

# CONTROLLED SUBSTANCES ORDERING SYSTEM (CSOS)

## Pharmaceutical Training Seminar

Diversion Control Division

Diversion Technology Section

Chris Jewell

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
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# CSOS HISTORY & OVERVIEW

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# 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
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# 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

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# 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
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# 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 & CURRENT STATS

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# 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 *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

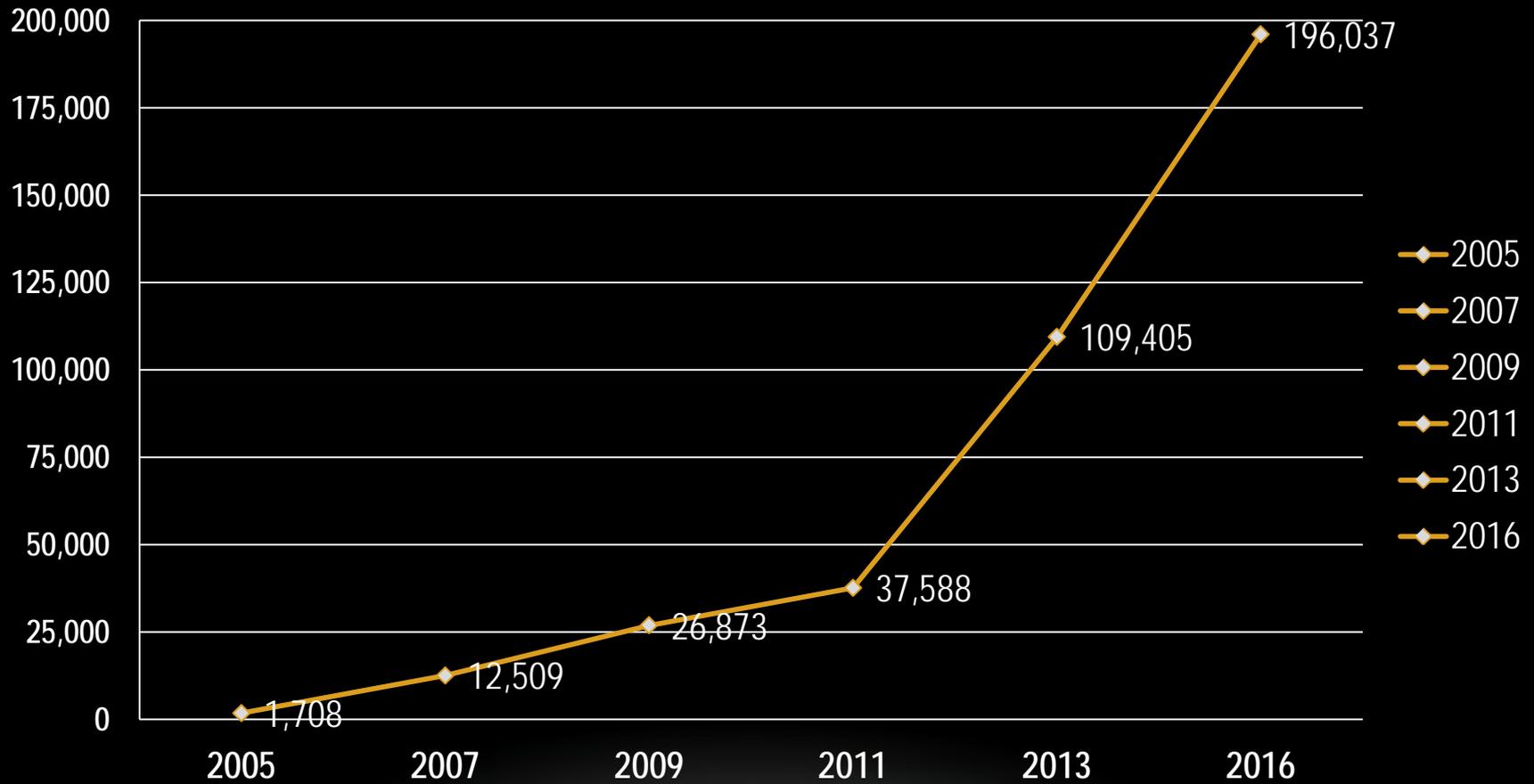


# CSOS APPLICANTS BY BUSINESS TYPE

Business Activity	Registrations (DEA# Locations)
Pharmacy	59,466
Hospital/Clinic	9,076
Practitioner	9,547
Mid-level Practitioner	528
Manufacturer	78
Distributor	348
Researcher	137
Analytical Lab	17
Importer	1
Exporter	15
Teaching Institution	9
Narcotic Treatment Maintenance	52
Narcotic Treatment Maintenance & Detoxification	379
Narcotic Treatment Detoxification	41
Narcotic Treatment Compounder/Maintenance	1
Narcotic Treatment Compounder/Maint & Detox	24



# CSOS Active Certificates Trending

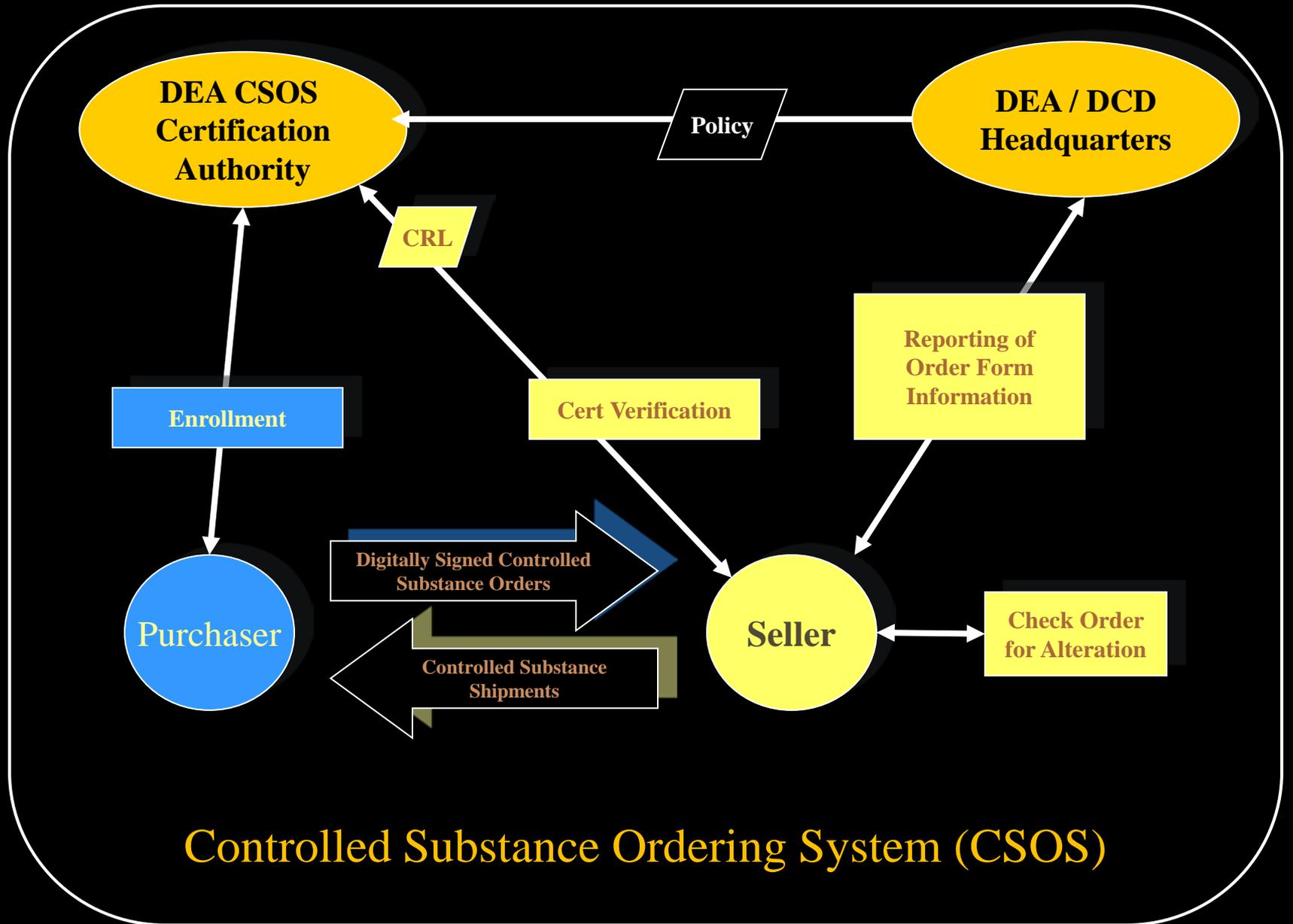




# CSOS CONCEPT OF OPERATIONS (CONOPS)

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# CSOS CONCEPT OF OPERATIONS





# Enrollment Process

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# CSOS CONCEPT OF OPERATIONS



**DEA CSOS  
Certification  
Authority**

**Enrollment**

**Purchaser**

**Controlled Substance Ordering System (CSOS)**



# DEA CSOS ENROLLMENT ROLES

DEA CSOS  
Certification  
Authority



- 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

Purchaser



- 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 organizations 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



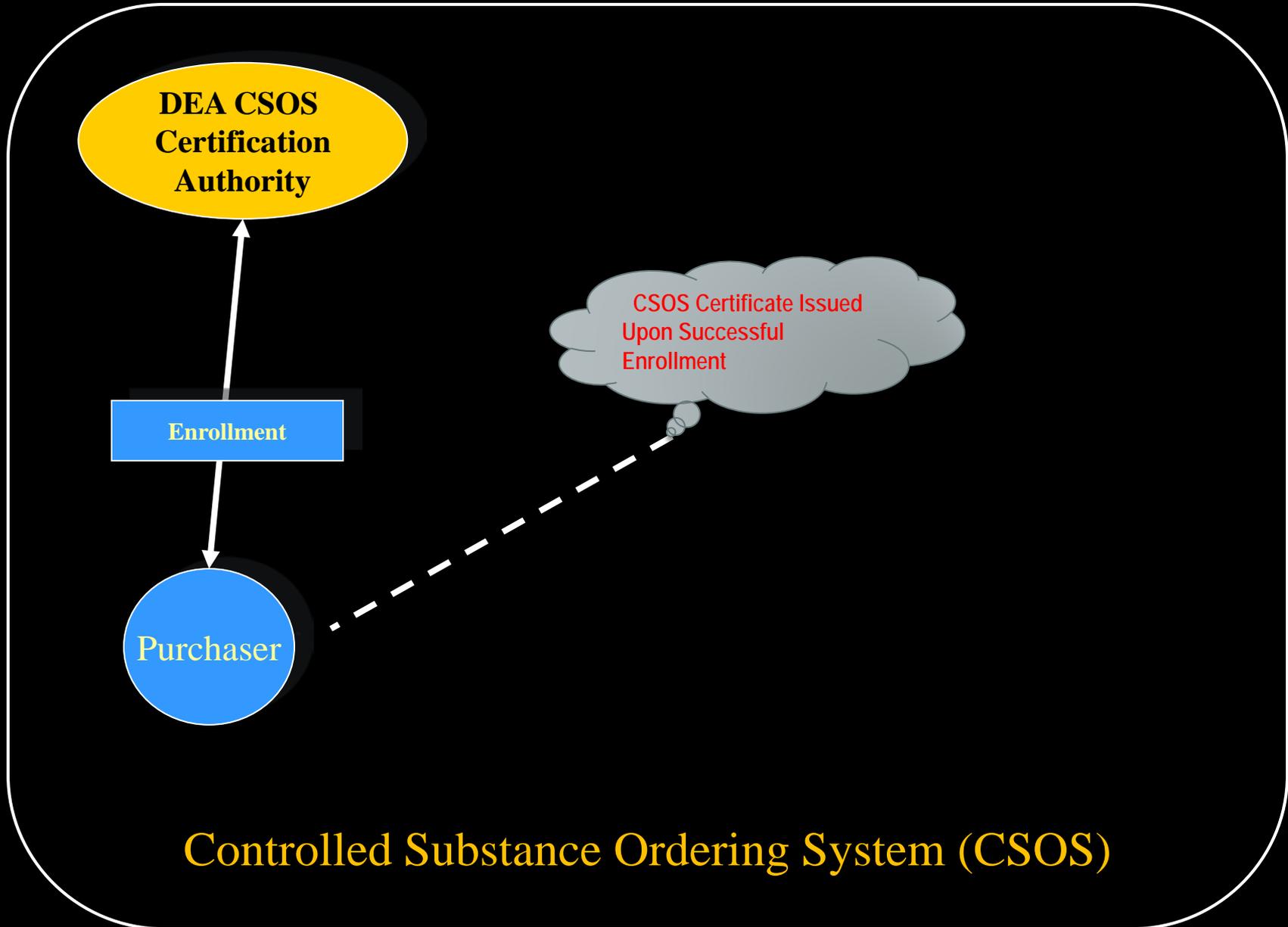
**DEA CSOS  
Certification  
Authority**

**Enrollment**

**Purchaser**

**CSOS Certificate Issued  
Upon Successful  
Enrollment**

**Controlled Substance Ordering System (CSOS)**





# Ordering Process

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# CSOS CONCEPT OF OPERATIONS



**Controlled Substance Ordering System (CSOS)**



# DIGITALLY SIGNING & TRANSMITTING A PURCHASE ORDER

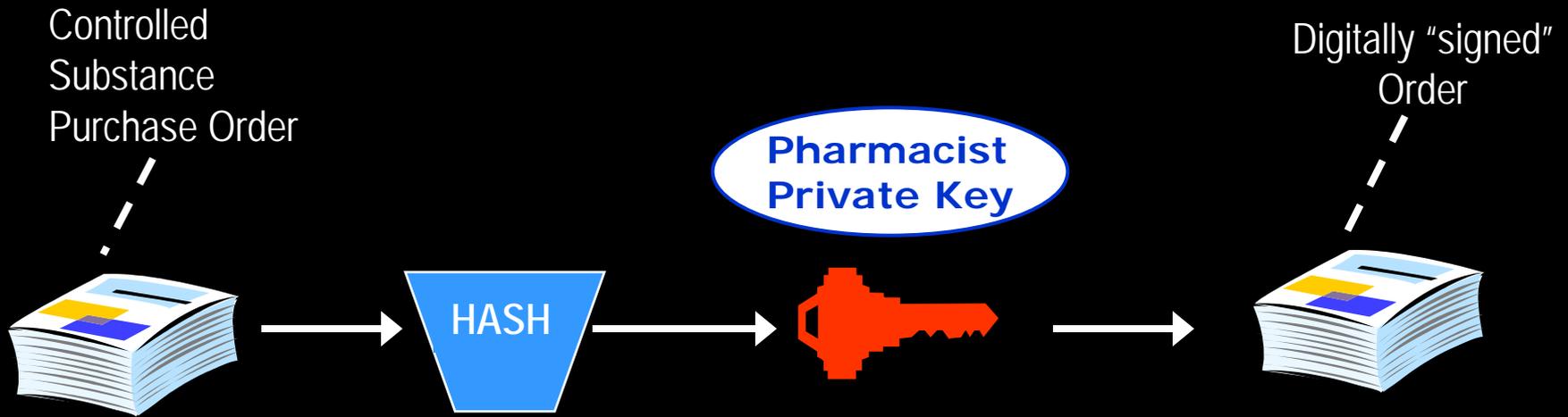


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Electronic Orders Defined



# DIGITALLY SIGNING ORDERS





# 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



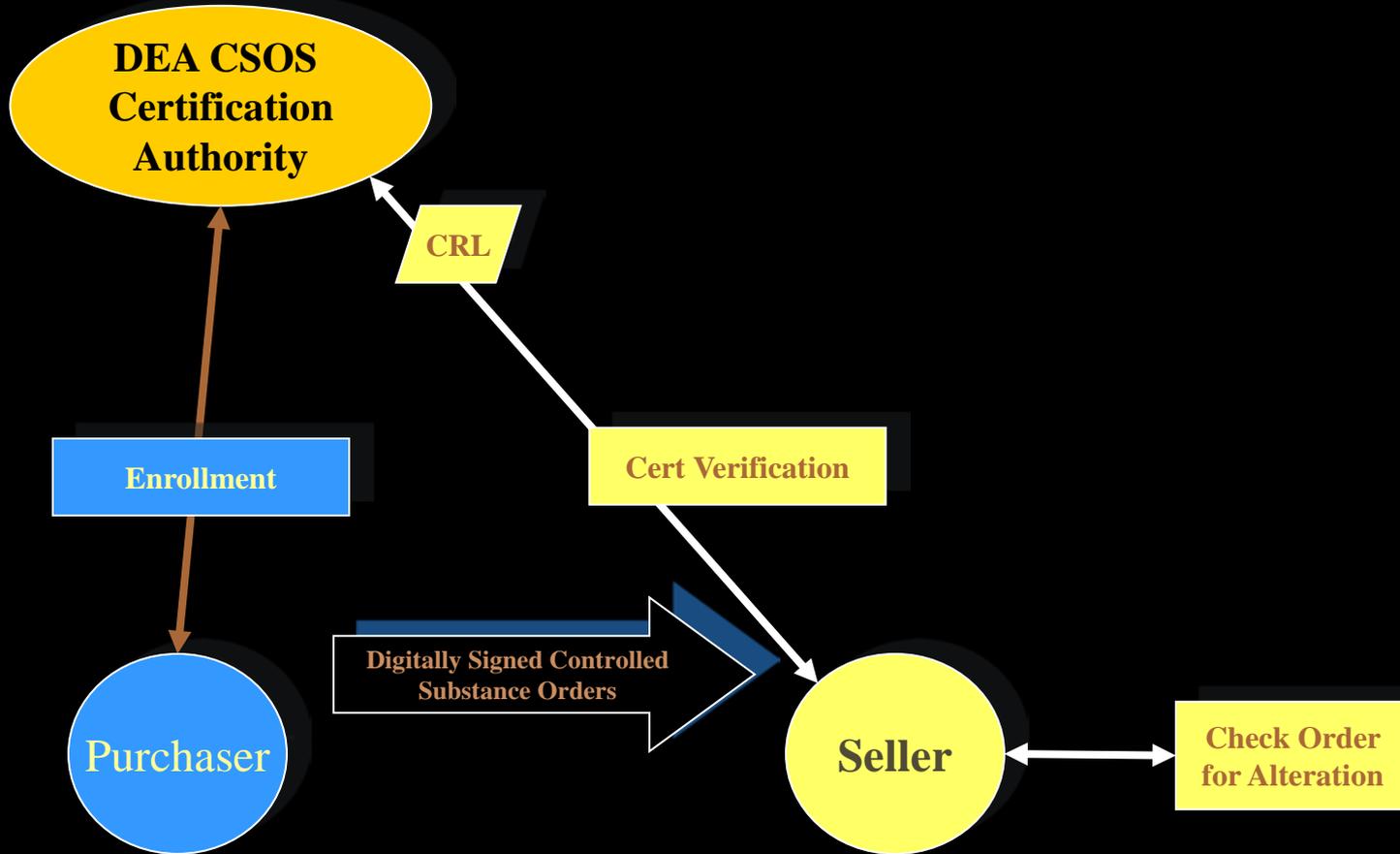
**Controlled Substance Ordering System (CSOS)**



# Certificate & Order Verification Process

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# CSOS CONCEPT OF OPERATIONS



**Controlled Substance Ordering System (CSOS)**



# Certificate Verification Process

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# VERIFYING A SIGNED ORDER



Cert Verification

## Step 1 - Signing Process (Purchaser)

Controlled Substance  
Purchase Order



Digitally "signed"  
Order

## Step 2 - Verification Process (Supplier)



Controlled Substance  
Purchase Order



# Certificate Revocation List

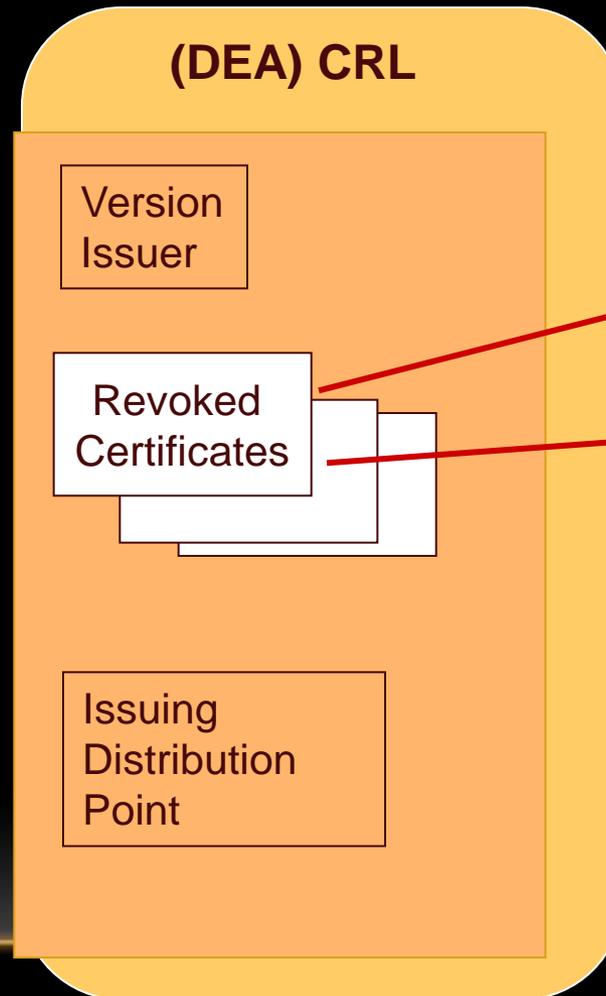
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# WHAT IS A CERTIFICATE REVOCATION LIST (CRL)

CRL

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



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

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# ORDER VERIFICATION

Check Order  
for Alteration

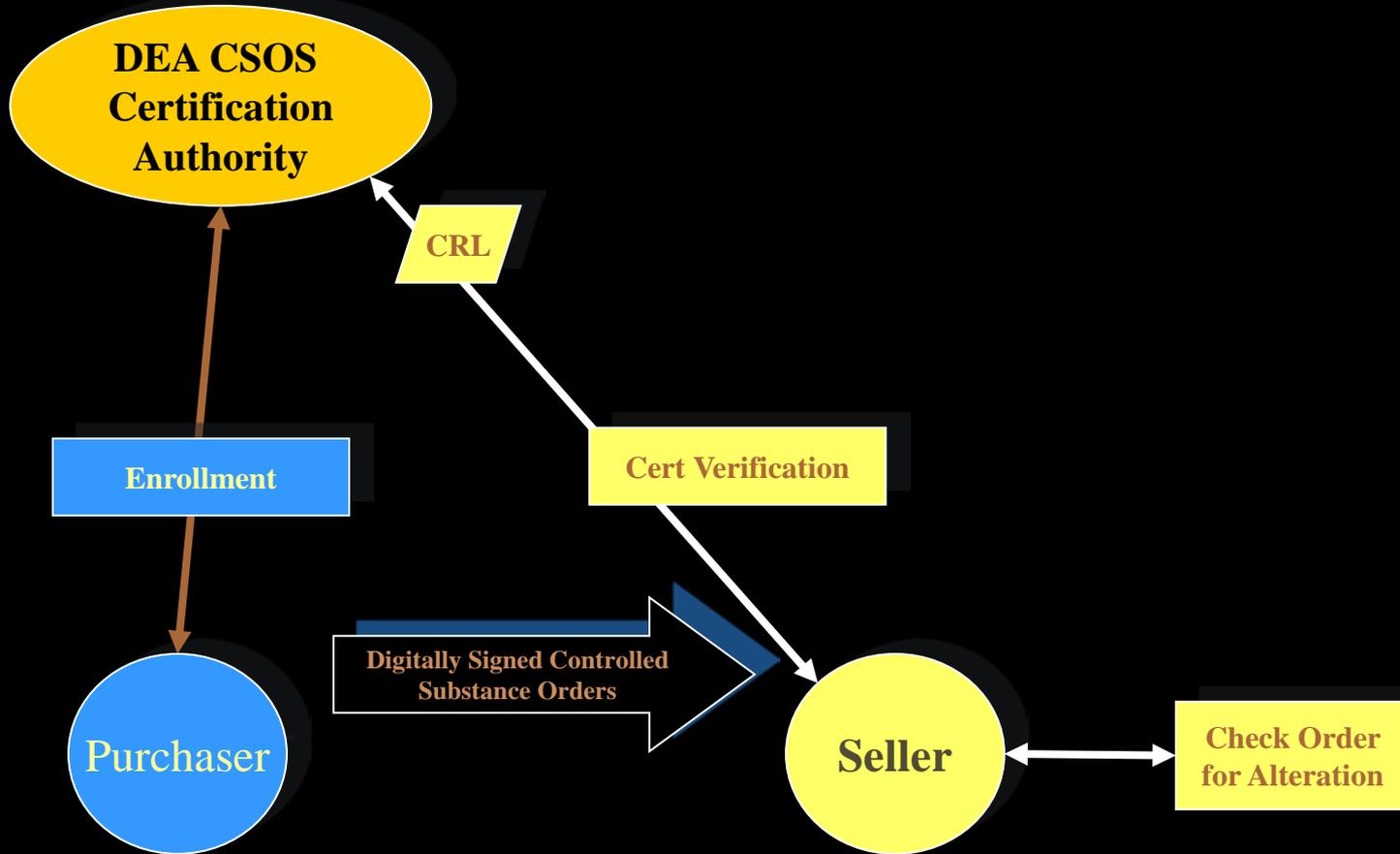
- Sellers system must determine the order has not been altered during transmission
- Seller must invalidate any order that has been altered
- Seller must check the substances ordered against the schedules the registrant is allowed to order
- Seller must invalidate any order that includes substances the 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



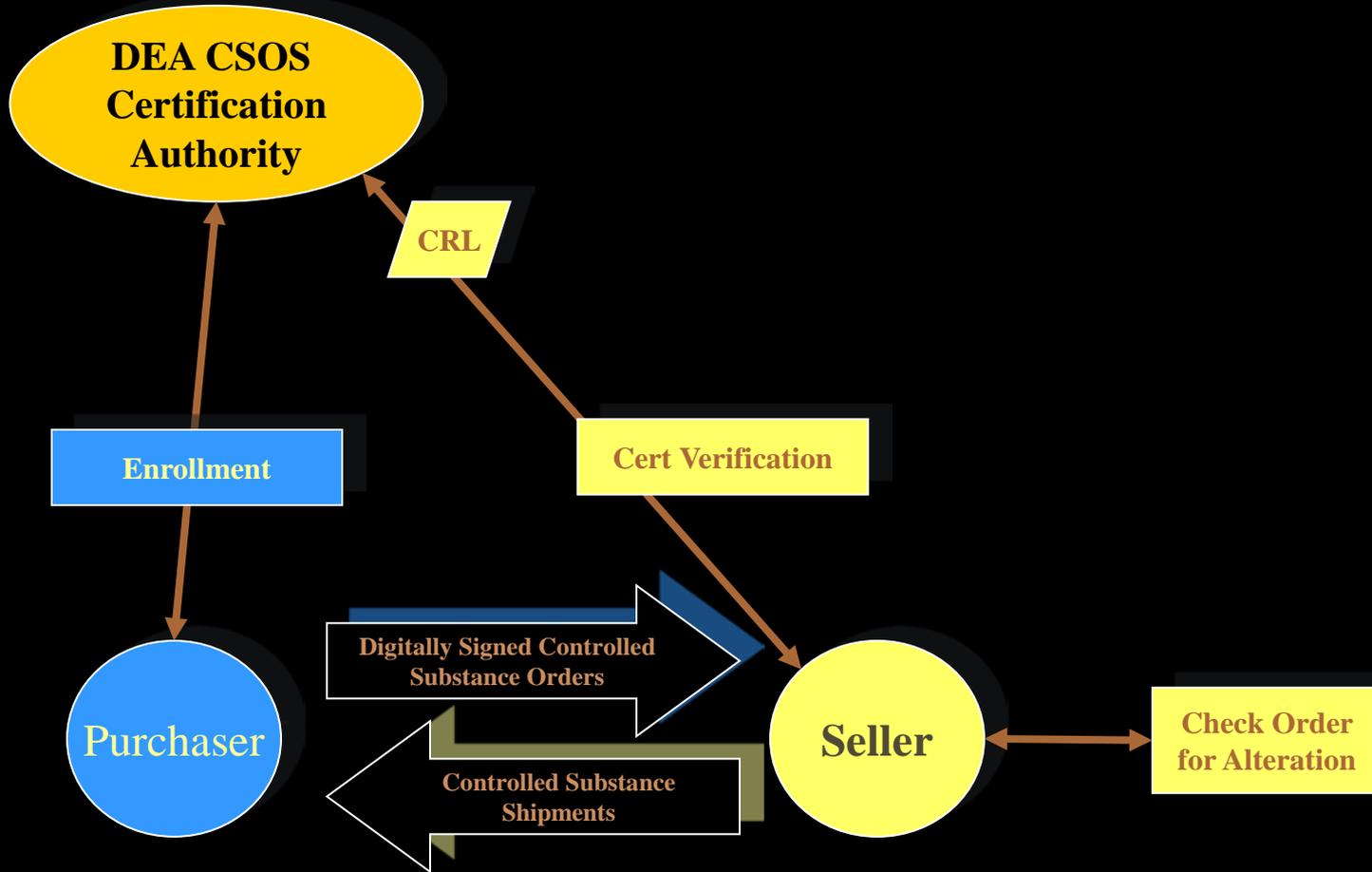
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# Order Shipment Process

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# CSOS CONCEPT OF OPERATIONS



**Controlled Substance Ordering System (CSOS)**



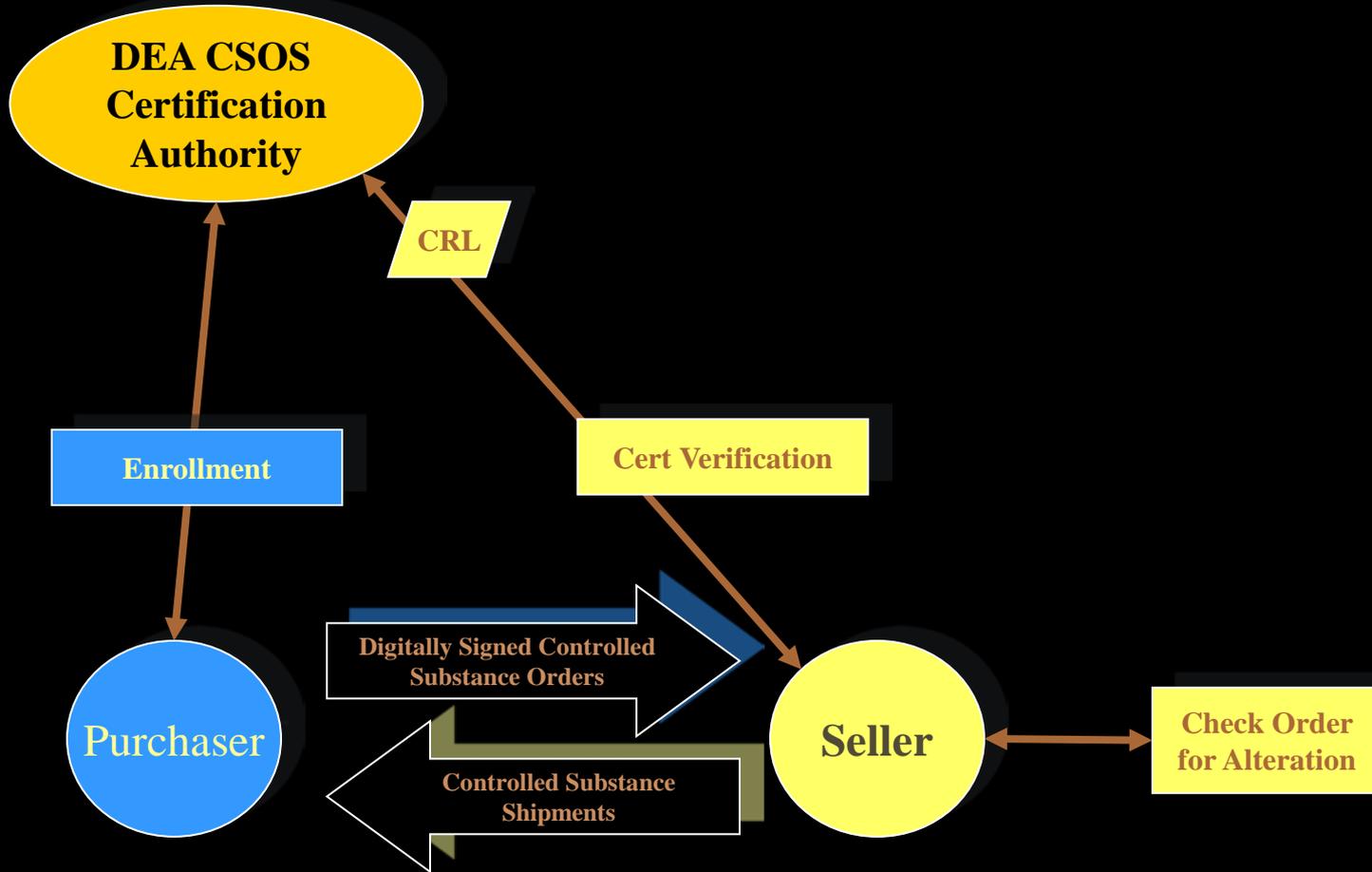
# CONTROLLED SUBSTANCE ORDERING SHIPMENTS



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



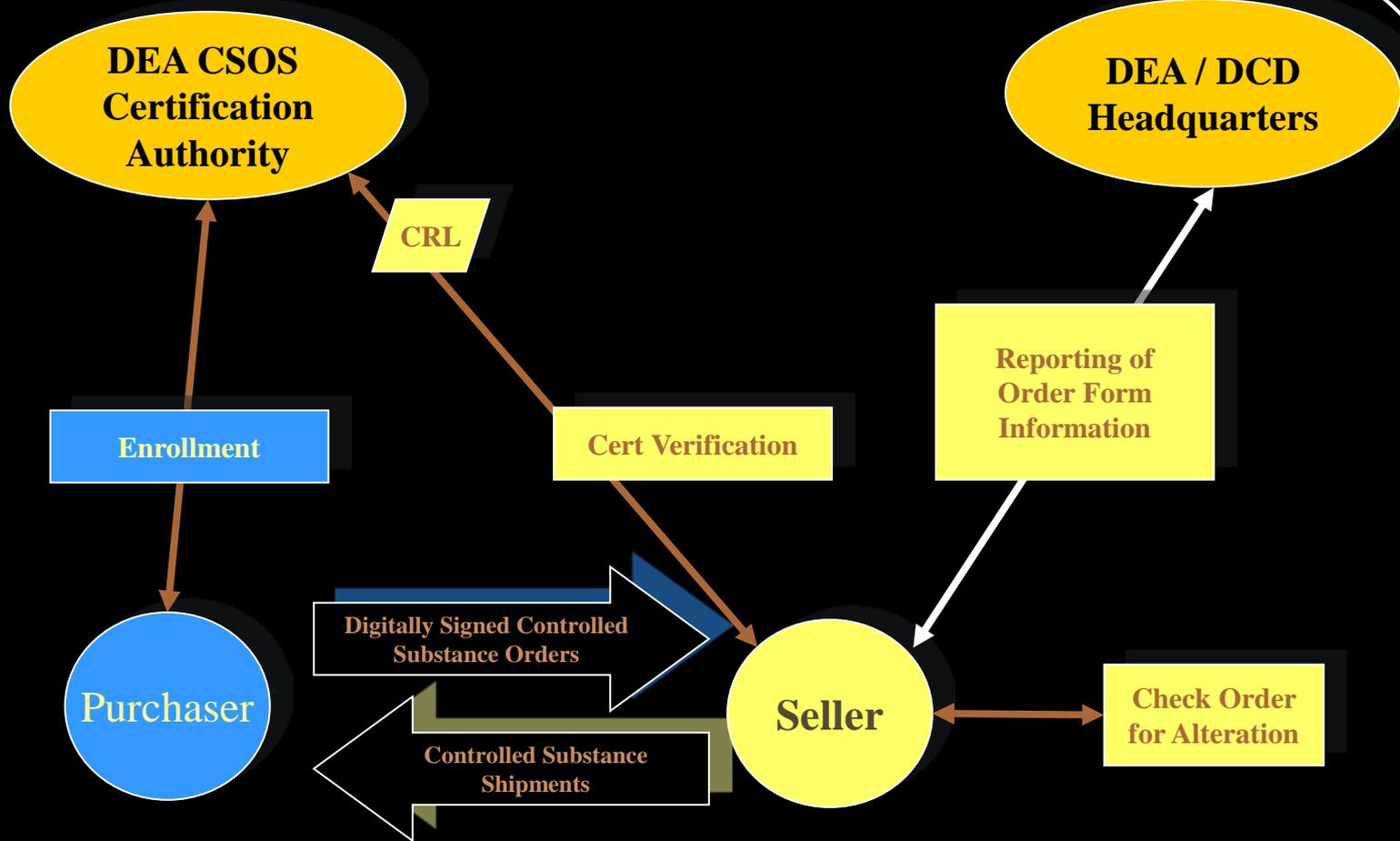
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# CSOS TWO-DAY REPORTING (SELLER)

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# CSOS CONCEPT OF OPERATIONS



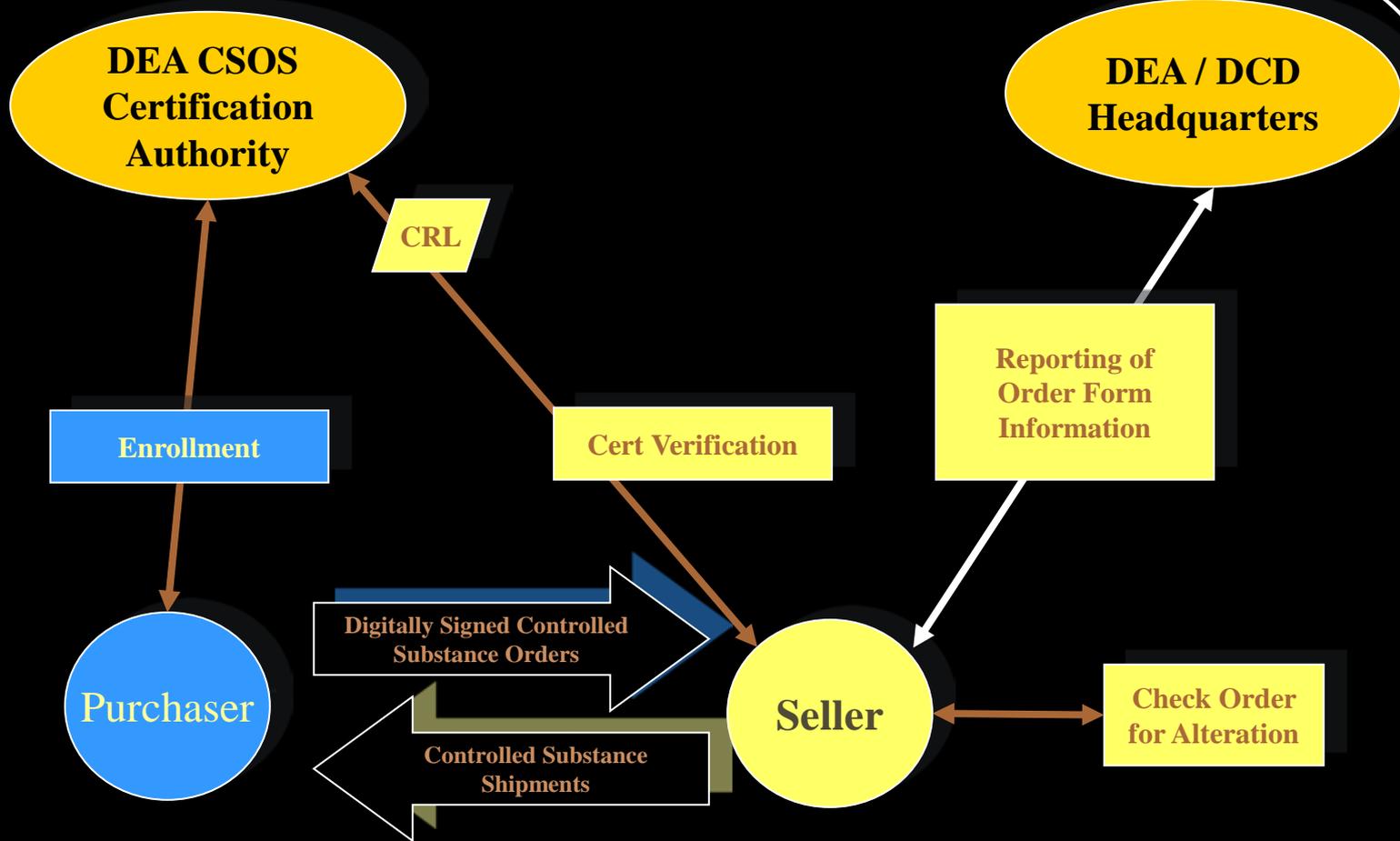
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# SUPPLIER – CSOS REPORTING

- 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



**Controlled Substance Ordering System (CSOS)**

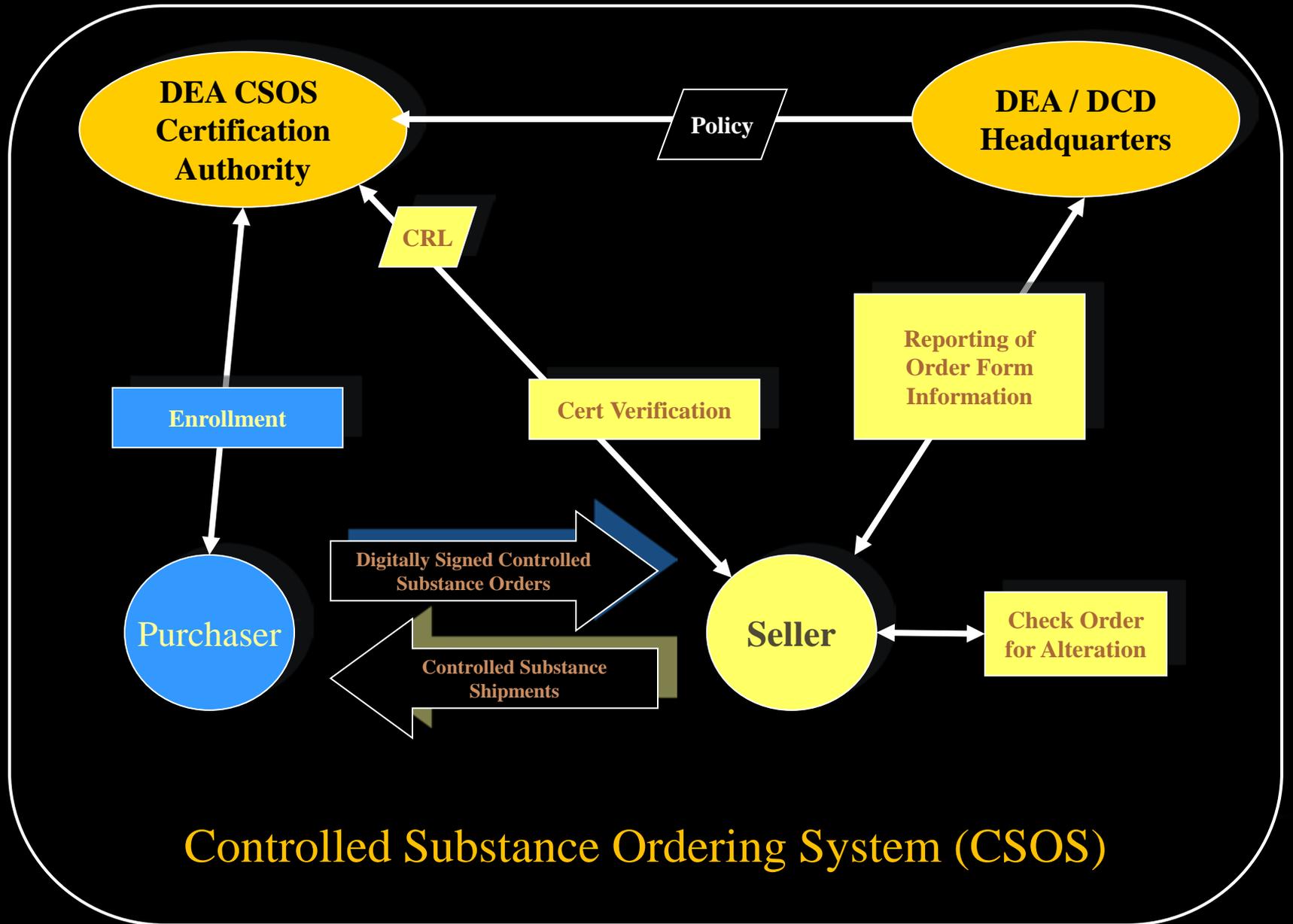


# CSOS CONCEPT OF OPERATIONS (CONOPS)

RECAP

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# CSOS CONCEPT OF OPERATIONS



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**DEA CSOS  
Certification  
Authority**

**Enrollment**

**Purchaser**

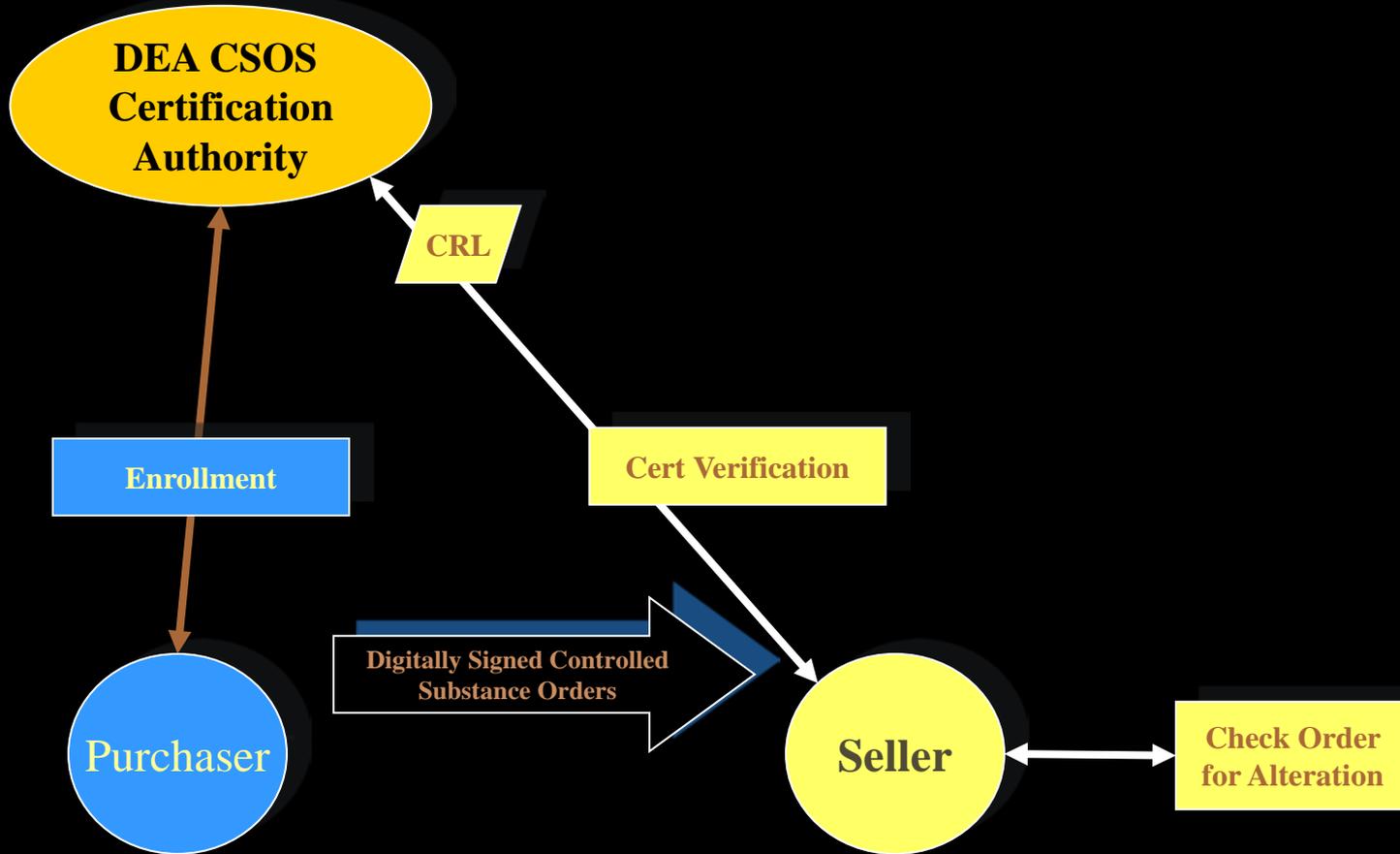
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# CSOS CONCEPT OF OPERATIONS



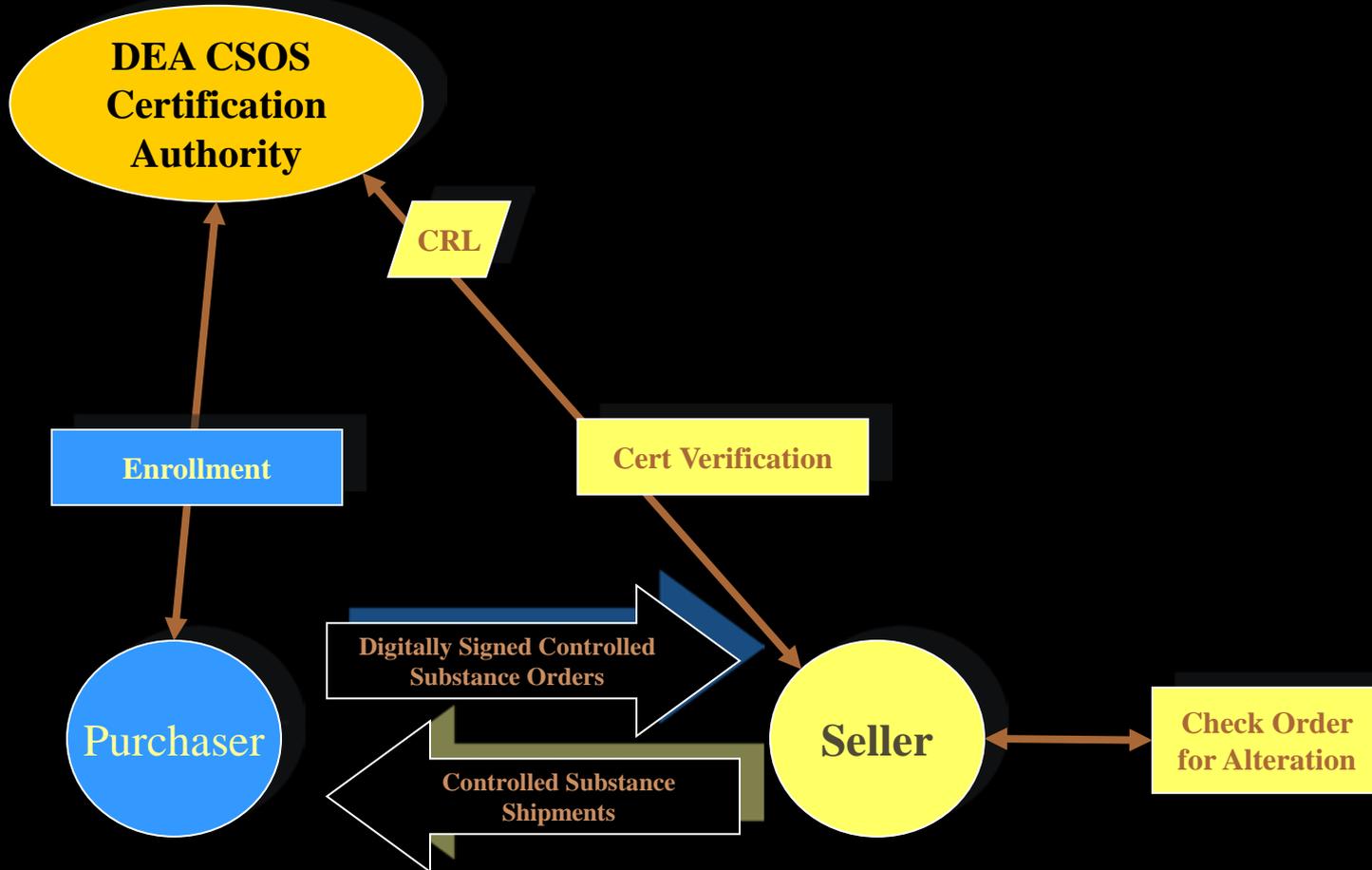
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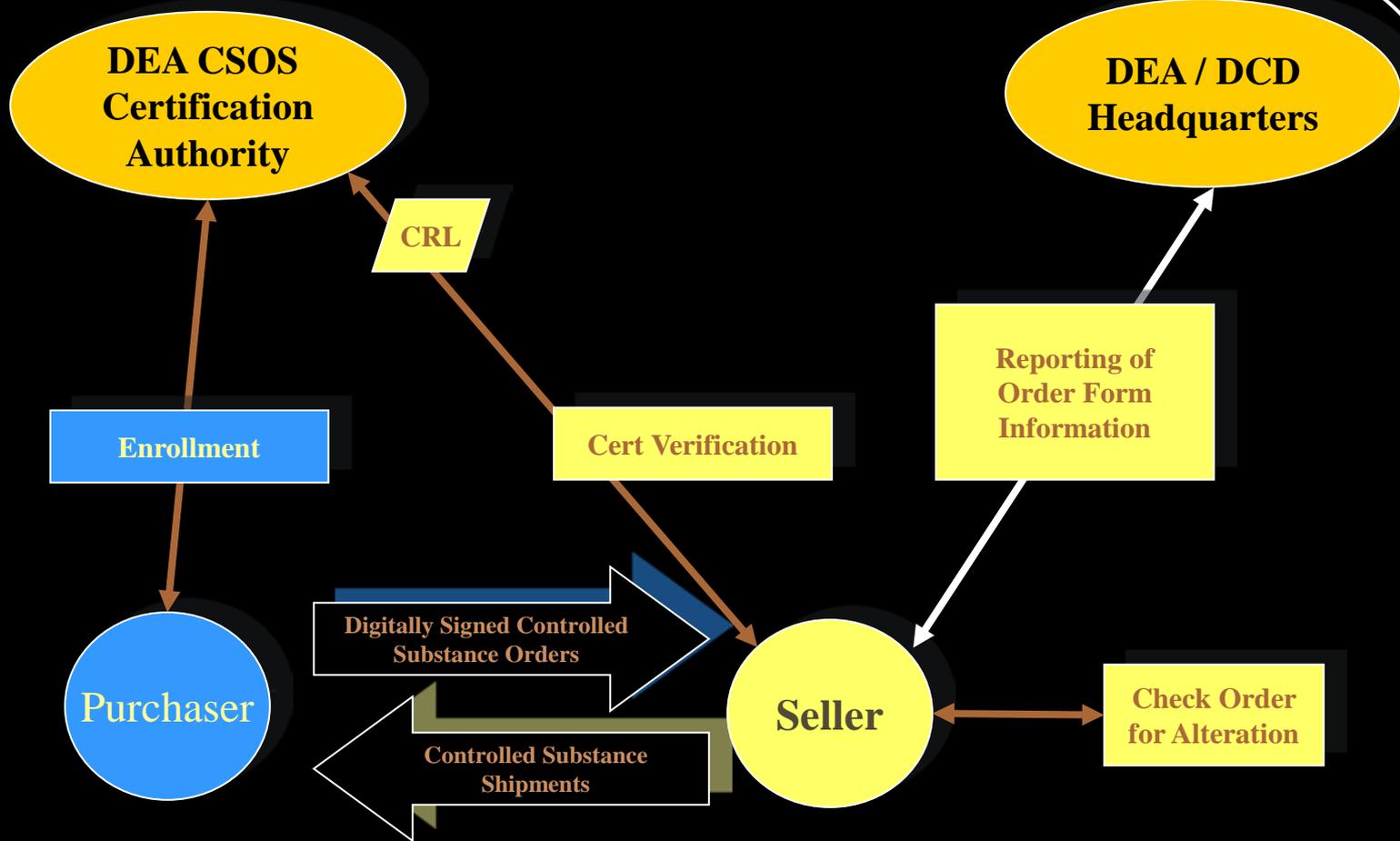
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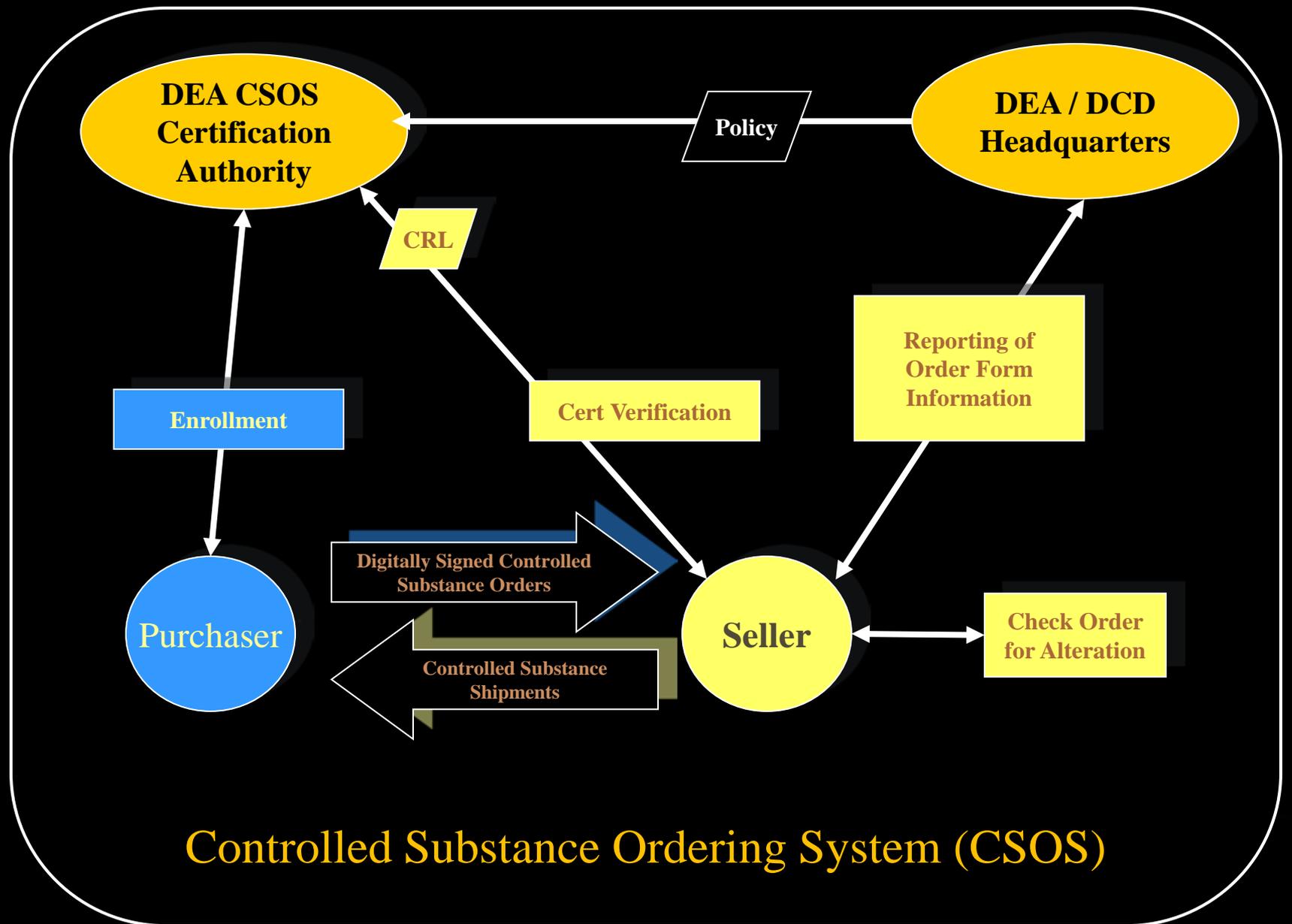
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# CSOS CONCEPT OF OPERATIONS



**Controlled Substance Ordering System (CSOS)**

# CSOS CONCEPT OF OPERATIONS





# ADMINISTRATIVE & REGULATORY FINDINGS

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# COMMON REGISTRATION ENROLLMENT ISSUES

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# 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
-



# REGISTRATION ENROLLMENT ISSUES

## 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

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# CERTIFICATE MANAGEMENT

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# 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

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# 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



# REGULATORY AUDIT FINDINGS RECAP

- 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

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

**[www.deaecom.gov](http://www.deaecom.gov)**

# QUESTIONS

