DEA & PHARMACY: Working Together to Prevent Prescription Drug Abuse

Ruth A. Carter, Chief Liaison & Policy Section Office of Diversion Control
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.
The DEA is responsible for:

– the **oversight** of the system
– the **integrity** of the system
– the **protection** of the public health and safety
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 Morality 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 Morality Weekly Report (MMWR); January 1, 2016
*Email: Between CDC (Rudd) and DEA (Prevoznik) 2/18/2016*
Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family...For Free!!
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
Prescription Drug Abuse is driven by Indiscriminate Prescribing Criminal Activity
Legal Obligations: DEA Registrant
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)
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)
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!!!
The DEA Response
We will not arrest our way out of this problem!!!!!!

- Enforcement is just as important as....
- Prevention/Education
- Treatment
Prescription Opiates  v. Heroin
Circle of Addiction & the Next Generation

- Hydrocodone
  - Lorcet®
  - $5-$7/tab

- Oxycodone Combinations
  - Percocet®
  - $7-$10/tab

- Heroin
  - $15/bag

- OxyContin®
  - $80/tab

- Roxicodone®
  - Oxycodone IR
  - 15mg, 30mg
  - $30-$40/tab

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.
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
**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
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.
Completed PDACs

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Proposed FY-2016 PDACs

- 32-Wilmington, Delaware - March 19 & 20, 2016
- 33-Towson, Maryland - April 17 & 18, 2016
- 34-Little Rock, Arkansas - June 12 & 13, 2016
- 36-Charleston, South Carolina - August 2016
- 37-New Brunswick, New Jersey - September 2016

29 STATES 31 PDAC CONFERENCES
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.
“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.
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)
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
Since 2011, Eleven States have Passed Legislation Mandating Prescriber Education
National Take Back Initiative
April 30, 2016

Got Drugs?
Turn in your unused or expired medication for safe disposal
Saturday April 30, 2016
Click here for a collection site near you.

10:00 AM – 2:00 PM
U.S. Drug Enforcement Administration
Office of Diversion Control
10th National Take Back Day: September 26, 2015
Total Weight Collected (pounds): 742,771 (371 Tons)
Secure and Responsible Drug Disposal Act of 2010
The Problem: Easy Access
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:
  o Decreasing the supply of pharmaceutical controlled substances available for misuse, abuse, diversion, and accidental ingestion; and
  o Protecting the environment from potentially harmful contaminants by providing alternate means of disposal for ultimate users.
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 (*ONGDP 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
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

Authorized collectors, as registrants, are readily familiar with the security procedures and other requirements to handle controlled substances.
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
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)*
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)
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)
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)
Registrant Disposal
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)
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)
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)
Pharmaceutical Wastage
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](http://www.deaDiversion.usdoj.gov)