



U.S. DRUG ENFORCEMENT ADMINISTRATION

September 13, 2019

Health Care Compliance Association
Minneapolis, Minnesota

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Diversion Program Manager
Omaha Field Division



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LEARNING OBJECTIVES

- ❖ Recognize some controlled substance prescription red flags.
- ❖ Discuss the requirements of a prescription.
- ❖ Reporting requirements for a theft or loss.
- ❖ Understand the pharmacist corresponding responsibility.
- ❖ Understand the Administrative, Civil and Criminal Penalties.
- ❖ Discuss current drug trends.
- ❖ Recognize the potential avenues for diversion.
- ❖ Discuss physical and electronic security for controlled substances.
- ❖ Where to find DEA regulations and information.



PRESCRIPTION - RED FLAGS



RED FLAGS

Patterns of Prescribing

- If it's the same drug
- If it's the same quantity
- If it's the same combinations



The Trinity Equals

An Opioid

A Benzodiazepine

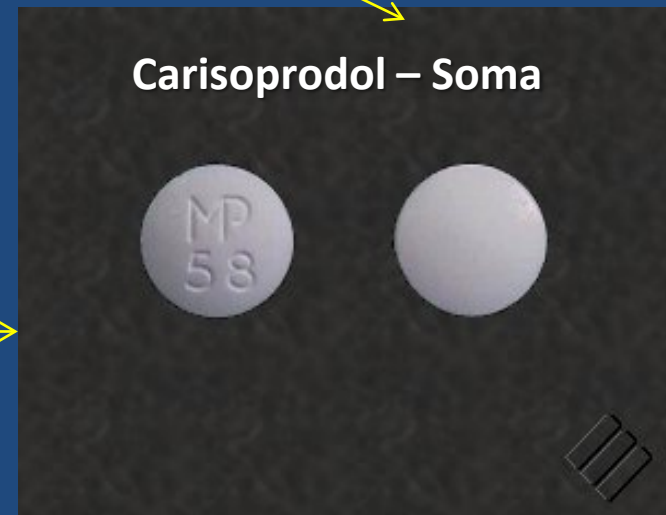
Carisoprodol *Soma



An often sought out combination
of drugs – **A dangerous cocktail**



THE TRINITY





RED FLAGS

Cash Payments

- Always pays cash
- Has insurance but pays cash



The Unknown

- Practitioner not known
- Patient not known
- Patient not from your town





RED FLAGS

Patients asking for specific Drugs

- No generics
- By manufacturer

Combinations of abused Drugs
Masking with other substances

Patient may not fill all the “other”
prescribed items





RED FLAGS

Patients located at the same address, not family members



Refills requested before the prescription should have run out





PURPOSE OF ISSUE OF PRESCRIPTION



PURPOSE OF ISSUE OF PRESCRIPTION

Lic # M-454	DEA # AA1235265
Dr. John Anyone M.D. (123) 456-2222	
2545 Where Park Drive	Way, WV 99099
<hr/>	
Name _____	Age _____
Address _____	Date _____
Rx	Drug Name
	Quantity & Strength
	Dosage Form
	Directions for Use
Refill - 0 - 1 - 2 - 3 - 4 - 5	Signature _____

Title 21 Code of Federal Regulations § 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. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but....



PHARMACIST CORRESPONDING RESPONSIBILITY

Lic # M-454	DEA # AA1235265
Dr. John Anyone M.D. (123) 456-2222	
2545 Where Park Drive	Way, WV 99099
<hr/>	
Name _____	Age _____
Address _____	Date _____
Rx	Drug Name
	Quantity & Strength
	Dosage Form
	Directions for Use
Refill - 0 - 1 - 2 - 3 - 4 - 5	Signature _____

Title 21 Code of Federal Regulations § 1306.04

a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.



PRACTITIONER - PHARMACIST



EQUAL IN THE RESPONSIBILITY



MANNER OF ISSUANCE OF PRESCRIPTION

Lic # M-454	DEA # AA1235265
Dr. John Anyone M.D. (123) 456-2222	
2545 Where Park Drive	Way, WV 99099
<hr/>	
Name _____	Age _____
Address _____	Date _____
Rx	Drug Name
	Quantity & Strength
	Dosage Form
	Directions for Use
Refill - 0 - 1 - 2 - 3 - 4 - 5	Signature _____

Title 21 Code of Federal Regulations § 1306.05

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.



DEA DIVERSION WEB-SITE



DEA DIVERSION WEB-SITE



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION DIVERSION CONTROL DIVISION

 Search[HOME](#)[REGISTRATION](#)[REPORTING](#)[RESOURCES](#)[ABOUT US](#)

Report Illicit Pharmaceutical Activities

***RX Abuse Online
Reporting***



Registration Support

Call: 1-800-882-9539 (8:30 am-5:50 pm ET)

Email: DEA.Registration.Help@usdoj.gov

Locate Field Registration Specialists

New Applications

Renewal Applications

Registration Changes (Address, Drug Code, Name, Schedule)

CMEA (Combat Meth Epidemic Act)

Registration for Disposal of Controlled Substances

Duplicate Certificate Request

Duplicate Receipt of Registration

Order Forms (DEA 222)

Registration Validation

Search for an Authorized Collector Location

What's New

Mehdi Nikparvarfard, M.D.; Decision and Order (April 4, 2018)

Catalent Pharma Solutions, LLC (April 4, 2018)

Wildlife Laboratories Inc. (April 4, 2018)

Bernard Wilberforce Shelton, M.D.; Decision and Order (April 2, 2018)

Angela L. Lorenzo, P.A.; Decision and Order (April 2, 2018)

Fisher Clinical Services, Inc. (March 29, 2018)

Get Email Updates:



**DEA Forms &
Applications**



**Publications
& Manuals**



**Questions &
Answers**



**Meetings &
Events**

DEADiversion.usdoj.gov



DEA DIVERSION WEB-SITE

DEA 222 Order Forms
Re-Order

Link to verify a
Practitioners DEA
Registration

Registration Support

Call: 1-800-882-9539 (8:30 am-5:50 pm ET)

Email: DEA.Registration.Help@usdoj.gov

Locate Field Registration Specialists

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DEADiversion.usdoj.gov



DEA REGISTRANT POPULATION

DEA Registrant Population as of August 2019

RETAIL LEVEL

- Practitioner 1,256,651
- Mid-Level Practitioner 387,693
- Retail Pharmacy 71,120
- Hospital Clinic 18,413
- Teaching Institution 262



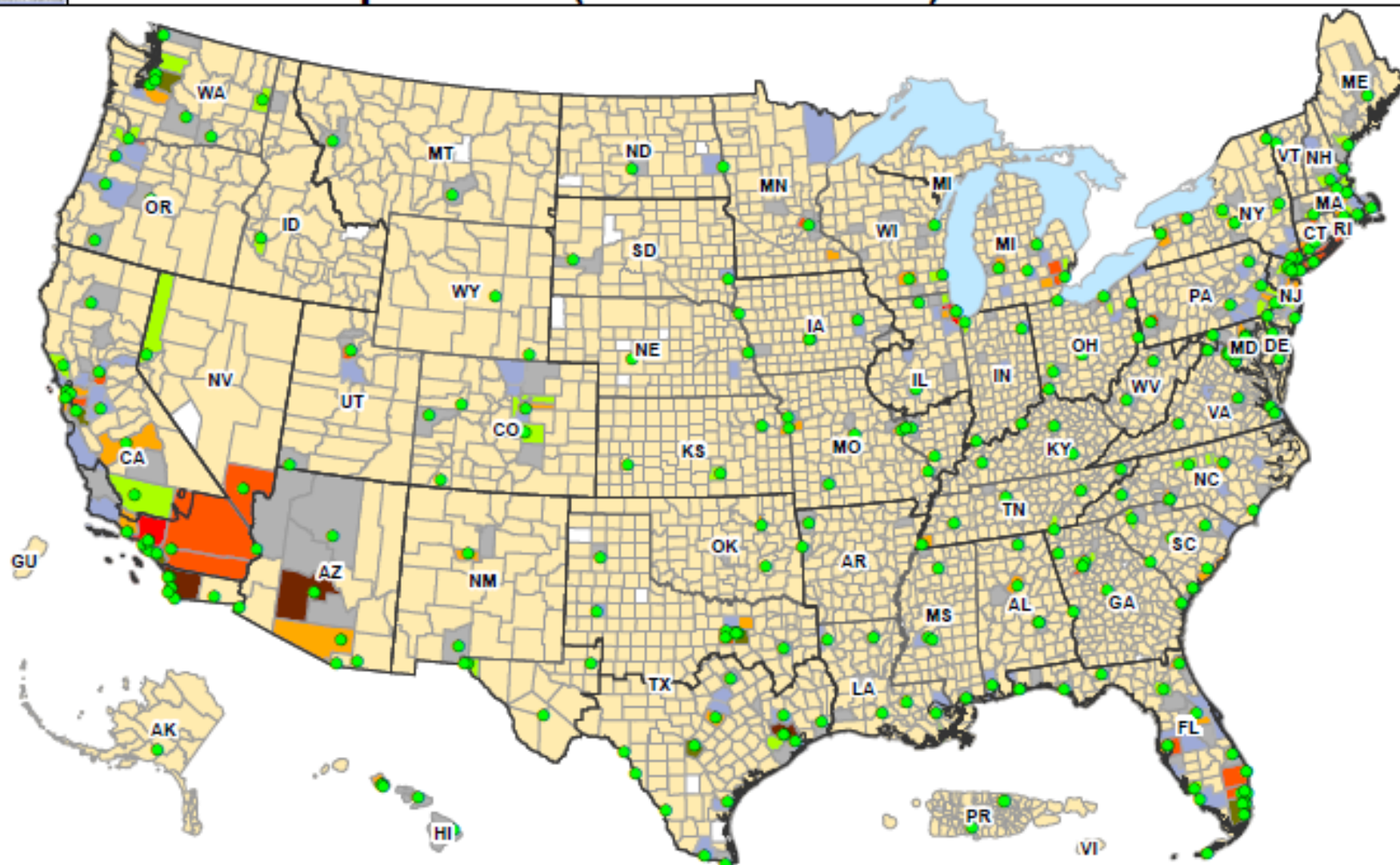
WHOLESALE LEVEL

- Researcher 12,071
- Analytical Lab 1,531
- NTP 1,748
- Distributor 925
- Manufacturer 580
- Exporter 262
- Importer 250
- Reverse Distributor 69

**TOTAL REGISTRANT
POPULATION 1,846,284**

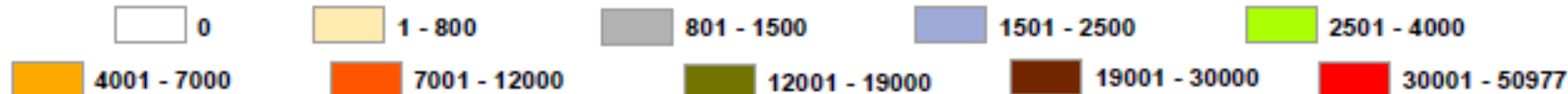


CSA Population (DEA Form 224) United States



Legend

DEA Form - 224 Registrant Population Density by County



● DEA Office Locations



DIVERSION AVENUES



Diversion Potential changes on many factors

Business Activity – Supply - Access



Hospital/Clinic



Retail Pharmacy



Distributor



Physicians Office



Analytical Lab



Manufacturer



Physical Security Protection deployed



Cage



Vault



Safe



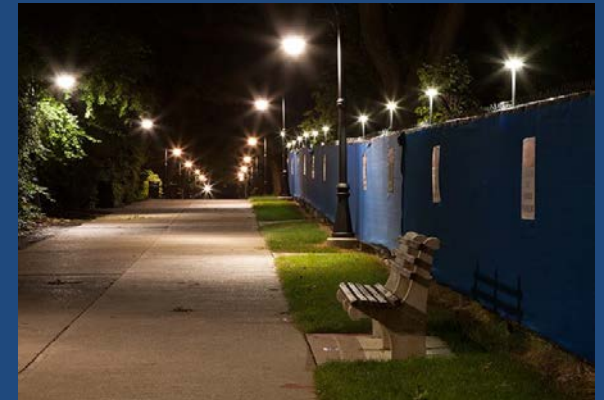
Locked Cabinet



Dispersed amongst other stock



Physical and Electronic Security Protection deployed

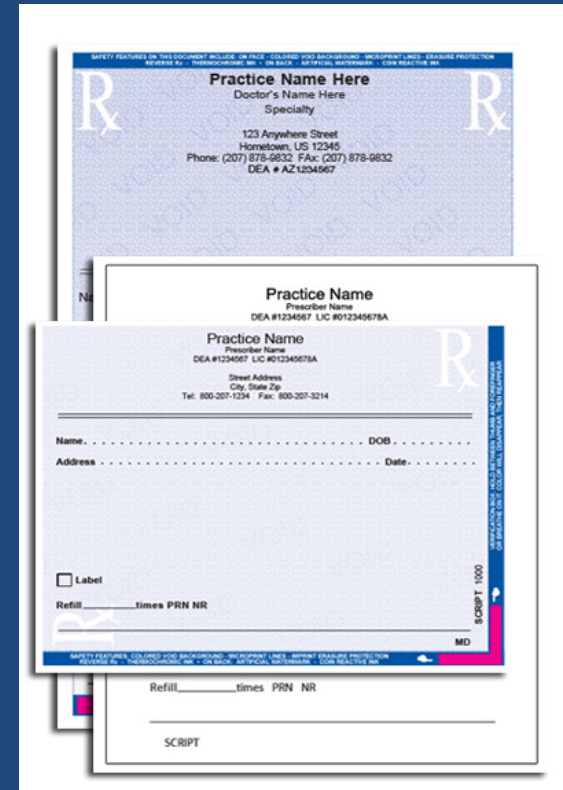




Avenues for Diversion



Armed Robberies



Fake or not legitimate prescriptions



The Largest Avenue for Diversion Pharmacies



Pharmacists, Pharmacy Technicians,
Employees who have access to the
Pharmacy...



Burglaries





Hospital Diversion Potential



Why is it a
Diversion
Potential

- Overrides – Cancel Orders
- Sharing of pass codes
- Inventory of ADS machines not completed
- Training on pass codes – Changing of pass codes
- Failure to completely empty for servicing



– Criminal Investigation –



Nurse in ICU admits to taking Fentanyl from the Pyxis machine and replacing the Fentanyl with sterile solution.

She then cancelled the request when returning the Fentanyl to the Pyxis machine.







Factors in Reporting a Theft or Loss

- The actual quantity of controlled substances lost in relation to the type of business;
- The specific controlled substances lost;
- Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
- A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,



Reporting the Theft or Loss On-Line

NEW - DEA Form 106 / 107

The screenshot shows the DEA Diversion Control Division website. At the top is the U.S. Department of Justice Drug Enforcement Administration logo and the text "DIVERSION CONTROL DIVISION". Below this is a navigation bar with links: HOME, REGISTRATION, REPORTING, RESOURCES, and ABOUT US. The main content area is titled "REPORTING > Reports Required by 21 CFR > Theft/Loss Reporting". A yellow arrow points to the "Theft/Loss Reporting" section. This section contains an "IMPORTANT NOTICE" stating that only registered or regulated persons can use these forms. It then lists "Theft/Loss Reporting Online (TLR)" with details for DEA Form 106 (Report of Theft or Loss of Controlled Substances) and DEA Form 107 (Report of Theft or Loss of Listed Chemicals). A paragraph explains that data is entered through a secure connection and that the web browser must support 128-bit encryption. Another paragraph states that federal regulations require registrants to notify their local diversion field office. A final paragraph explains that the NDC number is used to track controlled substances and listed chemical products. On the right side of the page, there is a "Get Email Updates:" section with a list of topics: ARCOS, BCM Online, Chemical Import/Export Declarations, CSOS (Controlled Substances Ordering System), Theft/Loss Reporting, Import/Export, Medical Missions, Quotas, Registrant Record of Controlled Substances Destroyed, Regulated Machines (Tableting and Encapsulating), Submit a Tip to DEA, and Year-End Reports.

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION

HOME REGISTRATION REPORTING RESOURCES ABOUT US

REPORTING > Reports Required by 21 CFR > Theft/Loss Reporting

Theft/Loss Reporting

IMPORTANT NOTICE: Only those persons registered or regulated with DEA to handle controlled substances or listed chemicals may utilize these reporting forms.

Theft/Loss Reporting Online (TLR)

DEA Form 106 – Report of Theft or Loss of Controlled Substances (and disposal receptacles)

DEA Form 107 – Report of Theft or Loss of Listed Chemicals (The DEA amended **§1310.05** to require reports of unusual or excessive loss or disappearance of a listed chemical to be filed through the DEA Diversion Control Division secure network application)

Data will be entered through a **secure connection** to the online application system. **Your web browser must support 128-bit encryption.** If you have questions regarding the electronic submission, please contact **DEA Call Center 1-800-882-9539**.

Federal regulations require that registrants notify the **Local Diversion Field Office** in their area of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete the online theft and loss report (**21 C.F.R. §1301.76(b)** and **21 U.S.C. §830(b)(1)(C)**).

In order to better track controlled substances and listed chemical products reported as lost or stolen, DEA uses of the National Drug Code (NDC) number. The NDC number identifies the manufacturer, product, dosage form, and package size. Entry of the NDC number will prompt the system to auto-populate additional fields such as the name of the product, dosage form, dosage strength, and quantity per container. If it is a listed chemical, a chemical code and name will be provided in a list to select.

Get Email Updates:

- ARCOS
- BCM Online
- Chemical Import/Export Declarations
- CSOS (Controlled Substances Ordering System)
- Theft/Loss Reporting
- Import/Export
- Medical Missions
- Quotas
- Registrant Record of Controlled Substances Destroyed
- Regulated Machines (Tableting and Encapsulating)
- Submit a Tip to DEA
- Year-End Reports

DEADiversion.usdoj.gov



Reporting the Theft or Loss On-Line DEA Form 106 / 107



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

DIVERSION CONTROL DIVISION

INSTRUCTIONS for Form DEA-106, Report of Theft or Loss of Controlled Substances - Approved OMB Form No. 1117-0001 Expires: 10/31/2020 and for Form DEA-107, Report of Theft or Loss of Listed Chemicals - Approved OMB Form No. 1117-0024 Expires: 09/30/2020

What's New

The DEA Diversion Drug Theft Loss (DTL) system has been replaced by the Theft Loss Reporting (TLR) system. The Theft Loss Reporting system provides the capability for a registrant to submit a Form 106 and/or a Form 107. The Theft Loss Reporting system automatically determines which form(s) need to be generated and submitted based on the type of registrant and the data entered.

Purpose of Form 106

The DEA-106 is for reporting any theft or loss of controlled substances, mail-back packages, and/or inner liners. Use this form if:

1. You are registered with the DEA, or
2. You are reporting the theft or loss of a controlled substance.

DO NOT use this form to correct minor inventory shortages.

Purpose of Form 107

The DEA-107 is for reporting any theft or loss of Listed Chemicals. Use this form if:

1. You are reporting the theft or loss of a listed chemical.

DO NOT use this form to correct minor inventory shortages.

DEADiversion.usdoj.gov

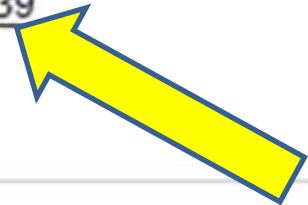


Reporting the Theft or Loss On-Line DEA Form 106 / 107

Additional Questions or Clarification

For additional questions or clarification, the following services are available:

1. Contact a customer service representative at 1-800-882-9539
2. Email ODT@usdoj.gov



Chemical and Drug Theft/Loss Reporting Login

Business or Last Name*

DEA, CMEA, or List II Reporter
Number*

Login

DEADiversion.usdoj.gov



Reporting the Theft or Loss On-Line

DEA Form 106 / 107

Theft/Loss Types:

- Break-in/Burglary
- Employee Theft (or Suspected)
- Hijacking of Transport Vehicle
- Packaging Discrepancy
- Robbery
- Customer Theft (or Non Employee)
- Loss in Transit
- Disaster (fire, weather, etc.)

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Penalties for Violations



Administrative, Civil & Criminal Penalties

Criminal Charges –
Federal or State Law



Civil Fines – Federal

\$\$\$ Per Violation

Administrative Actions –
Revocation
Restrictions
Letter of Admonition
Memorandum of Agreement

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
DENVER FIELD DIVISION

MEMORANDUM OF AGREEMENT

IN THE MATTER OF

Any Doctor

Any Doctor, hereinafter referred to as "Respondent" is requesting registration with the Drug Enforcement Administration (DEA) as a Practitioner with privileges to handle Schedules II, III, IV, V and VI controlled substances under Control No. 1400006034C.

FINDINGS OF FACT

Respondent admits that he filed an application for Distribution 1 indicating that he was ordering controlled substances (Xanax and Zolpidem) for personal use and stated he gives controlled substances to a "limited number of friends and family." Additionally Respondent indicated that he remembers who he gave the controlled substances to rather than keeping a written record of the dispensing. In October of 2011, Respondent surrendered his DEA Registration to DEA Diversion Investigation. After surrendering his DEA Registration, Respondent wrote prescriptions for controlled substances without having the authority to do so. Respondent complied with the DEA and subsequently withdrew his DEA application. Respondent has made it known that he does contract work for local practitioners to fill in as an absence of a practitioner.

Respondent entered into an Interim Cession of Practice Agreement with the Board on August 21, 2011. On March 11, 2014, Respondent signed a Stipulation and Final Board Order with the Board. This Stipulation states Respondent shall not prescribe any controlled substance until and unless the Board has lifted this prescribing restriction, attend and successfully complete, within one year, the Professional Boardman, Inc. "PBI Prescribing Course", a 21 hour course, attend and successfully complete a six hour record keeping course, and that Respondent's license is on a two year probation.

Respondent has provided proof to Diversion Investigators that he is in compliance with the requirements of the Stipulation and Final Board Order with the Board and that the prescribing restriction regarding controlled substances has been lifted by the Board.

STIPULATION AND AGREEMENT

Respondent agrees that the above findings are true and correct and these facts constitute sufficient grounds to deny his application.



Doctor convicted of murder for patients drug overdoses gets 30 years to life in prison



In 2016 Dr. Hsiu-Ying “Lisa” Tseng was sentenced to 30 years to life in prison for the murders of three of her patients who fatally overdosed, making Tseng the first doctor to be convicted of murder in the United States for overprescribing drugs. On appeal.



Pharmacist sentenced for conspiracy to distribute oxycodone

Associated Press |

Apr 13, 2018 | 4:30 AM

A pharmacist convicted of taking part in a long-running conspiracy to illegally distribute large quantities of oxycodone and other drugs from two pharmacies he owned is now headed to prison.

Federal prosecutors say Michael Ludwikowski received a 15-year sentence Thursday. He had been found guilty of six counts last August, including conspiracy and maintaining drug-involved premises.

Prosecutors say the 46-year-old Medford man and an employee at his two pharmacies in Medford distributed the drugs to addicts and others who presented phony prescriptions. The employee pleaded guilty December 2016.



Abington hospital to pay \$510,000 in pharmacist's theft of 35,000 pills, including oxycodone

January 09, 2017



The pharmacist pleaded guilty to possession with the intent to distribute oxycodone, she was sentenced to six years in prison and three years of supervised release.

Montgomery County Hospital will pay more than half a million dollars to resolve allegations stemming from an employee's theft of controlled substances.

Abington Hospital agreed to pay \$510,000 to settle allegations that its controls and practices enabled a staff pharmacist to take prescription medications for illegal use, according to the U.S. Attorneys Office in Philadelphia.



Civil Monetary Penalties Inflation Adjustment - 2016

42502 **Federal Register** / Vol. 81, No. 126 / Thursday, June 30, 2016 / Rules and Regulations

U.S.C. Citation	Name/Description	CFR Citation	DOJ Penalty as of 11/2/15 (\$) ¹	New DOJ penalty ²
21 U.S.C. 842(c)(1)(A)	Controlled Substances Act ("CSA"); Violations of 842(a)—other than (5), (10) and (16)—Prohibited acts re: controlled substances (per violation).	25,000	62,500 **
21 U.S.C. 842(c)(1)(B)	CSA; Violations of 842(a)(5) and (10)—Prohibited acts re: controlled substances.	10,000	14,502
21 U.S.C. 842(c)(1)(C)	CSA; Violation of 825(e) by importer, exporter, manufacturer, or distributor—False labeling of anabolic steroids (per violation).	500,000	500,855
21 U.S.C. 842(c)(1)(D)	CSA; Violation of 825(e) at the retail level—False labeling of anabolic steroids (per violation).	1,000	1,002
21 U.S.C. 842(c)(2)(C)	CSA; Violation of 842(a)(11) by a business—Distribution of laboratory supply with reckless disregard ⁹	250,000	375,613
21 U.S.C. 856(d)	Illicit Drug Anti-Proliferation Act of 2003; Maintaining drug-involved premises ¹⁰	250,000	321,403

(5) to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter;



Civil Penalties Record Keeping Violations

Sample DEA Form 222

See Reverse of PURCHASER's Copy for Instructions		No order form may be issued for Schedule I and II substance unless completed application form has been received. (21 CFR 1305.04)		OMB APPROVAL NO. 1117-0010	
TO:		STREET ADDRESS			
CITY and STATE		DATE		TO BE FILLED IN BY SUPPLIER	
				SUPPLIER DEA REGISTRATION No.	
TO BE FILLED IN BY PURCHASER					
No. of Packages	Size of Package	Name of Item	National Drug Code	Packaging Shipped	Date Shipped
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
LAST LINE COMPLETED (MUST BE 10 OR LESS)			SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT		
Date Issued		DEA Registration No.		Name and Address of Registrant	
Schedules					
Registered as a		No. of this Order Form			

DEA Form 222 (Oct. 1992)

US OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
SUPPLIER'S Copy 1

Date Received

Failed to document date received - shipped on Official Order Form

\$14,502.00 per line

Civil Fines can add up quickly on record keeping violations!



Drug Abuse Education



Would it benefit your business to educate your employees and their families

Investing in education benefits the employee and the business

Positive re-enforcement for the employee that the company is engaged with current events – the opioid epidemic

Employees are informed with the direction of the business relating to drug use - abuse

The company places employees on notice with education and policy

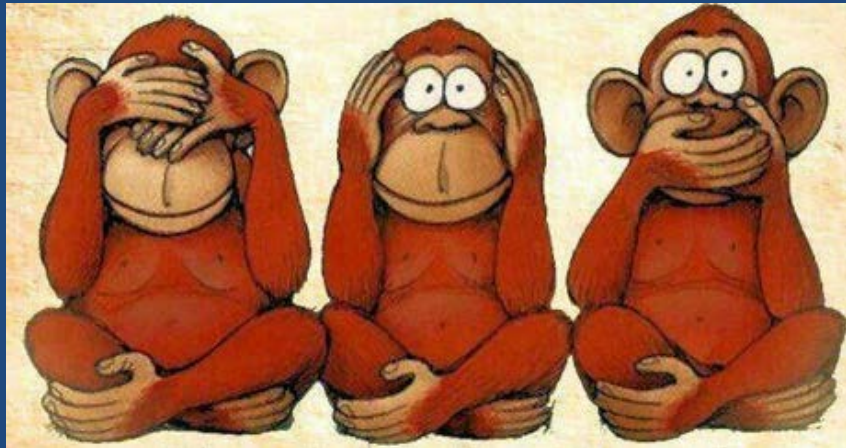


What is your company doing with your employees

Do you have a zero tolerance policy on drug abuse and theft

Do you provide drug abuse & prevention education

Or





Current Trends



Clandestine Laboratory Oxycodone Counterfeit & Real Tablets





Xanax Counterfeit and Real Tablets





Heroin, Fentanyl and Carfentanyl



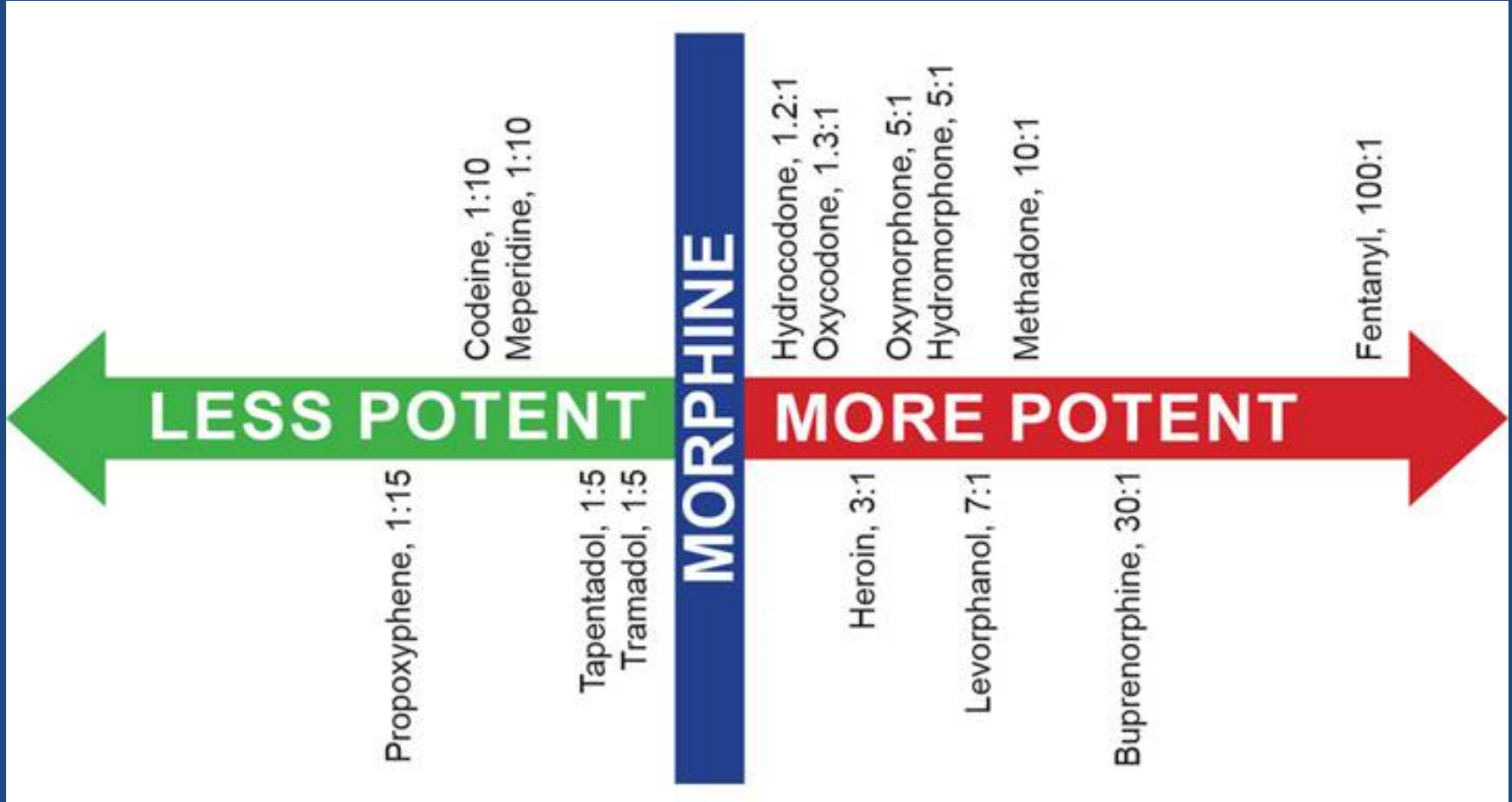
Photo depicts fatal
amounts of each drug



As a matter of reference it has
been determined that it would
only take 2-3 milligrams of
fentanyl to induce respiratory
depression



Potency Level of Fentanyl





Lab Equipment & Supplies



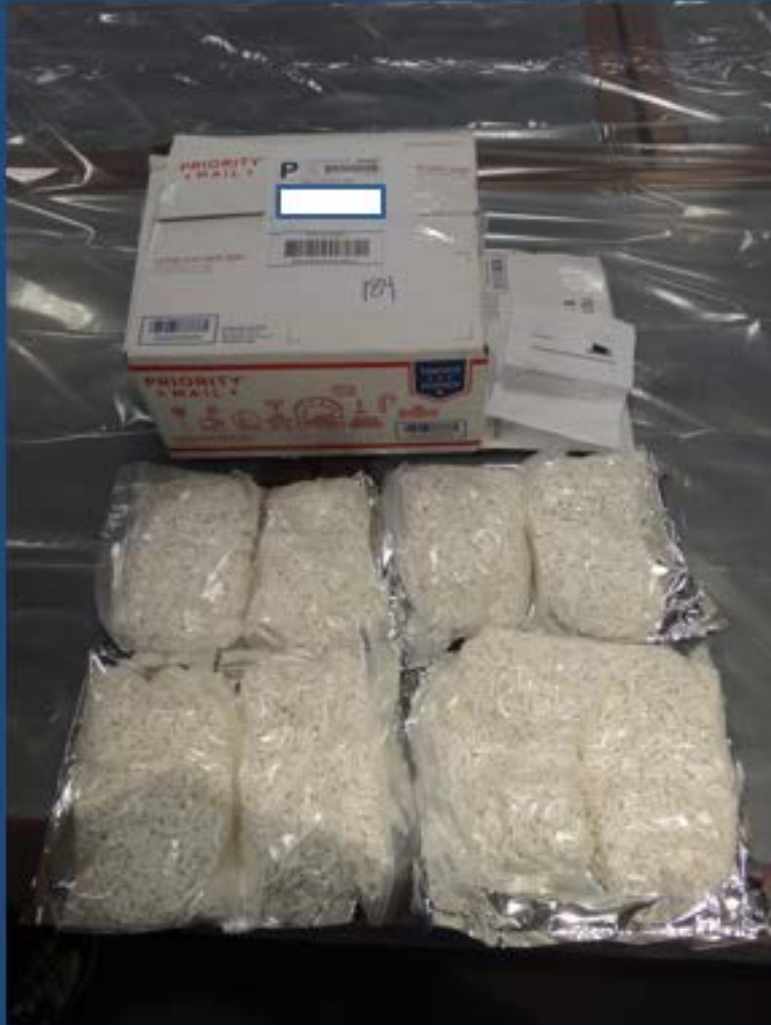


Distributed by U.S. Mail





Tablets & Cash



PAUL C. SINK CO.

FOUNDED 1936

LAUNDRY &

CLEANING MACHINERY

NO STOPPING
4-6 PM





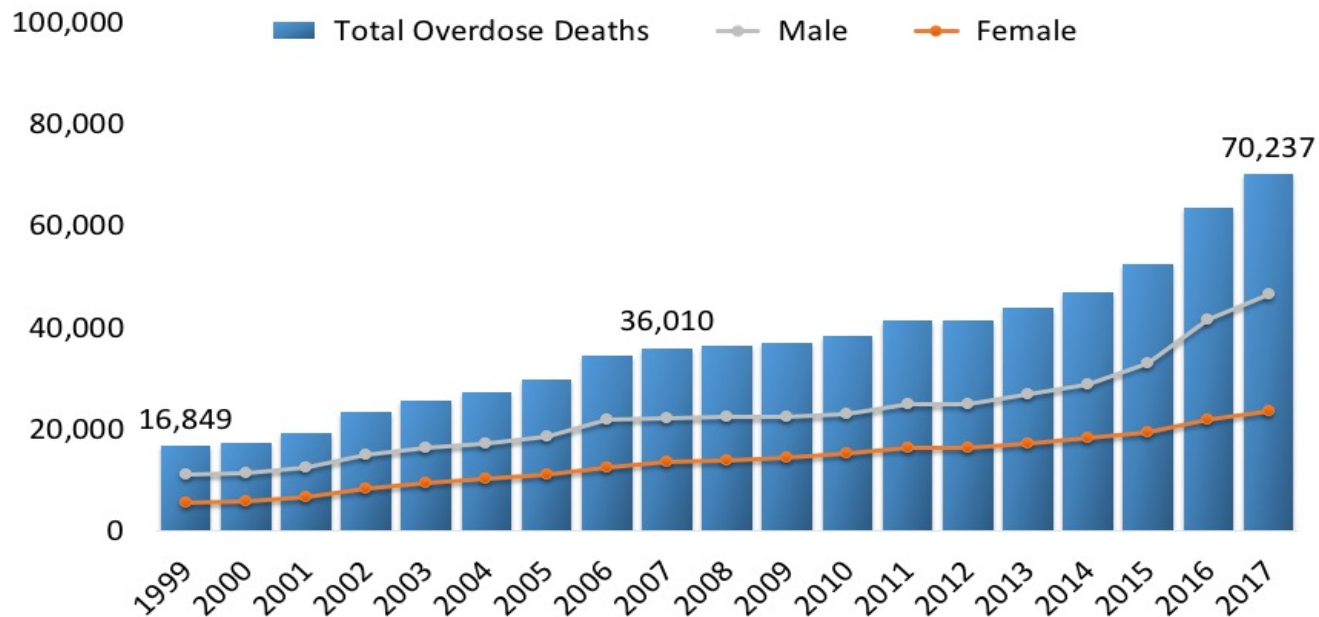
Opioids in the United States (CDC)

- In 2017 – 70,237 drug overdose deaths in the U.S.
 - Over 192 deaths a day
 - 1,350 a week
 - 5,853 a month
- Opioids were involved in 47,600 of those deaths ($\approx 68\%$).



2017 - CDC

Figure 1. **National Drug Overdose Deaths**
Number Among All Ages, by Gender, 1999-2017

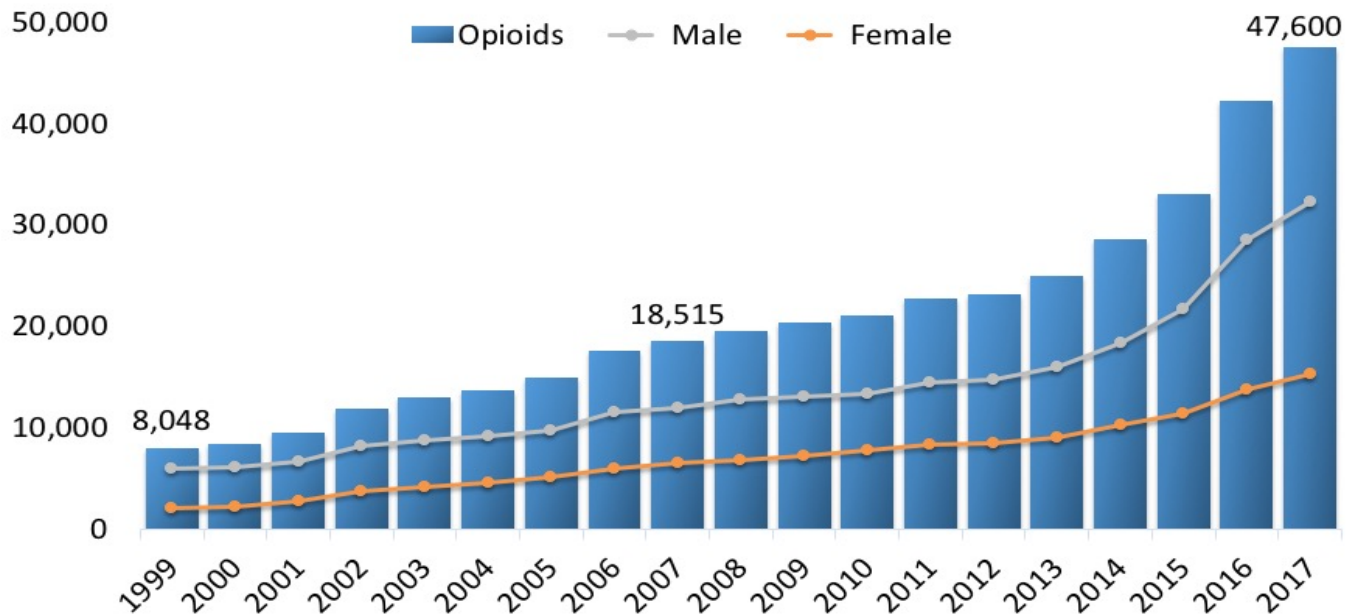


Source: : Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018



2017 - CDC

Figure 3. **National Drug Overdose Deaths Involving Any Opioid, Number Among All Ages, by Gender, 1999-2017**

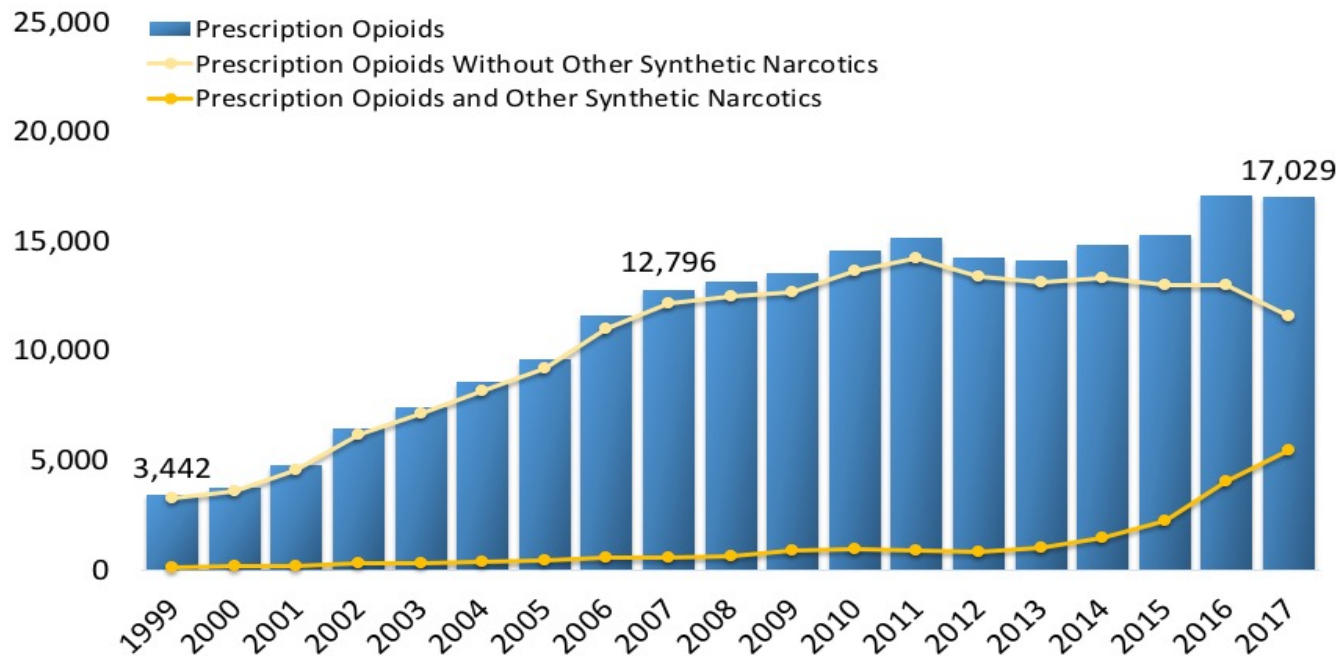


Source: : Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018



2017 – CDC

Figure 4. **National Drug Overdose Deaths Involving Prescription Opioids**, Number Among All Ages, 1999-2017



Source: : Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018



EXAM Time



Question...?

1. A pharmacist is obligated to fill a prescription that is presented by a patient or is demanded to be filled by a practitioner.

A. True

B. False



Question...?

3. What is the best safeguard to identify a patient who is doctor shopping?

- A. Secure prescriptions**
- B. Routinely use the PDMP**
- C. Conduct routine examinations**
- D. Never sign blank prescriptions**



Questions...?

4. Diversion of controlled substances can be conducted by:

- A. Staff members**
- B. Practitioners**
- C. Patients**
- D. All of the above**



Questions



DEA

Contact Information

Minneapolis – St. Paul District Office
Diversion Group 612-344-4143

deadiversion.usdoj.gov