



# Electronic Reporting

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# Purpose of Presentation

- What is the Diversion Technology Section
- What is electronic reporting
  - What is the Controlled Substance Ordering System (CSOS)
  - What is the Drug Theft and Loss System (DTL)



# What is the Diversion Technology Section?

- The Diversion Technology Section (ODT) is responsible for maintaining all of the Office of Diversion Control's (OD) Information Technology (IT) Systems
- ODT is responsible for modernization of OD's IT systems
- ODT provides enhanced registration and reporting capabilities to the DEA registrant community through a secure Internet connection



# What is Electronic Reporting?

The Drug Enforcement Administration, Office of Diversion Control (OD) implemented a program to modernize all of the paper based registration and reporting systems. In the last seven years OD has deployed the following electronic web interactive forms:

- Applications for DEA registration (CSA)
- Self-certification of retail vendors to comply with the Comprehensive Methamphetamine Epidemic Act (CMEA)
- Submission of controlled substance distribution reports (ARCOS)
- Submission of year end manufacturing reports (YERS)
- Controlled Substance Ordering System (CSOS)
- The Drug Theft and Loss reporting system (DTL)



# How do I Access Electronic Reporting?

Through our website: [www.dea diversion.usdoj.gov](http://www.dea diversion.usdoj.gov)

This screenshot shows the current website layout. A vertical navigation menu on the left is highlighted with two red arrows. The main content area features a 'WELCOME TO THE DIVERSION CONTROL PROGRAM' message, contact information (Registration Number, Toll Free: 1-800-882-9539), and a 'REGISTRATION SUPPORT' section. A 'RENEWAL' button is visible on the right side of the main content area.

Current Home Page

Coming Soon

This screenshot shows the proposed new website design. It features a prominent header with the U.S. Department of Justice Drug Enforcement Administration logo and the text 'Office of Diversion Control'. A central banner reads 'Report Suspicious Internet Pharmacies' with the phone numbers '1-800-RX-ABUSE' and '1-800-792-2873'. A 'REGISTRATION SUPPORT' box highlights the 'Registration Number Toll Free: 1-800-882-9539' and includes a 'SAVE TIME' graphic. A 'Quick Links' sidebar on the right lists various services like 'Renew Applications Online' and 'New Application Online'. A 'What's New' section mentions 'Cerilliant Corporation' from September 25, 2009. The footer includes 'Regulations.gov' and 'Good Medicine. Bad Behavior. Drug Diversion'.

# What is the Controlled Substance Ordering System (CSOS)?

- An electronic substitute for the paper Order Form (DEA-222) and its submission process
- An ordering system that integrates electronic Order Form requirements with a company's electronic ordering system
- An ordering system that allows users to place orders for controlled substances in a secure Public Key Infrastructure (PKI) environment
  - PKI Provides
    - Authentication: Positively identifies the signer
    - Non-repudiation: Strong evidence of signer's identity
    - Message Integrity: Ensures messages were not altered
- A voluntary ordering system
- Paper Order Forms can still be used



# Official Order Forms

- Statutory authority: 21 U.S.C. § 828
  - Requires that no schedule I or II controlled substance can be distributed without executing an Official Order Form (DEA-222)
- Regulatory authority: 21 C.F.R. § 1305 (Order Forms)  
21 C.F.R. § 1311 (Digital Certificates)
  - Establishes the rules for completing paper Order Forms
  - Establishes the rules for completing electronic orders



# A Brief History of CSOS

- Pre-1999 DEA and industry had numerous meetings to develop an electronic alternative to the paper Official Order Form 222
- CSOS project Initiated in 1999
- Industry pilot conducted from 2002 to 2005
- Final rule published in June 2005
- CSOS deployed August 8, 2005
- Obtained the initial WebTrust seal of approval for Certification Authorities on April 14, 2006 (Updated yearly)
- Awarded the initial Federal Bridge Certification Authority cross-certification in July 2006 (Updated yearly)



# General Information

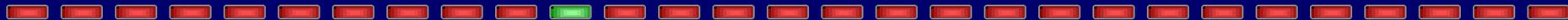
- Over 103,000 certificates issued to almost 25,000 Registered DEA locations
- Over 4.5 million transactions (order line items) ordered electronically
- Several large chain distributors have indicated a readiness to adopt in 2009
- Several commercial CSOS software vendors are now available to industry:
  - DEA is only the digital certificate providing authority – Industry is responsible for identifying and installing compliant CSOS software on their ordering systems





# Contents of Application Package

Application Package Contents	Applicant		
	DEA Registrant	Coordinators	Power of Attorney
Notarized Application	✓	✓	
Coordinator-Signed Application			✓
Registrant List Addendum	✓	✓	✓
Two Forms of Identification	✓	✓	✓
DEA Registration Cert. (223)	✓	✓	
Copy(ies) of Power of Attorney		✓	✓

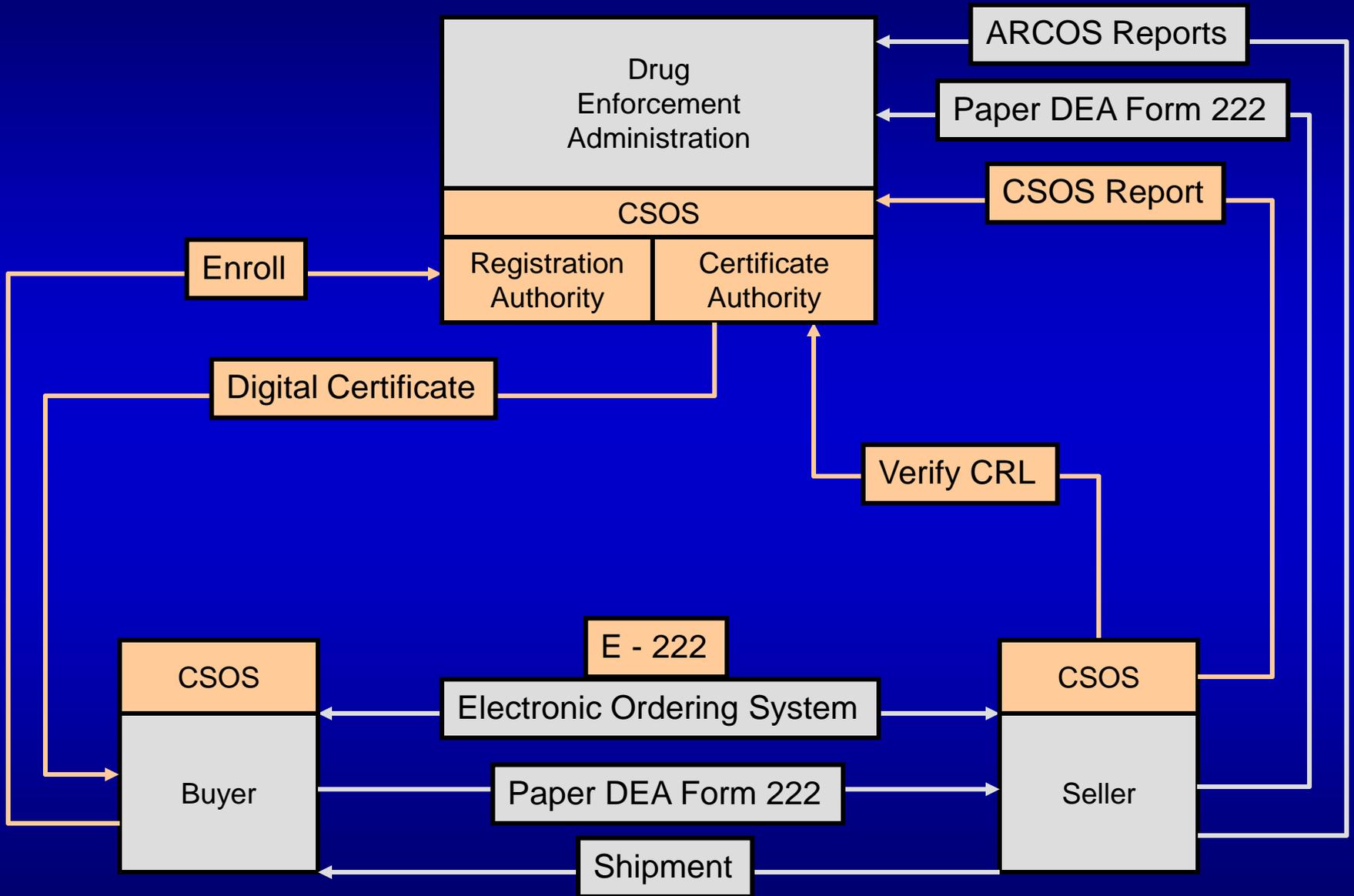


# CSOS Software Audit

- Must be performed by independent third-party auditor
- Must validate that Federal Information Processing Standards (FIPS) have been met
- Must validate that regulatory requirements have been met
- Once an audit is completed it does not have to be renewed unless modifications have been made to the CSOS application that would require a new audit

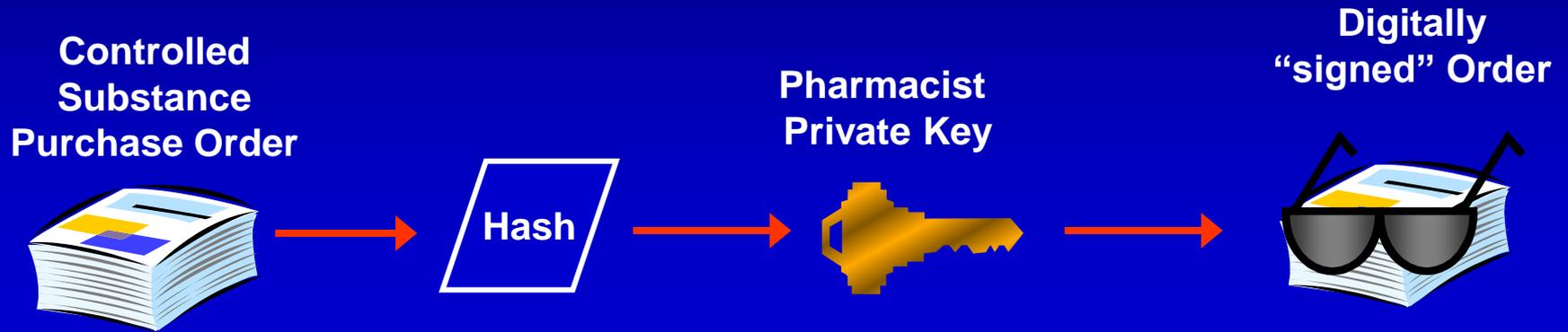


# Order Form Process

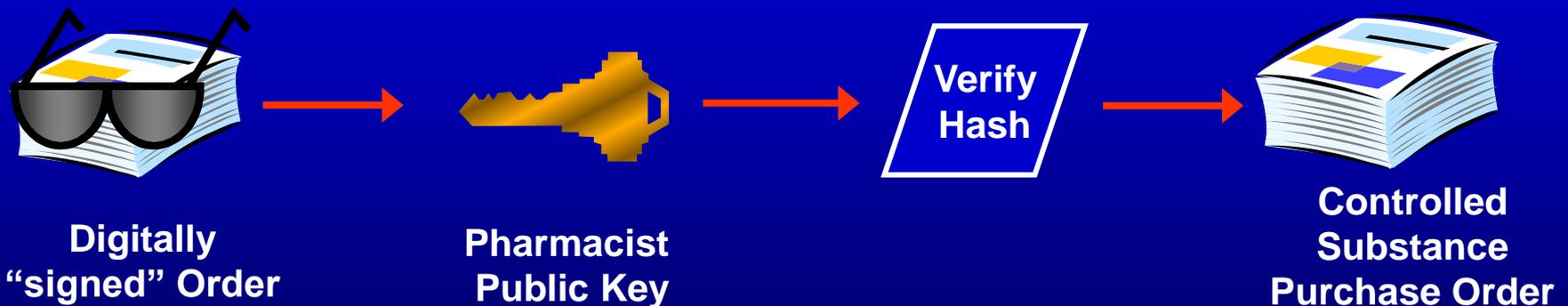


# Placing and Verifying a Signed Order

## Step 1 - Signing Process (Pharmacist)

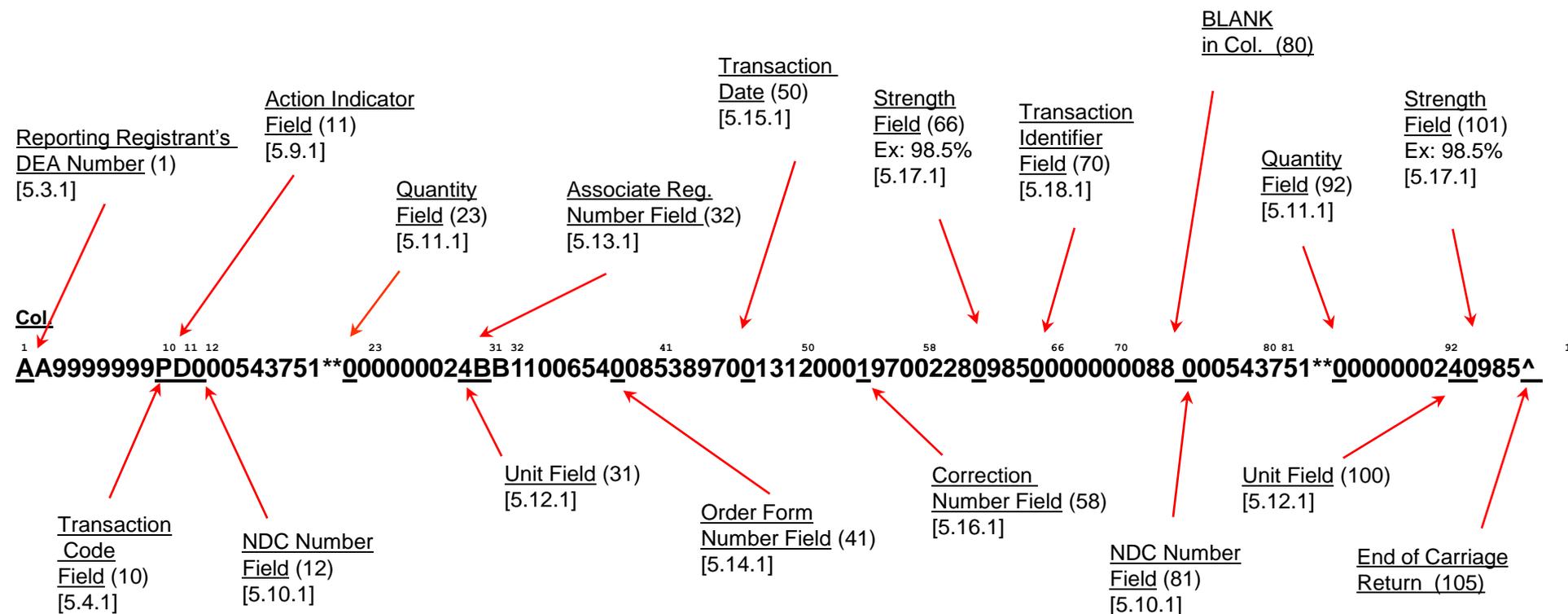


## Step 2 - Verification Process (Supplier)





# Transaction Record Format

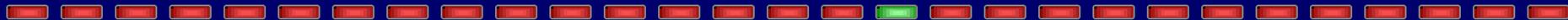


Note: numbers in brackets [ ] reference the appropriate section in the ARCOS Registrant Handbook found on the DEA DIVERSION web site at 'www.deadiversion.usdoj.gov'.



# Certificate Revocation List (CRL) Flags

Revocation Flag	CSOS Use Case
Key Compromise (1)	<b>Lose or compromise of key</b> Damaged Token Subscriber Agreement violation Access to the private key has been shared
Affiliation Change (2)	<b>Change of subscriber/POA Name</b> Termination of employment or POA <b>Change of Registrant Name</b> Due to marriage or other legal name change <b>Non-prejudicial change of DEA extensions</b> Address change, Schedule change <b>Self-revocation or termination</b> No longer performing Electronic transactions
Certificate Hold (3)	<b>Unauthenticated Revocation Request</b>



# CRL Flags (Continued)

Revocation Flag	CSOS Use Case
<b>Superseded (4)</b>	<b>DEA admin action</b> Restricted for Cause
<b>Cessation Of Operation (5)</b>	<b>Used to indicate if a revocation is a result of loss of the registrant's DEA number.</b> Surrendered for Cause Revoked Out of Business Suspended



# Stake Holders

## Subscribers

### Registrant

Individual who signed or is authorized to sign the DEA Registration Application

### Coordinator

Individual designated as primary correspondent to the CSOS program. Serves as Local Registration Authority for POA applicants.

### Powers of Attorney (POA)

Applicants who hold a valid POA to obtain and sign Schedule I & II controlled substances orders.

## Pharmacies

### Industry

DEA Registered pharmacy locations that obtain CSOS certificates to electronically order controlled substances from distributors.

### Distributors

DEA registered distributors that obtain a CSOS certificate to electronically order controlled substances from manufacturers. Distributors also act as a relying party when validating electronic orders from pharmacies.

### Manufacturers

DEA Registered manufacturers act as a relying party when validating electronic orders from distributors.

### Application Developers

Provide software applications to pharmacies, distributors and manufacturers that facilitates the electronic ordering of controlled substances.

## Government

### Office of Management and Budget (OMB)

OMB 300, A-130, FISMA

### Department of Justice

### Drug Enforcement Administration (DEA)

### Policy Management Authority (PMA)

Establish, interpret, and enforce policy for the CSOS and PKI initiatives in accordance with all applicable U.S. laws and regulations.

### National Institute of Standards and Tech. (NIST)

Establishes Information Security and Assurance Guidelines & Requirements.

## Third Party Accreditation

### WebTrust

American Institute of Certified Public Accountants (AICPA) WebTrust for Certificate Authorities, Investigate all aspects of the CA operations to ensure compliance with this CPS, the CP and other CA security policies and procedures.

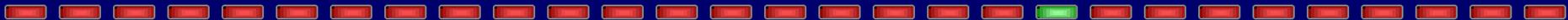
### Federal Bridge Certification Authority (FBCA)

Federal Government PKI facilitating trust across domains. DEA E-Commerce is Cross-Certified with the FBCA



# CSOS Recap

- CSOS is an ordering system that integrates electronic Order Forms with a vendor's electronic ordering system
- How do I become a CSOS participant?
  - Identify your specific requirements
  - Review your legal responsibilities in 21 C.F.R. §§ 1305 and 1311
  - Identify a certified CSOS software vendor (if applicable)
  - Go to the [www.deaecom.gov](http://www.deaecom.gov) website and apply
  - Install authorized software
  - Obtain and install your digital certificate from DEA
  - Begin electronic orders



# How do I find out more about CSOS?

Through our website: [www.deaecom.gov](http://www.deaecom.gov)

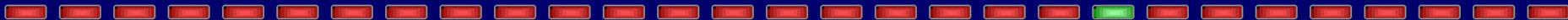
The screenshot displays the DEA E-Commerce Program website. At the top, it identifies the site as the Drug Enforcement Administration's Office of Diversion Control. The main heading is "E-Commerce Program". Navigation options include "Q & A's", "Site Map", "Privacy", and "About this Site".

The central content area is titled "Controlled Substance Ordering System" and includes tabs for "For Purchasers", "For Suppliers", and "For Developers". A descriptive paragraph states: "DEA's Controlled Substance Ordering System (CSOS) allows for secure electronic transmission of Schedule I-V controlled substance orders without the supporting paper Form 222." Below this, a list of links includes: "Enroll in CSOS", "Learn about CSOS", "Request your enrollment status", "Activate/Retrieve your certificate(s)", and "Transfer certificate(s) to another computer".

A callout box titled "Just getting started?" contains the text: "Schedule II controlled substances can now be ordered electronically without a paper form DEA-222. To be eligible, individuals must enroll in DEA's CSOS Program. Click here to enroll today." At the bottom of the main content area, there are links for "Back to Top", "DEA E-Com Home", "Privacy Statement", and "Contact Support".

On the left side, there is a "Site Navigation" menu with links to Home, About CSOS, Policies, Enroll in CSOS, Certificate Management, CSOS Reporting, Developer Resources, and Contact Support. Below this is a "Quick Links" section with a dropdown menu and an "External Links" section featuring logos for the Department of Justice, the Office of Diversion Control, and the FirstGov.gov portal.

On the right side, there is a "Latest News" section and a "CERTIFICATION AUTHORITIES" section featuring logos for WebTrust and KPMG.



# What is Drug Theft and Loss Reporting (DTL)?

- Regulatory authority: 21 C.F.R. § 1301.74(c)
  - Requires that the registrant notify the local Field Division Office, in writing, of any theft or significant loss of any controlled substance within one business day of discovery of the theft or loss.
  - Also requires that the registrant complete and submit a DEA Form 106 to the local Field Division Office.



# Brief History

- Prior to July 2005 only paper DEA Form 106s were available for reporting thefts and losses. These forms were sent to the local DEA Field Office and then forwarded to DEA Headquarters for data entry into the DTL database.

- On July 28, 2005 DEA launched version 1 of the Electronic DEA 106 on its website. This version was basically an electronic version of the paper form.



- On November 1, 2008, DEA deployed version 2 of the electronic DEA 106 on its website. The major enhancement was the addition of the National Drug Code (NDC) number field. This allows registrants to report a stolen or lost product by NDC number.

- Positive: Improved accuracy in reporting
- Negative: DEA must have a record of the NDC





### REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration.

Complete the front and back of this form in triplicate. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.

OMB APPROVAL  
No. 1117-0001

1. Name and Address of Registrant (include ZIP Code) 2. Phone No. (include Area Code)

ZIP CODE

3. DEA Registration Number 4. Date of Theft or Loss 5. Principal Business of Registrant (Check one)

6. County in which Registrant is Located 7. Was theft reported to Police? 8. Name and Telephone Number of Police Department (include Area Code)

9. Number of Thefts or Losses Registrant has Experienced in the Past 24 Months 10. Type of Theft or Loss (Check one and complete items below)

11. If Armed Robbery, was Anyone: Killed? Injured? 12. Purchase value to Registrant of controlled substances taken?

14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING: A. Names of Common Carrier B. Name of Consignee

D. Was the carton received by the customer? E. If received, did it appear to be tampered with?

15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identification?

16. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers.

17. What security measures have been taken to prevent future thefts or losses?

PRIVACY ACT INFORMATION  
AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513)  
PURPOSE: Report theft or loss of Controlled Substances.  
ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosure of information from this system are made to the following categories of users for the purposes stated:  
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.  
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.  
EFFECT: Failure to report theft or loss of controlled substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

FORM DEA-106 (October 28, 2006) Previous edition is obsolete.

FORM DEA-106 (October 28, 2006) Pg. 2

### LIST OF CONTROLLED SUBSTANCES LOST

Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
Examples Desoxyn	00074-3377-01	Methamphetamine Hydrochloride	5 mg	Tablets	300
Demerol	00409-1181-30	Meperidine Hydrochloride	50 mg/ml	Vial	150 ml
Robbussin A-C	00031-8874-25	Codeine Phosphate	2 mg/cc	Liquid	6476 ml
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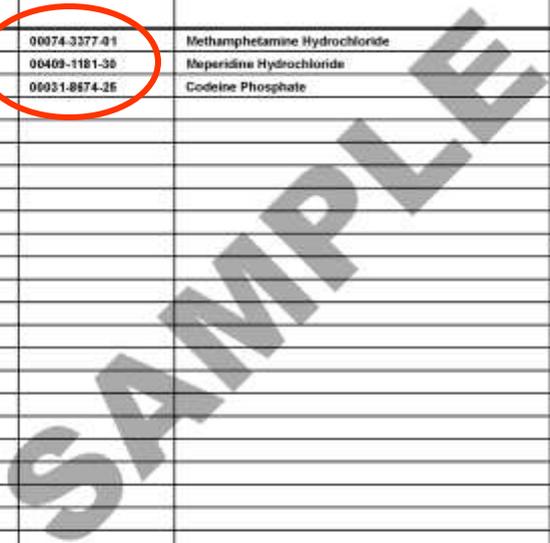
I certify that the foregoing information is correct to the best of my knowledge and belief.

Sign and Print Name Title Date

# Paper Form

← Same Front as old form

New Back with NDC added



# Electronic DEA-106

## Advantages:

- Immediate submission
- No data entry errors from using paper forms
- Online validation
- Auto-fills registrant information
- Print a receipt as proof of submission
- Allows amendments

U.S. Department of Justice  
Drug Enforcement Administration  
**DIVERSION CONTROL PROGRAM**  
**DEA FORM 106**

**HELP**

Click inside the individual data fields to get Help for that field.

[General Instructions.](#)

**Theft / Loss Details**

\* Date of Theft / Loss    -Month-    -Day-    -Year-

\* Police Report Filed     Yes     No

\* Type of Theft / Loss

\* Number of prior incidents in the past two years

\* Total Purchase Value of Controlled Substances (reported on this form)

Armed Robbery  
Customer Theft  
Employee Pilferage  
Lost In Transit  
Night Break-In  
Other

Items lost other than controlled substances     Yes     No

Identifying Marks, Symbols, Price Codes (Controlled Substances only)

DEA Form 222 Numbers (If Stolen)

New Security Measures

*Fields prefixed with \* are required.*

Please do not use your browser's BACK and FORWARD buttons while navigating this form.

<-Previous    -Cancel-    Next->



U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION  
**OFFICE OF DIVERSION CONTROL**

DEA Form 106 - Lost/Stolen Product Entry Page

NEW: [ [Single NDC Entry](#) ] [ [Multiple NDC Entry](#) ]

Single NDC Entry

NDC Number:  -  -

Total Quantity Lost/Stolen:

(Only one entry per NDC Number is possible. If an entry exists with the current NDC number, it will be replaced.)

**NDC Product Details:**

NDC Number: Please Enter a NDC Number

Trade Name:

Schedule:

Dosage:

- Current Entries

<u>NDC Number</u>	<u>Trade Name</u>	<u>Quantity Stolen/Lost</u>
-		

Entries with

← Add One NDC at a time

Or multiple NDC at a time

U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION  
**OFFICE OF DIVERSION CONTROL**

DEA Form 106 - Lost/Stolen Product Entry Page

NEW: [ [Single NDC Entry](#) ] [ [Multiple NDC Entry](#) ]

Multiple NDC Entries

(Only one entry per NDC Number is possible. Entries with the same NDC number will be replaced.)

- Current Entries

<u>NDC Number</u>	<u>Trade Name</u>	<u>Quantity Stolen/Lost</u>
-		



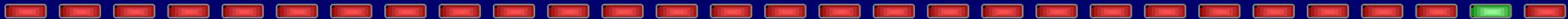
# DTL Recap

- DTL is the regulatory requirement to report the theft or significant loss of controlled substances to DEA
- How do I report drug thefts and losses?
  - Notify your local DEA Field office within one business of discovery of theft or loss
  - Review your responsibilities in 21 C.F.R. §§ 1301.74(c)
  - Go to the [www.deadiversion.usdog.gov](http://www.deadiversion.usdog.gov) and use the electronic DEA Form 106
  - If you cannot use the Internet, call 1 800 882-9539 to obtain a paper form, or for assistance



# Contact Information

- Diversion Customer Support Center: 1 800 882-9539
- CSOS Customer Support: 1-877-DEA-ECOM (1-877-332-3266)
- Diversion website: [www.deadiversion.usdog.gov](http://www.deadiversion.usdog.gov)
- CSOS Website: [www.deaecom.gov](http://www.deaecom.gov)



Questions?

