

Drug Enforcement Administration Regulations Update

Presenter:

- **Demetra Ashley**, Associate Deputy Assistant Administrator,
United States Drug Enforcement Administration

Moderator:

- **Chad C. Corum**, PharmD, Co-Owner and Pharmacist,
Corum Family Pharmacy, and Member, Operation
UNITE Board of Directors



Disclosures

Demetra Ashley and Chad C. Corum, PharmD, have disclosed no relevant, real, or apparent personal or professional financial relationships with proprietary entities that produce healthcare goods and services.



Disclosures

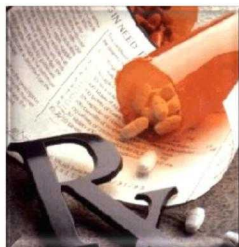
- All planners/managers hereby state that they or their spouse/life partner do not have any financial relationships or relationships to products or devices with any commercial interest related to the content of this activity of any amount during the past 12 months.
- The following planners/managers have the following to disclose:
 - John J. Dreyzehner, MD, MPH, FACOEM – Ownership interest: Starfish Health (spouse)
 - Robert DuPont – Employment: Bensinger, DuPont & Associates-Prescription Drug Research Center



Learning Objectives

1. Define the legal standard for dispensing medications pursuant to a valid Rx.
2. Identify regulations that establish practitioners' legal requirements under 21 USC.
3. List the factors the pharmacist should consider prior to dispensing.
4. Provide accurate and appropriate counsel as part of the treatment team.





2016 RX SUMMIT Atlanta, GA



DEA & PHARMACY: Working Together to Prevent Prescription Drug Abuse



The United States Department of Justice
Drug Enforcement Administration

Demetra Ashley
Associate Deputy Assistant
Administrator
Office of Diversion Control



Mission

The mission of the Office of Diversion Control is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels of distribution

while ...

ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical, commercial, and scientific needs.

U.S. Drug Enforcement Administration
Office of Diversion Control



Closed System of Distribution

The DEA is responsible for:

- the **oversight** of the system
- the **integrity** of the system
- the **protection** of the public health and safety



U.S. Drug Enforcement Administration
Office of Diversion Control



Consequences

From 2000-2014 the rate of unintentional drug overdose deaths in the United States has increased 137%, including a 200% increase in overdose deaths involving opioids.

During this time period nearly half a million (500,000) people have died from drug overdoses.

In 2014, approximately 47,055 unintentional drug overdose deaths occurred--one death every 11.16 minutes.

There were approximately 1½ times more drug overdose deaths in the United States than deaths from motor vehicle accidents.

CDC National Center for Health Statistics/Morbidity and Mortality Weekly Report (MMWR); January 1, 2016



Consequences

In 2014, **61% (28,647)** of these deaths involved some type of opioid, including heroin.

In 2014, CDC indicates that there were about ***19,000** “prescription opioid pain reliever deaths”.

Prescription drug abuse is the fastest growing drug problem in the United States.

**Historically, CDC has programmatically characterized all opioid pain reliever deaths (natural and semisynthetic opioids, methadone, and other synthetic opioids) as “prescription” opioid overdoses. In 2014, a sharp increase in deaths involving synthetic opioids (other than methadone) coincided with law enforcement reports of increased availability of illicitly manufactured fentanyl, a synthetic opioid. However, illicitly manufactured fentanyl cannot be distinguished from prescription fentanyl in death certificate data.*

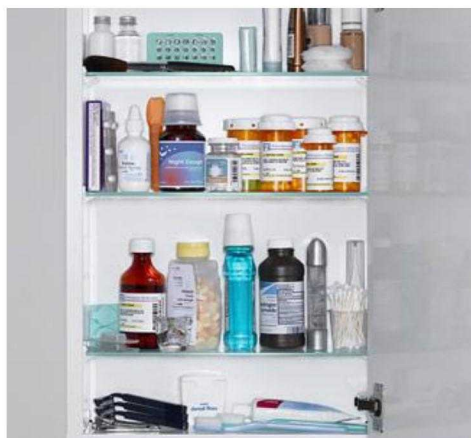
CDC National Center for Health Statistics/Morbidity and Mortality Weekly Report (MMWR); January 1, 2016
*Email: Between CDC (Rudd) and DEA (Prevoznik) 2/18/2016

U.S. Drug Enforcement Administration
Office of Diversion Control



Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family...For Free!!



U.S. Drug Enforcement Administration
Office of Diversion Control



Medicine Cabinets: Easy Access

- More than half of teens (**73%**) indicate that it's easy to get prescription drugs from their parent's medicine cabinet
- Half of parents (**55%**) say anyone can access their medicine cabinet
- Almost four in 10 teens (**38%**) who have misused or abused a prescription drug obtained it from their parent's medicine cabinet

Source: 2013 Partnership Attitude Tracking Study, published 7/23/14

U.S. Drug Enforcement Administration
Office of Diversion Control





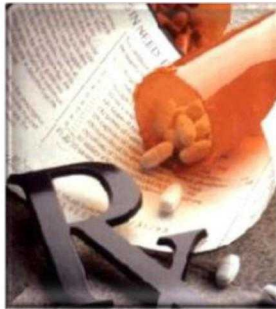
Prescription Drug Abuse
is driven by

**Indiscriminate Prescribing
Criminal Activity**

U.S. Drug Enforcement Administration
Office of Diversion Control



Legal Obligations: DEA Registrant



U.S. Drug Enforcement Administration
Office of Diversion Control

Thank you to US Attorney (David) Hickton and Attorney General (Linda) Kelly for hosting me here today.

Your focus on this issue and the commitment from every one here today are precisely what Pennsylvania needs to address the prescription drug abuse epidemic here, and nationwide.

Prescriptions

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.

21 CFR § 1306.04(a)

United States v Moore 423 US 122 (1975)



U.S. Drug Enforcement Administration
Office of Diversion Control



Corresponding Responsibility

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.

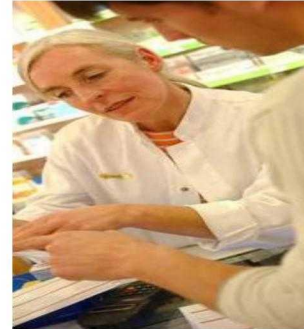
21 CFR § 1306.04(a)



U.S. Drug Enforcement Administration
Office of Diversion Control

Corresponding Responsibility

- A pharmacist, by law, has a corresponding responsibility to ensure that prescriptions are legitimate.
- When a prescription is presented by a patient or demanded to be filled for a patient by a doctor's office, a pharmacist is not obligated to fill the prescription!!!



U.S. Drug Enforcement Administration
Office of Diversion Control



The DEA Response



U.S. Drug Enforcement Administration
Office of Diversion Control

Thank you to US Attorney (David) Hickton and Attorney General (Linda) Kelly for hosting me here today.

Your focus on this issue and the commitment from every one here today are precisely what Pennsylvania needs to address the prescription drug abuse epidemic here, and nationwide.

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

- Enforcement is just as important as....
- Prevention/Education
- Treatment



U.S. Drug Enforcement Administration
Office of Diversion Control



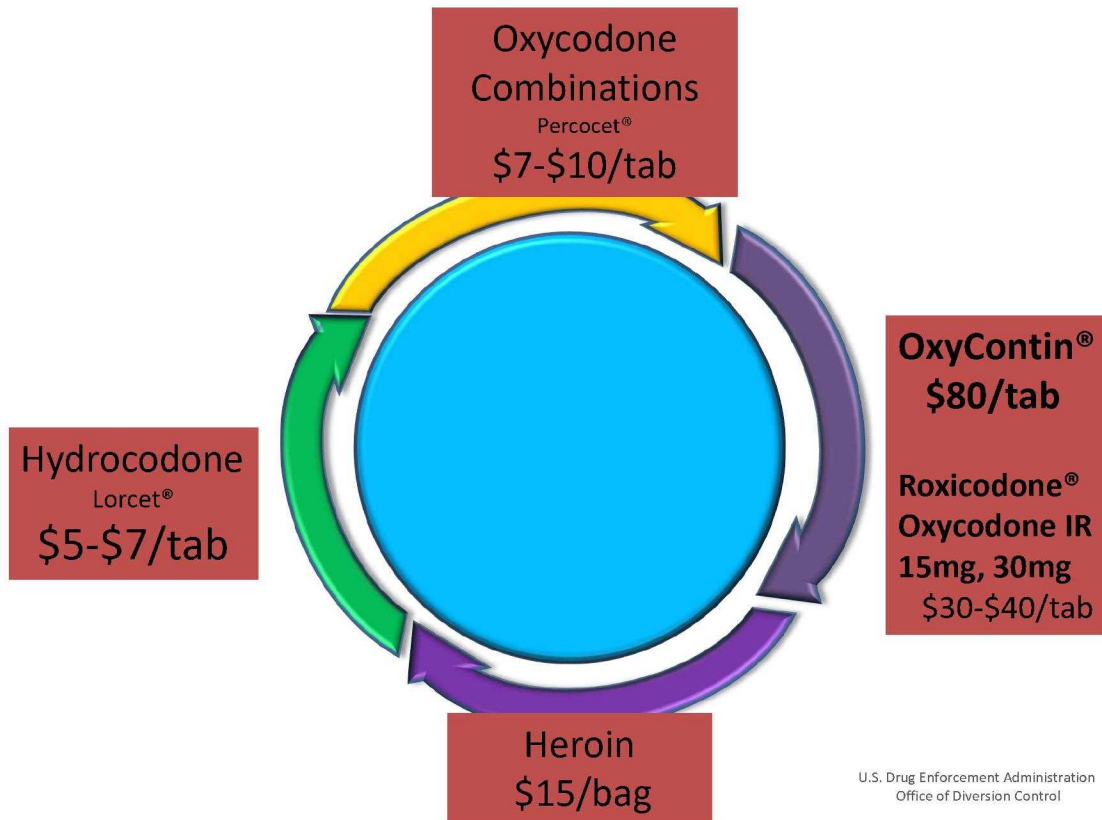
Prescription Opiates v. Heroin



U.S. Drug Enforcement Administration
Office of Diversion Control



Circle of Addiction & the Next Generation





360 Strategy is DEA's plan to deal with this challenge

Law Enforcement/Diversion Control/Community Outreach

Critical part is an Aggressive National Enforcement Operation titled Rolling Thunder - law enforcement tools to attack the Heroin supply side and TBR between Mexican Cartels/violent gangs or distribution cells

National Strategy...Field Offices....State/Locals rolled out to several specific cities but can be applied across Country

RT piece is Coordinated in our multi-agency SOD

Focus on the link points in our communities

Work up to the Mexican Cartels

Work to the violent gangs/distribution cells

Create Time and Space in devastated communities

Help communities maintain that time and space long term

Partnered with the DCP - Will talk about the Diversion piece of this

Robust Community Outreach

Part of broader USG efforts - ONDCP great partners



Community Partnerships



U.S. Drug Enforcement Administration
Office of Diversion Control

- DEA recognizes we cannot arrest our way out of the drug problem – our goal is lasting success in the communities we serve.
- Education and Prevention are key elements for a true 360 Strategy.
- Law enforcement operations provide an opportunity for community empowerment and a jumping off point for education and prevention efforts.

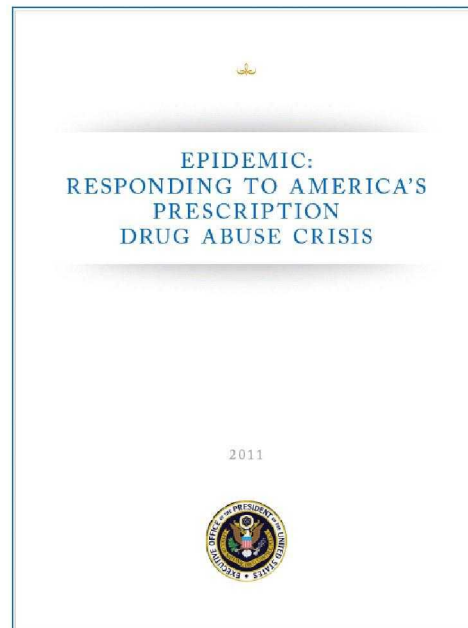
#RxSummit

NATIONAL
RX DRUG ABUSE & HEROIN
SUMMIT

Recognize can't arrest our way out of the problem
Goal of lasting success in the communities we serve
Education and prevention

Prescription Drug Abuse Prevention Plan

- Coordinated effort across the Federal Government
- Four focus areas:
 - 1) Education
 - 2) Prescription Drug Monitoring Programs
 - 3) Proper Disposal of Medication
 - 4) Enforcement



U.S. Drug Enforcement Administration
Office of Diversion Control

ONDCP also creates targeted strategies for addressing major emerging issues.

For example:

To address the prescription drug abuse problem, ONDCP and our Federal partners developed the Prescription Drug Abuse Prevention Plan.

This plan was intended to augment the Strategy, which emphasized universal prevention and treatment.

The plan focuses on addressing people who misuse prescription pharmaceuticals. It augments our NDCS which already addresses universal drug prevention efforts, healthcare integration and treatment and recovery.

I am going to run through our progress in each of these areas.

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 1, 2005 – January 7, 2016: Briefings to **84** firms with **279** registrations

U.S. Drug Enforcement Administration
Office of Diversion Control



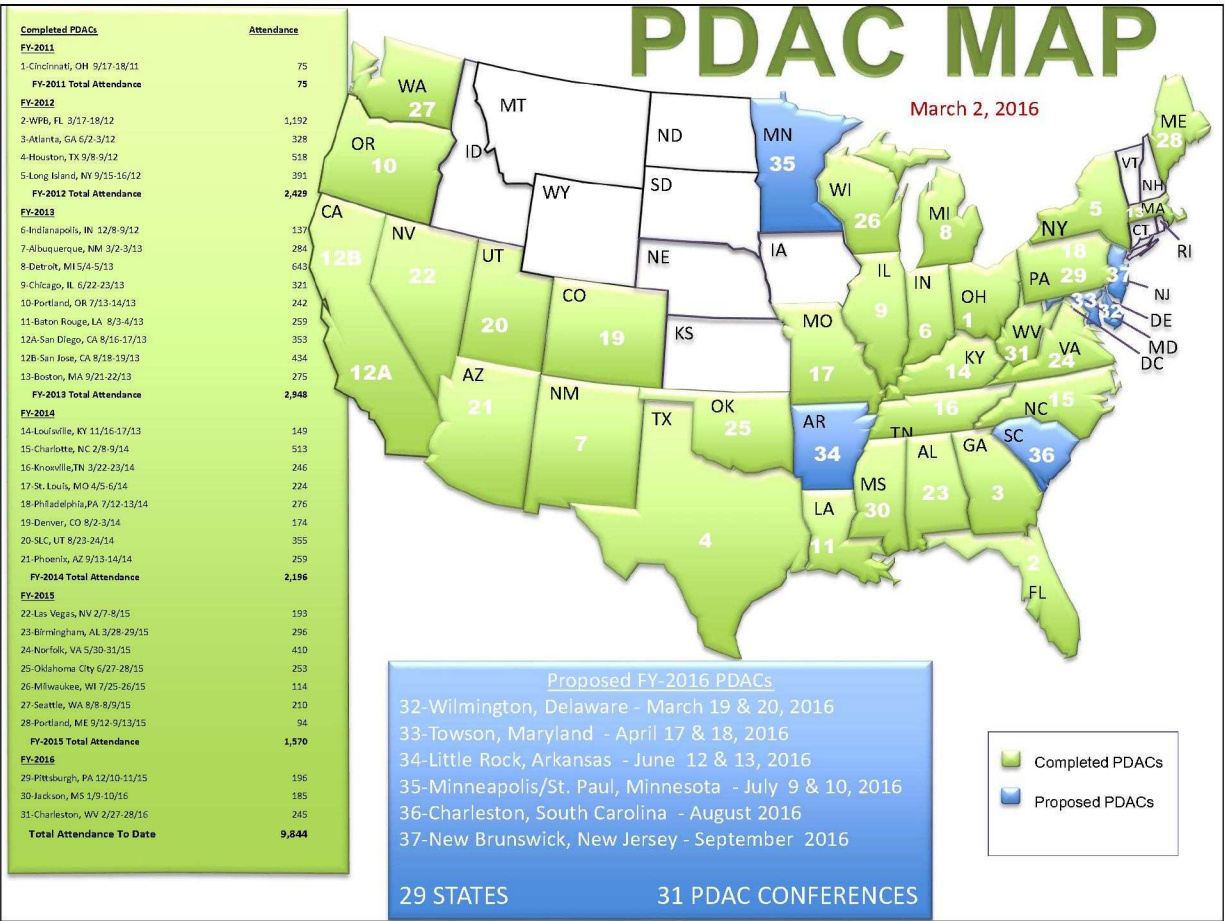
DEA Registrant Initiatives

Pharmacy Diversion Awareness Conference

This conference is designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity

U.S. Drug Enforcement Administration
Office of Diversion Control





DEA Registrant Initiatives

- The Federation of State Medical Boards (FSMB) promotes excellence in medical practice, licensure, and regulation on behalf of 70 state medical and osteopathic Boards across the country in their protection of the public
- DEA and FSMB are currently working on developing strategies to [work more effectively and jointly](#) on indiscriminate prescriber investigations in order to facilitate the administrative process to take action against those that are a threat to the public health and welfare quickly, and at the same time not jeopardize a criminal investigation

U.S. Drug Enforcement Administration
Office of Diversion Control



DEA Registrant Initiatives

“Stakeholders’ Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances”

- Represents the medical, pharmacist, and supply chain spectrum highlighting the challenges and “red flag” warning signs related to prescribing and dispensing controlled substance prescriptions
- The goal was to provide health care practitioners with an understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose, as well as to provide guidance on which red flag warning signs warrant further scrutiny
- NABP along with 10 national associations and 6 major pharmaceutical firms were the coalition of stakeholders of this document.

U.S. Drug Enforcement Administration
Office of Diversion Control

DEA & Associations Meeting

February 29, 2016

Pharmacy Associations

- American Society of Consultant Pharmacists (ASCP)
- American Pharmacists Association (APhA)
- National Association of Boards of Pharmacy (NABP)
- National Association of Chain Drug Stores (NACDS)
- National Community Pharmacists (NCPA)

Supply Chain Associations

- Healthcare Distribution Management Association (HDMA)
- Generic Pharmaceutical Association (GPhA)
- The Pharmaceutical Research and Manufacturers of America (PHRMA)
- Consumer Healthcare Products Association (CHPA)

U.S. Drug Enforcement Administration
Office of Diversion Control

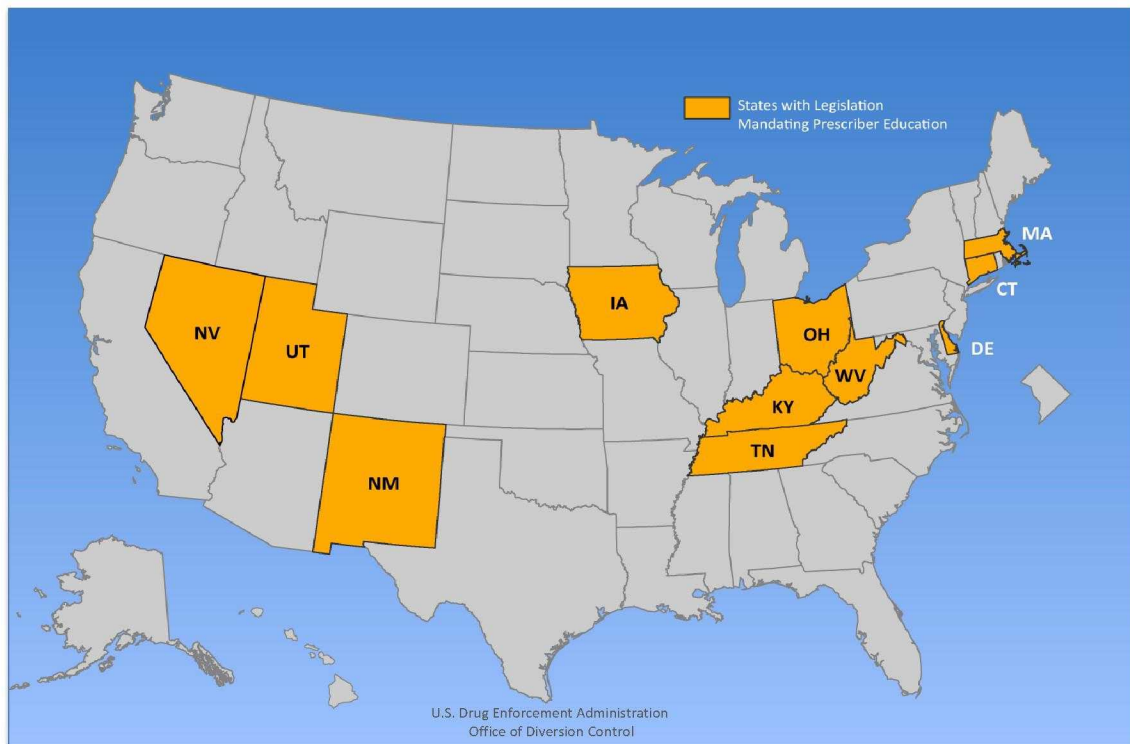
Scheduled Investigations

- Increase in the number of DEA registrants that are required to be investigated to ensure compliance with the Controlled Substances Act and its implementing regulations
- Increase in the frequency of the regulatory investigations
- Verification investigations of customers and suppliers

U.S. Drug Enforcement Administration
Office of Diversion Control



Since 2011, Eleven States have Passed Legislation Mandating Prescriber Education



Prescribers receive an average 11 hours (average) of pain training in medical school.
[Mezei, et al.]

Today we know that prescribers often use prescription drugs in ways that the research or the consensus does not support.

For example, The Neurologist's Guide to Migraine Therapy in the Emergency Room states, "There are numerous disadvantages to the use of opioids in the treatment of migraine, and they typically should not be used as first-line therapy."

However, we found in a study conducted by The American Academy of Pediatrics that opioids were used in 46 percent of children. Additionally, of those teens who received opioids, 25 percent had a diagnosis of migraine. This study was conducted across fourteen commercial health plans and looked at over 8,000 teens with two headache claims.

They followed the youth who received opioids and found that 52 percent of them ended up with 2 or more prescriptions for opioids in the year after the initial event.

This study underscores the fact that voluntary "guidelines" may have very little effect on real-world prescribing behavior when a provider is faced with a person in pain.

Our Prescription drug abuse plan calls for mandatory prescriber education on substance use and pain tied to the prescriber's DEA registration. The HHS Secretary's initiative supports changing prescriber behavior too.

Some states are passing legislation on this themselves. [Refer to slide]

Eleven states now have this legislation in place.

* * *

Sources: Mezei L, Murinson BB; Johns Hopkins Pain Curriculum Development Team. Pain education in North American medical schools. J Pain. 2011 Dec;12(12):1199-208. doi: 10.1016/j.jpain.2011.06.006. Epub 2011 Sep 25.

Gelfand AA1, Goadsby PJ. A Neurologist's Guide to Acute Migraine Therapy in the Emergency Room. Neurohospitalist. 2012 Apr 1;2(2):51-59. At <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3737484/> linked to 9-18-2014
DeVries A, Koch T, Wall E, Getchius T, Chi W, Rosenberg A. Opioid use among adolescent patients treated for headache. J Adolesc Health. 2014 Jul;55(1):128-33. doi: 10.1016/j.jadohealth.2013.12.014. Epub 2014 Feb 25.
PMID: 24581795

States depicted on map:

Iowa Board of Medicine. "New rules require physicians to complete training on chronic pain, end-of-life care." State of Iowa. [August 2011]. Available:
http://medicalboard.iowa.gov/Board%20News/2011/New%20rules%20physicians%20to%20complete%20training%20chronic%20pain_08182011.pdf

Kentucky Board of Medical Licensure. "House Bill 1." Commonwealth of Kentucky. [2012]. Available:
<http://kbml.ky.gov/hb1/Pages/default.aspx>

Executive Office of Health and Human Services. "PMP and Mandatory Educational Requirements for Prescribers." Commonwealth of Massachusetts. [October 2011]. Available:
<http://www.mass.gov/eohhs/provider/licensing/occupational/dentist/pmp-and-mandatory-educational-requirements-for-pre.html> this cite did not check out

Please try below:

<http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/dentist/alerts/pmp-and-mandatory-educational-requirements-for-pre.html>

General Assembly of the State of Ohio. "129th General Assembly – Amended Substitute Senate Bill Number 83." [2012]. Available: http://www.legislature.state.oh.us/bills.cfm?ID=129_SB_83 this cite did not check out ERROR

Please try below:

http://archives.legislature.state.oh.us/bills.cfm?ID=129_SB_83

State of Tennessee. "Public Chapter No. 430 – Senate Bill 676." [April 18, 2013]. Available:

<http://www.tn.gov/sos/acts/108/pub/pc0430.pdf>

New Mexico Medical Board. "Title 16 Chapter 10 Part 14 Section 11 – "Pain Management Continuing Education." [effective November 2012]. Available at: http://www.nmmb.state.nm.us/pdf/files/Rules/NMAC16.10.14_PainManagement.pdf this cite did not check out PAGE NOT FOUND

Please try below:

http://www.nmmb.state.nm.us/docs/rules/NMAC16.10.14_PainManagement.pdf

State of Delaware. "Uniform Controlled Substances Act Regulations." 24 Del. Admin. Code § 3.1.1. Available at:

<http://regulations.delaware.gov/AdminCode/title24/Uniform%20Controlled%20Substances%20Act%20Regulations.shtml>

West Virginia Legislature. "Chapter 30. Professions and Occupations – Article 1. General Provisions Applicable to All State Boards of Examination or Registration Referred to in Chapter." WV Code § 30-1-7a. Available at:

<http://www.legis.state.wv.us/wvcode/Code.cfm?chap=30&art=1>

Utah Division of Occupational and Professional Licensing. Utah Controlled Substances Act, 58-37-6.5. State of Utah. [May 2012]. Available: <http://www.dopl.utah.gov/laws/58-37.pdf#page=24> this cite did not check out PAGE NOT FOUND

Please try below:

<http://le.utah.gov/xcode/Title58/Chapter37/58-37-S6.5.html>

NEW: CONNECTICUT: CONN. GEN. STAT. § 20-10b (2015), available at <http://www.cga.ct.gov/2015/ACT/PA/2015PA-00198-R00HB-06856-PA.htm>

NEW: Nevada law SB 459 (2015) Sec. 15.1. Chapter 630 of NRS is hereby amended by adding thereto a new section to read as follows: The Board may, by regulation, require each physician or physician assistant who is registered to dispense controlled substances pursuant to NRS 453.231 to complete at least 1 hour of training relating specifically to the misuse and abuse of controlled substances during each period of licensure. Any licensee may use such training to satisfy 1 hour of any continuing education requirement established by the Board.

Sec. 15.3. Chapter 631 of NRS is hereby amended by adding thereto a new section to read as follows: The Board may, by regulation, require each holder of a license to practice dentistry who is registered to dispense controlled substances pursuant to NRS 453.231 to complete at least 1 hour of training relating specifically to the misuse and abuse of controlled substances during each period of licensure. Any such holder of a license may use such training to satisfy 1 hour of any continuing education requirement established by the Board.

Sec. 15.5. Chapter 632 of NRS is hereby amended by adding thereto a new section to read as follows: The Board may, by regulation, require each advanced practice registered nurse who is registered to dispense controlled substances pursuant to NRS 453.231 to complete at least 1 hour of training relating specifically to the misuse and abuse of controlled substances during each period of licensure. An advanced practice registered nurse may use such training to satisfy 1 hour of any continuing education requirement established by the Board

Sec. 15.6. Chapter 633 of NRS is hereby amended by adding thereto a new section to read as follows: The Board may, by regulation, require each osteopathic physician or physician assistant who is registered to dispense controlled substances pursuant to NRS 453.231 to complete at least 1 hour of training relating specifically to the misuse and abuse of controlled

substances during each period of licensure. Any licensee may use such training to satisfy 1 hour of any continuing education requirement established by the Board.

Sec. 15.7. Chapter 635 of NRS is hereby amended by adding thereto a new section to read as follows: The Board may, by regulation, require each holder of a license to practice podiatry who is registered to dispense controlled substances pursuant to NRS 453.231 to complete at least 1 hour of training relating specifically to the misuse and abuse of controlled substances during each period of licensure. Any such holder of a license may use such training to satisfy 1 hour of any continuing education requirement established by the Board.

Sec. 15.8. Chapter 636 of NRS is hereby amended by adding thereto a new section to read as follows: The Board may, by regulation, require each optometrist who is certified to administer and prescribe therapeutic pharmaceutical agents pursuant to NRS 636.288 and who is registered to dispense controlled substances pursuant to NRS 453.231 to complete at least 1 hour of training relating specifically to the misuse and abuse of controlled substances during each period of licensure. Any licensee may use such training to satisfy 1 hour of any continuing education requirement established by the Board.

National Take Back Initiative

April 30, 2016



10:00 AM – 2:00 PM

U.S. Drug Enforcement Administration
Office of Diversion Control

U.S. Drug Enforcement Administration
Office of Diversion Control

The Problem: Easy Access



U.S. Drug Enforcement Administration
Office of Diversion Control

Secure and Responsible Drug Disposal Act of 2010

- ✓ Ultimate users now have more locations where they can securely, safely, responsibly, and conveniently dispose of their unwanted pharmaceutical controlled substances.
- ✓ Expected benefit to the public by:
 - Decreasing the supply of pharmaceutical controlled substances available for misuse, abuse, diversion, and accidental ingestion; and
 - Protecting the environment from potentially harmful contaminants by providing alternate means of disposal for ultimate users.



U.S. Drug Enforcement Administration
Office of Diversion Control



Ultimate User

Ultimate user means as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.”

21 USC § 802(27)

Ultimate user methods of destruction prior to Disposal rule:

- ✓ Disposal in Trash ([ONDCP method](#)); or
- ✓ Flushing ([FDA opioids and select CSs](#))
- ✓ National Take-back Event (DEA)
- ✓ Transfer to Law Enforcement
- ✓ (Police Station Receptacles or local Take-back events)
- ✓ DEA

U.S. Drug Enforcement Administration
Office of Diversion Control



Secure and Responsible Drug Disposal Act of 2010

- CSA amended to provide ultimate users and LTCF with additional methods to dispose of unused, unwanted or expired controlled substance medication in a secure, safe and responsible manner

21 USC § 822(f) & (g)

- Participation is voluntary

21 USC § 822(g)(2)

- Registrants authorized to collect:

- Manufacturers
- Distributors
- Reverse Distributors
- Narcotic Treatment Programs
- Hospitals/clinics with an on-site pharmacy
- Retail Pharmacies

21 CFR § 1317.40

U.S. Drug Enforcement Administration
Office of Diversion Control

*Authorized
collectors, as
registrants, are
readily familiar with
the security
procedures and
other requirements
to handle controlled
substances.*

 #RxSummit

NATIONAL
RX DRUG ABUSE & HEROIN
SUMMIT

Secure and Responsible Drug Disposal Act of 2010

- Disposal rule eliminated existing 21 CFR § § 1307.12 & 1307.21
- New part 1317 contains the requirements on:
 - disposal procedures;
 - registrant inventory
 - collected substances
 - collection of pharmaceutical controlled substances from ultimate users;
 - return and recall; and
 - destruction of controlled substances

U.S. Drug Enforcement Administration
Office of Diversion Control



Collection



Collection

Collection means to receive a controlled substance for the purpose of destruction from an:

- Ultimate user,
- Person lawfully entitled to dispose of an ultimate user decedent's property, or
- LTCF on behalf of an ultimate user who resides or has resided at the facility.

21 USC § 822(g)(3) & (4) and 21 CFR § 1300.01(b)



U.S. Drug Enforcement Administration
Office of Diversion Control



Collection Receptacles

- Ultimate users *shall* put the substances directly into the collection receptacle.
- Controlled and non-controlled substances may be comingled.
- Collected substances shall not be counted, sorted, inventoried, or otherwise individually handled.
- Registrants **shall not dispose of stock/inventory** in collection receptacles.

21 CFR § 1317.75(b) and (c)

U.S. Drug Enforcement Administration
Office of Diversion Control



Collection at LTCF

A registered hospital/clinic with an **on-site pharmacy** or a registered retail pharmacy may request modification of their registration to become an authorized collector to maintain a collection receptacle at a LTCF

21 CFR § 1317.80

Request must include:

- Name and physical location of each LTCF at which a collection receptacle will be operated

No fee is required for this modification request

21 CFR § 1301.51(b)(2) and (c)

U.S. Drug Enforcement Administration
Office of Diversion Control



Collection Receptacle Location

- **Registered location** – immediate proximity of designated area where controlled substances are stored and at which an employee is present.
- **LTCF** – located in secure area regularly monitored by LTCF employees.
- **Hospital/clinic** – located in an area regularly monitored by employees---**not** in proximity of where emergency or urgent care is provided.
- **NTP** – located in a room that does not contain any other controlled substances and is securely locked with controlled access.

21 CFR § 1317.75(d)

U.S. Drug Enforcement Administration
Office of Diversion Control



Registrant Disposal

U.S. Drug Enforcement Administration
Office of Diversion Control



Registrant Disposal - Inventory

Practitioner & Non-Practitioner may **dispose of inventory**:

- Prompt on-site destruction
- Prompt delivery to **reverse distributor** by **common or contract carrier** or **reverse distributor pick-up**
- Return and recall : Prompt delivery by common or contract carrier or pick-up at the registered location

Practitioner may **also** request assistance from the SAC

Non-practitioner may **also** transport by its own means

21 CFR § 1317.05(a) and (b)

U.S. Drug Enforcement Administration
Office of Diversion Control



DEA Form 41

- Form 41 shall be used to record the destruction of all controlled substances, including controlled substances acquired from collectors.
 - The Form 41 shall include the names and signatures of the two employees who witnessed the destruction.
 - Exceptions for DEA Form 41:
 - Destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (i.e. wastage) shall be properly recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41
 - Transfers by registrant to a reverse distributor must be recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41

21 CFR § 1304.21(e)

U.S. Drug Enforcement Administration
Office of Diversion Control



Abandoned Controlled Substances

- Circumstances when there is no authorized person to dispose of controlled substances
 - School
 - Summer camp
 - Hospital
- Return to ultimate user is not feasible
- Options
 - Contact law enforcement or DEA
 - Destroy on-site

79 FR 53546 (Disposal Final Rule)

U.S. Drug Enforcement Administration
Office of Diversion Control



Pharmaceutical Wastage

U.S. Drug Enforcement Administration
Office of Diversion Control



Pharmaceutical Wastage

- **Not** subject to 21 CFR Part 1317
 - Destruction does not have to be “non-retrievable”
 - DEA Form 41 must not be utilized
- Dispensing must be recorded as a record
21 CFR § 1304.22(c)
- Clarification memorandum on DEA website at
www.deaDiversion.usdoj.gov

U.S. Drug Enforcement Administration
Office of Diversion Control





ODLP@USDOJ.GOV

U.S. Drug Enforcement Administration
Office of Diversion Control

