

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

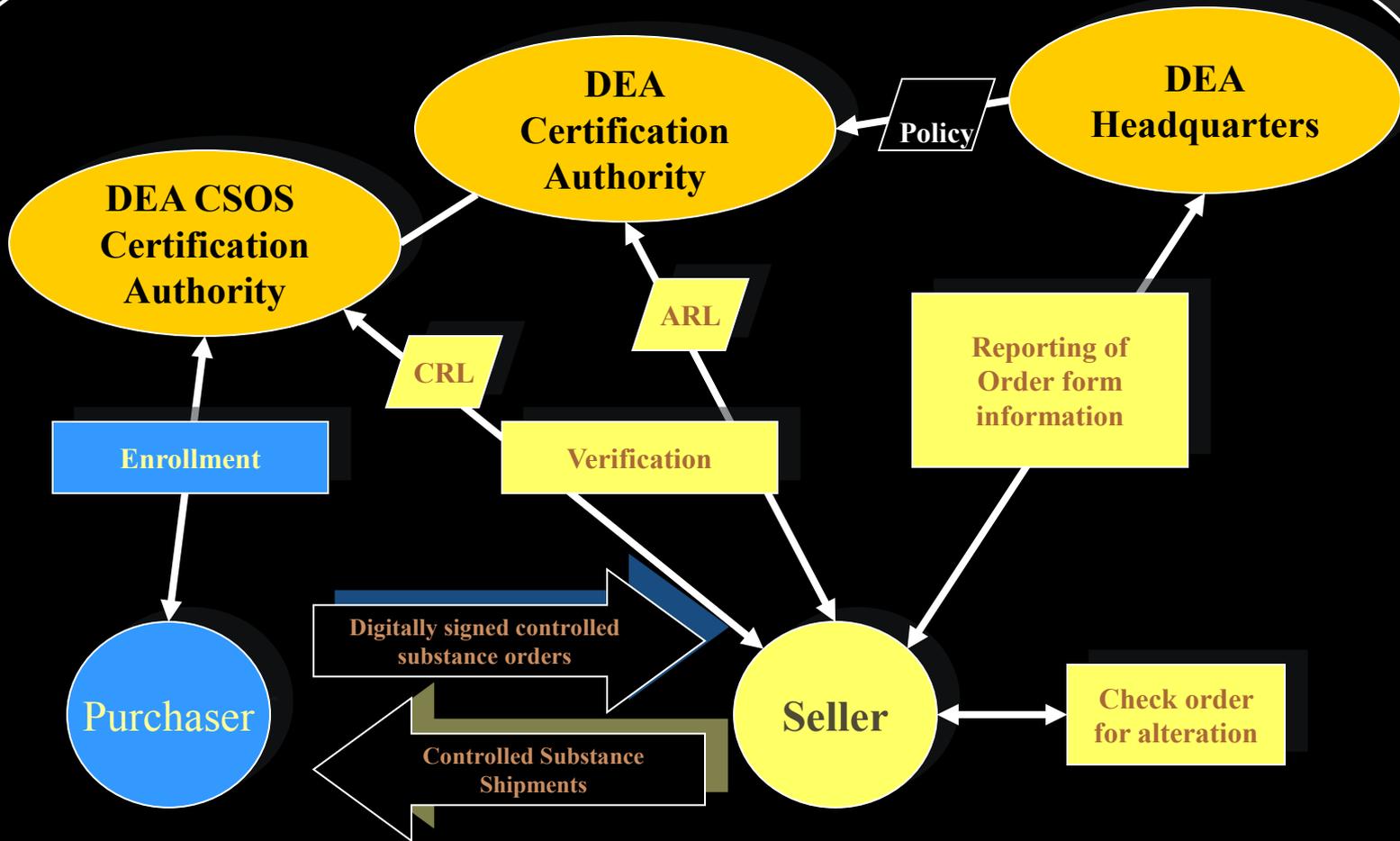
- DEA tasked under the Controlled Substances Act of 1970 to regulate controlled substances
- Purchasers (pharmacies and distributors) of controlled substances have historically used a controlled paper DEA Form 222 to place their orders
- Industry requested DEA provide a provision to enable electronic 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)

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



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

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.DEAECOM.GOV

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