CONTROLLED SUBSTANCES ORDERING SYSTEM (CSOS)

DEA Distributor Conference
National Harbor, Maryland
Chris Jewell, Unit Chief
Office of Diversion Control, Technology Section
April 15, 2015
Agenda

- CSOS History & Overview
- Celebrating 10 Years of Success
- Ongoing Challenges
  - ✓ Registration Enrollment
  - ✓ Certificate Management
  - ✓ Record Keeping
- Moving Forward - Technology Enhancements
CSOS HISTORY
History of CSOS

- DEA tasked under the Controlled Substances Act of 1970 to regulate controlled substances
- Purchasers (pharmacies and distributors) of controlled substances have historically used a controlled paper DEA Form 222 to place their orders
- Industry requested DEA provide a provision to enable electronic orders for controlled substances to integrate with their existing electronic orders for non-controlled substances
  - An allowance to existing regulations, not a mandate
CSOS Milestones

- Initiation Phase began 1999
  - Public Key Infrastructure (PKI) technology introduced
- Industry Pilot conducted 2002 through 2005
- Final Rule published June 2005
- CSOS launched August 2005
CSOS CONCEPT OF OPERATIONS
CSOS CONCEPT OF OPERATIONS

Controlled Substance Ordering System (CSOS)

- DEA CSOS Certification Authority
- DEA Certification Authority
- DEA Headquarters
- Reporting of Order form information
- Check order for alteration
- Controlled Substance Shipments
- Digitally signed controlled substance orders
- Verification
- Policy
- Enrollment
- Purchaser
- Seller
- CRL
- ARL
- DEA Certification Authority
- DEA Headquarters

DEA

Authority
CSOS BENEFITS
Benefits of CSOS

- Improved customer service
  - The Regulations provide allowances for new business processes such as centralized ordering from a single location for all stores within a chain

- Reduced manual effort
  - Manually prepared paper order forms are replaced by electronically generated orders
  - Paper order form is limited to ten line items per order; No limit on the number of line items on electronic orders
Benefits of CSOS

- **Reduced errors**
  - Paper order form requires handwritten product description
  - Electronic orders identify the product by its National Drug Code (NDC)

- **Improved security measures**
  - Order originator authentication
  - Order content integrity
  - Non-repudiation of involvement by parties to a transaction
CELEBRATING 10 YEARS OF SUCCESS
2005 – 2015
Results

- Over 67,000 registered DEA locations have applied to CSOS
- Over 626,000 certificates have been issued
- Larger chains have now adopted CSOS into their ordering process
CSOS Active Certificates Trending

Number of Certificates

Years

Active Certificates

2005 1,708
2007 12,509
2009 26,873
2011 37,588
2013 109,405
2015 121,741
ONGOING CHALLENGES
Registration Enrollment Delays

Insufficient coordination of subscriber roles within organization

- Must have one Principle Coordinator per DEA registration
- Must have Principle Coordinator prior to enrolling other applicants
- Individual may only have one role per DEA registration
  - (i.e.) Principle Coordinator, Power of Attorney
Registration Enrollment Delays

Incorrectly Filling Out Application Form

- Missing signatures
- Incorrect / Invalid e-mail address
- Missing / Expired identification
- Submitting application under an expired DEA registration
Incomplete Application Process

- Initial rejection e-mail sent stating errors to correct
- 45 day rejection reminder notice sent
- 90 day / final rejection notice sent

** No response to these notices results in application resubmission
SUBSCRIBER ROLES
Subscriber Roles

Registrant

- Individual who signed or is authorized to sign the most recent DEA registration application (Form DEA-223)
- May choose to be Principle Coordinator
- Submits Form DEA 251
Subscriber Roles

**Principle Coordinator**

- Must enroll for each DEA registration number participating in CSOS
- Primary CSOS contact with regards to CSOS certificate applications, renewals, and revocations
- Submits Form DEA 252
Subscriber Roles

Alternate Coordinator

- CSOS contact in the absence of the Principal Coordinator for the DEA registration(s)
- Optional designated role for organization
- Submits Form DEA 252
Subscriber Roles

Power of Attorney

- Individual authorized by the Registrant or Coordinator for signing controlled substance orders
- Submits Form DEA 253
CERTIFICATE MANAGEMENT
Certificate Management

- Sharing certificates / passwords
  - 21 C.F.R. § 1311.30
- Making backup copies of user certificate
  - 21 C.F.R. § 1311.30
- Maintaining subscriber agreement
  - 21 C.F.R. § 1311.60
Certificate Management

- Expired DEA registration and renewing digital certificates
  - 21 C.F.R. § 1311.40

- DEA registration changes and renewing digital certificates (i.e.) name change, address change...
  - 21 C.F.R § 1311.40

- Assignment / Maintaining of Principle Coordinator
  - 21 C.F.R. § 1311.20
Record Keeping

- Recording Shipments
  - 21 C.F.R § 1305.22
- Readily Retrievable Records
  - 21 C.F.R § 1311.60
- Maintaining / Accessing Centralized Ordering
  - 21 C.F.R § 1305.24
MOVING FORWARD - TECHNOLOGY ENHANCEMENTS
Moving Forward / Technology Enhancements

- Evaluating New Web Enrollment Process
  - Online registration form (Optional)
  - Mail identification & signature forms
- Upgraded Customer Support System
  - Evaluating new Integrated Voice Response (IVR) System
QUESTIONS?

WWW.DEAEACOM.GOV

1-877-DEA-ECOM (332-3266)