DEA Trends & Update

Little Rock Pharmacy Diversion Awareness Conference

June 12 & 13, 2016
Goals and Objectives

- Public Health Epidemic
- Impact on Society
- Drugs of Abuse
- Criminal Activity
- The Controlled Substances Act: Checks & Balances
- Legal obligations: DEA registrant
- The DEA Response
- Disposal
- Miscellaneous Pharmacy Topics
Public Health Epidemic
DRUG-FREE AMERICA

AGE 0-4
AMPICILLIN

4-12
RITALIN

12-18
APPETITE SUPPRESSANTS

18-24
NO-DOZ

24-38
PROZAC

38-65
ZANTAC

65-
EVERYTHING ELSE
Primum non nocere
2000-2014:
Unintentional drug overdose deaths in the US increased **137%**, which was a **200%** increase in overdose deaths involving opioids.

**500,000 deaths** due to prescription overdose

2014:

Over **47,000** drug-related overdose deaths

- **129 deaths** every 24 hours
- **46 deaths** by end of today’s PDAC
- **1 death** every 11.16 minutes

**28,647 deaths** involved opioids, including heroin
**19,000 deaths** involved prescription opioid
Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family... For Free!!
Where else do our kids get their information from?

www.erowid.org
Where do kids get their information from?  
www.bluelight.org
Violence
Starting the year with a bang

Saranac Hale Spencer, The News Journal  12:36 a.m. EST January 4, 2016

A 26-year-old Lewes man threatened to detonate explosives he said were strapped to his body if a pharmacist at a Walgreens near Magnolia didn't give him prescription drugs, according to state police.

The man, Curtis Kuhn, didn't actually have explosives strapped to his body, according to police.

Kuhn went into the pharmacy at about 9:30 a.m. on Saturday and put a note on the counter demanding Percocet and Xanax – he told the pharmacist that he had explosives strapped to his body and he was being forced to commit the robbery by someone who was sitting in a car in the parking lot, according to police.

When officers arrived shortly after that, they took Kuhn into custody without incident and found that he had no explosives and there was no car fitting his description in the parking lot, according to police.

Kuhn was charged with first-degree attempted robbery, attempted theft of a controlled substance and two counts of terrorististic threatening. He was arraigned and sent to Vaughn Correctional Center near Smyrna for lack of $27,000 secured bond and
Drugs of Abuse
Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen
Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)

- Similarities:
  - Structurally related to codeine
  - Equal to morphine in producing opiate-like effects

- Brand Names: Vicodin®, Lortab®, Lorcet®

- October 6, 2014 moved to SCHEDULE II

- “Cocktail” or “Trinity”
  - Hydrocodone
  - Soma® / carisoprodol
  - Alprazolam / Xanax®

Street prices: $2 to $10+ per tablet depending on strength & region
The Trinity

Hydrocodone

Opiate

Carisoprodol

Muscle Relaxant

C-IV as of 1/11/2012

Alprazolam

Benzodiazepine

U.S. Drug Enforcement Administration
Office of Diversion Control
Oxycodone

- OxyContin controlled release formulation of Schedule II oxycodone
  - The controlled release method of delivery allowed for a longer duration of drug action so it contained much larger doses of oxycodone
  - Abusers easily compromised the controlled release formulation by crushing the tablets for a powerful morphine-like high
  - 10, 15, 20, 30, 40, 60, 80mg available

- Effects:
  - Similar to morphine in effects and potential for abuse/dependence
  - Sold in “Cocktails” or the “Holy Trinity”
    - Oxycodone, Soma® / Xanax®

- Street price: Approx. $80 per 80mg tablet

NOTE: New formulation introduced into the marketplace in 2010 that is more difficult to circumvent for insufflation (snorting) or injection. Does nothing to prevent oral abuse.
Oxycodone HCL CR
(OxyContin®) Reformulation
New OxyContin® OP

08-27-2010, 01:11 AM

mz.mary420
Member

Join Date: May 2010
Location: down south
Posts: 6

well just got ours and they suck! when snorted the pill balls up in your nose and gets stuck, so I tried sucking on one and it did ok, but tastes nasty. No way you can shoot them as mentioned in a previous post. havent tried smoking it yet, kinda in a hole money wise, it cost me over $700.00 to get my 80's filled and I probably wont even get half my money back

if anyone has tried to smoke this new formulated shit, please post! thanks

08-27-2010, 06:09 AM

mephist00
Member

Join Date: Apr 2008
Location: NY
Age: 25
Posts: 628

ya my friend has tried to smoke the new ones... said its very harsh on the lungs and throat...

so far the only way i've been able to beat the time release, is use a hose clamp to grind it very fine, and snort it... it doesn't gel up like you would think (doesn't gel up like the football shaped generic 40's do anyways) it just kinda turns snotty... but if you can get it down fast it seems to work ok

Originally Posted by stalk
I've come to the conclusion it's because these psychedelic visions are simply vibrating on a higher, or different, spectrum of frequencies that normally the monkey does not perceive.
Oxymorphone Extended Release
Opana ER® (Schedule II)

- Opana ER® - (Schedule II)
  - Treats constant, around the clock, moderate to severe pain
  - Becoming popular and is abused in similar fashion to oxycodone; August 2010 (Los Angeles FD TDS)
  - Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
  - Street: $10.00 – $80.00
Other Opiates of Interest

- **Trade Name**: MS Contin
  Controlled Ingredient: morphine sulfate, 150 mg

- **Trade Name**: MS Contin
  Controlled Ingredient: morphine sulfate, 15 mg

- **Trade Name**: MS Contin
  Controlled Ingredient: morphine sulfate, 30 mg

- **Trade Name**: Oramorph SR
  Controlled Ingredient: morphine sulfate, 30 mg

- **Trade Name**: Oramorph SR
  Controlled Ingredient: morphine sulfate, 60 mg

- **Trade Name**: Dilaudid
  Controlled Ingredient: hydromorphone hydrochloride, 2 mg

- **Trade Name**: Dilaudid
  Controlled Ingredient: hydromorphone hydrochloride, 4 mg
Fentanyl

- Fentanyl Patches
- Fentanyl Citrate dispensed in a berry flavored lollipop-type unit
- Fentanyl is 100 times more potent than morphine
- Intended to be used for chronic cancer pain & only for people who are tolerant to prescription opioid (narcotic) pain medicines
- Abused for its intense euphoric effects
Methadone- 5mg & 10mg

Methadone 40 mg
Prescription Opiates  v. Heroin
Circle of Addiction & the Next Generation

Hydrocodone
Lorcet®
$5-$7/tab

Oxycodone Combinations
Percocet®
$7-$10/tab

OxyContin®
$80/tab

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

Heroin
$15/bag

U.S. Drug Enforcement Administration
Office of Diversion Control
Heroin Seizure

Pharmaceutical Oxycodone 30mg
Criminal Activity
Egregious Activity
(Not on the fringes)
Dr. Yee primarily met with his “patients” in Starbucks cafes throughout Orange County, California.

He would see up to a dozen patients each night between 7:00 and 11:00 p.m. and wrote these “patients” prescriptions, primarily for opiates, in exchange for cash.

Yee pled guilty to distributing millions of dollars in oxycodone, oxymorphone, hydrocodone, hydromorphone, Adderall® and alprazolam outside the course of professional practice and without a legitimate medical purpose.
During a one-year time period, Yee wrote prescriptions for a total of 876,222 dosage units of all medications combined.

52% of all prescriptions (458,056 dosage units) written by Yee were for oxycodone (92%-30mg) during the one-year period.

96% - oxycodone, hydrocodone, alprazolam, hydromorphone, and oxymorphone.

Almost half of Yee’s patients were 25 and under.
The Controlled Substances Act: Checks & Balances
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.
Closed System of Distribution

Foreign Mfr -> Importer -> Manufacturer -> Distributor

Closed System of Distribution

U.S. Drug Enforcement Administration
Office of Diversion Control

1,638,232 (06/09/2016)

- Practitioners: 1,233,795
- Retail Pharmacies: 73,665
- Hospital/Clinics: 16,951
Closed System of Distribution

Cyclic Investigations

Record Keeping Requirements

Security Requirements

Established Schedules

Registration

Established Quotas

ARCOS
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
Legal Obligations: DEA Registrant
Effective Controls

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

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

21 CFR § 1301.71(a)
Suspicious Orders

Non-practitioners of controlled substances

“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances…Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

21 CFR § 1301.74(b)
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)
Clinical Reminders:

- Opioids are not first-line or routine therapy for chronic pain
- Establish and measure goals for pain and function
- Discuss benefits and risks and availability of nonopioid therapies with patient

Use immediate-release opioids when starting

Start low and go slow

When opioids are needed for acute pain, prescribe no more than needed

Do not prescribe ER/LA opioids for acute pain

Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed

CDC Guidelines for Prescribing Opioids for Chronic Pain

- Evaluate risk factors for opioid-related harms
- Check PDMP for higher dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

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)
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 Last Line of Defense

U.S. Drug Enforcement Administration
Office of Diversion Control
Potential Red Flags

Many customers receiving the same combination of prescriptions; cocktail

Many customers receiving the same strength of controlled substances; no individualized dosing: multiple prescriptions for the strongest dose

Many customers paying cash for their prescriptions

Early refills

Many customers with the same diagnosis codes written on their prescriptions;

Individuals driving long distances to visit physicians and/or to fill prescriptions;
Potential Red Flags continued

Customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician; and

Customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.).

Overwhelming proportion of prescriptions filled by pharmacy are controlled substances

Pharmacist did not reach out to other pharmacists to determine why they were not filling a particular doctor’s prescription

Verification of legitimacy not satisfied by a call to the doctors office
Red Flag?

What happens next?

You attempt to resolve...
Resolution is comprised of many factors

- Verification of a valid practitioner DEA number! It is not, however, the end of the pharmacist’s duty. Invalid DEA number = Invalid RX
- Resolution cannot be based solely on patient ID and prescriber verification.
- You must use your professional judgment, training and experience… we all make mistakes
- Knowledge and history with the patient
- Circumstances of prescription presentation
- Experience with the prescribing practitioner
- It does not require a call to the practitioner for every CS RX
- This is not an all-inclusive list…
Who do I call to report a practitioner?

- State Board of Pharmacy, Medicine, Nursing, Dental
- State, County, Local Police
- DEA local office and Tactical Diversion Squad
- Health Department
- HHS OIG if Medicare, Medicaid fraud
The DEA Response
360 Degree Strategy
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.
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.

Briefings to 95 firms with 305 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 PDACs

- **Proposed FY-2016 PDACs**
  - 34-Little Rock, Arkansas - June 12 & 13, 2016
  - 36-Charleston, South Carolina - August 2016
  - 37-New Brunswick, New Jersey - September 2016

**32 STATES 68 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.
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
Maine

- Second State to Mandate Electronic Prescribing
- Prescribers are required to undergo addiction training every 2 years
- Set cap on daily strength for opioid prescribing:
  - Acute pain – 7 days
  - Chronic pain – 30 days
- To begin January 2017
National Take Back Initiative
April 30, 2016

Got Drugs?

Turn in your unused or expired medication for safe disposal on 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
11th National Take Back Day: April 30, 2016
Total Weight Collected (pounds): 893,498   (447 Tons)
Secure and Responsible Drug Disposal Act of 2010
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
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
Law Enforcement

Law Enforcement may continue to conduct take-back events.

Any person may partner with Law Enforcement.

Law Enforcement shall maintain control and custody of collected substances until secure transfer, storage, or destruction has occurred.

Authorized collection receptacles and inner liners “should” be used.

21 CFR § 1317.35 and 1317.65
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)
Securely fastened to a permanent structure.

Securely locked, substantially constructed container with permanent outer container and removable inner liner.

Outer container must have small opening that allows for contents to be added, but does not allow for removal of contents.

Outer container must display a sign stating only Schedule II-V and non-controlled substances are acceptable substances.

Schedule I controlled substances are not permitted to be collected.

21 CFR § 1317.75(e)
Collection Receptacle Inner Liner

- Waterproof, tamper-evident, and tear-resistant.
- Removable and sealable upon removal without emptying or touching contents.
- Contents shall not be viewable from the outside when sealed (i.e., can’t be transparent).
- Size shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.).
- Outside of liner shall have permanent, unique ID number.

21 CFR § 1317.60(a)
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 or inventory* in collection receptacles.

21 CFR § 1317.75(b) 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)
Mail-Back Program

Requirements of mail-back program

- Only lawfully possessed schedules II-V controlled substances may be collected
- Controlled and non-controlled substances may be collected together
- Must have method of on-site destruction
  21 CFR § 1317.70 (b)

DEA Registrant who sells mail-back packages for another registrant is NOT required to modify registration as a collector
Registrant Disposal
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)
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
  ſ School
  ſ Summer camp
  ſ Hospital

• Return to ultimate user is not feasible

• Options
  ſ Contact law enforcement or DEA
  ſ 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)
Miscellaneous Pharmacy Topics
Changes to a Schedule II Prescription

Pharmacist may change:

- Patient's address upon verification
- Dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner.
  - Consultation should be noted on the prescription
  - Must be in compliance with state law/regulation/policy

Pharmacy may not make changes:

- Patient's name
- Controlled substance prescribed (except for generic substitution permitted by state law), or
- Prescriber's signature
Multiple Prescriptions
Schedule II Controlled Substances

• Individual practitioner may issue multiple prescriptions which authorizes patient to receive 90-day supply of C-II
  ß Each separate prescription is for legitimate medical purpose issued by practitioner acting in usual course of professional practice
  ß Written instructions on each prescription indicating earliest date it can be filled
  ß Doesn’t cause undue risk of diversion by patient
  ß Compliance with all other elements of CSA and state laws

21 CFR § 1306.12(b)
Faxed Prescription vs. EPCS

- True electronic prescriptions are transmitted as **electronic data files** to the pharmacy, whose application imports the data file into its database.

- A system that allows the prescriber to “sign” his/her name does **NOT** conform to EPCS regulations.

- A facsimile with a written signature is **NOT** an electronic Rx.

21 CFR § 1306.05(d)
Schedule II narcotic substances may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile

- Practitioner (or agent) must note it is hospice patient
- Facsimile serves as original written prescription

21 CFR § 1306.11(f), (g) & 1306.13(b)

Schedule III-V prescription
- Written prescription signed by a practitioner, or
- Facsimile of a written, signed prescription transmitted by the practitioner (or agent) to the pharmacy, or
- Oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist
Distribution by Pharmacy to Practitioner

- Practitioner registered to dispense may distribute a quantity of such substance to another practitioner for general dispensing
  - Purchaser must be registered with DEA
  - Schedule III-V - records by purchaser and receiver must conform to 21 CFR § 1304.22(c)
  - Schedule I or II - an order form must be used and must conform to 21 CFR § 1305
  - Total number of controlled substances dispensed cannot exceed 5% of total controlled substances dispensed

21 CFR § 1307.11(a)(1)
Repacking by Pharmacy

- Practitioner can prepare, compound, package, or label in the course of his professional practice 21 CFR § 1300.01(b)

- Pharmacy can **NOT** repackage drugs (ie 100 ct bottle packaged in smaller size bottles) and sell the drugs in the form of a distribution to any DEA Registrant - including practitioner office.

- Violation of DEA and FDA regulations
Questions?