DEA Trends & Update

Charleston Pharmacy Diversion Awareness Conference

February 27 & 28, 2016
I have no financial relationships 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
CHARLESTON, W.Va. - Former Pratt Mayor Gary Fields admitted to selling the powerful prescription painkiller oxycodone.
Beckley caregiver accused of stealing prescription medications

By Paul Hess, WVVA Internet Director
Posted: Jan 29, 2016 1:13 PM EST

BECKLEY, WV (WVVA) - Police in Raleigh County arrest a woman for allegedly stealing prescription drugs from elderly patient.

Michelle Redden is charged with four counts of obtaining a controlled substance by fraud. She is currently being held in Southern Regional Jail on $25,000 bond.

Police say Redden worked as a homemaker for the Raleigh County Commission on Aging. The prescription drug thefts occurred over the past couple of months at a residence in the Wildwood House Complex on Autumn Lane in Beckley. The Commission on Aging were notified and "immediately took action to remove the homemaker from the residence," according to a police news release.

Redden was arrested by members of the U.S. Marshals Fugitive Task Force.

Read: 3 arrested on heroin charges in Beckley
Read: Lewisburg man sentenced on drug charges
Read: Man accused of soliciting teenager for sex enters plea
W.Va. pharmacist charged in multistate prescription-drug ring

MARTINSBURG, W.Va. — Authorities may have disrupted a prescription-drug ring allegedly involving a Martinsburg pharmacist, a physician employee in Georgia and two Kentucky women who obtained hundreds of pills each month from a Charles Town, W.Va., pharmacy since August.

The pharmacist, David M. Wasanyi, 47, was charged last week in Jefferson County, W.Va., with conspiracy to distribute controlled substances from City Pharmacy at 82 Somerset Blvd., according to Jefferson County Magistrate Court records.
Richlands nurse practitioner admits to writing illegal prescriptions

By Paul Hess, WVVA Internet Director

ABINGDON, VA (WVVA) A former Richlands nurse practitioner enters a plea in federal court to writing illegal prescriptions for the pain-killer oxycodone.

According to court documents, Gloria W. 'Faye' Kennedy conspired with her husband Darryl Lynn Wells to distribute 3,780 oxycodone (15 mg) pills.

Kennedy was "licensed as a nurse practitioner in the state of Virginia and had prescribing privileges granted by the United States Department of Justice Drug Enforcement Administration." Between April 22, 2014 and September 3, 2015 she wrote numerous prescriptions "without a legitimate medical purpose and beyond the bounds of medical practice," to her husband and others.

On Tuesday, Kennedy entered a plea to one count of conspiring to distribute controlled substances and one count of making false statements to investigators. She is scheduled to be sentenced on March 22, 2016.

Wells entered a plea to federal drug charges earlier this month.

Read: Doctor indicted on federal drug charges in Beckley

Read: Greenbrier County cracks down on alleged food stamp card scam

Read: West Virginia woman sues mining company, claims gender discrimination
Dr. Stan Xuhui Li outside State Supreme Court in Manhattan on Friday. He was convicted of 200 of the 211 charges against him after a four-month trial. Anthony Lanziote for The New York Times
Paul Volkman, Chicago Doctor, Gets 4 Life Terms In Drug Overdose Case
Impact on Society
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.
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

U.S. Drug Enforcement Administration
Office of Diversion Control
National Overdose Deaths
Number of Deaths from Prescription Drugs

Source: National Center for Health Statistics, CDC Wonder
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
In 2012, Southern states had the most per person.

The top three states were Alabama, Tennessee, and West Virginia:
- Alabama: 143 per 100 people
- Tennessee: 143 per 100 people
- West Virginia: 138 per 100 people

Lowest—Hawaii: 52 per 100 people
Some states have more painkiller prescriptions per person than others.

Opioid-Involved Drug Poisoning Death Rates by State, 2013

U.S. National Rate: 5.1 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, 2016.
Pharmaceutical Abuse

Rush Limbaugh

Steven Tyler

Eminem

Brett Farve
DEATHS

Marilyn Monroe
August 5, 1962

Elvis Presley
August 16, 1977

Gerald Levert
November 10, 2006

Anna Nicole Smith
February 8, 2007

Heath Ledger
January 22, 2008

Michael Jackson
June 25, 2009

Luna Vachon
August 27, 2010

Michael Baze
May 10, 2011

Whitney Houston
February 11, 2012

Thomas Kinkade
April 6, 2012
Our Youth
Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family... For Free!!
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 (44%)</th>
<th>B (57%)</th>
<th>A-B Difference</th>
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<tbody>
<tr>
<td>School</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parents</td>
<td>31%</td>
<td>38%</td>
<td></td>
</tr>
<tr>
<td>Friends</td>
<td>25%</td>
<td>34%</td>
<td></td>
</tr>
<tr>
<td>On the Street</td>
<td>14%</td>
<td>21%</td>
<td></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:”

Partnership for Drug-Free Kids | The Partnership Attitude Tracking Study | Teens & Parents 2013

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 an act of desperation. No amount of drug loss is worth your life or the life of your patients
Violence Related to Controlled Substance Pharmaceuticals

NEW YORK POST
Page Six

ASSASSIN

Chilling anatomy of drugstore massacre

DRUGSTORE MASSACRE

Husband and wife busted in Rx-slay horror

PAIN KILLER

U.S. Drug Enforcement Administration
Office of Diversion Control
Slain Lansing Rite Aid pharmacist, father of toddler, may not have known attacker

LANSING — Michael Addo, known as a friendly Rite Aid pharmacist with a "million dollar smile," had a toddler and wife in Ghana, where he hoped to return in a year.

By Melissa Anders | manders@mlive.com
Follow on Twitter
on May 13, 2014 at 4:14 PM, updated May 14, 2014 at 5:38 PM

Do you know a WWII vet?

Michigan has 39,000 living WWII veterans -- help us find them

... Read more about the project

Source:
Pharmacist slain in Beach robbery was much beloved

By Stacy Parker
The Virginian-Pilot
© April 15, 2014

VIRGINIA BEACH

When pharmacist David Kilgore left Rite Aid three-plus years ago, customers transferred their prescriptions to his new, small independent business.

They admired the way he connected with them on a personal level.

Monday, they placed flowers at his pharmacy's doorstep after learning the 46-year-old was shot during a morning robbery and later died.

"It was always, 'Hey Pete, how you doing?'" said Peter Carlson, who dropped off a colorful bouquet at Beach Pharmacy on Monday evening.

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Related: Suspect identified, charged with murder

The pharmacist was working at Rite Aid on Laskin Road near the Oceanfront when development

Source: http://hamptonroads.com/2014/04/pharmacist-slain-beach-robbery-was-much-beloved
Pharmacy Armed Robberies
January 1 thru August 31, 2015

- U.S. (Nationwide) - 853
- State of West Virginia - 10

<table>
<thead>
<tr>
<th>West Virginia Counties</th>
<th>Number of Pharmacy Thefts</th>
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<tbody>
<tr>
<td>KANAWHA</td>
<td>4</td>
</tr>
<tr>
<td>MONONGALIA</td>
<td>2</td>
</tr>
<tr>
<td>JEFFERSON</td>
<td>1</td>
</tr>
<tr>
<td>BRAXTON</td>
<td>1</td>
</tr>
<tr>
<td>PUTNAM</td>
<td>1</td>
</tr>
<tr>
<td>MARION</td>
<td>1</td>
</tr>
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</table>

No Reported Armed Robberies in remaining counties

Source: DEA Drug Theft & Loss Database as of 02/22/2016
Drugs of Abuse
Opiates
Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen
INCB Annual Report Narcotic Drugs

Estimated World Requirements for 2015

Statistics for 2013
The United States was the country with the highest consumption of the following drugs:

<table>
<thead>
<tr>
<th>2013</th>
<th>DRUG</th>
<th>2012</th>
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<tbody>
<tr>
<td>99%</td>
<td>Hydrocodone</td>
<td>99%</td>
</tr>
<tr>
<td>78%</td>
<td>Oxycodone</td>
<td>82%</td>
</tr>
<tr>
<td>57%</td>
<td>Morphine</td>
<td>57%</td>
</tr>
<tr>
<td>51%</td>
<td>Hydromorphone</td>
<td>42%</td>
</tr>
<tr>
<td>51%</td>
<td>Methadone</td>
<td>49%</td>
</tr>
<tr>
<td>31.5%</td>
<td>Fentanyl</td>
<td>37%</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®, Lorce

- 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
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

August 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. haven't tried smoking it yet, kinda in a hole money wise, it cost me over $700.00 to get my 80s filled and I probably won't even get half my money back 😞

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

August 27, 2010, 06:09 AM

mephist00
Member

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

My friend has tried to smoke the new ones... said it's 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

Quote:

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

U.S. Drug Enforcement Administration: Office of Diversion Control
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, 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

U.S. Drug Enforcement Administration
Office of Diversion Control
Dextromethorphan (DXM)

- Cough suppressant in over 125 OTC medications (e.g. Robitussin and Coricidin)
- Bulk form on the Internet
- At high doses, has Ketamine- and PCP-like effects
- Produces physical and psychological dependence
- Deaths associated with DXM abuse
Teen OTC Cough Medicine Misuse and Abuse

Prevalence of Teen OTC Cough Medicine Abuse
% Used at Least Once (n=3705)

- Lifetime
- Annual
- Monthly

- 17% ACD
- 11% CDE
- 8%
- 6%
- 5%

- 12%
- 12%
- 5%

2009 (A) 2010 (B) 2011 (C) 2012 (D) 2013 (E)

“(In your lifetime/in the past 12 months/in the past 30 days), how many times have you taken a non-prescription cough or cold medicine to get high?”

A-E indicates a significant difference at the 95% confidence level.
**Cough Syrup Cocktails**

- “Syrup and Soda”
- “Seven and Syrup”
- “Purple D rank”

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U.S. Drug Enforcement Administration
Office of Diversion Control
METHADONE
Methadone - 5mg & 10mg

Mallinckrodt Pharmaceuticals 5 mg & 10mg

Methadone 40 mg

U.S. Drug Enforcement Administration
Office of Diversion Control
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

Oxycodone Combinations
Percocet®
$7-$10/tab

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

OxyContin®
$80/tab

Hydrocodone
Lorcet®
$5-$7/tab

Heroin
$15/bag

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

Pharmaceutical Oxycodone 30mg
Past Month and Past Year Heroin Use Among Persons Aged 12 or Older: 2002-2013

+ Difference between this estimate and the 2013 estimate is statistically significant at the .05 level.
HEROIN: NO LONGER CONFINED TO URBAN AREAS

Heroin use spikes in area suburbs
Pill addicts risk deadly drug
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.

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.

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

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

2. Ibid
Criminal Activity
Egregious Activity
(Not on the fringes)
United States V. Alvin Yee, M.D.

Dr. Alvin Yee
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.
DOCTOR SOLD PRESCRIPTIONS AT STARBUCKS

By StopOxy · Comments Comments Off

It was never our intention to become a watchdog website that would use our outlet to humiliate unethical doctors criminals.

Yet recently we are reading some stories that compel us to provide as much of a “comeuppance” as we can to shady and unethical doctors like

Alvin Ming-Czech Yee of Mission Viejo (medical practice was in Irvine).

This “doctor” sat in a Starbucks Coffee Shop and sold prescriptions for OxyContin - also known as “legal heroin” (or also known as “the prescription drug that is shattering families in record numbers”).

Again, let us reiterate that Dr. Yee would perform his examinations in Starbucks. the “examinations” would last about a minute. Yee would meet up with a dozen people per night in Starbucks throughout Orange County. The “examinations” drug deals consisted of taking blood pressure and
Pain Clinics
Operation “As the Pill Turns”
Ft. Lauderdale, FL
Dr. Vijay Chowdhary and Jason Boyd
1 ½ year long Title III investigation targeting Intercostal Medical Group, a Rouge Pain Clinic in Ft. Lauderdale.

Jason RODRIGUEZ and Jason BOYD both convicted felons were involved in operating the pain clinic.

7 undercover agents were introduced into the clinic as prescription pill buyers, pain clinic patients and a pain clinic sponsor.

Agents executed 4 federal search warrants and arrested 7 people on federal drug and money laundering charges.

Seized during the enforcement action were 18 vehicles and approximately $900,000 in assets.
Jason Boyd, the Pain Clinic Owner

Between his late Twenties and early Thirties, Jason Boyd tried his hand at several drug trades. He dabbled in cocaine, hydrocodone, LSD, marijuana, MDMA, methamphetamine, and steroids between 1996 and 2002, according to his criminal court records in Broward County, Florida.

It didn’t get him very far, except for free trips to the county jail on petty drug charges for slinging nickel-and-dime quantities of illicit narcotics.

However, by the time he turned 38 in 2008, Boyd had found his calling in the Sunshine State’s lucratively addictive prescription pill mill racket, according to a July 3 20-count federal indictment against him and six other co-conspirators accused of operating a bogus pain management clinic in Fort Lauderdale, Florida, that collected $4.2 million from the illegal sale of Oxycodone, Ambien, and prescription Mirtin during a two year period.

His criminal defense lawyer Fred Haddad did not return a message seeking comment about Boyd, his criminal history, and the current charges against him. Boyd, along with four of his co-defendants, are in federal custody pending their bond hearings.

A burly 6’5” man weighing 330 pounds, Boyd has a rap sheet dating back to 1990. He’s been arrested by various police departments in Broward County on a variety of charges from grand theft to possession of MDMA with intent to sell to illegal possession of a firearm by a convicted felon. In one case, he was arrested on October 17, 1997 by Pembroke Pines Police for allegedly trafficking a general store of illicit narcotics, including LSD, marijuana, anabolic steroids, and hydrocodone. He also has a 2003 federal felony conviction for identity and credit card fraud.
• Jason Rodriquez, the Office Manager
In May 2014, five defendants from Intracoastal Medical Group were sentenced in Ft. Lauderdale, Florida for Conspiracy to Distribute:

- Dr. Vijay CHOWDHARY was sentenced to 24 month’s incarceration and a $25,000 fine.

- Physician’s Assistant Harish CHOWDHARY was sentenced to 48 month’s incarceration.

- Pain clinic owner Jason BOYD (also charged with Money Laundering) received 84 months.

- Office manager Jason RODRIGUEZ was sentenced to 168 months incarceration.

- Facilitator Amanda BOZER received four years’ probation.
Does your Doctors Office look like this?
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
- Practitioner
- Pharmacy/Hospital/Clinic
- Patient

1,604,158 (09/04/2015)

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

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

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
Legal Obligations: DEA Registrant
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)
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;
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
We will not arrest our way out of this problem!!!!!

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

Drug Enforcement Administration

Law Enforcement

Diversion Control

Community Outreach
• 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
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

<table>
<thead>
<tr>
<th>Year</th>
<th>Location</th>
<th>Attendance</th>
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<tbody>
<tr>
<td>FY-2011</td>
<td>Cincinnati, OH 9/17-18/11</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td>FY-2011 Total Attendance</td>
<td>75</td>
</tr>
<tr>
<td>FY-2012</td>
<td>WPB, FL 3/17-18/12</td>
<td>1,192</td>
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<tr>
<td></td>
<td>Atlanta, GA 6/2-3/12</td>
<td>328</td>
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<td>Houston, TX 9/8-9/12</td>
<td>518</td>
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<td>Long Island, NY 9/15-16/12</td>
<td>391</td>
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<td>FY-2012 Total Attendance</td>
<td>2,429</td>
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<td>FY-2013</td>
<td>Indianapolis, IN 12/8-9/12</td>
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<td></td>
<td>Albuquerque, NM 3/2-3/13</td>
<td>284</td>
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<td>Detroit, MI 5/4-5/13</td>
<td>643</td>
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<td>Chicago, IL 6/22-23/13</td>
<td>321</td>
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<td>Portland, OR 7/13-14/13</td>
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<td>Baton Rouge, LA 8/3-4/13</td>
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<td>FY-2013 Total Attendance</td>
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<td>Charlotte, NC 2/8-9/14</td>
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<td>Knoxville, TN 3/22-23/14</td>
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<td>St. Louis, MO 4/5-6/14</td>
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<td>Philadelphia, PA 7/12-13/14</td>
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<td>Denver, CO 8/2-3/14</td>
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<td>St. Louis, MO 8/23-24/14</td>
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<td>Phoenix, AZ 9/13-14/14</td>
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<td>FY-2014 Total Attendance</td>
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<td>FY-2015</td>
<td>Las Vegas, NV 2/7-8/15</td>
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<td>Birmingham, AL 3/28-29/15</td>
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<td>Norfolk, VA 5/30-31/15</td>
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<td>Oklahoma City 6/27-28/15</td>
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<td>Milwaukee, WI 7/25-26/15</td>
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<td>Seattle, WA 8/8-9/15</td>
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<td>Portland, ME 9/12-9/13/15</td>
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<td>FY-2015 Total Attendance</td>
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<td>FY-2016</td>
<td>Pittsburgh, PA 12/10-11/15</td>
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<td>Jackson, MS 1/9-10-116</td>
<td>185</td>
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<td>Total Attendance To Date</td>
<td>9,599</td>
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Proposed FY-2016 PDACs

31-Charleston, WV February 27 & 28, 2016
32-Wilmington, Delaware March 19 & 20, 2016
33-Towson, Maryland April 17 & 18, 2016
34-Little Rock, Arkansas June 15 & 16, 2016
35-Minneapolis/St. Paul, Minnesota July 16 & 17, 2016
36-Charleston, South Carolina August 2016
37-New Brunswick, New Jersey September 2016

U.S. Drug Enforcement Administration
Office of Diversion Control
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
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)
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)
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 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
Secure and Responsible Drug Disposal Act of 2010
The Problem: Easy Access
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)

- Registrants authorized to collect:
  - Manufacturers
  - Distributors
  - Reverse Distributors
  - Narcotic Treatment Programs
  - Hospitals/clinics with an on-site pharmacy
  - Retail Pharmacies

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

21 CFR § 1317.40
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**

*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 *(ONDACP 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

- Regulations did not limit the ways that ultimate users may dispose of pharmaceutical controlled substances ...
  - they expanded them
- Any method of pharmaceutical disposal that was valid for ultimate users prior to these regulations remains valid
- Participation is voluntary
- The DEA may not require any person to establish or operate a disposal program

21 USC § 822(g)(2)
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)
Collection Receptacles
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)
Design of Collection Receptacles
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.

21 CFR § 1317.75(e)
Design of Collection Receptacles

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

- Substances **Not Permitted** to be collected:
  - Schedule I controlled substances,
  - Controlled substances that were not lawfully possessed by the ultimate user, and
  - All other illicit substances (including marijuana in states like CO and WA)

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)
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
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)

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)
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)
DEA Web-based Resources

www.DEA.gov
DEA Web-based Resources

www.JustThinkTwice.com

THINK YOU KNOW WHAT METHAMPHETAMINE IS MADE OF?

Maybe you've heard it's made of the same stuff as cold medicine. Well, that's not all. Some of the ingredients used to make meth include battery acid, gasoline, and drain cleaner.

GET THE FACTS ABOUT METHAMPHETAMINE

Marijuana, Cocaine, Meth

Did You Know? Combine toxic chemicals with neglected hygiene, and you get a condition called "meth mouth"—rotten and decaying teeth.
DEA Web-based Resources

www.GetSmartAboutDrugs.com
Ruth.A.Carter@usdoj.gov

Drug Enforcement Administration/ Operations Division/ Office of Diversion Control