

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
-



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
- 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 & CURRENT STATS



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

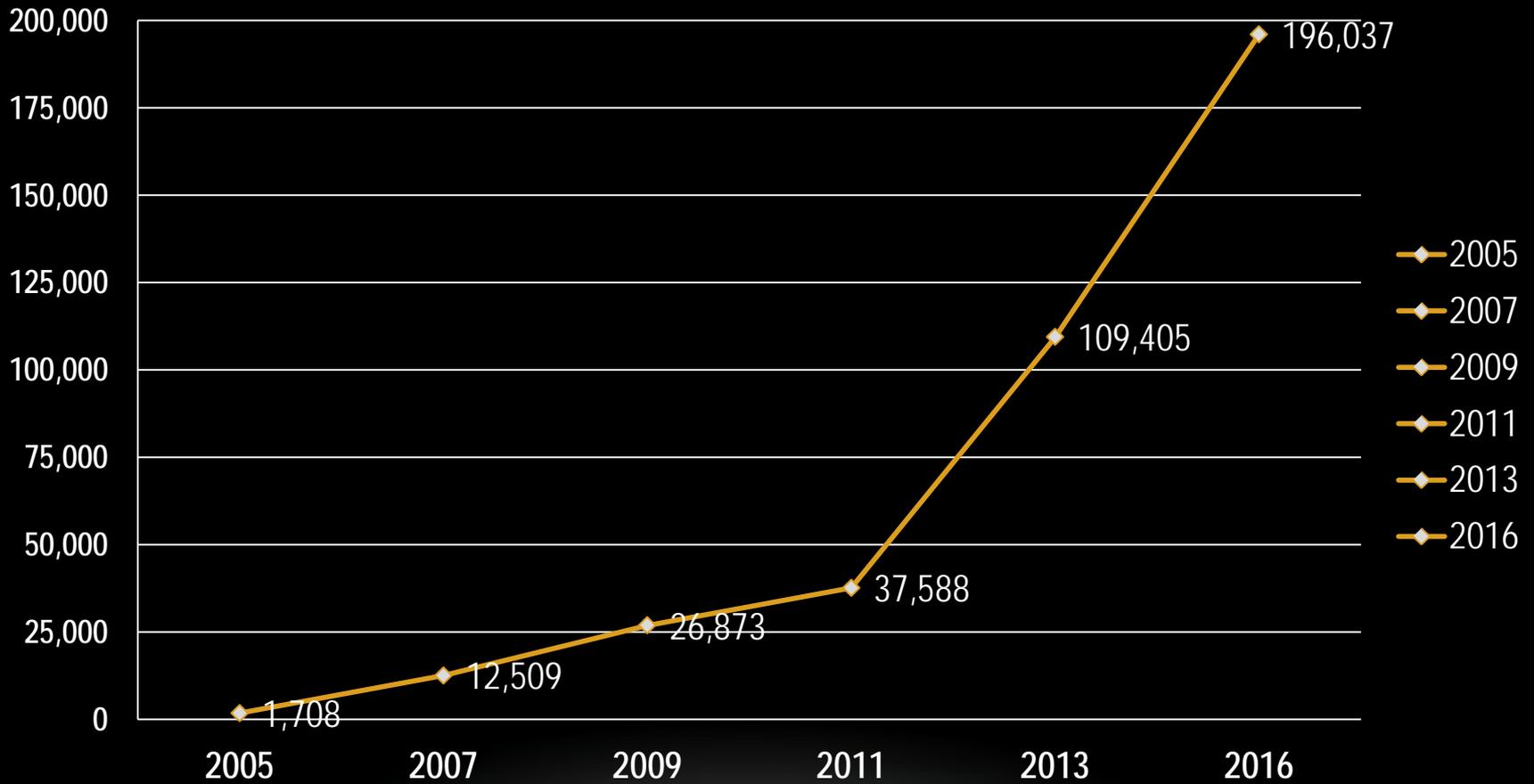


CSOS APPLICANTS BY BUSINESS TYPE

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



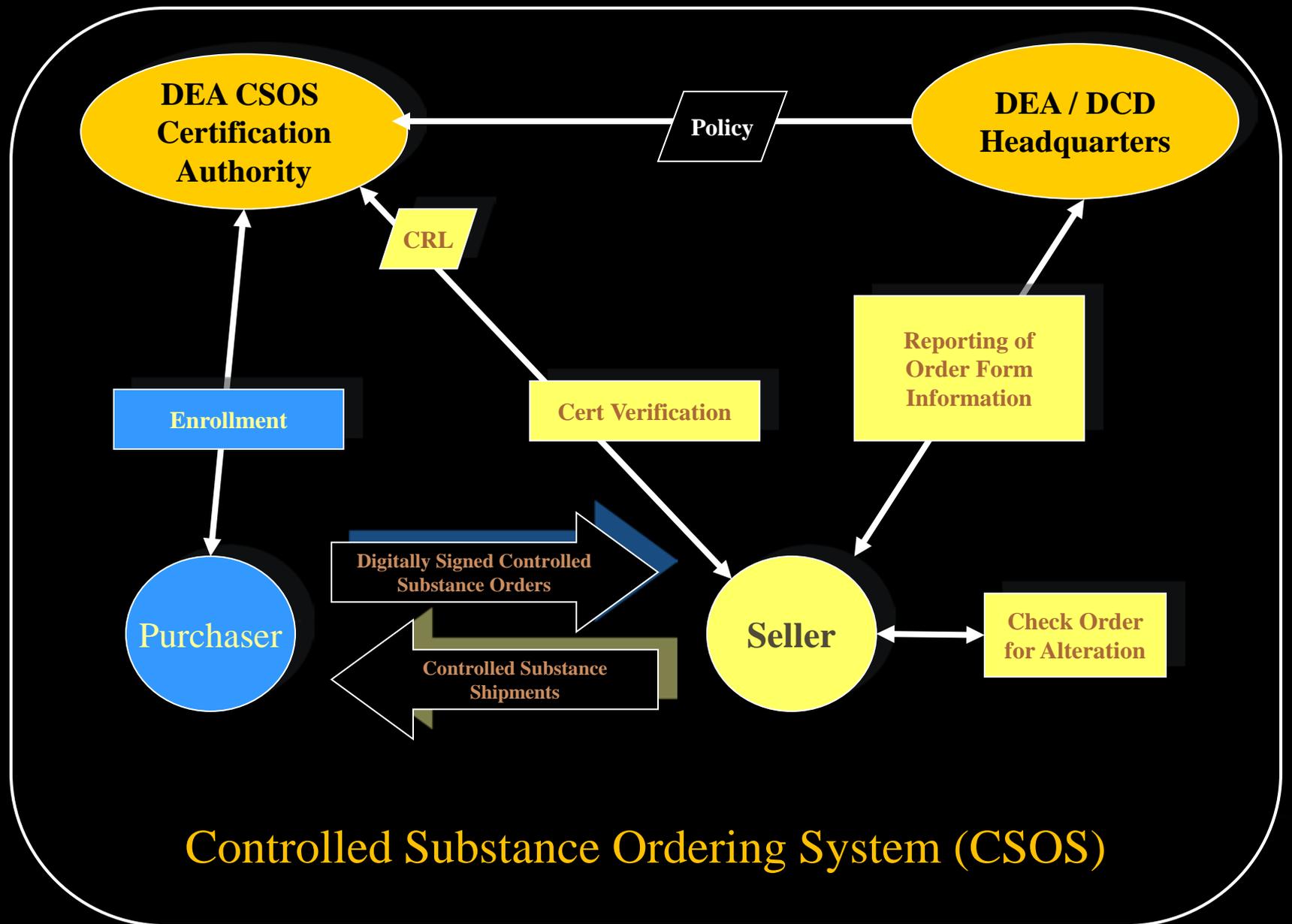
CSOS Active Certificates Trending





CSOS CONCEPT OF OPERATIONS (CONOPS)

CSOS CONCEPT OF OPERATIONS





Enrollment Process

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



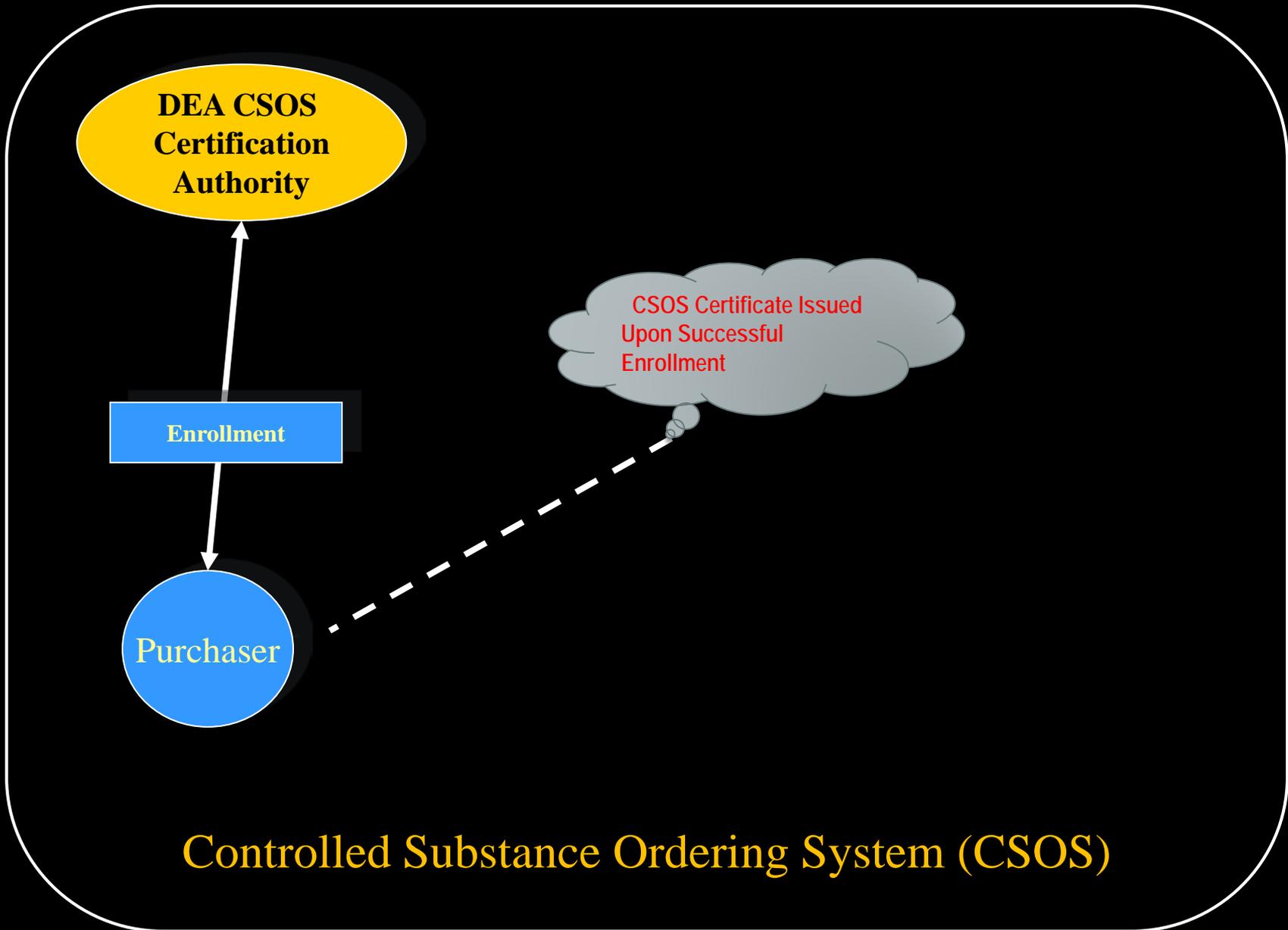
**DEA CSOS
Certification
Authority**

Enrollment

Purchaser

**CSOS Certificate Issued
Upon Successful
Enrollment**

Controlled Substance Ordering System (CSOS)





Ordering Process

CSOS CONCEPT OF OPERATIONS



Controlled Substance Ordering System (CSOS)



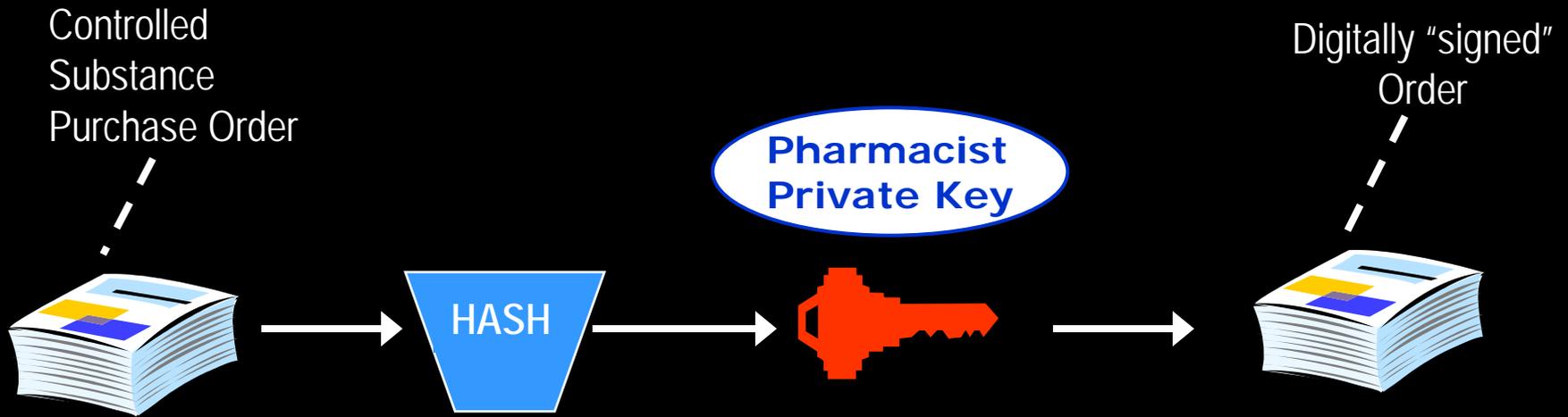
DIGITALLY SIGNING & TRANSMITTING A PURCHASE ORDER



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

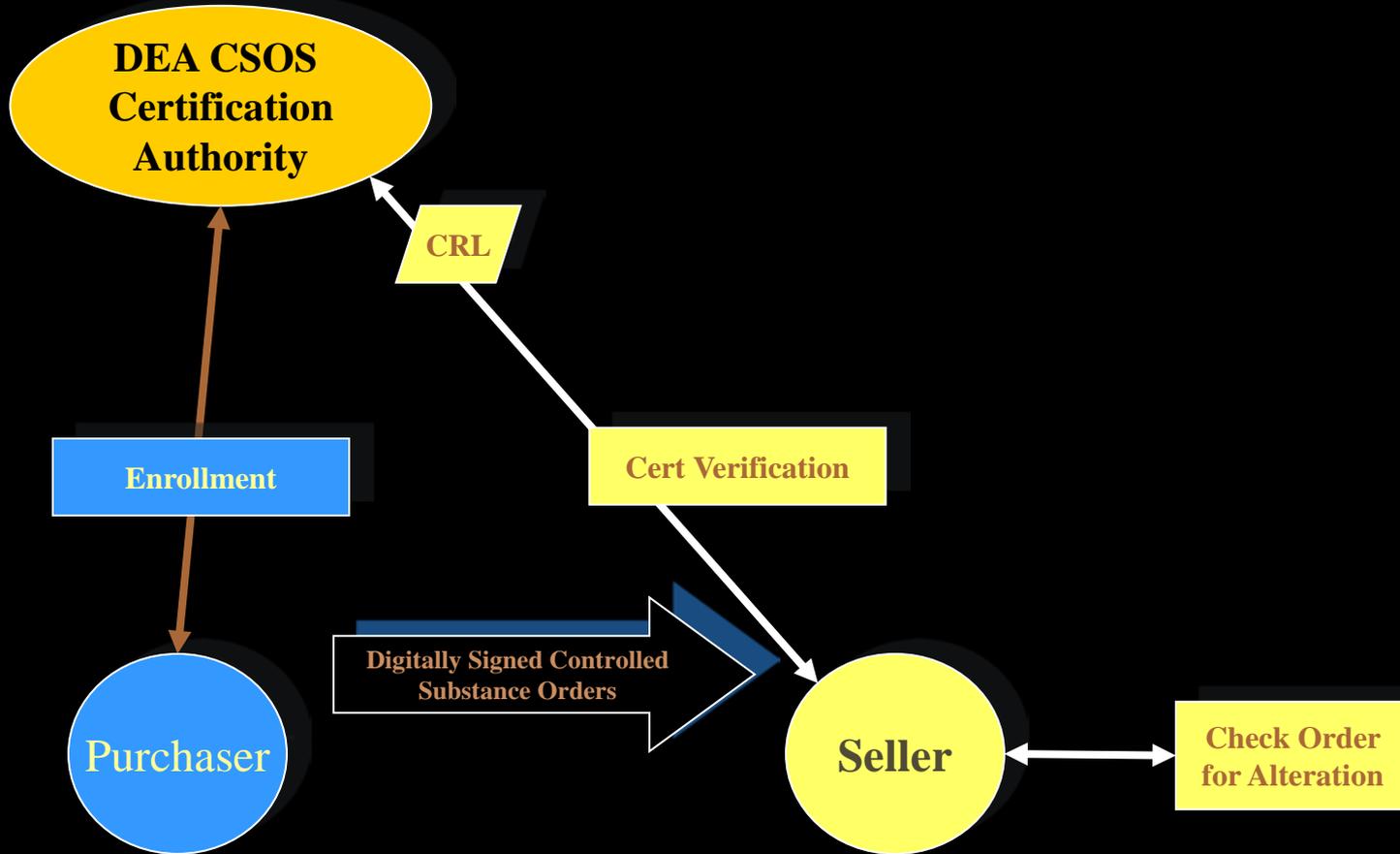


Controlled Substance Ordering System (CSOS)



Certificate & Order Verification Process

CSOS CONCEPT OF OPERATIONS



Controlled Substance Ordering System (CSOS)



Certificate Verification Process

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



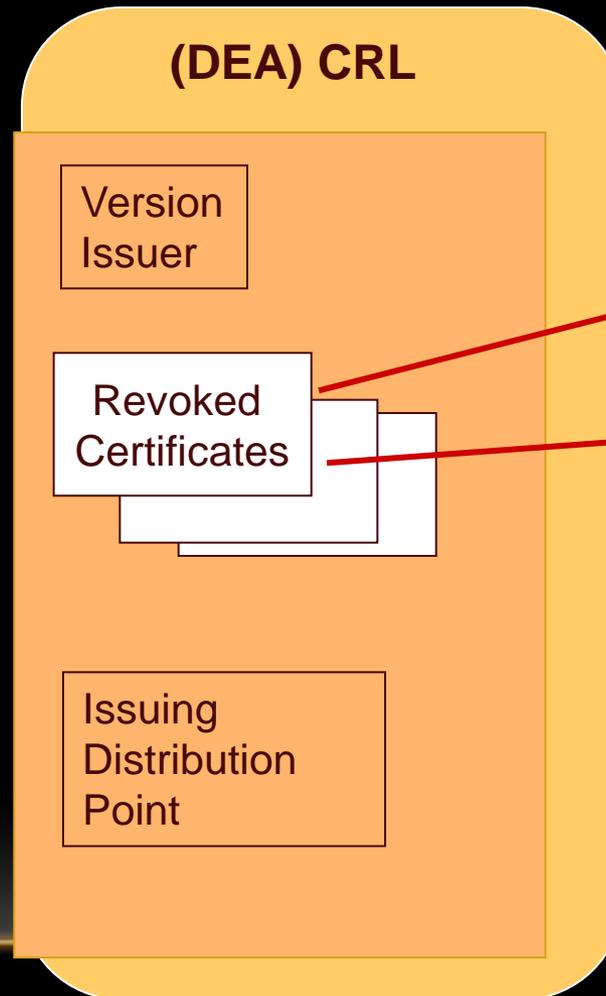
Certificate Revocation List



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



ORDER VERIFICATION

Check Order
for Alteration

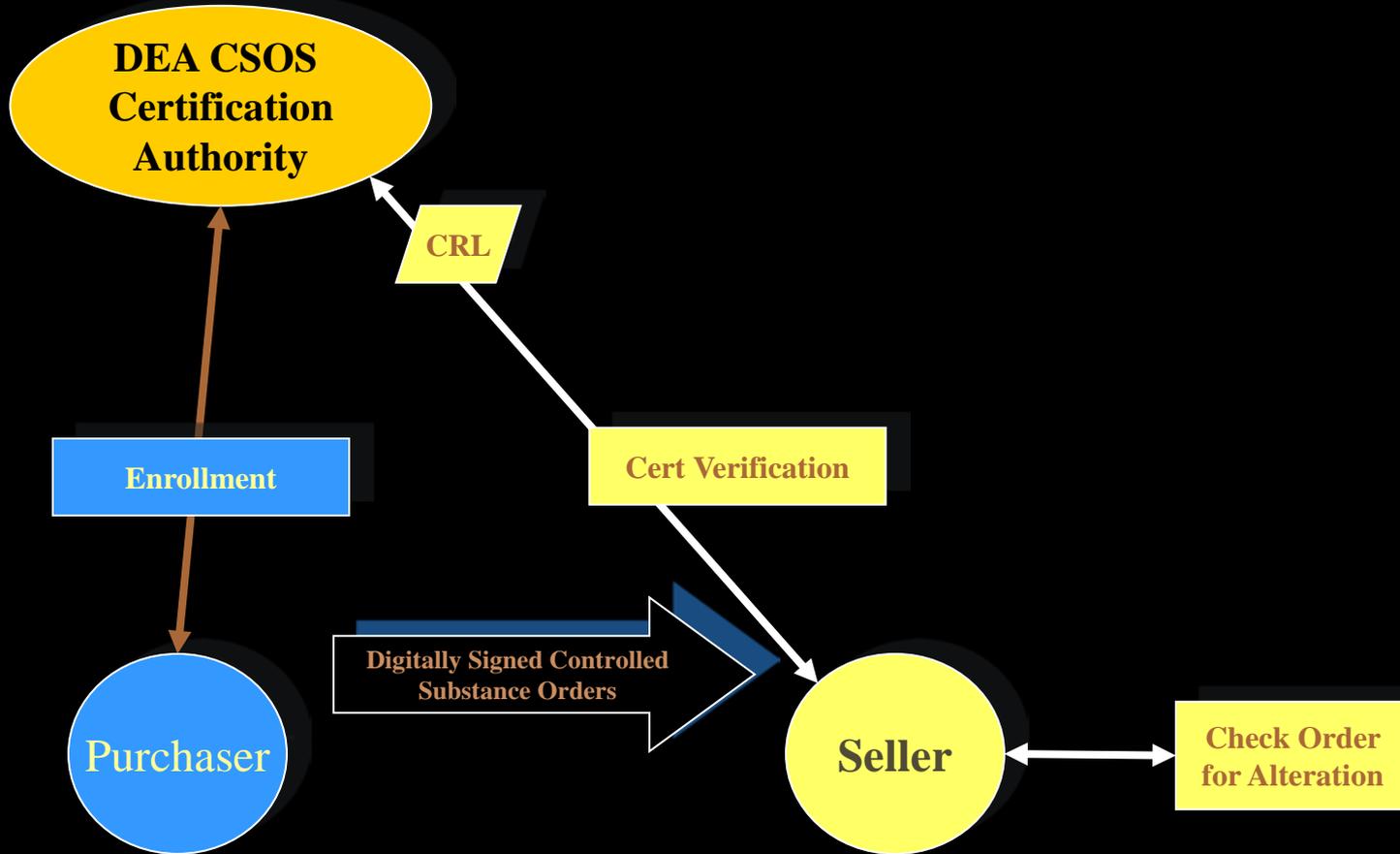
- Sellers system must determine the order has not been altered during transmission
- Seller must invalidate any order that has been altered
- Seller must check the substances ordered against the schedules the registrant is allowed to order
- Seller must invalidate any order that includes substances the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

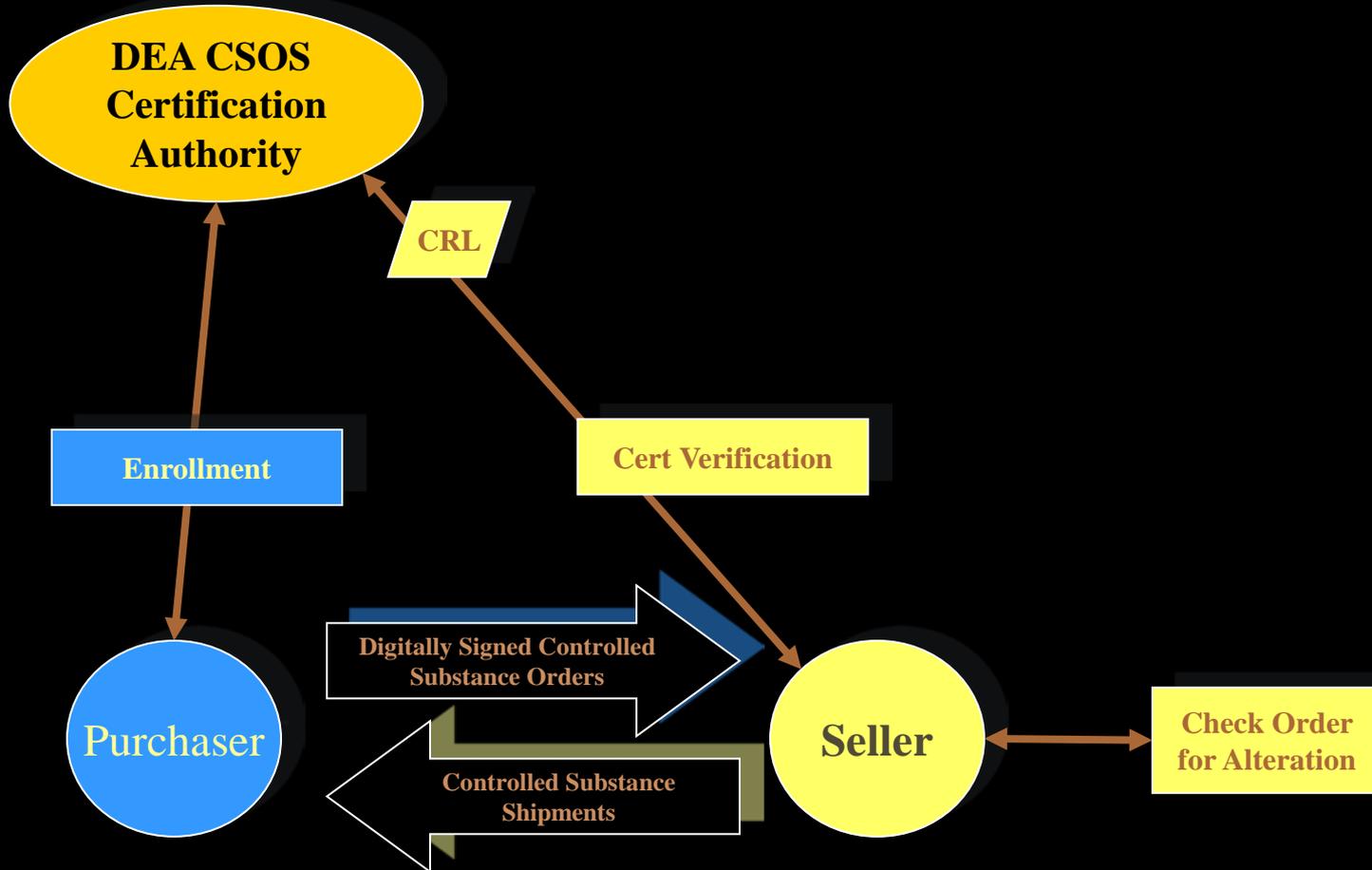


Controlled Substance Ordering System (CSOS)



Order Shipment Process

CSOS CONCEPT OF OPERATIONS



Controlled Substance Ordering System (CSOS)



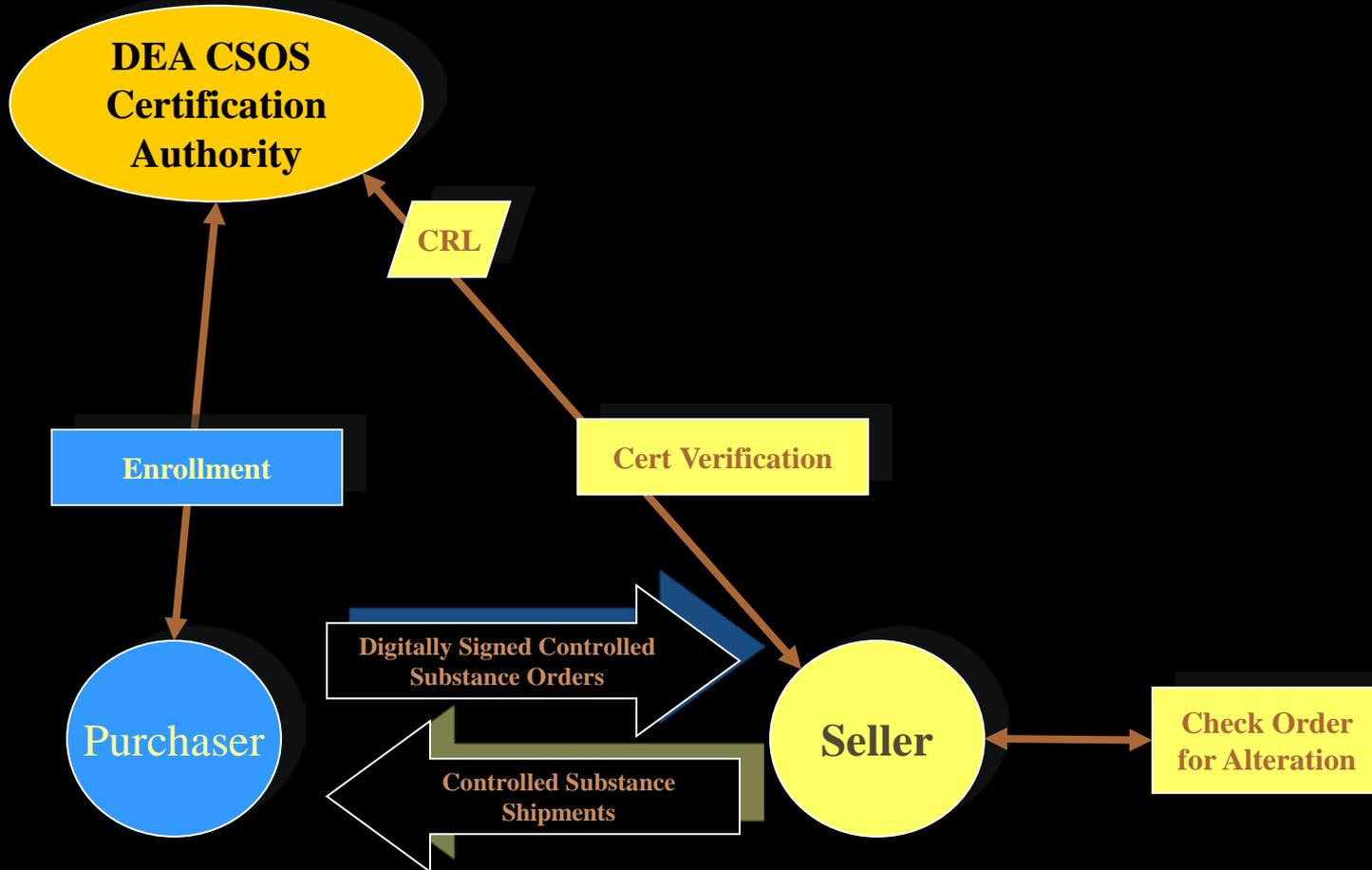
CONTROLLED SUBSTANCE ORDERING SHIPMENTS



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

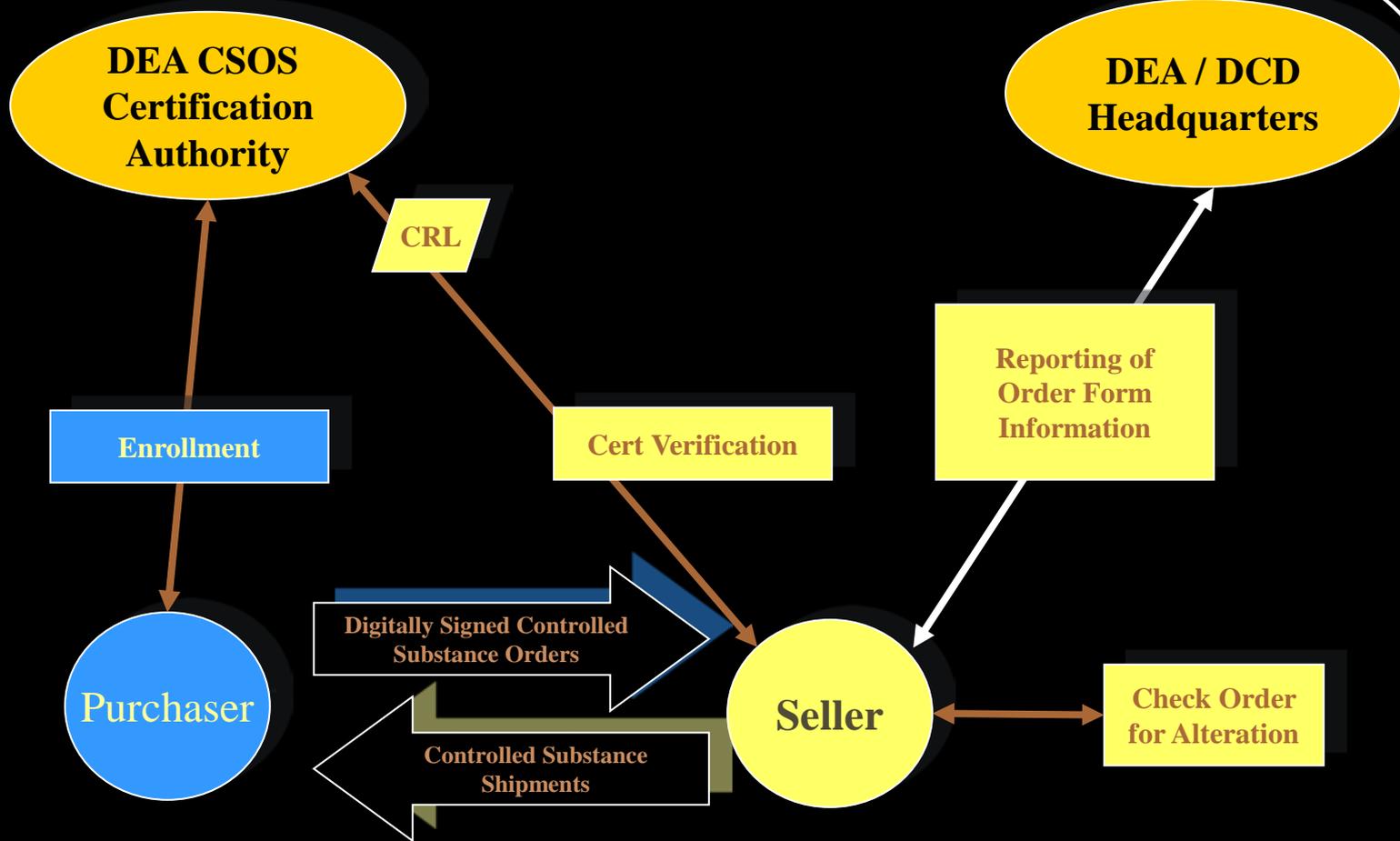


Controlled Substance Ordering System (CSOS)



CSOS TWO-DAY REPORTING (SELLER)

CSOS CONCEPT OF OPERATIONS



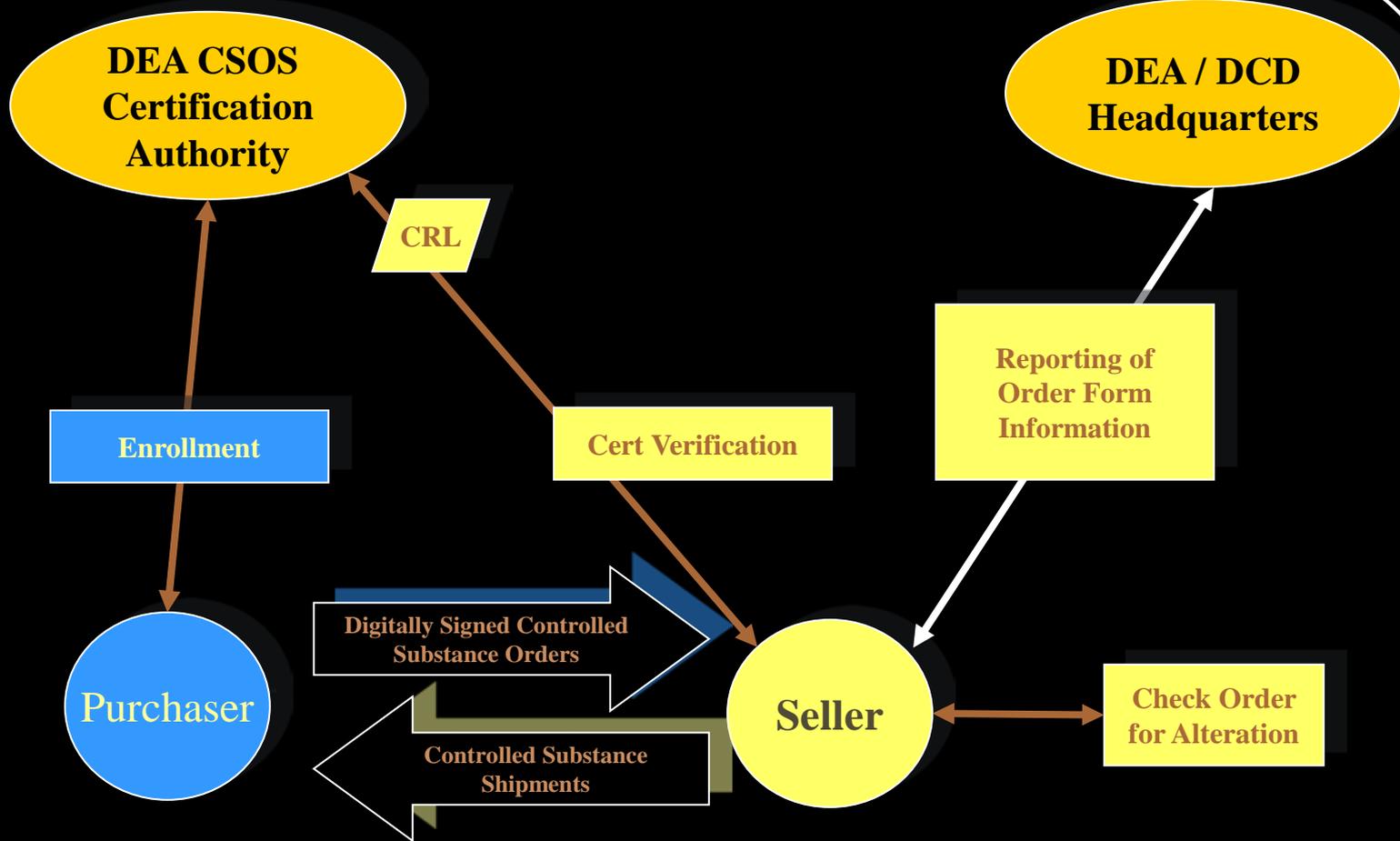
Controlled Substance Ordering System (CSOS)



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



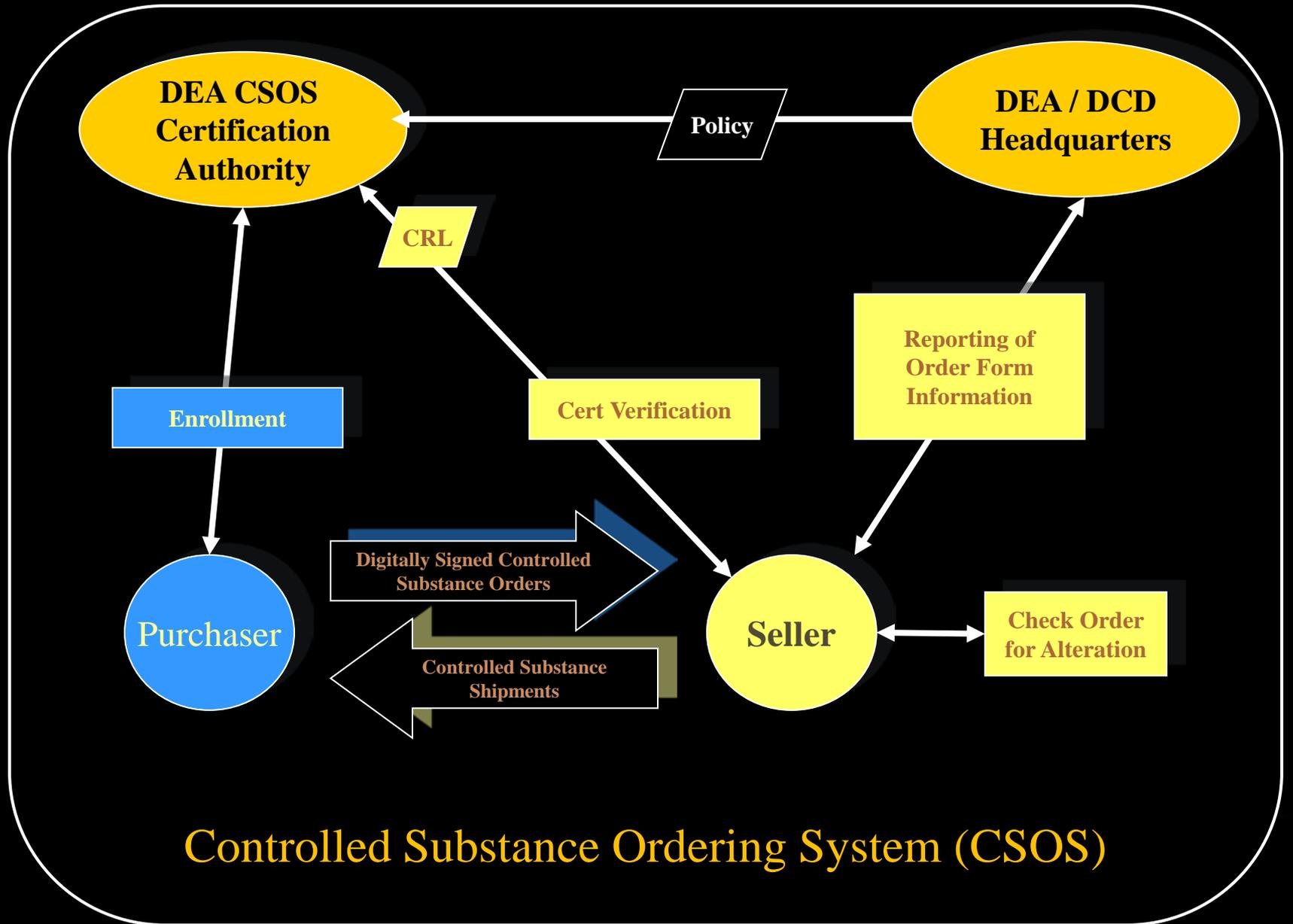
Controlled Substance Ordering System (CSOS)



CSOS CONCEPT OF OPERATIONS (CONOPS)

RECAP

CSOS CONCEPT OF OPERATIONS



CSOS CONCEPT OF OPERATIONS

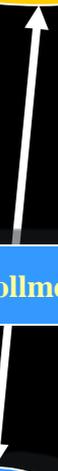


**DEA CSOS
Certification
Authority**

Enrollment

Purchaser

Controlled Substance Ordering System (CSOS)

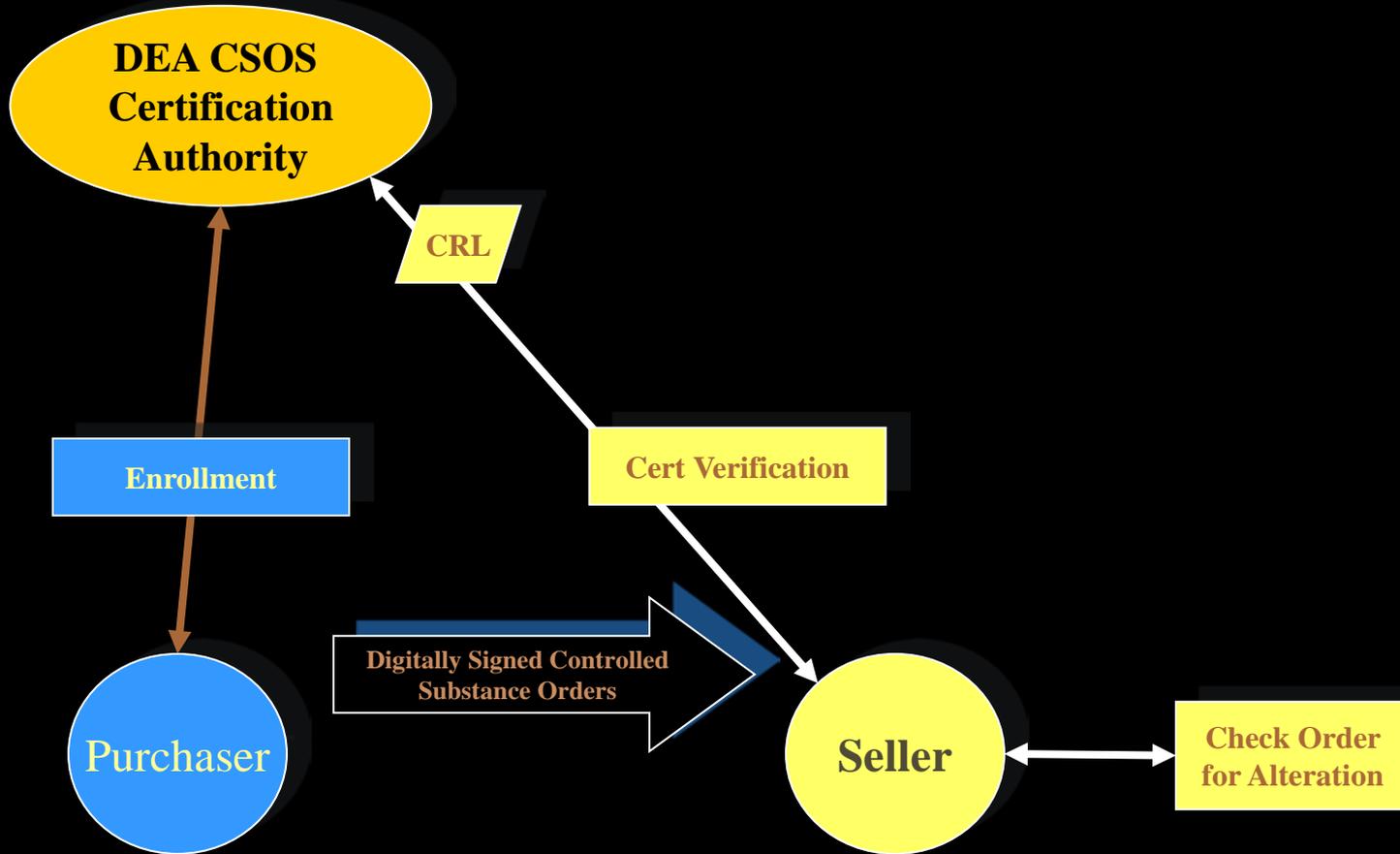


CSOS CONCEPT OF OPERATIONS



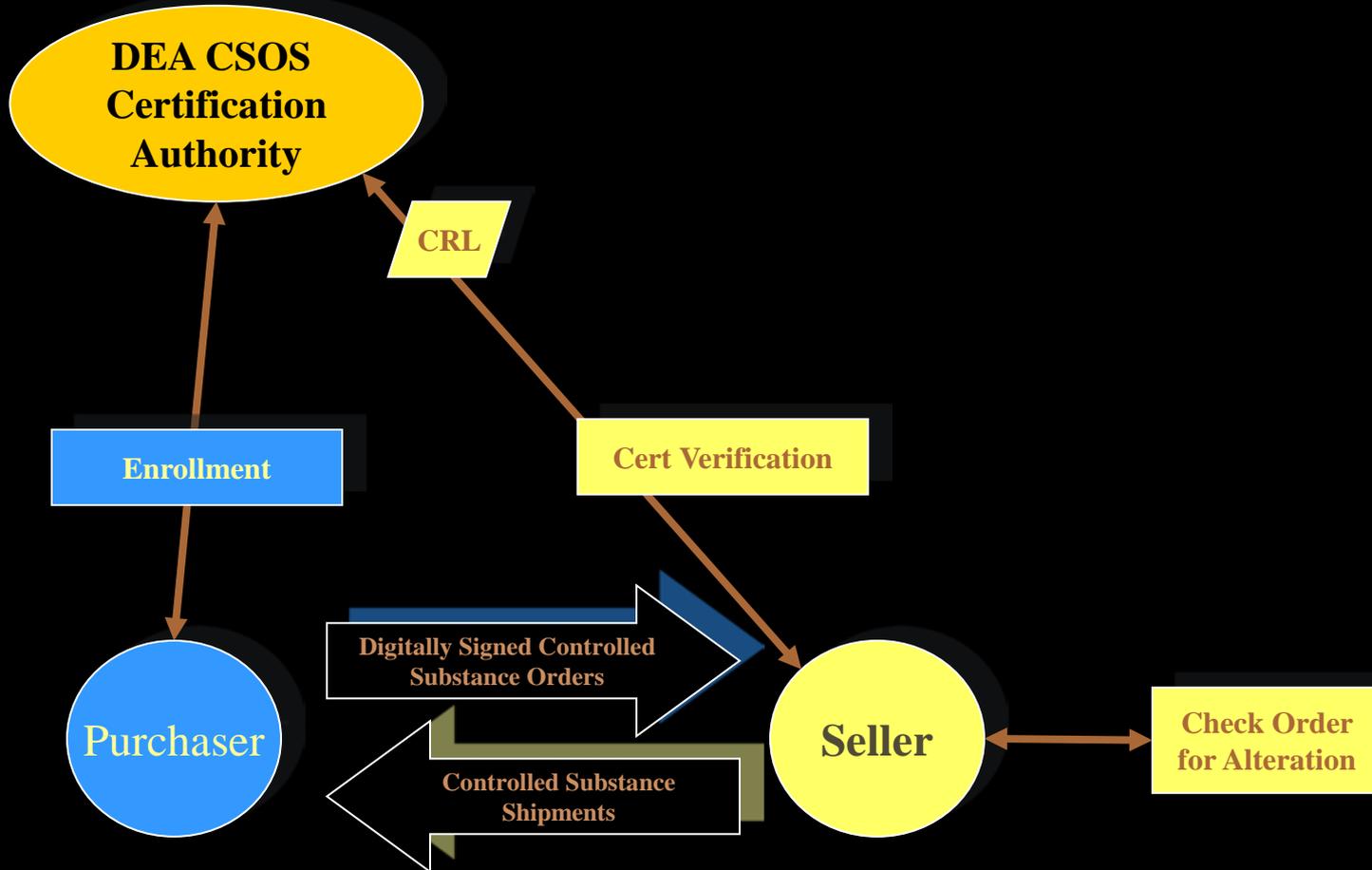
Controlled Substance Ordering System (CSOS)

CSOS CONCEPT OF OPERATIONS



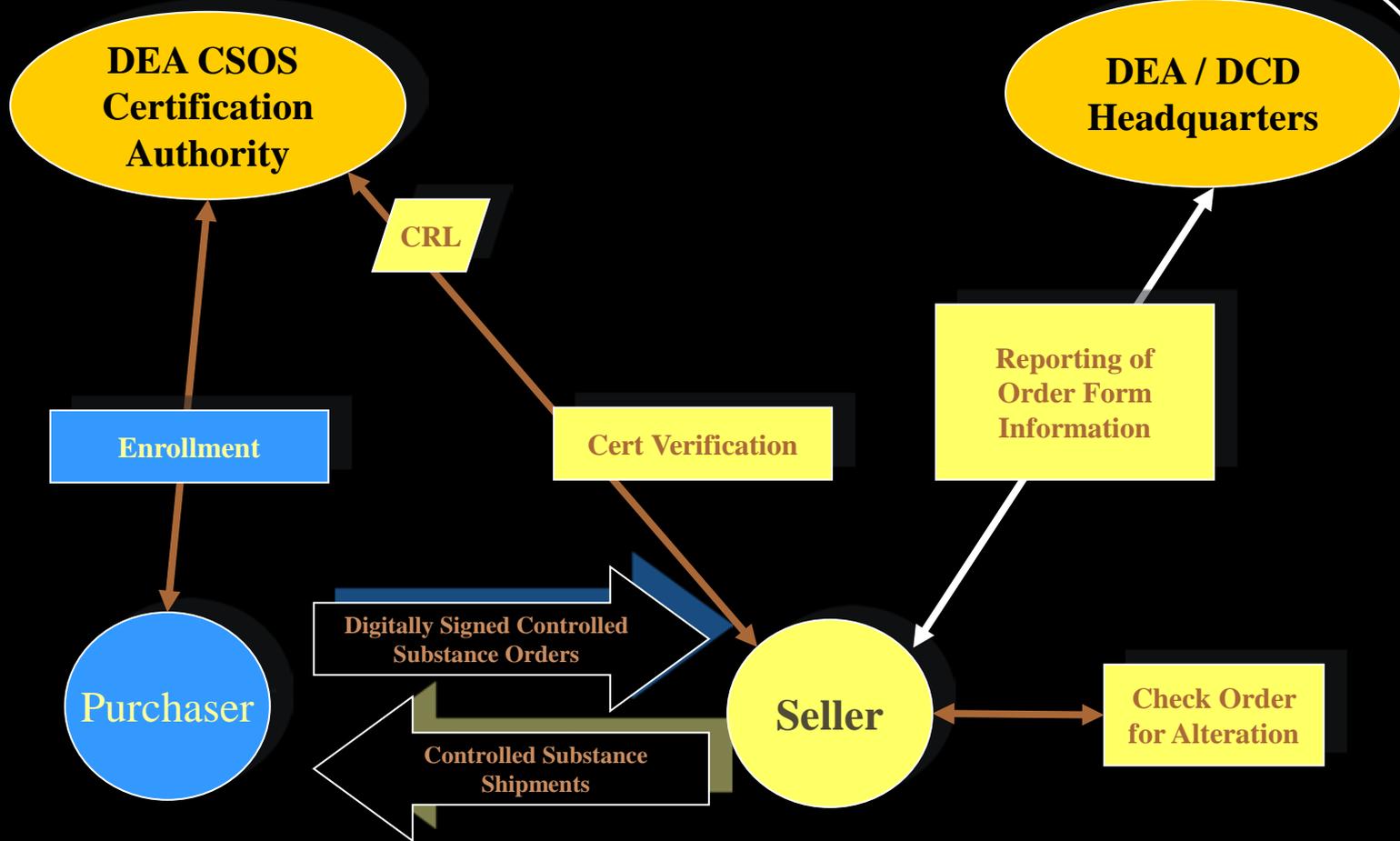
Controlled Substance Ordering System (CSOS)

CSOS CONCEPT OF OPERATIONS



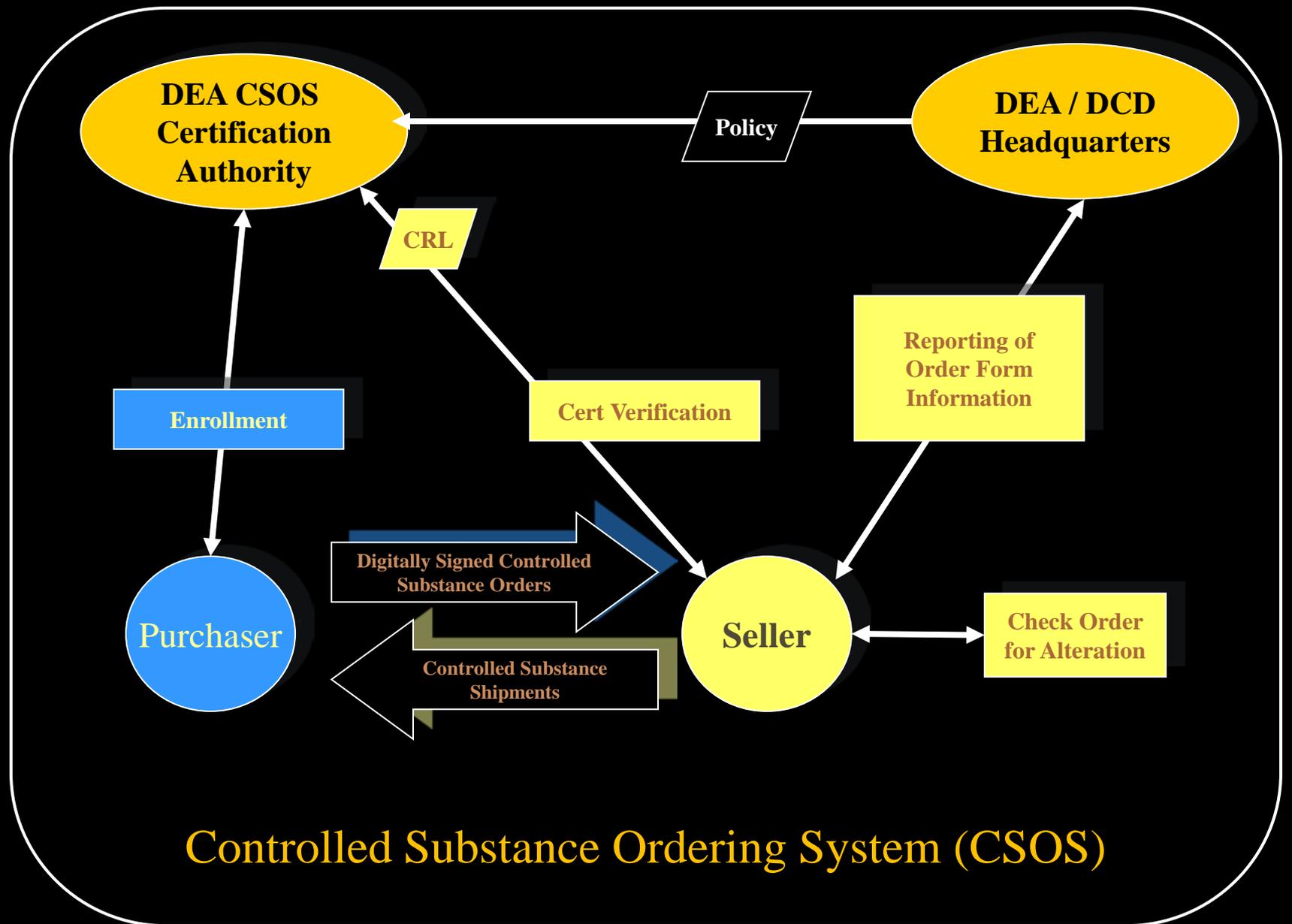
Controlled Substance Ordering System (CSOS)

CSOS CONCEPT OF OPERATIONS



Controlled Substance Ordering System (CSOS)

CSOS CONCEPT OF OPERATIONS



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
-



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



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



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

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

www.deaecom.gov

QUESTIONS

