DEA Trends & Update

Pittsburgh Pharmacy Diversion Awareness Conference

December 10 & 11, 2015

Thomas W. Prevoznik,
Unit Chief Liaison
Office of Diversion Control
Disclosure Statement

I have no financial relationships to disclose
Goals and Objectives

- Public Health Epidemic
- Impact on Society
- Drugs of Abuse
- The Controlled Substances Act: Checks & Balances
- Legal obligations: DEA registrant
- The DEA Response
- Miscellaneous Pharmacy Topics
- DEA Web-Based Resources
Public Health Epidemic
Prescription opioids are potentially dangerous drugs – overdoses involving these drugs claimed more than 175,000 lives between 1999 and 2013.

From 1999 to 2010, a 4-fold increase in opioid sales paralleled a more than 4-fold increase in prescription opioid-involved overdose deaths.
In four years of medical school, students receive, on average, only 11 hours of pain medication training.

The three most common types of prescriptions are antibiotics, antidepressants, and painkiller opioids.

70% of Americans are taking at least one prescription drug.

More than 50% are on at least two prescriptions.
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
Women to stand trial in theft of drugs from Norwin Pharmacy

By Paul Pierce
Friday, March 27, 2015, 12:01 a.m.

A North Huntingdon pharmacy technician confessed she stole 180 to 600 pain pills on every shift she worked for more than a year, then handed them over to be sold on the street, according to the state attorney general's office.

Agent Andrew Sakmar testified at a preliminary hearing that former Norwin Pharmacy technician JoAnn Gruber, 53, admitted in an interview last fall that she stole "tens of thousands" of pain pills including oxycodone, Xanax and OxyContin and gave them to Michele I. Ganelli and her boyfriend.

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Package detonated
Police detonate a suspicious package in Oakland's Ewart Biomedical Science Tower.
Washington County pharmacy owner charged with fraud

October 10, 2014 8:26 PM

By Madelyn Czubinski / Pittsburgh Post-Gazette

The owner of a Pennsylvania pharmacy was charged with fraud Friday after an investigation revealed he allegedly stole $346,000 from insurance companies by filing false prescription claims, falsified prescriptions and gave multiple patients narcotic pills, the state Attorney General’s office announced Friday.

Andrew F. Kuly, 61, of Washington County, has been charged with drug diversion, Medicaid fraud, insurance fraud and theft by deception, according to court records.
Physician assistants, two others charged in prescription drug scheme

September 22, 2015 10:55 AM

By Andrew Goldstein / Pittsburgh Post-Gazette

Four Allegheny County residents, including two physician assistants, were charged by the state attorney general’s office in a prescription drug ring, state Attorney General Kathleen Kane announced.

Dena J. Lazar, 26, of Overbrook; Jill S. Harlan, 32, of Springdale Township; Jodi L. Cantor, 50, of Bridgeville; and Brandon R. Bodnar, 29, of Carnegie, are accused of diverting prescription drugs between March and June 2015.
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 Lanzilote for The New York Times
Paul Volkman, Chicago Doctor, Gets 4 Life Terms In Drug Overdose Case
Impact on Society
Consequences

In 2011, approximately 41,340 unintentional drug overdose deaths occurred in the United States, one death every 12.45 minutes. (increased for 12th consecutive year)

Of this number, 22,810 deaths were attributed to Prescription Drugs (16,917 attributed to opioid overdoses/74.165%).

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

CDC National Center for Health Statistics/National Vital Statistics Report; June 2014
CDC Vital Signs: Opioid Painkiller Prescribing; July 2014
Drug-Poisoning Deaths Involving Opioid Analgesics or Heroin in the US, 1999-2013

Number of Deaths in Thousands

Year

Heroin

Opioid Analgesics

'99 2.0 4.03
'00 1.8 4.4
'01 1.8 5.528
'02 2.1 7.456
'03 2.1 8.517
'04 1.9 9.857
'05 2.0 10.928
'06 2.1 13.723
'07 2.4 14.408
'08 3.0 14.8
'09 2.4 15.597
'10 3.0 16.651
'11 4.4 16.917
'12 5.9 16.007
'13 8.3 16.235

Date Prepared/ Source: 01/28/15, CDC/NCHS, National Vital Statistics System, Mortality File

Drug Enforcement Administration/ Operations
Division/ Office of Diversion Control
• 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

SOURCE: CDC Vital Signs: Opioid Painkiller Prescribing; July 2014
Some states have more painkiller prescriptions per person than others.

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.

Drug Enforcement Administration/Operations Division/Office of Diversion Control
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, 2013.

Drug Enforcement Administration/Operations
Division/Office of Diversion Control
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
Violence Related to Controlled Substance Pharmaceuticals

ASSASSIN

Chilling anatomy of drugstore massacre

DRUGSTORE MASSACRE

Husband and wife busted in Rx-slay horror

PAIN KILLER

David Laffer is the man caught on video wearing a fake beard (top) who slaughtered four people in a pharmacy to feed his wife Melissa’s addiction, cops said yesterday.

Drug Enforcement Administration/Operations Division/Office of Diversion Control
Drugs of Abuse
Commonly Abused Controlled Substances

- Hydrocodone
- Oxycontin 80mg
- Oxymorphone
- Oxycodone 30mg
- Alprazolam

Drug Enforcement Administration/Operations Division/Office of Diversion Control

C-IV as of 1/11/2012
The Trinity

Hydrocodone

Opiate

Carisoprodol

C-IV as of 1/11/2012

Muscle Relaxant

Alprazolam

Benzodiazepine

Muscle Relaxant

Benzodiazepine
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
Worldwide Hydrocodone Use

- 67 countries reported an estimated need requirement for hydrocodone to the International Narcotics Control Board.
- 20 countries reported an estimated need of 1 kilogram or greater.
- 4 countries reported an estimated need between 500 grams and 999 grams.
- 10 countries reported an estimated need between 100 grams and 499 grams.
- 6 countries reported a need between 25 grams and 99 grams.
- 27 countries reported a need of less than 25 grams.

Of the 20 Countries that reported an estimated needs requirement for hydrocodone at one kilogram or more:

- 8 countries reported an estimated need of 1 kilogram to 5 kilograms
- 4 countries reported an estimated need over 5 kilograms to 10 kilograms
- 8 countries reported an estimated need over 10 kilograms

### Top 10 List

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<th>Rank</th>
<th>Country</th>
<th>Quantity</th>
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<tr>
<td>10</td>
<td>Guatemala</td>
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<tr>
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<td>India</td>
<td>10 kilograms</td>
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<tr>
<td>08</td>
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<tr>
<td>07</td>
<td>China</td>
<td>20 kilograms</td>
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<tr>
<td>06</td>
<td>Denmark</td>
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<tr>
<td>05</td>
<td>Columbia</td>
<td>30 kilograms</td>
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<tr>
<td>04</td>
<td>Syrian Republic</td>
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<tr>
<td>03</td>
<td>Canada</td>
<td>115.5 kilograms</td>
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<tr>
<td>02</td>
<td>United Kingdom</td>
<td>200 kilograms</td>
</tr>
<tr>
<td>01</td>
<td>United States</td>
<td>79,700 kilograms</td>
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OXYCODONE
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.
Prescription Opiates v. Heroin
Circle of Addiction & the Next Generation

Hydrocodone
Lorcet®
$5-$7/tab

Oxycodone Combinations
Percocet®
$7-$10/tab

OxyContin®
$80/tab

Heroin
$15/bag

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

Drug Enforcement Administration/Operations Division/Office of Diversion Control
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.

Date Prepared/ Source: 2013 National Survey on Drug Use and Health, published September 2014. Figure 2.4.

Drug Enforcement Administration/Operations Division/Office of Diversion Control
HEROIN: NO LONGER CONFINED TO URBAN AREAS
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
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

Record Keeping Requirements

Security Requirements

ARCOS

Established Schedules

Registration

Established Quotas

Drug Enforcement Administration/Operations Division/Office of Diversion Control
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)
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)
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

Drug Enforcement Administration/Operations Division/Office of Diversion Control
www.nabp.net
The DEA Response
We will not arrest our way out of this problem!!!!!

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

August 1, 2005 – May 15, 2015: Briefings to 84 firms with 279 registrations
Pharmacy Diversion Awareness Conference

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

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<th>Fiscal Year</th>
<th>Location</th>
<th>Date</th>
<th>Attendance</th>
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<td>9/17-18/11</td>
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<td><strong>FY-2011 Total Attendance</strong></td>
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<td>FY-2012</td>
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<td>Long Island, NY</td>
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<td>Boston, MA</td>
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<td>Portland, ME</td>
<td>9/12-9/15</td>
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<td><strong>Total Attendance To Date</strong></td>
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<td><strong>9,218</strong></td>
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ProposedFY-2016 PDACs

- 29-Pittsburgh, PA December 10 & 11, 2015
- 30-Jackson, MS January 9 & 10, 2016
- 31-Charleston, WV February 27 & 28, 2016
- 32-Wilmington, Delaware March 19 & 20, 2016
- 33-Charleston, South Carolina April 2016
- 34-Little Rock, Arkansas May 2016
- 35-Minneapolis/St. Paul, Minnesota July 2016
- 36-Towson, Maryland August 2016
- 37-New Brunswick, New Jersey September 2016
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
Secure and Responsible Drug Disposal Act of 2010
The Problem: Easy Access
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)

- 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

• 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)
• 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 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)
National Take Back Initiative
September 26, 2015

Got Drugs?
Turn in your unused or expired medication for safe disposal Saturday September 26, 2015

Click here for a collection site near you.

10:00 AM – 2:00 PM
Drug Enforcement Administration/Operations Division/Office of Diversion Control
10th National Take Back Day: September 26, 2015
Total Weight Collected (pounds): 742,771 (371 Tons)
Miscellaneous Pharmacy Topics
A pharmacy may not act as an agent of the physician

- A practitioner may authorize an agent to prepare the prescription, instructing agent as to required elements of the prescription
  21 CFR § 1306.05(f)

- An agent cannot legally perform duties that must be personally performed by the individual practitioner
  21 CFR § 1306.04(a)
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
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 and sell the drugs in the form of a distribution to any DEA Registrant – including practitioner office.

• Violation of DEA and FDA regulations
Registrant Disposal
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
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 C.F.R. § 1304.21(e)
Abandoned Controlled Substances

• Circumstances when there is no authorized person to dispose of controlled substances
  ○ School
  ○ Summer camp
  ○ Hospital

• Return to ultimate user is not feasible

• Options
  ○ Contact law enforcement or DEA
  ○ Destroy on-site

79 FR 53546 (Disposal Final Rule)
Pharmaceutical Wastage
• **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
DEA Web-Based Resources
DEA Web-based Resources
Office of Diversion Control
www.deadiversion.usdoj.gov