Federal Law, Regulations, and Dispensing Controlled Substances

American Society of Pain Management Nursing®
Phoenix, Arizona
September 14, 2017

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LEGAL DISCLAIMER
The following presentation was accompanied by an oral presentation on September 14, 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.

Goals and Objectives
In the News
Our Public Health Epidemic
Most Commonly Prescribed Drugs
New Dangers: Drugs that Produce Death
The Controlled Substances Act (CSA)
Mission of the Diversion Control Division
The Diversion of Controlled Substances
Inventories, Records, and Reports
Effective Controls for Controlled Substances
Resources for Practitioners
Some Final Notes
In the News

“Hendersonville nurse arrested, accused of selling Xanax bars”
May 17, 2017

“Mississippi nurse arrested for alleged opioid embezzlement”
May 26, 2017
“Nurse arrested after stealing Rx drugs at hospital, authorities say”

June 1, 2017

“MBN agents arrest Forest nurse on felony drug charge”

June 13, 2017

“Mississippi Nurse Practitioner Arrested In Opioid Case”

July 7, 2017
“CB nurse accused of stealing nearly 10,000 pain pills from nursing home residents”
July 20, 2017

“Oklahoma nurse arrested for fake prescription”
July 24, 2017

“Two Johnson City nurses indicted, arrested on several counts of drug diversion, fraud”
July 24, 2017
“Nurse accused of stealing oxycodone, hydrocodone from Mayo Clinic”

July 25, 2017

“SC nurse arrested, accused of stealing more than 130 doses of Oxycodone”

July 26, 2017

“Former nursing director charged with stealing opioids from patients”

August 2, 2017
Controlled Substance Abuse

Drug overdose is the leading cause of injury-related death in the United States.

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

Deaths from All Drugs
Deaths from Opioid Drugs

Deaths from Prescription Opioid Pain Relievers

Deaths from Benzodiazepines

Source: National Center for Health Statistics, CDC Wonder
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

Public Health Epidemic

“The preliminary numbers for 2016 show an increase to almost 60,000 deaths.”

Rod Rosenstein
Deputy Attorney General

Ten Most Commonly Prescribed Controlled Substances in the U.S.

• Hydrocodone  • Clonazepam
• Oxycodone  • Lorazepam
• Alprazolam  • Dextroamphetamine
• Tramadol  • Codeine
• Zolpidem  • Methylphenidate
The Most Common Drugs Involved in Prescription Opioid Overdose Deaths

- Hydrocodone
- Oxycodone
- Methadone

Total Controlled Substance Rx’s

Controlled Substances as a % of Total Market
On Average (From 2009-2016)

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

13.10 %

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

1.7
"It’s raining needles: Drug Crisis creates pollution threat."

Lowell, Massachusetts
Michael Casey
Associated Press
Comprehensive Drug Abuse Prevention and Control Act

October 27, 1970

Public Law 91-513

Drug Control Legislation

• In response to:
  – Single Convention on Narcotic Drugs 1961 (Ratified by the U.S. in 1967)
  – “The growing menace of drug abuse in the United States”
  – Need for unified legislation and more effective drug control efforts
### History of Drug Control Legislation

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<td>Harrison Narcotic Act</td>
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<tr>
<td>1914</td>
<td>Import Act</td>
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<td>1922</td>
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<td>1968</td>
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### “Controlled Substances Act”

- Created a system of controls for the legitimate manufacture, distribution, import, export, dispensing, and prescribing of controlled substances for legitimate medical, commercial, scientific, and research needs.

### 21 U.S.C. § 822 (a)(1)

- **Persons Required to Register:**

  - “Every person who manufactures or distributes any Controlled Substance or List I Chemical ...”
21 U.S.C. § 822 (a)(2)

- Persons Required to Register:

- “Every person who dispenses … any Controlled Substance ...”

21 U.S.C. § 957 (a)(1)

- Persons Required to Register:
  No person may

  (1) import into the customs territory of the United States … any controlled substance or list I chemical, or

21 U.S.C. § 957 (a)(2)

  (2) export from the United States any controlled substance or list I chemical, unless there is in effect with respect to such person a registration issued by the Attorney General …
21 U.S.C. § 827

All DEA Registrants Must:

• Make and Keep Inventories
• Make and Keep Records
• Make and Keep Reports

21 U.S.C. § 827

Inventories, Records, And Reports Must Be:

- In a Form as Required By Regulation
- Readily Retrievable
- Complete and Accurate
- Kept for Two Years

Drug Enforcement Administration

July 1, 1973
Closed System of Distribution

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

Closed System

• DEA is responsible for
  – the oversight of the system
  – the integrity of the system,
  – the protection of the public health and safety.
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.

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

Anytime,

Anyplace,

Under Any Circumstances,

with Anyone

The Common Denominator

“The Human Factor”
Nationwide Reported Thefts
(Armed Robbery, Employee Pilferage and Night Break-In Only)

January 1, 2009 – December 31, 2016

- Pharmacies: 25,207 Thefts (63%)
- Hospitals: 11,027 Thefts (27%)
- Practitioners: 3,082 Thefts (8%)
- Remaining Business Activities: 648 Thefts (2%)

Source: DEA
Date Prepared: 01/31/2017

Number of Practitioners Thefts Nationwide
January 1, 2009 – December 31, 2016
(Armed Robbery, Employee Pilferage and Night Break-In Only)

- Employee Pilferage: 2,507 Thefts (81%)
- Night Break-In: 570 Thefts (18%)
- Armed Robbery: 20 Thefts (1%)

Source: DEA
Date Prepared: 07/24/2017
Inventories, Records, and Reports

Inventories

• Initial Inventory
• Biennial Inventory
• Newly Controlled Drugs
**General Inventory Requirements**

- Separate Inventories For Each Registered Location.
- May be taken:
  - (OOB) Opening of Business/or
  - (COB) Close of Business
- 21 CFR 1304.11 (a)

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**Initial Inventory**

- Inventory of all Stocks of CS
- On The Date: First Engage in the Dispensing of Controlled Substances
- Should Be Labeled “Initial Inventory”
- Nothing on Hand: Record “0”
- 21 CFR 1304.11 (b)

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**Biennial Inventory**

- After the Initial Inventory
- New Inventory Every Two Years
- On Any Date Which is Within Two Years of The Previous Inventory Date
- Should Be Labeled “Biennial Inventory”
- Nothing on Hand: Record “0”
- 21 CFR 1304.11 (c)
Newly Controlled Substances

- For Any Newly Controlled Substances
- Inventory of all stocks on hand
- On The Effective Date of The Rule
- 21 CFR 1304.11 (d)

RECORDS

Records: General Requirements

- Maintain on a Current Basis...
- Complete and Accurate Record of Each Substance...Manufactured, Imported, Exported, Received, Sold, Delivered, or Otherwise Disposed of
- Except No Registrant is Required to Maintain a Perpetual Inventory
- 21 CFR 1304.21 (a)
**Records: General Requirements**

- **Schedule I & II:**
- Inventories and Records Shall Be Maintained Separately from All Other Records
- 21 CFR 1304.04 (f)(1); (h)(1)

**Records: General Requirements**

- **Schedules III, IV, & V**
- Separate from All Other Records or "Readily Retrievable"
  - Separated Out from all other Records in a Reasonable Time Period.
  - CS Items asterisk, redlined, or in some Manner which sets them Visually Apart
- 21 CFR 1304.04 (f)(2); (g); (h)(2)

**Records: General Requirements**

- Separate Records.. For Each Registered Location.

- 21 CFR 1304.21 (b)
Records: Dispensing

- Shall Maintain Records with the Same Information Required of Manufacturers Pursuant to Paragraph (a) (2) (i), (ii), (iv), (vii), and (ix) of this section.

- 21 CFR 1304.22 (c)

Records: Dispensing

- Name of CS, Form, Quantity, Strength
- Number of Units or Volume of Finished Form Dispensed
- Name, Address of the Person to Whom It Was Dispensed.
- Date of Dispensing

Records: Dispensing

- Written or Typewritten Name or Initials of the Individual Who Dispensed or Administered the Substance on Behalf of the Dispenser

- Amount Disposed of in Any Other Manner
Dates for Records

- Dates Must be the Actual Date of Transfer (Received, Imported, Exported, Distributed, or Otherwise Transferred ...)

- 21 CFR 1304.21 (d)

DEA Form 222

Order Forms are Required for Each Transfer of a CS in Schedule I & II

Reports
Reporting the Theft or Loss of Controlled Substances

21 CFR 1301.76 (b)

• The registrant shall notify the Field Division Office of the Administration in his area of any theft or significant loss of any controlled substances within one business day of discovery.

21 CFR 1301.76 (b)

• The registrant shall also complete, and submit DEA Form 106…
• “Significant Loss” is also defined here.
• Reporting is On-Line or DEA Form 106.
Theft/Loss of CS

- Theft Should also be Reported to Local Police with Jurisdiction where the Theft Occurred.
- Also Reported to Any State Agency Which May Also Require Such Reports
Prescriptions

§1306.03 Persons entitled to issue prescriptions.

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and

(2) either registered or exempted from registration pursuant to Secs. 1301.22 (c) and 1301.23 of this chapter.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

§1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.
Prescriptions

(d) A practitioner may sign a paper prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, paper prescriptions shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner.

Prescriptions

(e) Electronic prescriptions shall be created and signed using an application that meets the requirements of part 1311 of this chapter.

Prescriptions

(f) A prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.
Researchers Reveal Prevalence of Unused Prescription Opioids Following Surgery

News-Medical.net
(08/02/2017)

In a review of half a dozen published studies in which patients self-reported use of opioids prescribed to them after surgery, researchers at Johns Hopkins report that a substantial majority of patients used only some or none of the pills, and more than 90 percent failed to dispose of the leftovers in recommended ways. A summary of the review, published August 2 in *JAMA Surgery*, highlights the need for more personalized pain management to avoid overprescribing opioids and reduce risks linked to improperly stored opioids in the home.

Why are CS Diverted?

- Recreation
- Addiction
- Profit
- Sex
Points of Diversion

• Nurses
• Physicians
• Physician Assistants
• Pharmacists
• Pharmacy Technicians
• Office Managers
• Cashiers
• General Maintenance Personnel

Points of Diversion

• Fraudulent “Call-In” Prescriptions
• Forged Prescriptions
• Employee Theft
• Armed Robbery
• Burglary

Effective Controls

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

21 C.F.R. § 1301.75 (b):
Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet.

Preventative Measures

• Pre-Employment Screening
  – Background Checks
  – Drug Screening
• Updated Background Checks (Every 3-5 Years)
• Random Drug Screening

• 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

Tell Practitioners

(All DEA Registered Practitioners)

to secure their prescription pads
The Medicine Cabinet
and
Pharmaceutical Controlled
Substances

Collection Receptacles
Resources for Patients

www.drugdropbox.org
www.disposeymeds.org
www.sharpsinc.com/locations
www.fda.gov (Search: Disposal)
www.epa.gov (Search: Disposal)

Some Final Notes

JUST ONE THING
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.

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.

An order purporting to be a prescription issued not in the usual course of professional treatment … is not a prescription…
Solutions to the Problem

Prevention/Detection

Education

Treatment

Enforcement

Resources

www.DEADiversion.usdoj.gov

www.dea.gov

“Chasing the Dragon”
Resources

- www.getsmartaboutdrugs.com (for parents)
- www.justthinktwice.com (for teens)
- www.operationprevention.com (for teachers)
- www.campusdrugprevention.gov (for higher education)

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www.cdc.gov

“Guideline for Prescribing Opioids for Chronic Pain”

“Checklist for Prescribing Opioids for Chronic Pain”

https://www.cdc.gov/drugoverdose/prescribing/trainings.html

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Thank You