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**New & Existing Law,
Regulations, and Policy:
Hot Topics**

National Association of Boards of Pharmacy
Districts 6, 7, & 8
San Antonio, Texas
October 11, 2017

The United States Department of Justice
Drug Enforcement Administration

James A. Arnold, Chief
Liaison and Policy
Diversion Control Division

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LEGAL DISCLAIMER
The following presentation was accompanied by an oral presentation on **October 11, 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.**

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Hot Topic Issues

- Public Health Epidemic
- Narcotic Drug Treatment
- Partial Fills
- Changes to a Prescription
- Multiple Prescriptions
- Transfer (Forwarding) of Prescriptions
- Marijuana
- Effective Controls
- Resources
- National Emergencies
- What's New
- A Final Note

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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

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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

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Public Health Epidemic

The preliminary numbers for 2016
show an increase to almost
(if not over)
60,000 deaths.

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**The Most Common Drugs
Involved in Prescription Opioid
Overdose Deaths**

Oxycodone

Hydrocodone

Methadone

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

• Hydrocodone	• Clonazepam
• Oxycodone	• Lorazepam
• Alprazolam	• Dextroamphetamine
• Tramadol	• Codeine
• Zolpidem	• Methylphenidate

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**The Most Common
Controlled Substances Involved
in Medicare/Medicaid Fraud**

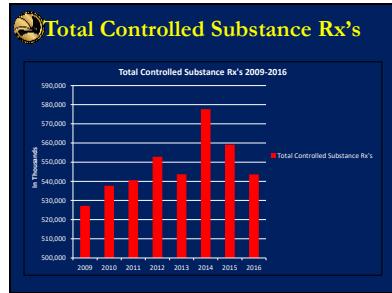
Hydrocodone

Oxycodone

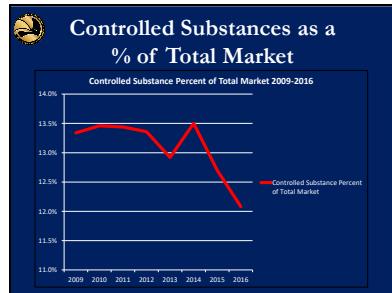
Fentanyl

Buprenorphine

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On Average (From 2009-2016)

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 **Narcotic Drug Treatment**

- **Comprehensive Addiction and Recovery Act of 2016 (P.L. 114-198)**
- Effective: July 22, 2016
- Amended 21 U.S.C. 823(g)
- **New HHS/SAMHSA Regulations:**
- “Medication Assisted Treatment for Opioid Use Disorders”
- Effective: August 8, 2016

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 **New Law: C.A.R.A.**

“Qualifying Practitioners”
(Qualifying Physicians)

(Nurse Practitioners/Physician Assistants)

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 **New SAMHSA Regulations**

- **Qualifying Practitioners**
(Qualifying Physicians)
- Administer, Dispense, and Prescribe as Allowed by Federal Law and Regulations.
- 30, 100, **275** Patients
- “Active Script, Active Patient”

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Qualifying Other Practitioners

- A properly State Licensed, DEA Registered, Nurse Practitioner or Physician Assistant can Prescribe as allowed under Current Federal and State Law and Regulations.
- Limited to **30, 100** Patients
- The nurse practitioner or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.

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Partial Fills

Comprehensive Addiction and Recovery Act of 2016 (P.L. 114-198) Effective: July 22, 2016

- In addition to current regulations on partial fills in 21 C.F.R. § 1306.13
 - If cannot supply full amount/72hrs
- Does not replace or contradict
- Additional Options for Patient, if state law permits.
- Patient does not have to take the Full Amount of Prescribed Quantity/Has 30 days to Take All if So Desired

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Partial Fills

Comprehensive Addiction and Recovery Act of 2016 (P.L. 114-198) Effective: July 22, 2016

- In emergency situation as outlined in 21 U.S.C. § 829(a)
- The remaining portions of a partially filled prescription shall be filled no later than 72 hours after the prescription is issued.

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Multiple Prescriptions CII

Individual practitioner may issue multiple prescriptions which authorizes a patient to receive a total of up to a 90-day supply of a C-II.

21 CFR § 1306.12(b)

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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

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Multiple Prescriptions CII

The issuance of multiple prescriptions is permissible under state law

Nothing under DEA regulations limits the quantity or the number of scripts. However, state law may have limits.

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Transfer (Forwarding) of Script

- Electronic EPCS prescriptions Schedule 2-5 can be transferred
- Refills for Schedule 3-5 can be transferred.
- Original C2 -C5 (Paper, Faxed, or Oral) prescriptions cannot be transferred.

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Compounding vs. Manufacturing (Current Situation)

Compounder : Retail Pharmacy

- Patient Specific Prescription

Compounder : Manufacturing

- Compounded Medications for “anticipatory compounding” and general distribution to a Doctor for general dispensing
- Compounded medications by a Retail Pharmacy must be delivered directly to a patient

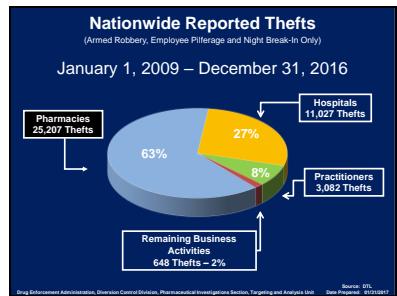
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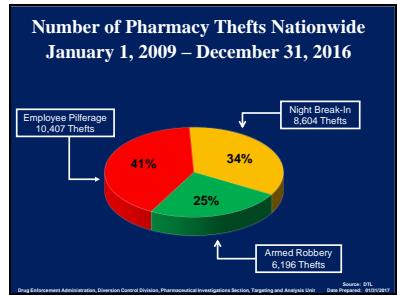
Marihuana

- Marihuana is a Schedule I Controlled Substance
- High Potential for Abuse
- No Currently Accepted Medical Use in Treatment in the U.S.
- Lack of Accepted Safety for Use Under Medical Supervision

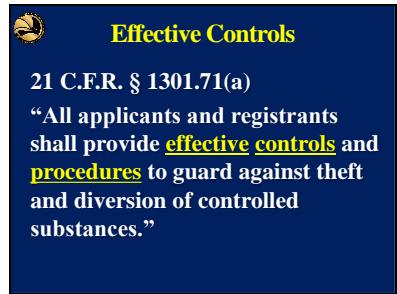
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Preventative Measures

- Cameras in areas where CS are being dispensed
- **Complete and Accurate Dispensing Records**
- **Periodic Physical Inventories**

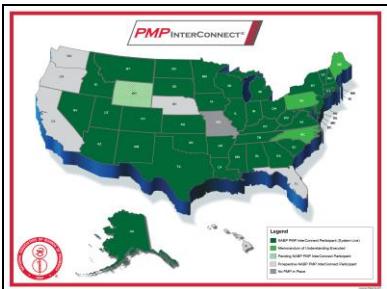
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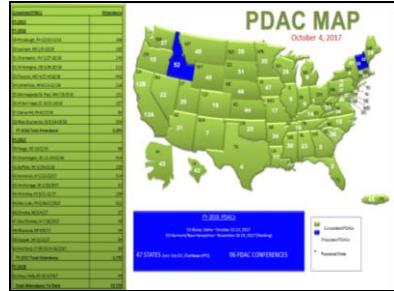
Preventative Measures

- 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)

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States with Limits CII

Kansas	30 Day Supply (Substances to treat obesity)
Kentucky	3 Day Supply (acute pain with exceptions)
Louisiana	10 Day Supply: CII-III (Prescribers not licensed in Louisiana)
Maine	30 Day Supply (chronic pain) 7 Day Supply (acute pain)

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States with Limits CII

Massachusetts	7 Day Supply (unless more indicated) 7 Day Supply (all opioids for minors)
Massachusetts	30 Day Supply: CII-III 60 Day Supply (Dextroamphetamine)
Missouri	30 Day Supply: CII 90 Day (If medical reason given)
New Hampshire	34 Day Supply: CII 60 Day Supply (ADD/ADHD)

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States with Limits CII

New Jersey	First prescription: 5 Day Supply
New York	30 Day Supply 7 Day Supply (initial prescription)
North Carolina	5 Day Supply (acute pain)
Ohio	7 Day Supply 5 Day Supply (for minors)
Oregon	7 Day Supply (initial prescription) 7 Day Supply (for minors)

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States with Limits CII

Pennsylvania	7 Day Supply (for minors) 7 Day Supply (emergency department and urgent care centers)
Rhode Island	20 Doses for opioids (initial prescription) No more than 30 morphine MME/day
South Carolina	31 Day Supply (Except Transdermal patches) 90 Day Supply: CHI-V

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States with Limits CII

Tennessee	30 Day Supply of Opioids and Benzodiazepines
Texas	90 Day Supply (multiple prescriptions)
Utah	30 Day Supply: CII
Vermont	90 Day Supply 72 MME (first prescription for minors) 350 MME – 7 Day limit (acute pain first prescription)

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States with Limits CII

Virginia	Limitations on Number of Days 7 Day Supply (acute pain) 14 Day Supply (surgical procedures) (Some exceptions)
Washington	7 Day Supply (initial prescription) 3 Day Supply (dentist)
West Virginia	72 Hour Supply 30 Day Supply: Hydrocodone

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The Medicine Cabinet and Pharmaceutical Controlled Substances

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Study: Sharing of Medication

- 1. University of Pennsylvania Dental School Study:**

More than half of the narcotics prescribed for wisdom teeth removal go unused...findings suggest that more than 100 million pills prescribed go unused...leaving the door open for possible misuse or abuse.

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Study: Sharing of Medication

2. John Hopkins Study:

- 60% had leftover opioids they hung on for “future use”
- 20% shared their medications
- 8% likely will share with a friend
- 14% likely will share with a relative
- 10% securely lock their medication

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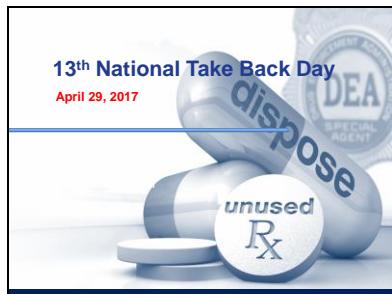
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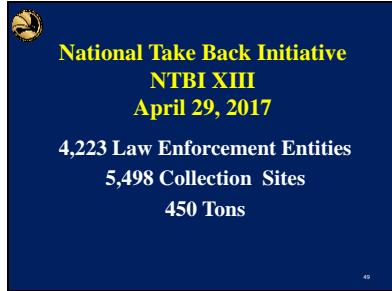
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Resources for Patients

- www.DEAdiversion.usdoj.gov
- www.rxdrugdropbox.org (Police)
- www.disposemymeds.org
- www.sharpsinc.com/locations
- www.fda.gov (Search: Disposal)
- www.epa.gov (Search: Disposal)

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Resources: DEA

- www.operationprevention.gov
- Collection of Resources for Students, Teachers, and Parents:
 - Digital Classroom Lessons
 - Parent Toolkit
 - On Demand Virtual Field Trip
 - Student Learning Modules

Elementary Schools

Middle Schools

High Schools

Spanish Resources

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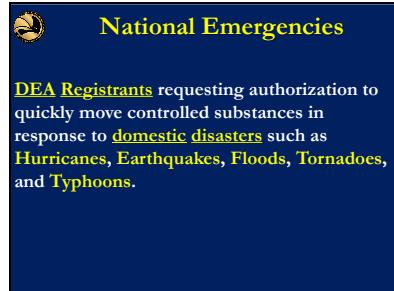
Resources: DEA

- www.campusdrugprevention.gov
 - Publications
 - Information on the 5 Drug Categories
 - Articles offering Federal, national, state, and local perspectives
 - Contacts

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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 .

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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...

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Solutions

Prevention/Detection

Education

Treatment

Enforcement

