Federal Law and Regulations and Dispensing Controlled Substances

American Pharmacists Association
San Francisco, California
March 26, 2017

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Goals & Objectives
In the News
The Public Health Epidemic
The “Real” Mission of the DCD
“Diversion”
Effective Controls
Preventative Measures
Miscellaneous Pharmacy Topics
The Good Guys & The Bad Guys
A Final Note

LEGAL DISCLAIMER
The following presentation was accompanied by an oral presentation on March 26, 2017, and does not purport to establish legal standards that are not contained in statutes, regulations, or other competent law. Statements contained in this presentation that are not embodied in the law are not binding on DEA. Summaries of statutory and regulatory provisions that are summarized in this presentation do not purport to state the full extent of the statutory and regulatory requirements of the cited statutes and regulations. I have no financial relationships to disclose.

In the News

“Doctor charged with pushing painkiller, receiving kickbacks”

“Employees Stealing Drugs From Ohio Pharmacies, Health Care Facilities”
“Doctor Accused of Prescribing Addictive Painkillers to Patients in Exchange for Sex Pleads Guilty”

“Former Ford Dealership Manager Pleads Guilty to Prescription Drug Distribution Charges”

“Sandy Springs foot doctor faces federal charges of distributing narcotics”

“Former Employee of … Hospital Sentenced to 39 Years in Connection with Widespread Hepatitis C Outbreak”

“Addicts putting pharmacies under siege”

“22 Pharmacists, Doctors Arrested in DEA's Drug Abuse Crackdown”
“Hoboken pharmacist arrested for stealing morphine from city hospital, police say”

“Local Doctor and Pharmacist Arrested in Pill Mill Investigation Indictment Charges Numerous Individuals in Conspiracy to Distribute Oxycodone and Hydrocodone at Dallas Pill Mill”

“Doctor suspended in Wyoming and Arizona amid pill probe”

“Madison, IN pharmacist arrested”

“Pharmacist arrested after reported thefts”

“Oklahoma Pharmacist Arrested for Embezzling Oxycodone”
“West Virginia sues 3rd pharmacy over painkillers”

“Two Doctors, Pharmacist Arrested In Biloxi”

“Four Facing Federal Robbery, Prescription Opioid and Firearms Charges Arising Out of Armed Robbery of Pharmacy in Raton”

“Pharmacist arrested, deputy fired over pills”

“(Hospital) will Pay $2.3M To Settle Drug Violations”

“Pharmacist arrested for stealing $5.6M in painkillers”
“$2.4 million: The amount brought in by a prescription drug ring that authorities say involved a Richmond area doctor.... (T)he operation involved the sale of ...120,000 oxycodone pills for $14 to $25 dollars each.”

March 6, 2017

“Pills laced with deadly opioid infiltrating drug market, DEA says”

“Smash and Grab” Drug Store Burglary Suspect Arrested in Illinois”

Public Health Epidemic
In 2014, there were 47,055 drug overdose deaths,
...one death every 11.16 minutes,
...approximately 128 per day,
...19,000 were due to prescription opioid pain relievers

Public Health Epidemic
In 2015, there were 55,403 drug overdose deaths,
...one death every 9.54 minutes,
...approximately 151 per day,
...20,101 were due to prescription opioid pain relievers

Controlled Substance Abuse
Drug overdose is the leading cause of injury-related death in the United States

Figure 1: Number of Injury Deaths by Drug Poisoning, Suicide, Homicide, Ransoms, and Malher

Source: Centers for Disease Control and Prevention

2000-2016
Controlled Substance Abuse

Prescription opioids cause more drug overdose deaths than cocaine and heroin combined.

Deaths from All Drugs

Deaths from Prescription Opioid Pain Relievers

Deaths from Benzodiazepines

Opioid Involvement in Benzodiazepine Overdose

Prescription drug poisoning deaths include deaths from prescription opioids and benzodiazepines.
Deaths from Heroin

Ten Most Commonly Prescribed Controlled Substances in the U.S.
- Hydrocodone
- Oxycodone
- Alprazolam
- Tramadol
- Zolpidem
- Clonazepam
- Lorazepam
- Dextroamphetamine
- Codeine
- Methylphenidate

Source: National Center for Health Statistics, CDC Wonder

The Most Common Drugs Involved in Prescription Opioid Overdose Deaths
- Hydrocodone
- Oxycodone
- Methadone

Mission
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...

What is “Diversion”?
The movement of legitimate controlled substances and chemicals into other than legitimate medical, scientific, research, or industrial channels.

Mission
... while ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical, commercial, and scientific needs.
“Diversion” Can Occur

Anytime,
Anyplace,
Under Any Circumstances,
with Anyone

The Common Denominator

“The Human Factor”

Total Controlled Substance Rx’s

Controlled Substances as a % of Total Market

On Average (From 2009-2015)

What % of All Prescriptions Filled By A Pharmacy Involve Controlled Substances?

13.25 %
On Average
How Many Controlled Substance
Prescriptions
Have Been Issued For
Every Man, Woman, and Child
in the United States?

1.7

Why are CS Diverted?
Recreation
Addiction
Profit
Sex

Points of Diversion
• Pharmacists
• Pharmacy Technicians
• Managers
• Cashiers
• Stock Personnel
• Contractors
• General Maintenance Personnel

Points of Diversion
• Automated Dispensing Systems (ADS)
• Fraudulent “Call-In” Prescriptions
• Forged Prescriptions
• Employee Theft
• Armed Robbery
• Burglary

Nationwide Reported Thefts
(Armed Robbery, Employee Pilferage and Night Break-in Only)
January 1, 2009 – December 31, 2016

Pharmacies
25,207 Thefts
Hospitals
11,027 Thefts
Practitioners
3,082 Thefts
Employee Pilferage
10,407 Thefts
Remaining Business Activities
648 Thefts – 2%

Armed Robbery
6,196 Thefts
Night Break-In
8,604 Thefts

Number of Pharmacy Thefts Nationwide
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21 C.F.R. § 1301.71(a)
“All applicants and registrants shall provide **effective controls** and **procedures** to guard against theft and diversion of controlled substances.”

**Effective Controls**

**Preventative Measures**

- SOP’s for Handling CS
- Limited Access to CS
- Limited Access to Alarms, Keys, and Pass Codes
- Limited Access to Dispensing Areas
- Physical Security (Cameras, PB’s)

**Preventative Measures**

- Cameras in areas where CS are being dispensed
- **Complete and Accurate Dispensing Records**
- **Periodic Physical Inventories**
- Medications to be Administered by Authorized Personnel Only as Expressly Authorized by an Individual Practitioner

**Collection Receptacles**

Tell Practitioners **(All DEA Registered Practitioners)** to **secure** their prescription pads

*(All DEA Registered Practitioners)*
The Last Line of Defense

U.S. Drug Enforcement Administration

Potential Red Flags

• Many customers receiving the same combination of prescriptions; cocktails
• 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

• 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
• Verification of legitimacy not satisfied by a call to the doctors office

Miscellaneous Pharmacy Topics

Opioid Drug Treatment

The Comprehensive Addiction and Recovery Act of 2016
“CARA”
July 22, 2016
Public Law 114-198
Qualifying Other Practitioners

(I) The nurse practitioner or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.

(aa) completed not fewer than 24 hours of initial training…

(bb) has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner or physician assistant to treat and manage opiate-dependent patients.
 Qualifying Other Practitioners

(III) The nurse practitioner or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner or physician assistant is required by State law to (do so).

Opioid Drug Treatment
Qualifying Practitioners

(30, 100, 275 Patients)

Qualifying Other Practitioners

(30, 100 Patients)

Partial Fills: 21 C.F.R. 1306.13

The Partial Filling of a Prescription for Schedule II is Permissible if the Pharmacist is Unable to Supply the Full Quantity Called for in a Written or Emergency Oral Prescription

Partial Fills: 21 C.F.R. 1306.13

The Remaining Portion of the Prescription May Be Filled Within 72 hours of the First Partial Filling

CARA: Partial Fills (New)

Section 702
Amended 21 U.S.C. 829
(1) A Prescription For A Controlled Substance In Schedule II May Be Partially Filled If—

CARA: Partial Fills (New)

(A) it is not prohibited by State Law;
(B) the prescription is written and filled in accordance with Federal and State Law & Regulations.
CARA: Partial Fills (New)
(C) the partial fill is requested by the patient, or the practitioner that wrote the prescription; and
(D) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

CARA: Partial Fills (New)
(2) remaining portions of a partially filled prescription for a controlled substance in Schedule II—
(i) may be filled; and
(ii) shall be filled not later than 30 days after the date on which the prescription is written.

Multiple Prescriptions CII
Individual practitioner may issue multiple prescriptions which authorizes patient to receive a 90-day supply of a C-II

21 CFR § 1306.12(b)

Multiple Prescriptions CII
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

Pre-Populated Prescriptions
An agent may not legally perform duties that must be personally performed by the individual practitioner.

Pre-Populated Prescriptions
The practitioner must first determine that a prescription for a controlled substance is for a legitimate medical purpose; then, the practitioner may authorize an agent to prepare the prescription.
Pre-Populated Prescriptions
A pharmacy cannot provide in whole, or in part, pre-populated information on a document and have that document then become the prescription.

The Good Guys and The Bad Guys

21 C.F.R. § 1306.04 (a)
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 C.F.R. § 1306.04(a)
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 C.F.R. § 1306.04(a)
An order purporting to be a prescription issued not in the usual course of professional treatment ... is not a prescription...

A Final Note
Solutions

- Prevention/Detection
- Education
- Treatment
- Enforcement

www.DEAdversion.usdoj.gov

www.cdc.gov

- "Pharmacists: On The Front Lines"
- "Guideline for Prescribing Opioids for Chronic Pain"
- "Checklist for Prescribing Opioids for Chronic Pain"

www.AWARERX.org

- Educational Video
- "RED FLAGS"

Resources

- www.DEADiversion.usdoj.gov
- www.dea.gov
- www.operationprevention.com
- "Chasing the Dragon"

Thank You / Questions