Disclosure: Ruth A. Carter

I have no relevant personal/professional/financial relationship(s) to disclose
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
• Miscellaneous Pharmacy Topics
• DEA Web-Based Resources
Public Health Epidemic
Laurel caretaker charged with medicine theft


A caretaker was charged with stealing medicines from a disabled woman in her 70s, police said Wednesday.

Ranada Pritchett, 34, of Millsboro, was arrested after police were notified of a medication theft from a home in Laurel, said Patrolman First Class Christopher Story, public information officer for the Laurel Police Department.

She was arrested after investigation determined she stole several prescriptions for Xanax and Lorazepam, Story said.

In addition to taking the woman's prescribed tranquilizers from her home, he said, she also had the prescriptions refilled at an undisclosed drugstore.

Pritchett later was released on $4,000 unsecured bail.

Contact robin brown at (302) 324-2856 or rbrown@delawareonline.com. Find her on Facebook and follow her on Twitter @rbrowndelaware.
Camden nurse arrested on fraud charges

A Camden-area nurse, identified as Danielle M. Tharp-Strouse, 31, working at the Delaware Hospital for the Chronically Ill in Smyrna has been arrested on a number of fraud and forgery charges.

By Staff reports

Posted Mar. 24, 2014 at 4:05 PM

Dover, Del.

A Camden-area nurse working at the Delaware Hospital for the Chronically Ill in Smyrna has been arrested on a number of fraud and forgery charges.

Danielle M. Tharp-Strouse, 31, of the 6100 block of Mud Mill Road, was taken into custody March 21 by members of the state Medicaid Fraud Unit, said Department of Justice spokesman Jason Miller.

The investigation began on March 19, 2013, when an administrator at the Smyrna health care facility reported to the Smyrna Police Department that an employee had been illegally obtaining Oxycodone, a powerful prescription painkiller, Miller said.

Smyrna Police turned the investigation over to the Medicaid Fraud Unit and its ongoing investigation found that between Feb. 1 and March 19, 2013, Tharp-Strouse allegedly forged the
Two Del. doctors tangled in Silk Road legal mess

Esteban Parra, The (Wilmington, Del.) News Journal  11:39 a.m. EST December 5, 2013

Investigators say pair teamed up to sell controlled substances on black market website.

WILMINGTON, Del. — Agents from the U.S. Drug Enforcement Administration say greed drove two Delaware doctors into a life of illegal drug sales on the black market Silk Road website.

Olivia L. Bolles, 32, who recently completed her residency program at Christiana Care Health Center, is charged with illegal distribution of controlled substances including Oxycodone, mixed amphetamine salts and Tetrahydrocannabinol or THC, the chemical responsible for marijuana's high.

Olivia Bolles is charged with illegal distribution of controlled substances on the Silk Road website.
Delaware Pharmacist Gets 20 Years in Prison

Posted: Dec 20, 2012 1:25 PM EST

WILMINGTON, Del. (AP)- A former Claymont pharmacist who illegally distributed 45,000 Oxycodone pain pills was sentenced to 20 years in federal prison Thursday after tearfully asking his family and court officials for forgiveness.

Bruce E. Costa Jr., 37, wept as he described how greed, pride and arrogance led him down a destructive path of drug dealing, addiction and lying, and how his wife and three children have suffered.

“They’re punished, and they don’t deserve it, all because of my greed and my stupidity,” the former owner of Renaissance Family Pharmacy told U.S. District Judge Leonard Stark.
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
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*
National Overdose Deaths
Number of Deaths from Prescription Opioid Pain Relievers

Source: National Center for Health Statistics, CDC Wonder
National Overdose Deaths
Number of Deaths from Benzodiazepines

Source: National Center for Health Statistics, CDC Wonder
National Overdose Deaths
Number of Deaths from Heroin

Source: National Center for Health Statistics, CDC Wonder
Some states have more painkiller prescriptions per person than others.

Prescription Opioid Analgesics Poisoning Deaths

Opioid-Involved Drug Poisoning Death Rates by State, 1999
U.S. National Rate: 1.4 Deaths per 100,000 Population

Source: Centers for Disease Control and Prevention, National Center for Health Statistics, Underlying Cause of Death on CDC WONDER Online Database, extracted January 26, 2015.
Our Youth
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
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
Where our kids learn about drugs!

Learned About Risk of Drugs From Following Sources by Teen Drug Use

(\% A lot) (n=3705)

- Teens Who Do Not Use Drugs (n=1409) (A)
- Teens Who Do Use Drugs (n=2087) (B)

<table>
<thead>
<tr>
<th>Source</th>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>School</td>
<td>44%</td>
<td>57%</td>
</tr>
<tr>
<td>Parents</td>
<td>38%</td>
<td>31%</td>
</tr>
<tr>
<td>Friends</td>
<td>25%</td>
<td>34%</td>
</tr>
<tr>
<td>On the Street</td>
<td>14%</td>
<td>21%</td>
</tr>
</tbody>
</table>

A-B indicates a significant difference at the 95\% confidence level.

“How much have you learned about the risks of drugs from each of the following:”

Date Prepared/ Source: 2013 Partnership Attitude Tracking Study, published 7/23/14
Where else do our kids get their information from?

www.erowid.org
Where do kids get their information from?
www.bluelight.org
Violence
Armed Robbery

- Keep calm – Do as directed
- Do not challenge the bad actor – give him what he wants
- Let him leave the store without any intervention.
- As soon as he clears the store lock the door, call 911 and check on your customers/patients
- Write down any observations (clothing, height, weight, distinguishing features) while it is fresh in your mind
- Armed Robbery is usually an act of desperation. No amount of drug loss is worth your life or the life of your patients
Starting the year with a bang

Saranae 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 terroristic threatening. He was arraigned and sent to Vaughn Correctional Center near Smyrna for lack of $27,000 secured bond and
Fatal Links: Investigators put together puzzle to solve Rite Aid manager's murder

Murder victim Jason Scott McClay
Drugs of Abuse
Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen
The United States was the country with the highest consumption of the following drugs:

<table>
<thead>
<tr>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>99%</td>
<td>Hydrocodone</td>
</tr>
<tr>
<td>78%</td>
<td>Oxycodone</td>
</tr>
<tr>
<td>57%</td>
<td>Morphine</td>
</tr>
<tr>
<td>51%</td>
<td>Hydromorphone</td>
</tr>
<tr>
<td>51%</td>
<td>Methadone</td>
</tr>
<tr>
<td>31.5%</td>
<td>Fentanyl</td>
</tr>
</tbody>
</table>
Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)

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

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

- Currently, combination products are Schedule III
- 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

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 80s 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

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.
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
Hydromorphone
Other Opiates of Interest

Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 100 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, 10 mg

Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 100 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
Treatment of Narcotic Addiction
WHY IS IT ALSO USED AS AN ANALGESIC?

Cheapest narcotic pain reliever – synthetic

Insurance companies

What’s the problem?
Overdose...Why?

- Patients not taking the drug as directed
- Physicians not properly prescribing the drug
- Non medical users ingesting with other substances
- Opiate naive
Prescription Opiates v. Heroin
Circle of Addiction & the Next Generation

Hydrocodone
Lorcet®
$5-$7/tab

Oxycodone Combinations
Percocet®
$7-$10/tab

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

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

Heroin
$15/bag

OxyContin®
$80/tab

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

Pharmaceutical Oxycodone 30mg
Non-medical Prescription Opioid Users Who Try Heroin

- Prescription opioid use is a risk factor for heroin use. Approximately 4 out of 5 recent heroin initiates ages 12-49 used prescription opioids non-medically before heroin initiation.¹

- Transition from prescription opioid abuse to heroin use is relatively rare; approximately 4 percent of prescription opioid abuse initiates begin using heroin within five years of their initiation of prescription opioid abuse.²

- Injection-drug users report that tolerance motivates them to try heroin.³

- New research shows that heroin’s effects, price, availability, and ease of use motivate heroin users who formerly used prescription opioids.⁴

² Ibid
Criminal Activity
Egregious Activity
(Not on the fringes)
Overview

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 during the referenced time period.

The top five most commonly abused and diverted prescription drugs – oxycodone, hydrocodone, alprazolam, hydromorphone, and oxymorphone – accounted for 96% of all prescriptions written by Yee.
Of the oxycodone prescriptions written by Yee, 92% were for the strongest form of immediate release oxycodone available, 30 mg, which is also the highest in demand by both drug abusers and traffickers.

Almost half of Yee’s patients were 25 and under.
MEDICAL OFFICE
Various Locations, Orange County, California
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.
1,604,158 (03/15/2016)

- Practitioners: 1,221,972
- Retail Pharmacies: 71,439
- Hospital/Clinics: 16,500
Closed System of Distribution

- Cyclic Investigations
- Established Schedules
- Record Keeping Requirements
- Registration
- Security Requirements
- Established Quotas
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

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)
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
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

Drug Diversion Control
Law Enforcement
Community Outreach

DEA Special Agent
• 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
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 85 firms with 280 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

FY-2011
1-Cincinnati, OH 9/17-18/11
FY-2011 Total Attendance
75

FY-2012
2-WPB, FL 3/17-18/12
3-Atlanta, GA 6/2-3/12
4-Houston, TX 9/8-9/12
5-Long Island, NY 9/15-16/12
FY-2012 Total Attendance
2,429

FY-2013
6-Indianapolis, IN 12/8-9/12
7-Albuquerque, NM 3/2-3/13
8-Detroit, MI 5/4-5/13
9-Chicago, IL 6/22-23/13
10-Portland, OR 7/13-14/13
11-Baton Rouge, LA 8/3-4/13
12A-San Diego, CA 8/16-17/13
12B-San Jose, CA 8/18-19/13
13-Boston, MA 9/21-22/13
FY-2013 Total Attendance
2,948

FY-2014
14-Louisville, KY 11/16-17/13
15-Charlotte, NC 2/8-9/14
16-Knoxville, TN 3/22-23/14
17-St. Louis, MO 4/5-6/14
18-Philadelphia, PA 7/12-13/14
19-Denver, CO 8/2-3/14
20-SLC, UT 8/23-24/14
21-Phoenix, AZ 9/13-14/14
FY-2014 Total Attendance
2,196

FY-2015
22-Las Vegas, NV 2/7-8/15
23-Birmingham, AL 3/28-29/15
24-Norfolk, VA 5/30-31/15
25-Oklahoma City 6/27-28/15
26-Milwaukee, WI 7/25-26/15
27-Seattle, WA 8/8-9/15
28-Portland, ME 9/12-9/13
FY-2015 Total Attendance
1,570

FY-2016
29-Pittsburgh, PA 12/10-11/15
30-Jackson, MS 1/9-10/16
31-Charleston, WV 2/27-28/16
Total Attendance To Date
9,844

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 62 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.
 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
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

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

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)
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
   Each separate prescription is for legitimate medical purpose issued by practitioner acting in usual court of professional practice
   Written instructions on each prescription indicating earliest date it can be filled
   Doesn’t cause undue risk of diversion by patient
   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)
Hospice & LTCF Prescriptions

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
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)
Repackaging by Pharmacy

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

- Pharmacy can **NOT** repackaged 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
Secure and Responsible Drug Disposal Act of 2010
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.
**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.
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)
Design of Collection Receptacles
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)
U.S. Drug Enforcement Administration
Office of Diversion Control
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)
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)
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)
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

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
Pharmaceutical Wastage
Questions?