



# DEA Policy Update

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**Electronic Prescriptions for  
Controlled Substances  
(EPCS)**

# Federal Register Publication

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

# EPCS Terms

- Application Providers
- Audit/Certification
- Identity Proofing
- Credential
- Two-Factor Authentication
- Digitally signed
- Transmission
- Access Controls

# 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.
  - Independent certification organization approved by DEA
  - WebTrust, SysTrust, SAS 70
  - Certified Information System Auditor



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### Electronic Prescriptions for Controlled Substances

#### Approved Certification Processes

DEA recently amended its regulations to specify the conditions under which controlled substance prescriptions may be issued electronically. As set forth in the regulations, before any electronic prescription or pharmacy application may be used to transmit prescriptions, a third party must audit the application for compliance with the requirements of [21 CFR part 1311](#), or a certifying organization whose certification process has been approved by DEA must verify and certify that the application meets the requirements of 21 CFR part 1311. The following list provides the names and contact information of certifying organizations whose certification processes have been approved by DEA.

##### InfoGard Laboratories, Inc.

709 Fiero Lane  
San Luis Obispo, CA 93401  
Phone: 805-783-0810  
Email: [epcs@infogard.com](mailto:epcs@infogard.com)  
Web: [www.infogard.com](http://www.infogard.com)

See - [Electronic Prescriptions for Controlled Substances Clarification](#) (October 19, 2011)

##### Drummond Group Inc.

13359 North Hwy 183, Suite B-406-238  
Austin, TX 78750  
Phone: 817-294-7339  
Email: [info2@drummondgroup.com](mailto:info2@drummondgroup.com)  
Website: [www.drummondgroup.com](http://www.drummondgroup.com)

##### iBeta LLC

2675 South Abilene Street Suite 300  
Aurora, CO. 80014  
Phone: 303-827-1110  
Email: [epcs@iBeta.com](mailto:epcs@iBeta.com)  
Web: [www.iBeta.com](http://www.iBeta.com)

See: [Electronic Prescriptions for Controlled Substances Notice of Approved Certification Process](#) (August 1, 2012)

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# Application Providers

- 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

# 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 with what organization to work.

# How it Works

- 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.

# 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.

# 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.
- 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.

# 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.

# Pharmacy Overview

- Application provider makes audit or certification report available to pharmacy.
- Pharmacies may only process electronic cs 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.
- Pharmacy receives prescriptions and digitally signs upon receipt.

# 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.

# EPCS

## ■ Fax vs. Electronic Prescription

- True electronic Rxs are transmitted as electronic data files to the pharmacy, whose application import the data file into its database.
- A system that allows the prescriber to “sign” his/her name does not conform to EPCS regulations.
- A facsimile with a written signature is not an electronic Rx.



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### Electronic Prescriptions for Controlled Substances (EPCS)

On March 31, 2010, DEA's Interim Final Rule with Request for Comment titled "Electronic Prescriptions for Controlled Substances" [Docket No. DEA-218, RIN 1117-AA61] was published in the Federal Register. The rule became effective June 1, 2010.

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.

#### Federal Register Notices

- [Electronic Prescriptions for Controlled Substances Clarification](#) (October 19, 2011)
  - [PDF Version](#)
- [Interim Final Rule with Request for Comment: Electronic Prescriptions for Controlled Substances](#) (March 31, 2010)
  - [PDF Version](#)
  - [Economic impact Analysis of the Interim Final Rule](#) (PDF)
  - [Risk Assessment for the Interim Final Rule](#) (PDF)

#### Third Party Reviews of Prescriber or Pharmacy EPCS Applications

- [Third Party Reviews of Prescriber or Pharmacy EPCS Applications](#)
  - [Approved Certification Processes](#)

#### Outreach, Questions and Answers

- [Letter to Electronic Application Providers and Pharmacy Application Providers](#) (April 2, 2010)
- [DEA letter to affected associations](#) (March 26, 2010)
- [Questions and Answers](#)
  - [General Questions and Answers](#)
  - [For Prescribing Practitioners](#)
  - [For Pharmacies](#)
  - [For Providers of Electronic Prescription Applications, Pharmacy Applications, and Intermediaries](#)

#### Historical documents

- [Electronic Prescriptions for Controlled Substances - Correction](#) (July 14, 2008)
- [Proposed Rule: Electronic Prescriptions for Controlled Substances](#) (June 27, 2008)
  - [Initial Economic Impact Analysis of the Proposed Electronic Prescription Rule](#) (PDF)

#### Public meetings

- [EPCS Public Meeting Arlington, VA](#) ( July 11-12, 2008)
- [Pharmacists' Working Group](#) (May 2, 2002)
- [Working Group Meeting](#) (February 22, 2001)
- [Working Group Meeting](#) (November 16, 2000)

# Pharmacy Diversion Awareness Conferences (PDAC)

- PDACs are designed for pharmacists, pharmacist technicians and loss prevention specialists.
- Attendees receive CE credit via NABP.
- PDACs have been conducted in:
  - Ohio (October 2011)
  - Florida (March 2012)
  - Atlanta (June 2012)
  - Houston (September 2012)
  - New York (September 2012)

# Upcoming PDACs

- Indianapolis, IN December 2012
- Baton Rouge, LA March 2013
- Albuquerque, NM April 2013
- Louisville, KY May 2012
- California June 2013
- Detroit, MI July 2013
- Boston, MA September 2013

# Pre-Populated Prescriptions

# Disposal of Controlled Substances

# Got Drugs?

Turn in your unused or expired medication for safe disposal  
Saturday, Sept. 25th

Visit [www.dea.gov](http://www.dea.gov)  
for a collection  
site near you.



# Results

- Approximately 2 million pounds (1,018 tons) of medication has been taken from circulation.

# 6th DEA National Take Back Day

Tentative: April 27, 2012

# Thank You



# Be The Kayak

