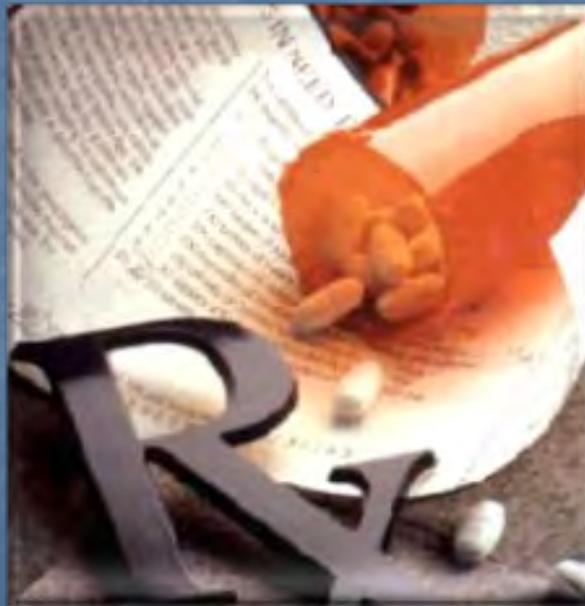


Distributor Initiative

A National Perspective

National Harbor
October 22, 2013



Thomas W. Prevoznik
Staff Coordinator
Liaison & Policy Section
Office of Diversion Control

Objectives

- Describe DEA's Role and Response to the National Pharmaceutical Epidemic.
- Present a National Distributor Initiative
 - Suspicious Orders
 - Know your Customer
 - National/State Data
 - Theft and Loss
 - Disposal

Lessons Learned



We will not arrest our way out of this problem!!!!!!

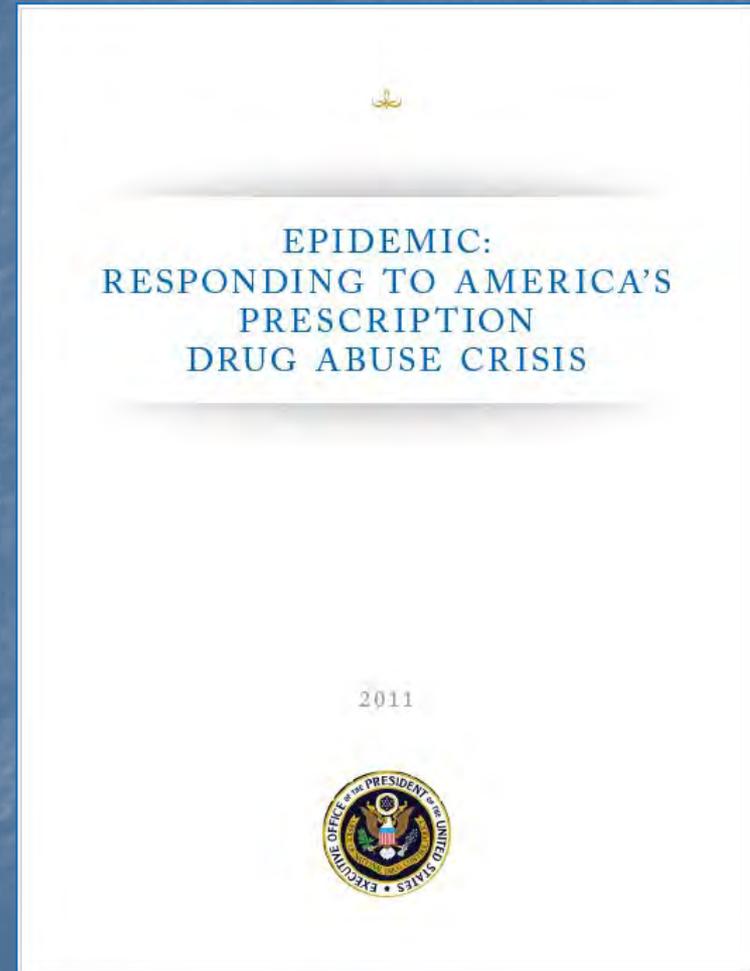
- Prevention/Education and
- Treatment are just as important as....
- Enforcement



Prescription Drug Abuse Prevention Plan

- Coordinated effort across the Federal government

- Four focus areas
 - 1) Education
 - 2) Prescription Drug Monitoring Programs
 - 3) Proper Medication Disposal
 - 4) Enforcement



Realignment of DEA's Diversion Control Efforts

- In October 2008, the then Acting Administrator authorized a two-pronged reorganization of the DEA Diversion Control Program.
- The first prong involved a substantial expansion in the number of Tactical Diversion Squads (TDS) and their deployment throughout the United States.
- The second prong of the reorganization plan called for a renewed focus on DEA's regulatory oversight of more than 1.4 million DEA registrants.

Scheduled Investigations

- Increase in the number of DEA registrants who are required to be investigated to ensure compliance to the CSA regulations.
- Increase in the frequency of the regulatory investigations.
- Verification investigations of customers and suppliers.

DEA Registrant Initiatives

Distributor Initiative:

Educate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances.

August 2005 – Present: Briefings to **81** firms with **233** locations

This presentation does not cover the totality of your obligations nor is it a substitute for your obligations as a DEA registrant under The Controlled Substances Act and its Regulations.

The information presented should not be considered new information. The substance of this presentation has been previously available and communicated through The Controlled Substances Act, its Regulations, Federal Register Notices, DEA and sponsored conferences, correspondence from the DEA, releases from the popular press, in addition to the Registrant's own sales data.

Mission

- The Office of Diversion Control's Mission is to Prevent, Detect, and Investigate the Diversion of Pharmaceutical Controlled Substances and Listed Chemicals from Legitimate Channels ...
- While Ensuring an Adequate and Uninterrupted Supply of ... Controlled Substances to Meet Legitimate Medical, Commercial, and Scientific Needs.

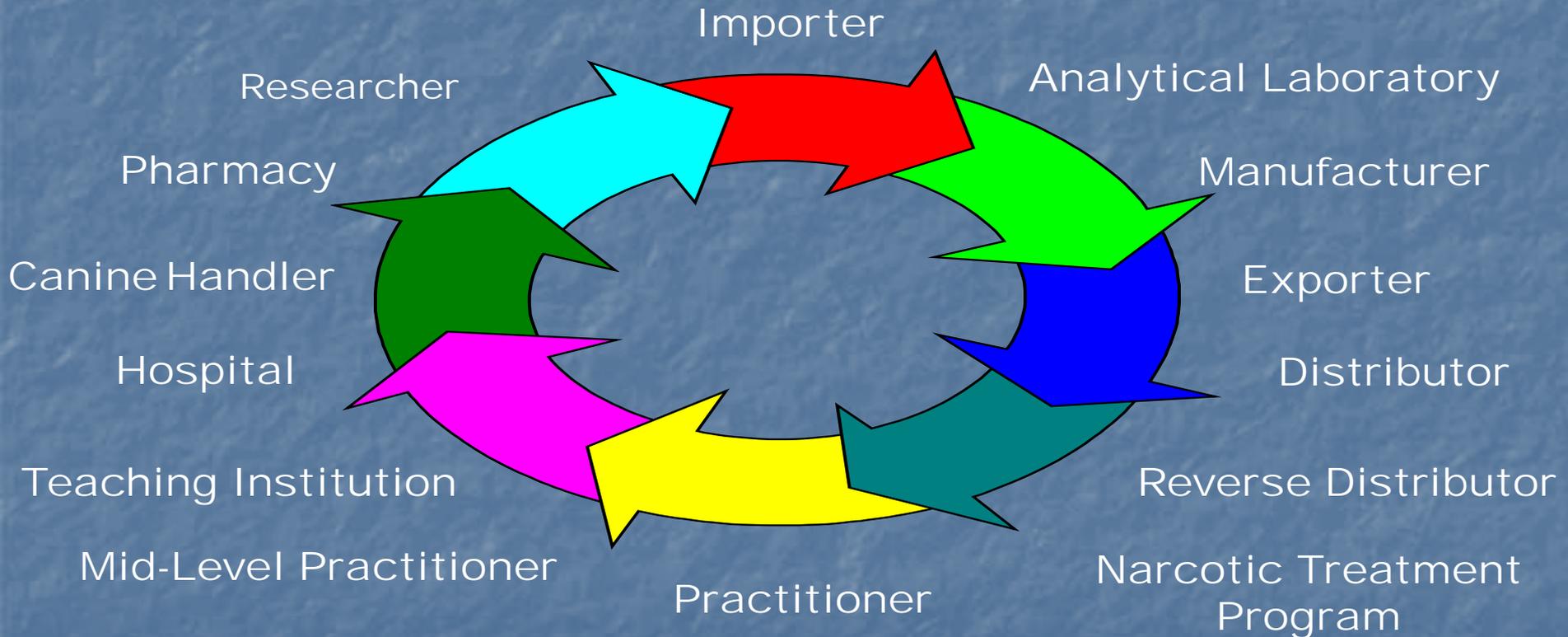


Closed System

The comprehensive Drug Abuse Prevention and Control Act of 1970, as amended in 1990 and 1994 created a system for the legitimate manufacturing, distribution, and prescribing/dispensing of controlled substances.

Each registrant within this “closed system of distribution” has defined privileges and responsibilities in which they must operate.

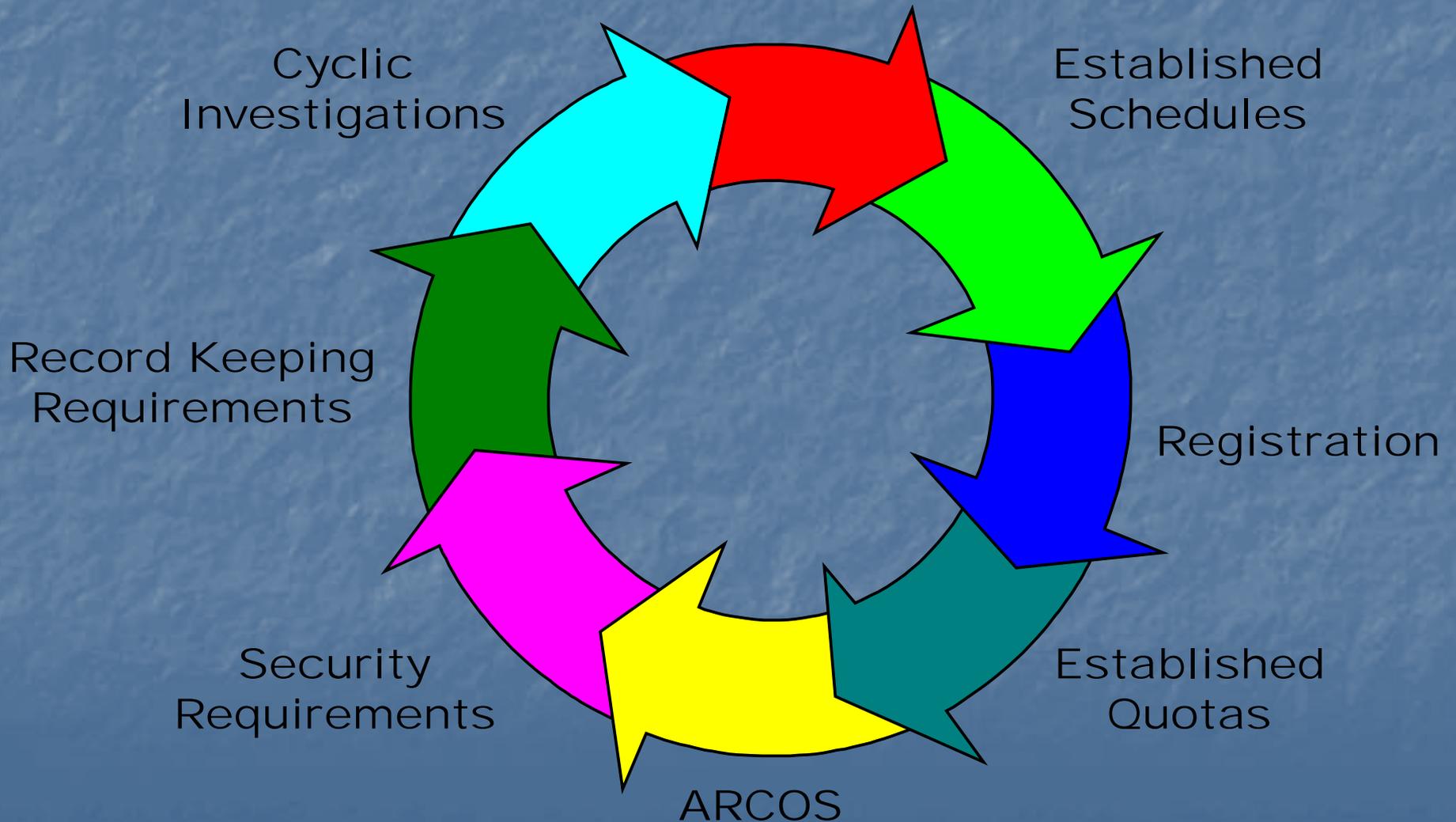
The CSA's Closed System of Distribution



1,511,258 DEA REGISTRANTS

As of 10/15/2013

The CSA's Closed System of Distribution



Closed System

DEA is responsible for:

- the oversight of the system
- the integrity of the system,
- the protection of the public health and safety.



Effective Controls

21 C.F.R. § 1301.71 (a):

All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.

Effective Controls

21 C.F.R. § 1301.71 (a):

In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72-1301.76 as standards for **physical security controls and operating procedures necessary to prevent diversion.**

Reports: Non-Practitioners

21 C.F.R. § 1301.74 (b):

- The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances.
- The registrant shall inform the Field Division Office ...in his area of suspicious orders when discovered by the registrant.

Suspicious Orders Include

Orders of Unusual Size

Orders Deviating Substantially
from a Normal pattern

Orders of Unusual Frequency

These criteria are **disjunctive**
(**They can stand alone or together**)

Reports: Chemical Handlers

Section 1310.05 Reports:

(a) Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, as follows:

Suspicious Chemical Orders

- (1) Any regulated transaction involving an
 - extraordinary quantity of a listed chemical,
 - an uncommon method of payment or delivery,
 - or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part.

Suspicious Orders

Reporting of a suspicious order to DEA does NOT relieve the distributor of the responsibility to maintain effective controls against diversion

Suspicious Orders

The responsibility for making the decision to ship or not to ship rests with the supplier.

Once a Suspicious Order is identified by the supplier the order must not be shipped.

Suspicious Orders

DEA will no longer accept “Excessive” Purchase Reports.

“Excessive” purchases were reported after the order had been filled.

Who are your Customers?

Practitioners

21 CFR 1306.04 (a):

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.



Pharmacies

21 CFR § 1306.04(a):

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.



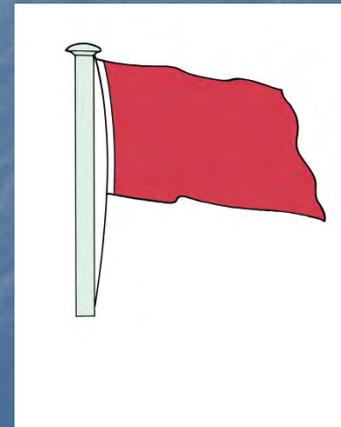
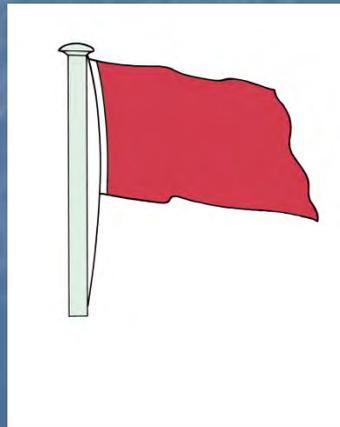
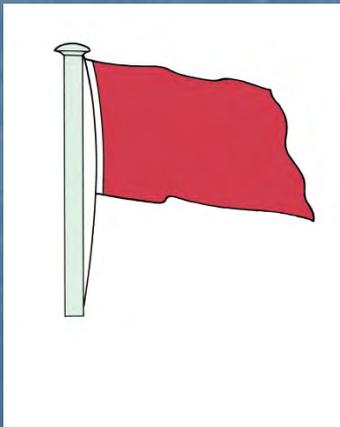
DEA Registrant Initiatives

- **Pharmacy Diversion Awareness Conferences:**
- This conference is designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity.
- **13 States** – OH, FL, GA, TX, NY, IN, NM, MI, IL, OR, LA, CA, and MA
- **5,452 Attendees**
- **8 more** – AZ, CO, KY, MO, NC, PA, TN, UT

Suspicious Orders

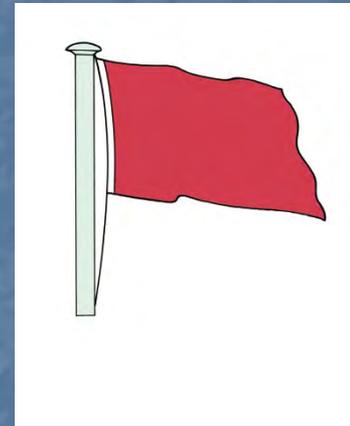
The Registrant must **KNOW THEIR CUSTOMERS.**

What are the “**RED**” flags?



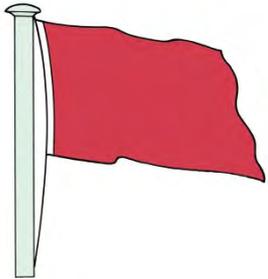
Corresponding Responsibility

- As a pharmacist, by law, you have a Corresponding Responsibility to ensure that prescriptions are legitimate.
- Just because a prescription is presented by a patient or demanded to be filled for a patient by a doctor's office, you are not obligated to fill the prescription!!!



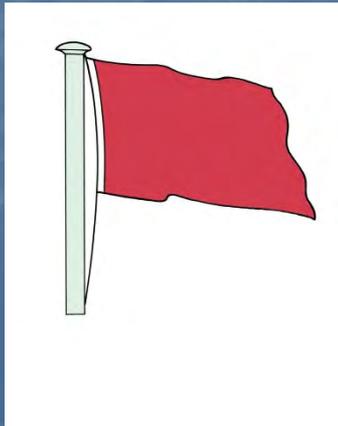
Corresponding Responsibility

- The doctor tells patients to fill their prescriptions at your pharmacy.
- The majority of the controlled substances prescriptions presented, originated from the same doctor.
- Many patients have identical prescriptions, regardless of age, sex or health.



Corresponding Responsibility

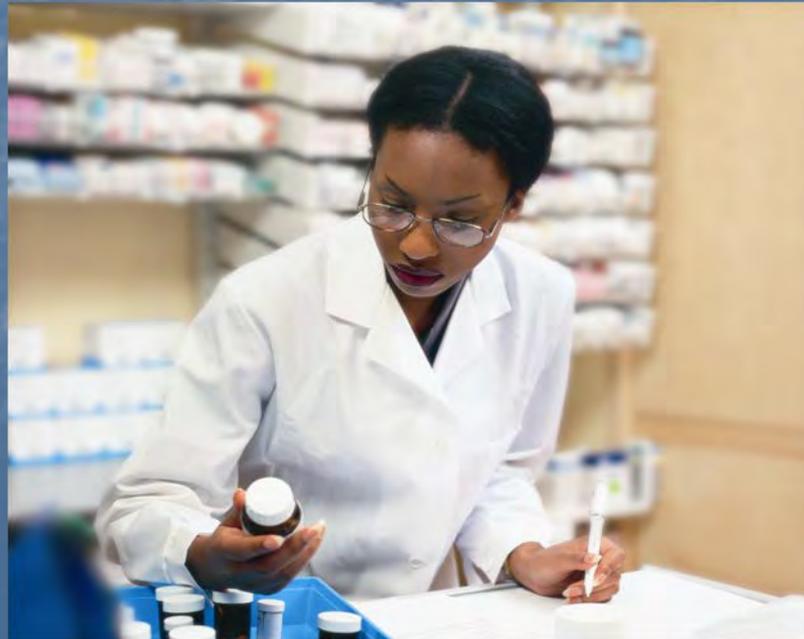
- Patients of the same physician, arrive at the pharmacy in groups with prescriptions for the same medications.
- Refills are authorized in advance.



System of Checks and Balances



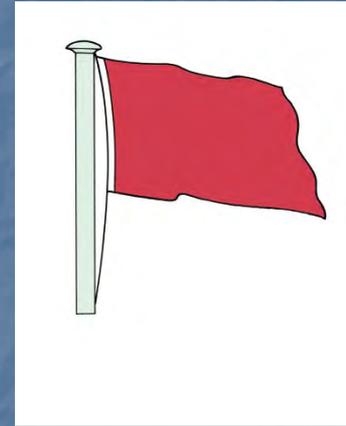
The Last Line of Defense



“Know Your Customers”

Some Factors to Consider:

- ✓ Where is it going?
- ✓ Who is it going to?
- ✓ How many other distributors are involved?
- ✓ Who are the Down Stream customers?

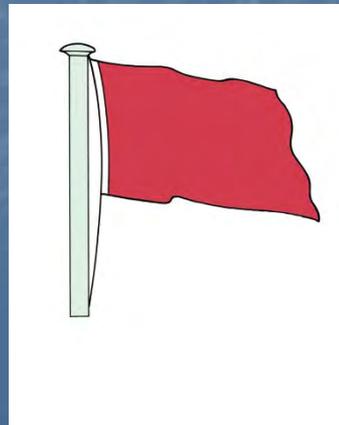


“Know Your Customers”

What do the news reports say about the state or geographical area where the controlled substances are being sold to?

Is there a problem with controlled substances in that particular state?

What is the problem? What are the controlled substances involved?



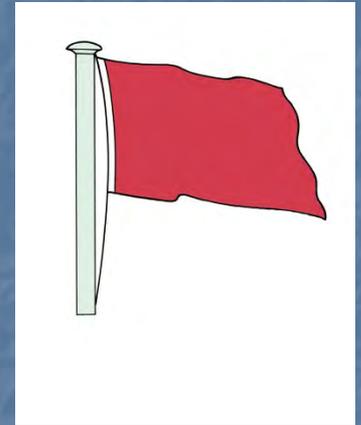
"Know Your Customers"

Range and Quantity of Products Being Purchased,

Location and hours of operation,

Methods of Payment Utilized
(cash, credit card, insurance),

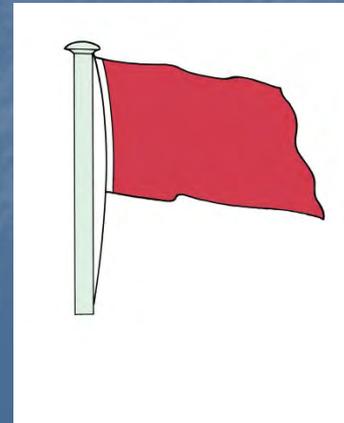
% Controlled vs. % Non-Controlled,



"Know Your Customers"

What is the average monthly purchase for an average type of registrant for a particular controlled substance? For a particular geographical area?

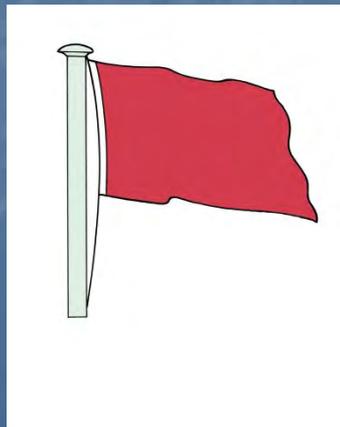
Does the requested purchase represent a quantity that far exceeds that average monthly purchase?
Why?



“Know Your Customers”

Are a large portion of the prescriptions being filled at a pharmacy for large quantities of controlled substances and are being paid for in cash or by credit card?

Are the prescriptions mostly for opioids, benzodiazepines (Lorazepam, Ativan, Diazepam), and muscle relaxers (Soma, Flexeril)?

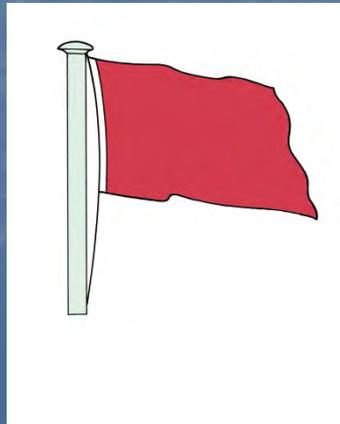


“Know Your Customers”

Are there security guards on the premises?
Why?

Is there a line of people waiting to get into the place?

Are there pain clinics in the area? How many? Is the pharmacy inside a pain clinic?



Closed System

When a registrant fails to adhere to their responsibilities, those violations represent a danger to the public and jeopardize the “closed system of distribution”.

Cutting off the Source of Supply



DEA Legal Recourse

- Administrative

 - Immediate Suspension Order (ISO)

 - Memorandum of Agreement (MOA)

 - Order to Show Cause (OTSC)

- Civil

 - Fines

- Criminal

 - Tactical Diversion Squads



How Do You Lose Your Registration?

The Order to Show Cause Process

21 USC § 824

- a) Grounds:
 1. Falsification of Application
 2. Felony Conviction
 3. State License or Registration suspended, revoked or denied – no longer authorized by State law
 4. Inconsistent with Public Interest
 5. Excluded from participation in Title 42 USC § 1320a-7(a) program

- b) AG discretion, may suspend any registration simultaneously with Order to Show Cause upon a finding of Imminent Danger to Public Health and Safety

Administrative Actions

- **Distributors only (January 1, 2007 to present):**
 - **Letters of Admonition**
 - **Memoranda of Agreement**
 - **Administrative Hearings**
 - **Surrender for Cause**
 - **Immediate Suspension**
 - **Order to Show Cause Issued**

Civil Action - Distributor Registrants

August 2005 – Present:

- Civil action against **35** distributor registrations:

Over \$188 million in civil fines

- These were negotiated settlements

National Data

State Rankings

- 2011 & 2012 Practitioner & Retail Pharmacies Sales Data for:
 - Oxycodone
 - Hydrocodone
 - Hydromorphone
 - Oxymorphone

2012 Oxycodone State Rankings

Practitioners

RANK	STATE
1	PA
2	GA
3	CA
4	TN
5	MD
6	CT
7	SC
8	AL
9	NV
10	CO

Retail Pharmacies

RANK	STATE
1	FL
2	PA
3	CA
4	NY
5	OH
6	NC
7	NJ
8	AZ
9	TN
10	MA

2012 Hydrocodone State Rankings

Practitioners

RANK	STATE
1	CA
2	GA
3	IL
4	PA
5	TN
6	AL
7	MI
8	VA
9	IN
10	AZ

Retail Pharmacies

RANK	STATE
1	CA
2	TX
3	TN
4	MI
5	FL
6	IL
7	OH
8	IN
9	GA
10	AL

2012 Hydromorphone State Rankings

Practitioners

RANK	STATE
1	CA
2	MD
3	CT
4	DE
5	IL
6	GA
7	TN
8	CO
9	PA
10	VA

Retail Pharmacies

RANK	STATE
1	CA
2	FL
3	NY
4	TX
5	VA
6	PA
7	WA
8	OH
9	MI
10	NJ

2012 Oxymorphone State Rankings

Practitioners

RANK	STATE
1	MD
2	PA
3	TN
4	KY
5	MI
6	HI
7	NV
8	NC
9	GA
10	ME

Retail Pharmacies

RANK	STATE
1	NC
2	CA
3	TN
4	NY
5	PA
6	FL
7	OH
8	TX
9	IN
10	VA

Theft or Significant Loss

Reporting Thefts or Losses

- **Must report thefts and significant losses to the DEA within one business day upon discovery (1301.76)**
- **Should report all thefts to the local law enforcement agency and board of pharmacy**
- **Must complete the DEA Form 106**

Reporting Thefts or Losses

- To report a theft or loss of controlled substances on-line, visit the DEA's Office of Diversion Control website at www.DEAdiversion.usdoj.gov
- The electronic version of the DEA Form 106, Report of Theft or Loss of Controlled Substances
- Complete the form and submit it electronically



U.S. Department of Justice Drug Enforcement Administration
Office of Diversion Control

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[Registration](#)

[Reporting](#)

[Info & Legal Resources](#)

[Inside Diversion Control](#)

Report Suspicious Internet Pharmacies

1-800-RX-ABUSE

1-800-792-2873



Quick Links

[Renew Applications Online](#)

[New Application Online](#)

[Registration Validation](#)

[Combat Meth Act 2005](#)

[Order Forms](#)

[CSOS](#)

[Duplicate Certificate Request](#)

[Cases Against Doctors](#)

[Online Pharmacy
Modification](#)

[Mailing Addresses for Topics
Related to Title 21 CFR](#)

[DEA Form 106: Report Theft
or Loss of Controlled
Substance](#)

FAQ

[ABCOS](#)



Regulations.gov

*The voice in Federal
decision-making*



What's New

[Cerilliant Corporation](#) (September 25, 2009)

[More](#)

Registration Support

**Registration Number
Toll Free:
1-800-882-9539**

Save time by applying for and/or renewing your DEA Registration online. Data will be entered through a secure connection to the ODWIF on-line web application system.

Minimum requirements:

Credit Card and a web browser that supports 128-bit encryption.

[Field Offices with Registration](#)

Electronic DEA-106

APPLICATION STRUCTURE

Section 1: Authentication and Report

Section 2: Theft/Loss Details

Section 3: Lost/Stolen Product Entry Page

Section 4: Signature

Section 5: Theft/Loss Summary

Section 6: Controlled Substance Summary and Certification

Section 7: Submit Report

Section 8: Print

The image shows a screenshot of the DEA Form 106 application structure page. At the top, there is a header for the U.S. Department of Justice Drug Enforcement Administration, featuring the DEA logo and the text "DIVERSION CONTROL PROGRAM" and "DEA FORM 106". Below the header, the title "Report of Theft or Loss of Controlled Substances Under Controlled Substance Act of 1970" is displayed. The main content is organized into two columns: "General Instructions" and "SPECIFIC INSTRUCTIONS".

General Instructions

WHATS NEW

Changes to the Controlled Substances Section. The DEA is now requiring registrants to enter the National Drug Code (NDC) of the controlled substances lost or stolen.

Discontinued Fields. With the implementation of the NDC number, DEA will no longer require registrants to enter specific information pertaining to product lost or stolen. Inputting the NDC number will auto-populate all require information needed for data collection and report generation.

Purpose of Form

The DEA-106 is for reporting any theft or loss of controlled substances. Do not use this form if:

1. You have not previously registered with the DEA.
2. The theft or loss you are reporting is not of a controlled substance, or
3. You want to correct minor inventory shortages.

Additional Information

The online version of Form DEA 106 has 8 sections. What follows is a description of each section and the information you will need to successfully fill out this online form. Please note that all pages where you are required to supply information, there is a section labeled "Help." For any field on the page for which you require clarification, place the cursor in the field and click. Help text will appear in the Help section.

SPECIFIC INSTRUCTIONS

Section 1. Authentication and Report Selection
You will be asked to enter your DEA Number and your last name or the business name you used to register with the DEA. The name you supply must match exactly the name on your registration. You also will be able to choose whether to file a new report, or amend a report previously entered.

Section 2. Theft/Loss Details
You will be asked to provide background information relating to this loss or theft incident, such as the date and place, the type (night break-in, armed robbery, etc.), and the estimated value of the controlled substances, etc. Responses may require additional information, for example, indicating that a police has been filed will open new fields requesting the police department's name and telephone number.

Section 3. Controlled Substances
You will be asked to provide the National Drug Code (NDC) and quantity of the controlled substance being reported as a theft or loss. If the substance is liquid or powder, you will need to enter the total milliliters/milligrams, if tablet, enter the total count of tablets.

Section 4. Signature
You will be asked to supply the name and title of the person filing this report.

Section 5. Theft/Loss Summary
Information regarding the details of the theft or loss will be presented to you for confirmation; changes to the information may be made. You may also change information in the Signature section.

Section 6. Controlled Substances Summary and Certification
Information on the substances will be displayed, and may be changed. Additionally, you will be required to enter the name of the certifying official who attests to the validity of the information included in the report.

Section 7. Submit Report
Submitting the report will generate an amendment key. Please save the amendment key in order to be able to modify information using the online DEA-106 report in the future.

Section 8. Print
You may send a copy of the DEA-106 report to your local printer. DEA regulations specify that you keep a copy of this report for two years.

PLEASE DO NOT USE YOUR BROWSER'S BACK AND FORWARD buttons while navigating this form.

Begin

DRUG THEFT LOSS SYSTEM - Electronic DEA-106

Section 1: Authentication & Report

U.S. Department of Justice
Drug Enforcement Administration

DIVERSION CONTROL PROGRAM

DEA FORM 106

HELP

Please enter the registrant's DEA number. The first two characters must be uppercase. [Required]

[General Instructions.](#)

User Login

Form 106 Login

DEA Number:

Last Name:

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

<-Previous **-Cancel-** **Login**

Drug Theft/Loss Login Screen

DRUG THEFT LOSS SYSTEM

Electronic DEA-106

The Login Confirmation Screen will be displayed, showing the registrant's name, address, and business activity.

This is a sample of the login confirmation page, with registrant name and address information removed.

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

Form 106 Login Confirmation

WASHINGTON, DC 20003
PRACTITIONER

If you are not [redacted], or the address is not the one assigned to this DEA number, please DO NOT PROCEED. Instead, contact the DEA Call Center at 800-882-9539, or click here to change the address.

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

-Cancel- **Next->**

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

HELP

You may create a new report or amend an existing report.

[General Instructions.](#)

NEW: It is now possible to enter multiple reports with the same Date of Loss. In order to do this, select the Add / Amend Report button below. For privacy and security purposes, you will need the Amendment Key from a report entered on the same date. When adding a report for a date with an existing report, please ensure the new report is really new, and not an amendment to an existing report.

New Report Date **-Cancel-** **Add / Amend Report**

New Report will open a blank report for completion

Cancel will terminate the application without transmitting any data

Add/Amend Report will allow registrants to change data on previously submitted reports after verifying user credentials

DRUG THEFT LOSS SYSTEM

Electronic DEA-106



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	<input type="radio"/> Yes <input type="radio"/> No
* Type of Theft / Loss	<div style="border: 1px solid black; padding: 2px;">Armed Robbery Customer Theft Employee Pilferage Lost In Transit Night Break-In Other</div>
* Number of prior incidents in the past two years	
* Total Purchase Value of Controlled Substances (reported on this form)	
Items lost other than controlled substances	<input type="radio"/> Yes <input type="radio"/> No
Identifying Marks, Symbols, Price Codes (Controlled Substances only)	<input type="text"/>
DEA Form 222 Numbers (If Stolen)	<input type="text"/>
New Security Measures	<input type="text"/>

*Fields prefixed with * are required.*

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

Section 2: Theft Loss Details

In this section you will provide background information relating to the theft or loss incident including:

- Date, place, and time
- Type of incident
- Estimated value

Responses to the type of incident may require additional information.

Previous - Return to Login Confirmation page;

Cancel - Terminate the application without transmitting any data;

Next will proceed with the application



Disposal

EDITORIAL CARTOON *By Nate Beeler/Examiner*





National Take Back Initiatives

Over 2.8 million pounds (1,409 tons) collected

September 30, 2010: 242,383 pounds (121 tons)

April 30, 2011: 376,593 pounds (188 tons)

October 29, 2011: 377,086 pounds (189 tons)

April 28, 2012: 552,161 pounds (276 tons)

September 29, 2012: 488,395 pounds (244 tons)

April 27, 2013: 742,497 pounds (371 tons)





Take-Back Event



Boxed, Sealed, Counted, Weighed,
Consolidated, Secured, and
Incinerated



Secure and Responsible Drug Disposal Act of 2010

- 12/21/2012 – Proposed Drug Disposal Regulations are published in Federal Register
- 2/19/2013 – Comment period on proposed regulations
- Review of comments, and hearings if requested
- Finalization of rule



Summary

- Prescriptions not written in the usual course of professional practice are not valid.
- Drugs dispensed pursuant to invalid prescriptions are not for legitimate medical purpose, the drugs are being diverted.
- Not limited to Internet pharmacies.



Summary

- A pattern of drugs being distributed to pharmacies who are diverting controlled substances demonstrates the lack of effective controls against diversion by the distributor
- The DEA registration of the distributor could be revoked under public interest grounds



Summary

- Any Distributor who is selling controlled substances that are being dispensed outside the course of professional practice must stop immediately
- DEA cannot guarantee that past failure to maintain effective controls against diversion will not result in action against a distributor



Summary

www.deadiversion.usdoj.gov

- Current Revocation Actions
- Policy Changes
- Validation of Registration
- Links to web sites with useful information (AMA, Pain Management, Pharmacy, etc.)
- Other



Questions ?

