

CONTROLLED SUBSTANCES ORDERING SYSTEM (CSOS)

Import/Export Manufacturer Conference

Diversion Control Division

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AGENDA

- § CSOS History & Overview
 - § Concept Of Operations
 - § Subscriber Roles & Responsibilities
 - ü Registration Enrollment
 - ü Certificate Management
 - ü Record Keeping
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CSOS HISTORY & OVERVIEW



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



What CSOS is...

- An ordering system which allows users to place orders in a secure electronic environment
 - A replacement for the DEA Paper 222 Order Form – but may be used in conjunction with the paper order form
 - A **Voluntary** option for ordering Controlled Substances
 - 100% funded by DEA Diversion Control Fee Account
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What CSOS is...

- A PKI Technology Based Trust Framework...

That must provide the following:

- Authentication: must positively verify the signer
- Nonrepudiation: strong and substantial evidence of the sender's identity
- Message Integrity: must determine whether the contents of the order have been altered in transmission



CSOS MILESTONES & CURRENT STATS

CSOS Milestones

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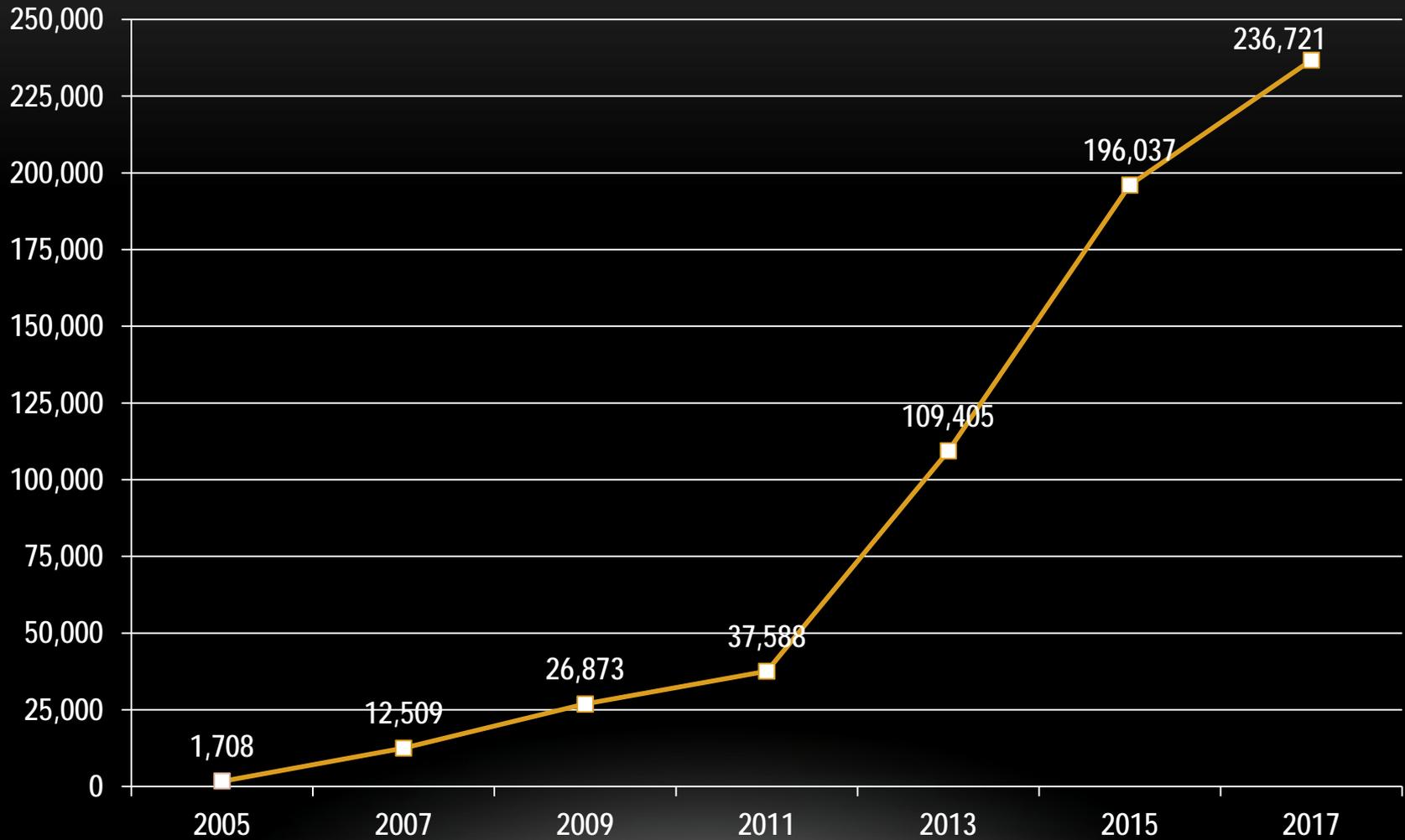


CURRENT RESULTS

- Over *86,000* registered DEA locations have applied to CSOS
- Over *236,000* active certificates in production
- Larger chain pharmacies have now adopted CSOS into their ordering process



CSOS Active Certificates Trending



CSOS Applicants by Business Type



Business Activity	Registrations (DEA# Locations)
Pharmacy	63,733
Hospital/Clinic	9,633
Practitioner	10,787
Mid-level Practitioner	620
Manufacturer	83
Distributor	370
Researcher	150
Analytical Lab	19
Importer	2
Exporter	16
Teaching Institution	11
Narcotic Treatment Maintenance	67
Narcotic Treatment Maintenance & Detoxification	430
Narcotic Treatment Detoxification	43
Narcotic Treatment Compounder/Maintenance	1
Narcotic Treatment Compounder/Maint & Detox	28



CSOS BENEFITS



The Benefits of CSOS

- **Ordering Freedom**
 - Electronic ordering of Schedule I and II controlled substances, in addition to Schedule III-V substances
 - *Centralized ordering* from a single location for all stores within a chain
 - No limit on the number of line items on electronic orders
 - Paper order form is limited to ten line items per order



The 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 through CSOS Certificate
 - Order content integrity
 - Non-repudiation of involvement by parties to a transaction



The Benefits of CSOS

- **Faster Transactions**
 - CSOS certificates contain the same identification information as DEA Form 222, which allows for timely and accurate validation by the supplier
 - Faster transactions allow for just-in-time ordering and smaller inventories.
- **Decreased Cost**
 - Order accuracy and decreased paper work result in a lower transaction cost.



CSOS FRAMEWORK FUNDAMENTALS

DEA / INDUSTRY CSOS RELATIONSHIP



CSOS DEA / Industry Workflow

1. Enrollment

An individual enrolls with DEA and, once approved, is issued a personal CSOS Certificate.

2. Digitally Signed Order

The purchaser creates an electronic 222 order using approved ordering software. The order is digitally signed using the purchaser's personal CSOS Certificate and then transmitted to the supplier. The paper 222 is not required for electronic ordering.

3. Certificate Validation

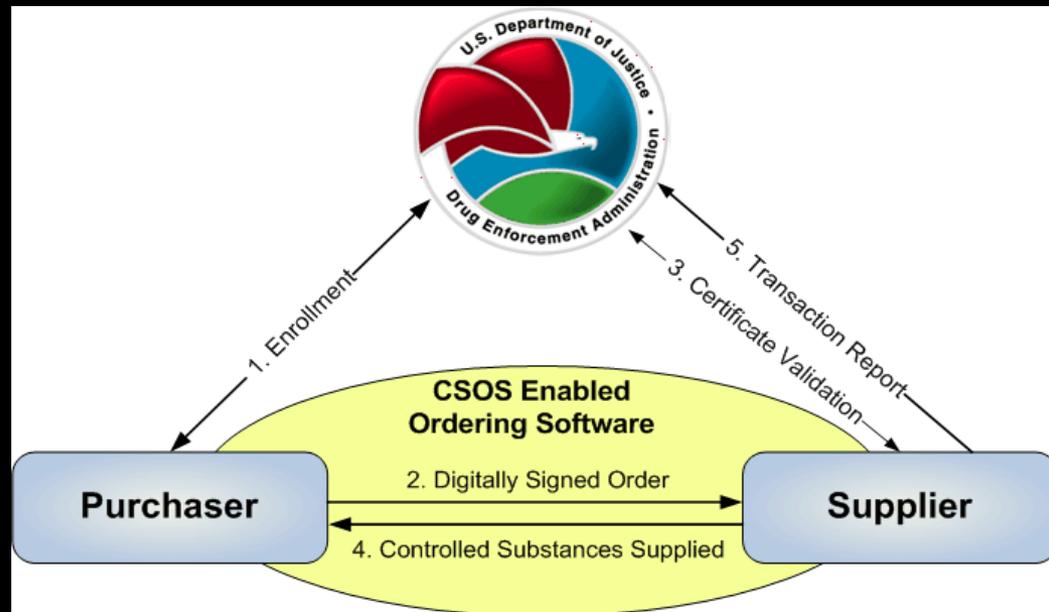
The supplier receives the purchase order and verifies that the purchaser's certificate is valid with DEA. Additionally, the supplier validates the electronic order information just like it would a paper order.

4. Controlled Substances Supplied

The supplier completes the order and ships to the purchaser. All communications regarding the order are sent electronically.

5. CSOS Transaction Report

The order is reported by the supplier to DEA within two business days.





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
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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
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Subscriber Roles

Power of Attorney

- § Individual authorized by the Registrant or Coordinator for signing controlled substance orders
 - § Submits Form DEA 253
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REGISTRATION ENROLLMENT DELAYS



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
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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



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
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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



QUESTIONS?

WWW.DEAECOM.GOV

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