

# Regulation and Policy Update

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# **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)

# What Identity Proofing Doesn't Include

- 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:
  - Something you know – password, PIN
  - Something you have – separate hard token
  - 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

# Disposal ANPRM – Comments

- 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

# Disposal – Comments

## 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

The background features a large, faint watermark of the Drug Enforcement Administration (DEA) logo. The logo consists of a circular emblem with a stylized eagle or bird in the center, surrounded by the text "U.S. Department of Justice" at the top and "Drug Enforcement Administration" at the bottom, separated by a small dot.

# 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



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### What's New

[Q&A For Prescribing Practitioners](#)

[Q&A For Pharmacies](#)

[Q&A For Providers of Electronic  
Prescription Applications, Pharmacy  
Applications, and Intermediaries](#)

[Noramco, Inc - Correction](#) (April 20,  
2010)

[Varian Inc.](#) (April 16, 2010)

[Siemens Healthcare Diagnostics Inc.](#)  
(April 16, 2010)

[Mylan Pharmaceuticals Inc.](#) (April  
16, 2010)

### Registration Support

**Registration Number  
Toll Free:  
1-800-882-9539**

Save time by applying for and/or  
renewing your DEA Registration  
online. Data will be entered through  
a secure connection to the ODWIF  
online web application system.

Minimum requirements:  
Credit Card and a web browser that  
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or Loss of Controlled  
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### FAQ

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# Questions/Comments

