Drug Enforcement Administration

STEPHEN M. BUZZEO SUPERVISORY INVESTIGATOR NEW YORK DIVISION – DIVERSION GROUP



Use, Misuse, Documentation, Safeguarding And Prescribing Of Controlled Substances

Outline

- DEA Diversion Program Overview
- DEA Registration Requirements
- DEA Recordkeeping/Reporting Requirements
- DEA Security Requirements
- Legitimate Medical Use and Prescribing/Administering of Controlled Substances
- Drug Trends
- Security Requirements

Diversion Program

The purpose of the Diversion Control Program is to prevent, detect, and investigate the diversion of controlled substances from legitimate channels, while at the same time ensuring an adequate and uninterrupted supply of controlled substances required to meet legitimate needs.

Prevention of diversion from legitimate drug traffic is a cooperative effort between Federal and state governments. DEA has primary responsibility for enforcing the Control Substance Act of 1970 (CSA) with respect to all nonpractitioner registrants. DEA also targets any registrant violator who meets established criteria. Investigative information developed on a violative practitioner registrant not meeting established criteria is generally referred to appropriate state authorities for investigation

Veterinary Medicine

The practice of veterinary medicine includes the diagnosis and treatment (including prescriptions and surgery) of all animal disease. "Animal" includes every living creature except humans.

The practice of veterinary technology includes the performance of services within the field of veterinary medicine by a person (called a veterinary technician) who carries out medical orders prescribed by a supervising veterinarian.

Most veterinarians offer a full range of diagnostic, surgical, and radiological procedures. Many practices also provide animal boarding services for the convenience of their clients.

Some veterinarians have completed advanced training and research in specialty areas such as ophthalmology, internal medicine, surgery, and dermatology, among others. Your veterinarian may refer you to such a specialist when it is necessary, and professional associations may be able to provide the names of their members who have been certified in specialty areas of practice. New York State does not issue these specialty credentials.

Under the supervision of a licensed veterinarian, veterinary technicians prepare and give medications as ordered by the veterinarian, take x-rays, induce and maintain anesthesia, and assist with medical and surgical procedures.

Source: NYS OPD

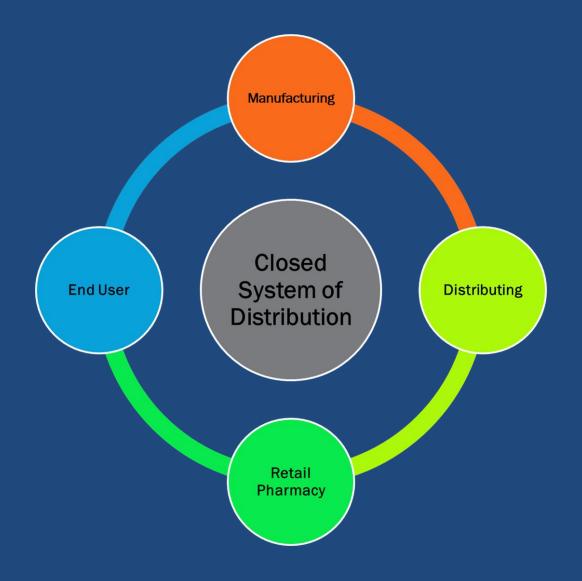
License Statistics

As of July 1, 2015, there are 6,365 licensed Veterinarians in New York State, and 4,679 licensed Veterinarian Technicians.

There are 94,548 licensed Physicians in New York State, and 13,621 Physician Assistants.

DEA does not register Veterinarian Technicians.

Closed System of Distribution



Diversion Field Offices



Diversion Field Offices

DEA New York Division

New York Field Division



DEA Registration Requirements

Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§1301.22 through 1301.26. Except as provided in paragraph (b) of this section, only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

Veterinary Mobility Act



U. S. Department of Justice Drug Enforcement Administration

www.dea.gov

Springfield, Virginia 22152 FEB 2 5 2016

Dear Registrant:

This correspondence outlines the policy of the Drug Enforcement Administration (DEA) regarding the *Veterinary Mobility Act of 2014*, which became effective on August 1, 2014. It is the DEA's position that the new law should be interpreted exactly as it is written.

The Veterinary Medicine Mobility Act of 2014 amended section 302(e) of the Controlled Substances Act. Title 21, United States Code, Section 822(e) (21 U.S.C. § 822(e)) to address separate registration requirements for veterinarians. Specifically, the Act states that a "registrant who is a veterinarian shall not be required to have a separate registration in order to transport and dispense controlled substances in the usual course of veterinary practice at a site other than the registrant's registered principal place of business or professional practice, so long as the site of transporting and dispensing is located in a State where the veterinarian is licensed to practice veterinary medicine and is not a principal place of business or professional practice."

A non-office setting that the veterinarian visits to treat animals on an occasional, as-needed basis would not be a principal place of business or professional practice. Although the following is not the only example covered by 21 U.S.C. § 822(e)(2), a prime example is that a veterinarian may dispense controlled substances while making "house calls" (e.g., at a stable) without being registered at that location. And, in such a scenario, the veterinarian **does not need to be registered with the DEA in the State where the dispensing occurs**, as long as the veterinarian is registered in some other State and is licensed to practice veterinary medicine in the State where the dispensing occurs.

Should you have any questions pertaining to this matter, please contact your local DEA Field office, or you may contact the DEA Office of Diversion Control, Liaison and Policy Section, at (202) 307-7297.

Louis J. Millione Deputy Assistant Administrator Office of Diversion Control

DEADIVERSION.USDOJ.GOV

Registrants will receive renewal notifications approximately 60 days prior to the registration expiration date. DEA Form 224a may be mailed, as applicable, to registrants; if any registered person does not receive such notification within 45 days before the registration expiration date, the registrant must promptly give notice of such fact and may request such forms by writing to the Registration Section, Drug Enforcement Administration.

Diversion Website



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



What's New

30-Day Notice (Extension): Reports of Regulated Transactions Involving Extraordinary Quantities, Uncommon Methods of Payment, and Unusual/Excessive Loss or Disappearance, and Regulated Transactions in Tableting/Encapsulating Machines (April 3, 2015)

30-Day Notice (Extension): Application for Registration Renewal, Affidavit for Chain Renewal (DEA Forms 225, 225a and 225b) (April 3, 2015)

30-Day Notice (Extension): Application for Registration and Application for Registration Renewal (DEA Forms 363 and 363a) (April 3, 2015)

Hospira (March 27, 2015)

Meda Pharmaceuticals, Inc. (March 27, 2015)





Search





Quick Links

ARCOS (Automation of Reports & Consolidated Orders System) Cases Against Doctors Chemical Control Program CSOS (Controlled Substances Ordering System)

http://www.deadiversion.usdoj.go

In The News

DEA FORM 224 – Registration Application

Form-224	APPLICATION FOR REGISTRATION APPROVED OMB NO FORM DEA- Under the Controlled Substances Act Previous editions a	224 (01-08)				
INSTRUCTIONS	 If you have any questions call 800-882-8539 prior to submitting your application. 	o you have other DEA registration numbers?				
MAIL-TO ADDRESS	IMPORTANT: DO NOT SEND THIS APPLICATION AND APPLY ON-LINE. L NO L YES Please print mailing address changes to the right of the address in this box. FEE FOR THREE (3) YEARS IS FEE IS NON-REFUNDABLE	\$551				
	PPLICANT IDENTIFICATIION Individual Registration Business Registration					
Name 1 (Las	ist realite of individual -OR- Busiless of Pacificy Name)	lood to the second s				
Name 2 (First	the base and Middle Name of Individual OP, Continuation of Suprementations					
Name 2 (First	rst Name and Middle Name of individual - OR- Continuation of business name)	Peedoo				
Street Address Li	ine 1 (if applying for fee exemption, this must be address of the fee exempt institution)	head				
Address Line 2						
City	State Zip Code	umm Personali				
Incolored and and a	alandarikarkarkarkarkarkarkarkarkarkarkarkarkark	haad				
Business Phone I	Number Point of Contact	1000000				
Laudana da anti-						
Business Fax Nu	Imber Email Address					
DEBT COLLECTION	Social Security Number (if registration is for individual) Tax Identification Number (if registration is for	or business)				
Mandatory pursuant to Debt Collection	Provide SSN or TIN. See additional information note #3 on page 4.	,				
FOR Practitioner	Professional Professional School : Year of Graduation :	TTT				
	National Provider Identification: Date of Birth (MM-DD-YYYY): MM = DD = Y Y Y Y					
SECTION 2 BUSINESS ACTIVITY	Central Fill Pharmacy Practitioner (DDS, DMD, DO, DPM, DVM, or MD)					
Check one business activity	Retail Pharmacy Practitioner Military (DDS, DMD, DO, DPM, DVM, or MD)	lter				
box only	Nursing Home Mid-level Practitioner (MLP) Hospital/Cli	nic				
	Automated Dispensing System (ADS)	stitution				
FOR Automated Dispens (ADS) ONLY:	sing System DEA Registration # OF Retail Pharmacy for this ADS is automatically fee-expension of Retail Pharmacy Skip Section 6 and Section 7 or Skip Section 6 and Section 7 or You must attach a notorized affect.	n page 2.				
SECTION 3 DRUG SCHEDULES	Schedule 2 Narcotic Schedule 3 Narcotic Schedule 4					
Check all that apply	Schedule 2 Non-Narcotic (2N)					
Check this box if you require official order forms - for purchase of schedule 2 controlled substances.						
	NEW - Page 1					

DEA APPLICATION – Page 2

SECTION 4 STATE LICENSE(S)	You MUST be currently authorized to prescribe, distribute, dispense, conduct research, or othe in the schedules for which you are applying under the laws of the state or jurisdiction in which	erwise handle the controlled substances you are operating or propose to operate.					
Be sure to include both state license numbers if applicable	State License Number	Expiration / /					
if applicable	State Controlled Substance License Number (if required)	Expiration / /					
	(if required) What state issued the license(s)?	MM - DD - YYYY					
Puerto Rico ONLY	Puerto Rico College of Physicians License Number	Expiration / /					
SECTION 5	as the applicant ever been convicted of a crime in connection with controlled substance(s) und	YES NO					
LIABILITY OF	is any such action pending?	ler state or federal law,					
	IMPORTANT Date(s) of incident MM-DD-YYYY:						
this section must	as the applicant ever surrendered (for cause) or had a federal controlled substance registration stricted, or denied, or is any such action pending? ate(s) of incident MM-DD-YYYY:	levoked, suspended, La La					
3. Ha	as the applicant ever surrendered (for cause) or had a state professional license or controlled su	ubstance registration					
	voked, suspended, denied, restricted, or placed on probation, or is any such action pending? ate(s) of incident MM-DD-YYYY:	YES NO					
4. If pa co re re	the applicant is a corporation (other than a corporation whose stock is owned and traded by the intreship, or pharmacy, has any officer, partner, stockholder, or proprietor been convicted of a introlled substance(s) under state or federal law, or ever surrendered, for cause, or had a federa gistration revoked, suspended, restricted, denied, or ever had a state professional license or co gistration revoked, suspended, denied, restricted or placed on probation, or is any such action p	e public), association, crime in connection with					
Da	ate(s) of incident MM-DD-YYYY: Note: If question 4 does not It will slow down processing	ot apply to you, be sure to mark 'NO'. g of your application if you leave it blank.					
EXPLANATION OF "YES" ANSWERS	Liability question # Location(s) of incident:						
Applicants who have answered "YES" to any of the four questions above must provide a statement to explain each "YES" answer.	Nature of incident:						
Use this space or attach a separate sheet and Disposition of incident: return with application							
	IPTION FROM APPLICATION FEE this box if the applicant is a federal, state, or local government official or institution. Does not ap	ply to contractor-operated institutions.					
ELEVEN .	or Facility Name of Fee Exempt Institution. Be sure to enter the address of this exempt instit						
The undersigned hereby certifies that the applicant named hereon is a federal, state or local government official or institution, and is exempt from payment of the application fee.							
CERTIFIER	Signature of certifying official (other than applicant) Dat	e					
Provide the name and phone number of the certifying official	Print or type name and title of certifying official Tele	ephone No. (required for verification)					
SECTION 7	Check See page 4 of instructions for important information.						
METHOD OF PAYMENT		Mail this form with payment to:					
Check one form of payment only	Credit Card Number Expiration Date	U.S. Department of Justice Drug Enforcement Administration					
		P.O. Box 28083 Washington, DC 20038-8083					
Sign if paying by credit card	Signature of Card Holder	FEE IS NON-REFUNDABLE					
	Printed Name of Card Holder						
SECTION 8	I certify that the foregoing information furnished on this application is true and correct.						
APPLICANT'S SIGNATURE Sign in ink	Signature of applicant (sign in ink)	Date					
	Print or type name and title of applicant						
	WARNING: Section 843(a)(4)(A) of Title 21, United States Code states that any person who knowingly or in fraudulent information in the application is subject to imprisonment for not more than four years, a fine of no NEW - Page 2	tentionally furnishes false or t more than \$30,000, or both.					
	THEFT THE PARTY OF						

DEA.Registration.Help@usdoj.gov

- Office of Diversion Control (DEA Headquarters) Diversion Field Office Locations Locate Field Registration Specialists Viailing Addresses for Topics Related to the Title 21 Code of Federal Regulations Submit a Tip to DEA Tactical Diversion Squads Customer Service Plan (January 2010) Meetings & Events Privacy Notice Nhat's New
- EPCS@usdoj.gov (Electronic Prescriptions)

DIVERSION CONTACT INFORMATION

HQ Mailing Address

Drug Enforcement Administration Attn: Registration Section/ODR PO Box 2639 Springfield, VA 22152-2639 **HQ** Registration Call Center (800) 882-9539 8:30 am-6:00 pm EST **Email Address:** www.DEADIVERSION.USDOJ.GOV

New York Division Office

New York Division Office 99 10th Ave New York, NY 10011 Phone 1: (877) 883 5789 Phone 2: (212) 337 1593 Phone 3: (212) 337 1594

Phone 1: (212) 337 3900 Fax 1: (212) 337 1536

DEA REGISTRATION

Practitioner, Schedules II–V New–224 Renewal– 224a (Fee is \$731 for 3 years) May conduct research and instructional activities with those substances for which registration was granted, including administering, procuring, dispensing, and prescribing.

May distribute expired medication to a reverse distributor.

Mid-Level Practitioners

Under the Controlled Substance Act (CSA), the term "mid-level practitioner" (MLP) means an individual practitioner other than physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or jurisdiction in which he/she practices, to dispense administer, and prescribe a controlled substance in the course of professional practice.

Examples include:

Nurse Practitioners Physician Assistants Optometrists Registered Pharmacist Medical Psychologist Nursing Home Homeopathic Physician Naturopathic Physician Doctors of Oriental Medicine Ambulance Service ANIMAL SHELTER EUTHANASIA TECHNICIANS Registration with DEA is not required for a MLP who only administers controlled substances on behalf of a registered practitioner so long

as the activity is in the practitioner's presence.

applications for research in Schedule I substances

Section 1301.32 Action on applications for research in Schedule I substances

(a) In the case of an application for registration to conduct research with controlled substances listed in Schedule I, the Administrator shall process the application and protocol and forward a copy of each to the Secretary of Health and Human Services (Secretary) within 7 days after receipt. The Secretary shall determine the qualifications and competency of the applicant, as well as the merits of the protocol (and shall notify the Administrator of his/her determination) within 21 days after receipt of the application and complete protocol, except that in the case of a clinical investigation, the Secretary shall have 30 days to make such determination and notify the Administrator. The Secretary, in determining the merits of the protocol, shall consult with the Administrator as to effective procedures to safeguard adequately against diversion of such controlled substances from legitimate medical or scientific use.

CI Research

(b) An applicant whose protocol is defective shall be notified by the Secretary within 21 days after receipt of such protocol from the Administrator (or in the case of a clinical investigation within 30 days), and he/she shall be requested to correct the existing defects before consideration shall be given to his/her submission.

(c) If the Secretary determines the applicant qualified and competent and the research protocol meritorious, he/she shall notify the Administrator in writing of such determination. The Administrator shall issue a certificate of registration within 10 days after receipt of this notice, unless he/she determines that the certificate of registration should be denied on a ground specified in section 304(a) of the Act (21 U.S.C. 824(a)). In the case of a supplemental protocol, a replacement certificate of registration shall be issued by the Administrator.

Research CI

(d) If the Secretary determines that the protocol is not meritorious and/or the applicant is not qualified or competent, he/she shall notify the Administrator in writing setting forth the reasons for such determination. If the Administrator determines that grounds exist for the denial of the application, he/she shall within 10 days issue an order to show cause pursuant to **Sec. 1301.37** and, if requested by the applicant, hold a hearing on the application pursuant to **Sec. 1301.41**. If the grounds for denial of the application include a determination by the Secretary, the Secretary or his duly authorized agent shall furnish testimony and documents

Section 1301.24

(e) Supplemental protocols will be processed in the same manner as original research protocols. If the processing of an application or research protocol is delayed beyond the time limits imposed by this section, the applicant shall be so notified in writing.

Research - CI

RESEARCHER REGISTRATIONS FOR SCHEDULE I CONTROLLED SUBSTANCES

In addition to the routine application process, applicant must also supply a research protocol

Prior to issuing a new registration, the protocol is coordinated with and must be approved by the Food and Drug Administration (FDA).

The registration is issued only after receiving a report of investigation from the responsible DEA Field Office and approval from the FDA on the protocol.

If the study in the protocol is completed and/or the researcher wishes to do other Schedule I research under the same registration, the new protocol is treated the same as an application for registration (same approvals must be done).

REGISTRANT REGISTRATION FEES

Registration Fee Schedule

DEA is authorized by 21 U.S.C. 821 to collect "reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and to the registration and control of regulated persons and of regulated transactions."

REGISTRANT REGISTRATION FEES AS OF FEES AS OF TYPE PERIOD :

RETAIL REGISTRANTS 3 YEARS \$ 731 Manufacturer CS/Chemical 1 Year \$ 3,047 Distributor CS/Chemical 1 Year \$1,523 Reverse Distributor 1 Year \$ 1,523 Researcher 1 Year \$ 244 Analytical Lab 1 Year \$ 244 Importer CS/Chemical 1 Year \$ 1,523 Exporter CS/Chemical 1 Year \$ 1,523 NTP 1Year \$ 244

FALSIFICATION OF APPLICAITON

Willful material falsification of an application is grounds for revocation or denial as well as a violation of 21 U.S.C. § (a)(4). An application on which information has been omitted, such as questions pertaining to state registration, felony conviction, suspension, revocation, or denial of application, should be returned to the applicant. An application reaching the field, which does not contain all pertinent information, should not be processed until a signed statement regarding the issue is obtained from the applicant.

LIABILITY QUESTIONS

SECTION 5			YES	NO
LIABILITY	1.	Has the applicant ever been convicted of a crime in connection with controlled substance(s) under state or federal law, or is any such action pending?		
		Date(s) of incident MM-DD-YYYY:	YES	NO
	2.	Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted, or denied, or is any such action pending?	0	
All questions in this section must be answered.		Date(s) of incident MM-DD-YYYY:	YES	NO
	3.	Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?	0	
		Date(s) of incident MM-DD-YYYY:	YES	NO
	4.	If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder, or proprietor been convicted of a crime in connection with controlled substance(s) under state or federal law, or ever surrendered, for cause, or had a federal controlled substance registration revoked, suspended, restricted, denied, or ever had a state professional license or controlled substance registration revoked, suspended, restricted or placed on probation, or is any such action pending?		
		Date(s) of incident MM-DD-YYYY: Note: If question 4 does not apply to you, be sure to n It will slow down processing of your application if you li	nark 'N eave it	10'. blank
EXPLANATION O		Liability question # Location(s) of incident:	-	
Applicants who ha answered "YES" to any of the four que above must provi a statement to ex each "YES" answ	o estic ide cpla			
Use this space or a separate sheet a return with applica	and	Disposition of incident:		

Exemption of Agents, Employees, Affiliated Practitioners

The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his/her business or employment.

(b) An individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner) registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself.

Exemption Continued

An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that: (1) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice; (2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she is practicing; (3) The hospital or other institution by whom he/she is employed has verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within the jurisdiction; (4) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution; (5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO123456-10 or APO123456-A12); and (6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.

Import or Export for Personal Use

Any individual who has in his/her possession a controlled substance listed in schedules II, III, IV, or V, which he/she has lawfully obtained for his/her personal medical use, or for administration to an animal accompanying him/her, may enter or depart the United States with such substance notwithstanding sections 1002-1005 of the Act (21 U.S.C. 952-955), provided the following conditions are met:

(a) The controlled substance is in the original container in which it was dispensed to the individual; and (b) The individual makes a declaration to an appropriate official of the Bureau of Customs and Border Protection stating:

(1) That the controlled substance is possessed for his/her personal use, or for an animal accompanying him/her; and (2) The trade or chemical name and the symbol designating the schedule of the controlled substance if it appears on the container label, or, if such name does not appear on the label, the name [[Page 36]] and address of the pharmacy or practitioner who dispensed the substance and the prescription number. (c) In addition to (and not in lieu of) the foregoing requirements of this section, a United States resident may import into the United States no more than 50 dosage units combined of all such controlled substances in the individual's possession that were obtained abroad for personal medical use. (For purposes of this section, a United States resident is a person whose residence (i.e., place of general abode—meaning one's principal, actual dwelling place in fact, without regard to intent) is in the United States.) This 50 dosage unit limitation does not apply to controlled substances lawfully obtained in the United States pursuant to a prescription issued by a DEA registrant

Export Exemption

Export Waiver for International Humanitarian/Veterinarian Charitable Assistance

The Drug Enforcement Administration (DEA), Office of Diversion Control, has established this link for DEAregistered practitioners* requesting a waiver of applicable federal requirements in order to legally export controlled substances from the U.S. for use in treatment procedures involving an international humanitarian or veterinarian charitable mission.

Please complete the checklist below and send it via email to or via facsimile at 202-307-4702. The approval of a waiver request is handled on a case-by-case basis.

Group Practice

When a group practice is licensed by a state as a hospital/clinic (Class 3) to practice medicine, DEA may also register the practice as a hospital/clinic. In group practice situations, one primary practitioner may register with DEA and the others in the practice may act as agents of the registrant when they administer or dispense controlled substances from a common stock. However, all practitioners who prescribe controlled substances must register with DEA. A secondary physician may also register at the business location to serve as a backup in the event the primary practitioner discontinues his/her professional practice or dies. When multiple practitioners dispense from a common stock, the primary registered practitioner should impose additional inventory requirements as a means of ensuring that the practice is maintaining adequate records and security. State requirements may be more restrictive.

Group Practice Prescriptions/Dispensing

- All prescribing Veterinarians must have a DEA registration.
- Multiple Veterinarians can be listed on a prescription, but the prescriber must list his or her DEA registration number.
- A Veterinarian must be registered to prescribe a controlled substance, but may administer or dispense in a group practice.

Military Veterinary Clinic

A. A military veterinary clinic is required to register with DEA only if it purchases controlled substances from commercial sources. A military veterinary clinic that purchases controlled substances exclusively from the Defense Logistics Agency (DLA), formerly the Defense Supply Agency, is exempt and does not require DEA registration.

B. DEA requires military veterinarians to have their own DEA registration number if they expect the civilian pharmacies to fill their prescriptions. Also, a number of states require state licensure of military veterinarians who write prescriptions to be filled outside the military installation at which they practice.

Licensing Actions

New York's Professional Misconduct Enforcement System Complaint Hot Line: 1-800-442-8106 or conduct Onvention http://www.op.nysed.gov/prof/

Recordkeeping

- Prescriptions
- Drug Disposal
- Drug Procurement DEA Order Forms/Supplier Invoices
- Inventories
- Dispensing/Administering
- Termination of practice
- Drug Thefts/Losses

Prescriptions

Practitioners Who Dispense, Prescribe, or Administer Controlled Substances

Title 21 generally defines when an individual practitioner must keep records documenting his/her handling of controlled substances. Title 21 C.F.R. § 1304 05 (b) and 21 C.F.R. § (c) provide guidance to the practitioner on what records he/she is required to generate and maintain when controlled substances are dispensed, including samples. Title 21 releases the practitioner from generating and maintaining records regarding his/her prescribing of controlled substances in schedules II-V, unless the practitioner is prescribing these controlled substances in the course of opioid maintenance or detoxification treatment of an individual. Title 21 C.F.R. § 1304 CE (d) outlines the conditions under which a practitioner must generate and maintain records documenting his/her administering of controlled substances in schedules II-V.

Prescriptions

- CII 90 day supply (1306.12(b) http://www.health.ny.gov/professionals/narcoti c/
- Prescribing from 2nd location
- Prescribing CIII-V 5 refills, 6 months
- Emergency RXS (1306.11(d)(1-4)
- Electronic Prescriptions (1306.08)
- Prescriptions not for office use (1306.04(b))
- Fax Prescriptions

Drug Disposal

Practitioners shall continue to record the destruction of pharmaceutical wastage in accordance with 21 C.F.R. § 1304.22(c), and that the new disposal regulations contained in Part 1317 do not alter a practitioner's existing obligations to destroy pharmaceutical wastage in accordance with applicable Federal, State, tribal, and local laws and regulations (e.g., environmental, hazardous/biohazard, and other safety-related laws and regulations).

Drug Disposal

The disposal of practitioner *inventory* (as opposed to pharmaceutical wastage) shall be accomplished in accordance with the new disposal requirements of Part 1317. For example, controlled substances contained within multi-dose vials remain part of the practitioner's inventory.

REVERSE DISTRIBUTORS

ARIZONA Environmental Pharmaceuticals, LLC – (480) 659-9611 **CALIFORNIA** EXP Pharmaceutical Services Corporation – (510) 476-0909 Far West Returns – (916) 524-6465 Outdate Rx, LLC – (909) 335-7071 **FIORIDA** CAVU Medical Products and Services LLC DBA Pharmatech Services – (813) 749-7113 **Clean Harbors Florida LLC – (863) 519-6363** PharmaLink – (800) 257-3527 RX Return Services – (727) 754-7848 **Rx Reverse Distributors Inc.** – (772) 388-1212 Woodfield Distribution, LLC – (561) 998-3885 GEORGIA Burke Horton, Inc. D/B/A The Rx Exchange – (678) 306-1866 Danox Environmental Services Inc. – (404) 671-9163 Maximum Rx Credit – (770) 985-2136 **Return Logistics – (912) 748-5100** Stericycle, Inc. – (678) 684 1541 Zinvictus, Inc. – (770)-702-0446

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Zinvictus, Inc. – (770)-702-0446
ILLINOIS
Pharma Logistics – (847) 837-1224
Pharmaceutical Returns Services – (800) 215-5878
Progressive Returns – (773) 622-9584
Qualanex, LLC – (800) 505-9291
INDIANA
Stericycle Inc. – (317) 860-1200
IOWA
National Pharmaceutical – (515) 252-7722
MICHIGAN
Drug & Laboratory Disposal, Inc. – (269) 685-9824
EQ Detroit Inc. – (313) 347-1350 Great Lakes Clean Water Org. – (989) 736-8179
Nortru LLC – (313) 824-5840
U S Industrial Technologies, Inc. – (734) 462-4100
MINNESOTA
E Z Pharmacy Returns, LLC – (800) 440-0613
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NEW JERSEY
Advanced RX Returns D/B/A Omega 2000 RX Returns – (201) 222-3800
NEW YORK
Ark Business Services Inc. Ark RX Returns Solutions – (347) 590-2779
Devos Ltd. DBA Guaranteed Returns – (631) 689-0191 Devos Ltd. D/B/A Guaranteed
Returns – (631) 689-0191
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NORTH CAROLINA
ALMAC Clinical Services, Inc. ALMAC Clinical Services LLC – (919) 479-8850
Assured Waste Solutions, LLC – (704) 865-7550
Pharmaceutical Dimensions – (336) 664-5287
OHIO
Achieva Group Returns, Inc. – (513) 474-9900 Environmental Enterprises Inc. – (513)
541-1823 Heritage Thermal Services Inc. – (330) 385-7336
OKLAHOMA
Total Returns – (580) 276-3056
PENNSYLVANIA
Chesapeake Waste Solutions – (717) 653-8882
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Complete RX Returns DBA CRX – (570) 706-9589 HDS Returns LLC – (724) 856-7049 Pharmareturns – (215) 653-7400 Prestigious RX Returns DBA PRX Returns – (570) 408-9260 Republic Environmental Systems (Pennsylvania), LLC – (215) 822-8995 Pharmaceutical Credit Company, LLC – (800) 624-5926 Clean Harbors Tennessee LLC Medsafe Waste LLC – (615) 431-2966 Pharma-Mate Inc D/B/A Returnco – (706) 250-4831 Quality RX Returns, LLC – (865) 223-5468 Reliable Pharmaceutical Returns, LLC – (615) 361-8856 Return Solutions – (865) 675-1355

Med-Turn, Inc. – (817) 868-5300 Philip Reclamation Services-Stericycle Environmental Solutions, Inc. – (713) 679-2300 Sharps Compliance, Inc. – (903) 693-2525 Clean Harbors Aragonite – (435) 884-8100 National Products Sales – (801) 972-4132 P.S. Industries Inc. – (206) 749-0739

Capital Returns, Inc. DBA Genco Pharmaceutical Services – (414) 967-2800 Veolia ES Technical Solutions, LLC – (262) 255-6655

DEA Order Form 222

§1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.
Either a DEA Form 222 or its electronic equivalent is required for each procurement/distribution of a Schedule I or II controlled substance.

§1305.05 One or more individuals may be authorized Power of Attorney to issue orders pursuant to a DEA Order Form

DEA Form 222 (Controlled Substance Order Form)

See Reverse of PURCHASER'S Copy for Instructions	No order form may be is	sued for Schedule I and II substances unless a rm has been received, (21 CFR 1305.04).	OMB APPROV	
TO: (Name of Supplier)		STREET ADDRESS	No. 1117-0010	
CITY and STATE	DATE	Design and the state of the state of the	augustistist	后的
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Date Issued DEA Registration No	Name and Address of	Registrant 777		1.5
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	SUPPLIER'S C	opy 1		

Supplier Invoices

§1304.22(c) Records for dispensers. Each person registered or authorized to dispense controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.

Inventories

- Inventory Requirements 1304.04;11
- Biennial/Initial Inventory 1304.11c every 2 years
- Inventory BOB/COB 1304.11a
- Inventory keep for 2 years 1304.04a

Dispensing Records

- §1304.22(c) Records for dispensers
- Title 21 C.F.R. § 1004 OF (d) outlines the conditions under which a practitioner must generate and maintain records documenting his/her administering of controlled substances in schedules II-V.

Termination of practice 1301.52

- 1. Notification
- 2. Address Modification
- 3. Termination of Practice
- Transfer Upon Discontinuation of Business -14 day notice

Drug Thefts/Losses

1301.76 b - The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft.

DEA Form 106 (Theft and Loss Report)

Enforcement Administration.				1.1						to the Drug	OMB APPROVAL		
Complete the front and back of th Retain the triplicate copy for your				ward the or may also re	iginal and o quire a cop	suplica by of t	ate copi his repo	es to the ort.	neares	t DEA Office.	No. 1117-0001		
Name and Address of Registrant (In	iclude i	ZIP Code)					z	P CODE		2. Phone I	No. (Include Area Code)		
DEA Registration Number			4. 1	Date of Theft	orLoss	5.	Princip	al Busines	is of Re	gistrant (Chec	k one)		
2 ltr. prefix 7 digit s	uffix						1	Pharma Practiti			Distributor Methadone Program		
							3	Manufa	cturer	7	Other (Specify)		
County in which Registrant is Located		s theft rep Police?	orted	8. Nam	e and Telep	hone				ment (Include)	Area Code)		
	_												
Number of Thefts or Losses Regist	rant		_	ft or Loss (Check one	and co	omplete	items bei	ow as a	ppropriate)			
has Experienced in the Past 24 Mo	nths	1	Night E	ireak-in	3 🗌 E	Imploy	yee Plifi	erage		Other (
		2	Armed	Robbery	4 🗖 0					Lost in	transit (Complete Item 14)		
1. If Armed Robbery, was Anyone:				12. Purchase value controlled subst							ny pharmaceuticals or andise taken?		
Killed? No Yes (How many) Injured? No Yes (How many)			— s							No Yes (Est. Value)			
IF LOST IN TRANSIT, COMPLETE													
Name of Common Carrier			B. Nan	ne of Consig	nee				C .	Consignee's I	DEA Registration Number		
Was the carton received by the cus	tomer?		E. If re	ceived, did i	It appear to	be tar	mpered	with?	F. 1	Have you exp	erienced losses in transit		
Yes No							from this same carrier in the past?						
5. What identifying marks, symbols,	or price	codes w	ere on t	_			that wo	uid assist					
If Official Controlled Substance Or	der Fo	ms (DEA-	222) we	re stolen, gi	ive number:	s.							
. What security measures have been	n taker	to prever	it future	thefts or los	ses?								
PRIVACY A	CTINF	ORMATIC	N			in ac	cordan	ce with th	e Pape	rwork Reduct	tion Act of 1995, no person is mation unless it displays a		
AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513). PURPOSE: Report theft or loss of Controlled Substances.					valid OMB control number. The Valid				The Valid OM				
UTINE USES: The Controlled Subs special reports required for statistica	al and a	analytical p	purpose	s. Disclosu	re of	colle	ction of	Informati	on is es	stimated to a	verage 30 minutes per Instructions, searching		
information from this system are ma purposes stated:						exist	ling data	a sources	gather	ring and main	itaining the data needed, and f information.		
A. Other Federal law enforcement a and regulatory purposes.													
 State and local law enforcement and regulatory purposes. 			-										
FECT: Failure to report theft or loss penalties under Section 402 and	403.0	the Contract	ustance miled S	s may resul ubstances A	uni et								

Trade Name of Substance or Preparation		NDC Number	Name of Controlled Substance In Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen Express Quantity In Dosage Units, or Milliters for Liquids	
Examples	Desoxyn	00074-3377-01	Methamphetamine Hydrochloride	5 mg	Tablets	300	
	Demerol	00409-1181-30	Meperidine Hydrochioride	50 mg/ml	Vial	150 ml	
Robitussin A-C		00031-8674-25	Codeline Phosphate	2 mg/cc	Liquid	5676 ml	
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Title

Sign and Print Name

-

Date

DRUG THEFT/LOSS

DRUG THEFT/LOSS

Effective October 28, 2008, the electronic **DEA Form-106** (Report of Theft or Loss of Controlled Substances) has been updated to include the **National Drug Code (NDC)** number. The NDC number identifies the manufacturer, product, dosage form, and package size.

For registrants who submit DEA 106 electronically, the entry of the NDC number will prompt the system to auto-populate additional fields to include the dosage form, dosage strength, and quantity per container.

Inclusion of the NDC number of the drug products that are lost or stolen will improve the accuracy and quality of the data contained in the Drug Theft Database, and will permit better accounting for lost or stolen controlled substances. Overall, this provision will significantly reduce the number of errors by the registrant and establish a more accurate database for the internal use.

Labeler Code Product Code Package Code

(5 digits) (3 or 4 digits) (2 digits) 63539 0014 61

Legitimate Medical Purpose

§1306.04 Purpose of issue of prescription.

(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 <u>usual course of his professional</u> <u>practice</u>

Administrative Action

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Order to Show Cause

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has <u>materially falsified</u> any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been <u>convicted of a felony</u> under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his <u>State license or registration suspended, revoked, or denied</u> by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 823 of this title inconsistent with the <u>public interest</u> as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of title 42.

Immediate Suspension Order

824(d) Suspension of registration in cases of imminent danger

The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 823(g)(1) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

Illegal Distribution

§841. Prohibited acts A

(a) Unlawful acts

Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.



Controlled Prescription Drugs (CPDs)

MIAMI NEWS July 9, 2014 Pensacola Veterinarian Arrested for Fraudulent Prescriptions

JUL 09 (TALLAHASSEE, Fla.) – Mark R. Trouville, Special Agent in Charge, Drug Enforcement Administration (DEA), Miami Field Division (MFD), announced yesterday that Dr. Michael Windley, a veterinarian at the Companion Animal Clinic, 470 Highway 29 South, Cantonment, Florida was arrested on state drug charges consisting of four counts of possession, delivery, and manufacture of a controlled substance (893.13.1a) and four counts of fraud in obtaining prescriptions (893.30). According to the arrest warrant, in August 2013, DEA received a call from pharmacist regarding the suspicious prescribing activities by Dr. Michael Windley. During an investigation, DEA learned that Dr. Windley was fraudulently obtaining methadone by writing prescriptions in the name of his ex-wife's dog and filling the prescriptions at various pharmacies within the Pensacola area and then providing the drugs to his ex-daughter-in-law. The records show that between December 11, 2012 and February 7, 2014, Dr. Windley filled 30 prescriptions (total of 5400 tablets) for methadone. This investigation was conducted by the DEA MFD, Pensacola Resident Office, Tallahassee Diversion Group. This case is being prosecuted by the Office of

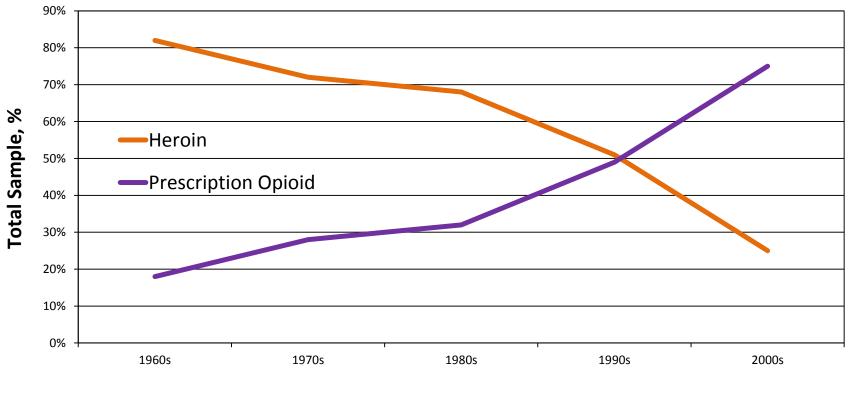
the State Attorney, First Judicial Circuit.

Heroin, prescription pain pills top drug threat in the US

WASHINGTON (AP) — Heroin and prescription pain pills are among the top drug threats in the U.S., according to the Drug Enforcement Administration's latest drug threat assessment Wednesday. Chuck Rosenberg, the DEA's acting administrator, said there were more than 46,000 drug overdoses in 2013. About half were from prescription drugs and about 8,000 more from heroin, he said. "Sadly this report confirms what we've known for some time," Rosenberg told reporters. The DEA's 2015 National Drug Threat Assessment found that heroin is most popular among drug users in the Northeast and Midwest, though availability of the potent street drug has increased across the country and use rose by about 50 percent between 2013 and 2014. Seizures of the drug nearly doubled between 2010 and 2014, from 2,761 kilos to 5,013 kilos. Rosenberg said the U.S. heroin market is supplied largely by Mexico's powerful and violent drug cartels. Methamphetamine, also supplied by Mexican drug cartels, was listed as another top drug threat by the DEA. One positive trend, Rosenberg said, was the declining use and availability of cocaine. In 2014, cocaine availability stabilized at "new normal" levels "well below availability levels observed prior to 2007." That was the first year that drug agents noted a significant decline in cocaine availability.

Prescription Opioids to Heroin

Percentage of the Total Heroin-Dependent Sample That Used Heroin or a Prescription Opioid as Their First Opioid of Abuse

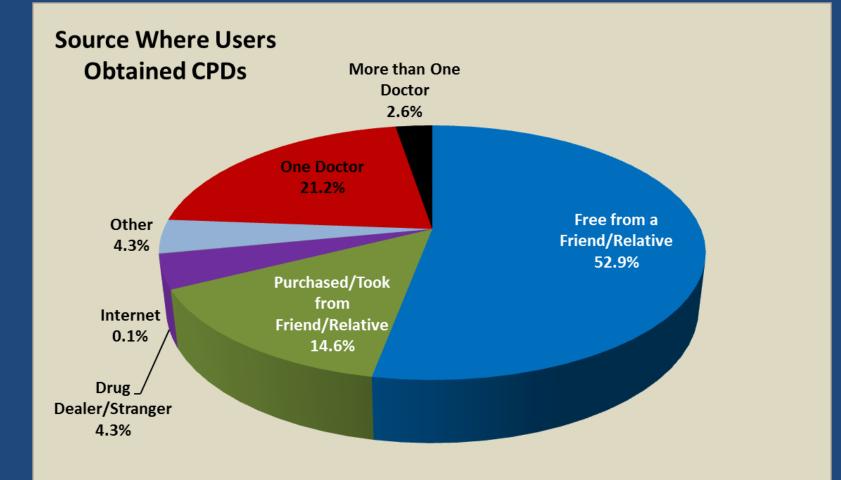


Decade of First Opioid Abuse

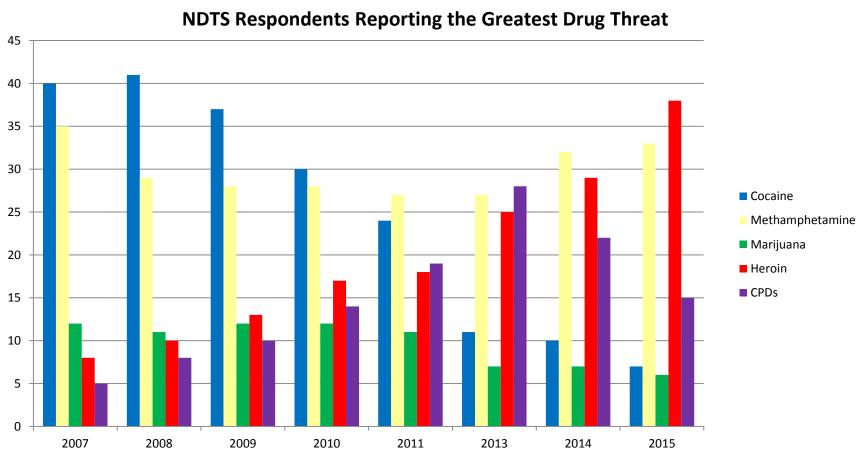
How Users Obtain CPDs

• Friends/Relatives

• Doctors



Heroin Threat Increasing

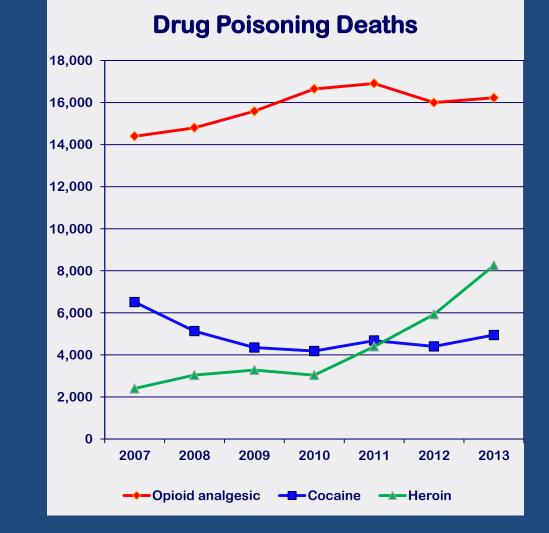


Note: The NDTS was not administered in 2012.

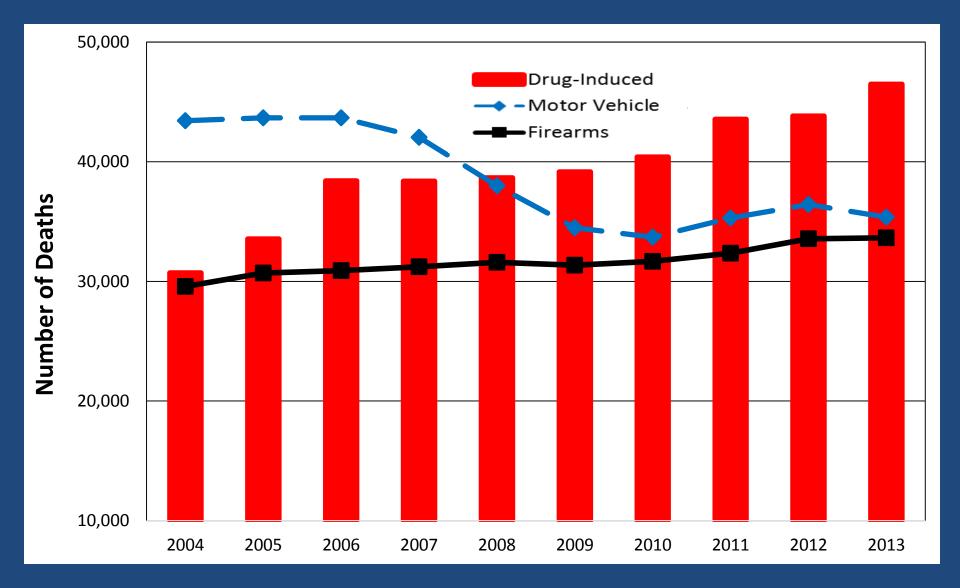
CPD Deaths

Drug poisoning deaths higher than for cocaine and heroin combined

Current use higher than most other drugs

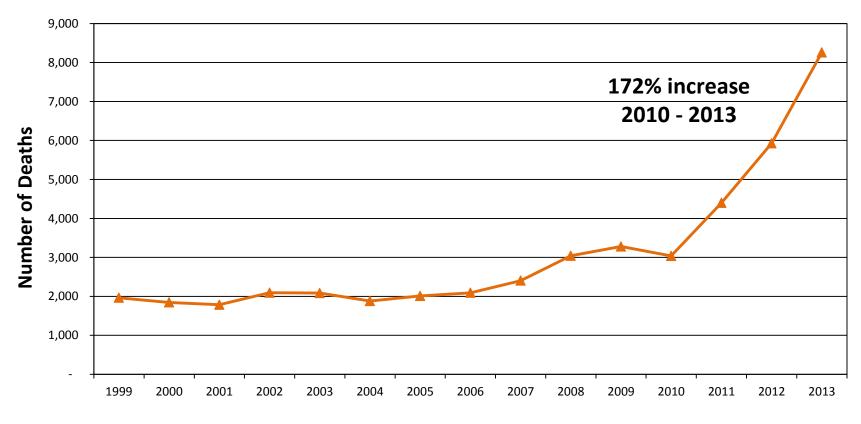


Drug-induced Deaths



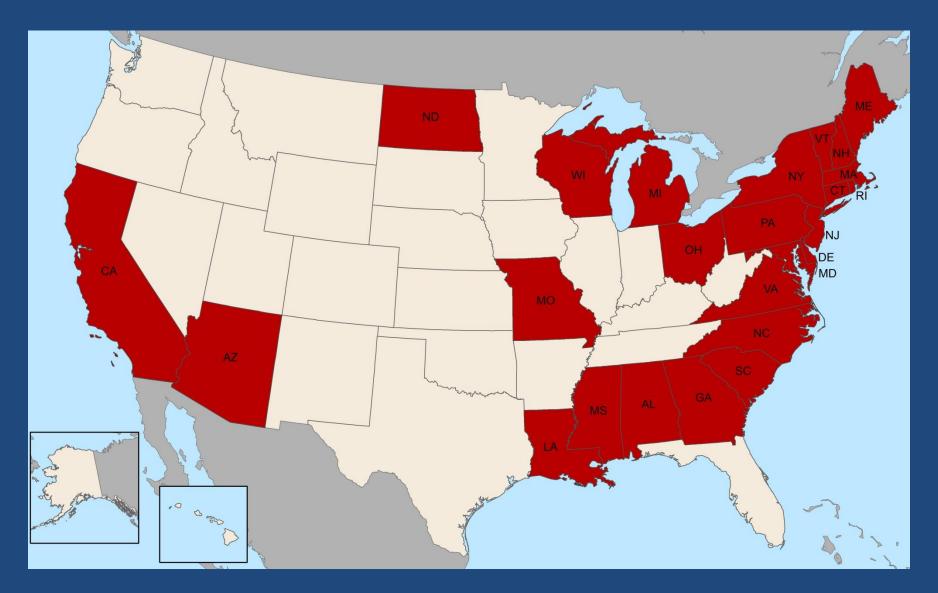
Heroin Overdose Deaths

Drug-poisoning Deaths Involving Heroin, 1999 - 2013



Source: National Center for Health Statistics/CDC

Fentanyl Deaths



More dogs are being poisoned by marijuana

Pets are also at risk. More dogs are being poisoned by marijuana. 2 A Los Angeles Times article on dog poisonings noted that: a Colorado study on the poisoning of dogs living in the state quadrupled after voters legalized "medical" marijuana in 2000; reports from the *Oregonian* newspaper in April 2013 related that cases are on the rise in the Pacific Northwest; and veterinarians in Los Angeles say that they frequently see ingestion cases.177 🛽 Eagle Rock Clinic Emergency veterinarian technician Bruce Castillo says he treats two to three stoner dogs a night. "I see a lot of cases where dogs have been walking in the park and then become lethargic, shaky and disoriented," Castillo said. Most dogs recover, but some do not.178 🛛 Veterinarian Leia Castaneda at the San Gabriel Valley Emergency Pet Clinic in El Monte noted that there was an uptick in her clinic beginning in about 2007. Dogs pick up discarded joints, blunts or buds, gulp down marijuana brownies, or even lick resin off pipes.179 "It's a really bad trip for dogs," veterinarian Paige Lorimer told *Steamboat Today*. Dogs can become very depressed, cry out, or have trouble walking. Their eyes get dilated and red. Their heart rate may slow and they can even become comatose. They may become anxious. Intoxication of animals is abnormal and uncomfortable. There is no antidote for marijuana ingestion in pets and no tests to diagnose it.180

Torbutrol 5mg



Ketamine

Ketamine has been misused as a hallucinogen for almost 30 years with effects similar to those of phencyclidine, but with a much shorter duration. Pre-clinical studies have shown its self-administration and drug discrimination properties, propensity to produce tolerance and observable withdrawals.

Human studies have assessed its subjective effects in recreational users as well as in experimental studies. Ketamine affects perception of body, time, surroundings and reality, producing a 'psychedelic' state of mind that resembles schizophrenic psychosis. It causes a dose related high and a biphasic effect on anxiety. The dissociative experience may discourage some experimental users from continued use. Tolerance to the effects of ketamine develops. Some users take ketamine in a compulsive binging pattern. There is insufficient evidence to show that ketamine causes an abstinence syndrome in humans.

Ketamine

- 4/24/2015 Toronto, CN 60 kgs of Ketamine is seized.
- 11/30/2014 Denver, Co. Senator Udall's son is arrested for possession of Ketamine.
- 2/18/16 Buffalo, NY 25 lbs marijuana, Ketamine, and methamphetamine seized at a traffic stop.
- 10/13/15 500 grams of Ketamine stolen from a Southbridge apt.
- 12/28/15 Indiana, Veterinarian hospitals ketamine stock burglarized.
- 6/3/2015 Central NYS 14 arrests for Ketamine possession.

Security Requirements

§1301.75 Physical security controls for practitioners.

(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(c) Sealed mail-back packages and inner liners collected in accordance with of this chapter shall only be stored at the registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access, except as authorized by the controlled to conduct (d).
(d) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.
(e) Carfentanil etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

Other Security Controls

§1301.76 Other security controls for practitioners.

(a) The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term "for cause" means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

Outlook

CPD availability and abuse will continue to pose a significant drug threat to the United States. Heroin use and overdose deaths are likely to continue to increase in the near term. The drug's increased availability and relatively low cost make it attractive to the large number of opioid abusers (both prescription opioid and heroin) in the United States. Fentanyl will remain a significant threat to as minute amounts can be lethal and, visually, can be mistaken for cocaine or white powder heroin. Ketamine diversion and abuse is trending upward.

Questions?

Stephen Buzzeo, Supervisory Investigator <u>Stephen.M.Buzzeo@usdoj.gov</u> 212-274-4534