversion Website
www.DEAdiversion.usdoj.gov
Questions/Comments