CONTROLLED SUBSTANCES ORDERING SYSTEM (CSOS)

Pharmaceutical Training Seminar
Diversion Control Division

Diversion Technology Section
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Richmond, VA
April 25 & 27, 2017
AGENDA

PROGRAM REVIEW

- CSOS History and Overview
- CSOS Concept of Operations
- Ongoing Program Challenges

ADMINISTRATIVE & REGULATORY

- Common Registration Enrollment Issues
- Common Regulatory Audit Findings
CSOS HISTORY

- 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.
- CSOS is an allowance to existing regulations, not a mandate.
WHAT CSOS IS…

• An ordering system which allows users to place orders in a secure electronic environment

• A **Voluntary** option for ordering Controlled Substances

• A replacement for the DEA Paper 222 Order Form – but may be used in conjunction with the paper order form

• 100% funded by DEA Diversion Control Fee Account
WHAT CSOS IS...

- A PKI Technology Based Trust Framework...

That must provide the following:

- **Authentication**: must positively verify the signer
- **Non-repudiation**: strong and substantial evidence of the sender’s identity
- **Message Integrity**: must determine whether the contents of the order have been altered in transmission
BENEFITS & CHALLENGES
THE 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
THE BENEFITS OF CSOS

• Reduced Errors
  • Paper order form requires handwritten product description
  • Electronic orders will identify the product by its National Drug Code (NDC)

• Improved Security Measures
  • Order originator authentication through CSOS Certificate
  • Order content integrity
  • Non-repudiation of involvement by parties to a transaction
THE BENEFITS OF ELECTRONIC ORDERING

**PAPER 222 FORM**
- Only CI-II allowed
- Only 10 lines/form
- Only one location fills
- Reports each month

**ELECTRONIC ORDER**
- Can include CI-V
- Any number of lines
- Multiple fill locations
- Reports every two (2) business days
ONGOING PROGRAM CHALLENGES

- Educating others on CSOS’ unique role DEA has as a Credential Service Provider (CSP) to industry
- Educating Pharma Community about PKI Technology
- Ensuring systems not under DEA governance are compliant with performance standards specified in 21 CFR
  - DEA requires external audit of ALL third-party ordering systems of to ensure that FIPS 140-2 (Federal Information Processing Standard) and 21 CFR requirements are met
ONGOING PROGRAM CHALLENGES

• Certificates only used in B2B transactions between supply chain partners within a regulated industry (Third-party ordering software)

• Commercial vendors and industry require sufficient lead time to update ordering software in accordance with changes to Regulations and / or NIST policies
CSOS MILESTONES

- Initiation Phase began 1999
- Industry Pilot conducted 2002 through 2005
- Final Rule published June 2005
- CSOS launched August 2005
CURRENT RESULTS

- Over 79,000 registered DEA locations have applied to CSOS
- Over 196,000 active certificates in production
- Larger chain pharmacies have now adopted CSOS into their ordering process
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<th>Registrations (DEA# Locations)</th>
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CSOS Active Certificates Trending

- 2005: 1,708
- 2007: 12,509
- 2009: 26,873
- 2011: 37,588
- 2013: 109,405
- 2016: 196,037

Nov. 2016
CSOS CONCEPT OF OPERATIONS

DEA CSOS Certification Authority

Purchaser

Digitally Signed Controlled Substance Orders

Cert Verification

Seller

Check Order for Alteration

DEA / DCD Headquarters

Reporting of Order Form Information

CRL

Enrollment

Controlled Substance Shipments

Policy
Enrollment Process
CSOS CONCEPT OF OPERATIONS

DEA CSOS Certification Authority

Enrollment

Purchaser

Controlled Substance Ordering System (CSOS)
DEA CSOS ENROLLMENT ROLES

- DEA Diversion Control Division CSOS
  - Credentialing Service Provider (CSP)
    - Provides Identity Proofing and Certificate Management

- DEA CSOS Registrant Authority (RA)
  - Performs applicant identity proofing
    - Receives & adjudicates applications
    - Receives & verifies revocations requests

- DEA CSOS Certificate Authority (CA)
  - Issues / Generates Certificates – Ordering & Administrative
    - Distributes Authorization and Reference Codes
    - Generates Certificate Revocation Lists (CRL’s)
    - Revokes Certificates
PURCHASER CSOS ENROLLMENT ROLES

- **DEA Registrant**
  - Individual who signed the most recent application for DEA Registration

- **Principal Coordinator**
  - Serve as an organization’s primary recognized CSOS contact

- **Alternate Coordinator**
  - Serve as an organization’s secondary recognized CSOS contact

- **Powers of Attorney (POA)**
  - Individuals who hold a valid POA to obtain and sign Schedule I and II controlled substance orders
PURCHASER CSOS ENROLLMENT PROCESS

• Organizations **must** select and enroll a CSOS Coordinator

• Organizations may have more than one CSOS Coordinator
  • (i.e.) primary coordinator / alternate

• Organizations CSOS Coordinators perform local identification and authentication required to issue a digital certificate

• Due to the complexity of the enrollment process, applicants should be directed to the Help Desk or CSOS web site for assistance with enrollment forms and processes
CSOS CONCEPT OF OPERATIONS

Controlled Substance Ordering System (CSOS)

DEA CSOS Certification Authority

Enrollment

Purchaser

CSOS Certificate Issued Upon Successful Enrollment
Ordering Process
Controlled Substance Ordering System (CSOS)

- DEA CSOS Certification Authority
- Enrollment
- Purchaser
- Seller
- Digitally Signed Controlled Substance Orders
DIGITALLY SIGNING & TRANSMITTING A PURCHASE ORDER

Electronic Orders Defined
DIGITALLY SIGNING ORDERS

Controlled Substance Purchase Order

HASH

Pharmacist Private Key

Digitally Signed Controlled Substance Orders

Digitally “signed” Order
ELECTRONIC ORDER CONTENT

• Order form number in the specified “YYX123456” format must be included in order content before order is signed
• The last 6 digits of the number should be sequential to aid in tracking outstanding orders
• Order number must be unique within a single registration location
• DEA number must be included in the body of the order
• Other registration information (i.e.) address, business activity, schedules, expiration date are contained in the certificate and are therefore not required to be in the body of the order
ELECTRONIC ORDER CONTENT (CONT’D)

• NDC Code may be used in lieu of product description
  • system for viewing orders must translate / provide product description to viewer
• Once an order number is assigned to the order and it is digitally signed, a copy of the order must be archived by purchaser regardless of whether order is rejected, voided, or cancelled
• Order must be readily retrievable at the registered location
AN ELECTRONIC ORDER MUST.....

Contain the same information as a paper order

Except:

• Customer Registration Information:
  
  Name, Address, Schedules, Business Activity and Expiration Date (which is contained in the digital certificate)

• NDC number may be substituted for product description

• Number of order lines

• Be signed using a digital signature issued by the CSOS Certification Authority (CA)
CSOS CONCEPT OF OPERATIONS

DEA CSOS Certification Authority

Enrollment

Purchaser

Digitally Signed Controlled Substance Orders

Seller

Controlled Substance Ordering System (CSOS)
Certificate & Order Verification Process
Controlled Substance Ordering System (CSOS)

- **DEA CSOS Certification Authority**
- **Enrollment**
- **Purchaser**
- **Cert Verifcation**
- **Seller**
- **Check Order for Alteration**
- **CRL**
- Digitally Signed Controlled Substance Orders
Certificate Verification Process
VERIFYING A SIGNED ORDER

Step 1 - Signing Process (Purchaser)

Controlled Substance Purchase Order

Digitally "signed" Order

Pharmacist Private Key

HASH

Step 2 - Verification Process (Supplier)

Digitally "signed" Order

Pharmacist Public Key

VERIFY

HASH

Controlled Substance Purchase Order

Cert Verification
Certificate Revocation List
WHAT IS A CERTIFICATE REVOCATION LIST (CRL)

- List of all revoked certificates
- Published by the CA that issued the certificate
- Includes Revocation Date
- Revocation Reason

(DeA) CRL

- Version
- Issuer

- Revoked Certificates

- Issuing Distribution Point

- Cert. Serial #
- Rev. Date
- CRL Entry Extensions
- Reason flag
# CRL REQUIREMENTS

| CRL Publishing Frequency | Publishes Certificate Revocation List (CRL) every 24 hours  
| In the event the Subscriber’s key has been compromised – or lost – the CRL must be published within 6 hours of notifying the DEA |
| Relying Parties | Must check each order against the most recently published CRL to ensure that the certificate has not been revoked since signed |
Order Verification Process
ORDER VERIFICATION

• Sellers system must determine the order has not been altered during transmission

• Seller must invalidate any order that has been altered

• Seller must check the substances ordered against the schedules the registrant is allowed to order

• Seller must invalidate any order that includes substances the registrant is not allowed to order
ORDER AUTHENTICATION

- Validate Signature and Subscriber certificate
- Orders that do not pass authentication must be rejected
- Supplier must notify the purchaser of any orders that have been rejected
- **Purchaser** must maintain a record of rejected orders, including the rejection notice from the supplier
- Orders that are not officially accepted, are rejected, and otherwise not filled need not be archived by the supplier
- Seller must be able to produce digitally signed order and linked records of distribution on demand
CSOS CONCEPT OF OPERATIONS

DEA CSOS Certification Authority

Enrollment

Purchaser

CRL

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Seller

Digitally Signed Controlled Substance Orders

Check Order for Alteration

Controlled Substance Ordering System (CSOS)
Order Shipment Process
CSOS CONCEPT OF OPERATIONS

Controlled Substance Ordering System (CSOS)

DEA CSOS Certification Authority

Enrollment

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Cert Verification

Seller

Check Order for Alteration

Digitally Signed Controlled Substance Orders

CRL

Controlled Substance Shipments
When purchaser receives order:

• Record of receipt must be linked to original order record

• For rejected or cancelled orders (or portions of orders) the suppliers rejection notice must be maintained and linked to the original, archived order
CSOS CONCEPT OF OPERATIONS

- Controlled Substance Ordering System (CSOS)
- DEA CSOS Certification Authority
- CRL
- Enrollment
- Cert Verification
- Digitally Signed Controlled Substance Orders
- Check Order for Alteration
- Seller
- Purchaser
- Controlled Substance Shipments
CSOS TWO-DAY REPORTING
(SELLER)
Controlled Substance Ordering System (CSOS)

Purchaser

DEA CSOS Certification Authority

Cert Verification

CRL

Digitally Signed Controlled Substance Orders

Reporting of Order Form Information

DEA / DCD Headquarters

Check Order for Alteration

Seller

Enrollment

Controlled Substance Shipments

CSOS CONCEPT OF OPERATIONS
SUPPLIER – CSOS REPORTING

• Report of the line items shipped must be transmitted to DEA within two business days (CSOS 2-Day Reporting)

• Orders partially filled must be reported as such when shipped

• Report must consist of the orders received plus the linked distribution records or a summary report containing the same information

• Format of report consists of Part A - 1st 80 characters standard ARCOS report of what was ordered

• Plus Part B - What was shipped; consisting of the following fields:
  * NDC # field (81) * Quantity field (92) * Unit field (100)
  * Strength field (101)
CSOS CONCEPT OF OPERATIONS

DEA CSOS Certification Authority

Purchaser

DEA / DCD Headquarters

Reporting of Order Form Information

Cert Verification

Seller

Check Order for Alteration

Digitally Signed Controlled Substance Orders

Controlled Substance Shipments

Enrollment

CRL
CSOS CONCEPT OF OPERATIONS (CONOPS)

RECAP
CSOS CONCEPT OF OPERATIONS

DEA CSOS Certification Authority

DEA / DCD Headquarters

Certification Authority

Policy

CRL

Reporting of Order Form Information

Check Order for Alteration

Digitally Signed Controlled Substance Orders

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Seller

Controlled Substance Shipments

DEA CSOS

Controlled Substance Ordering System (CSOS)
CSOS CONCEPT OF OPERATIONS

DEA CSOS Certification Authority

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Digitally Signed Controlled Substance Orders

Controlled Substance Shipments

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Purchaser

Seller

Controlled Substance Ordering System (CSOS)
ADMINISTRATIVE & REGULATORY FINDINGS
COMMON REGISTRATION ENROLLMENT ISSUES
REGISTRATION ENROLLMENT ISSUES

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

(e.g.) Principle Coordinator, Power of Attorney
REGISTRATION ENROLLMENT ISSUES

Incorrectly Filling Out Application Form

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

- 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*
COMMON REGULATORY AUDIT FINDINGS
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 of 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 A Principle Coordinator
  
  ✔️ 21 C.F.R. § 1311.20
CERTIFICATE MANAGEMENT

• Maintaining a Power of Attorney Certificate Listing by Coordinator
  ≠ 21 C.F.R § 1311.45
RECORD KEEPING
RECORD KEEPING

• Readily Retrievable Records
  
  21 C.F.R § 1311.60

• Recording Shipments / Linking of Orders
  
  21 C.F.R § 1305.22

• Maintaining / Accessing Centralized Ordering
  
  21 C.F.R § 1305.24
RECORD KEEPING

- Independent Third-Party Software Auditing Records
  - 21 C.F.R § 1311.55
• Missing copy of Subscriber Agreement
• Inability to electronically produce CSOS orders
• Inability to identify electronic record keeping process
• Sharing of CSOS certificates
• Maintaining certificates of employees no longer with the company
CSOS REGISTRANT SUPPORT

1-877-DEA-ECOM (1-877-332-3266)
www.deaecom.gov
QUESTIONS