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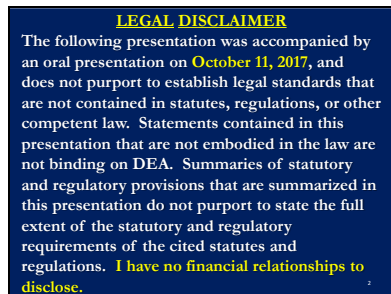
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Slide 2



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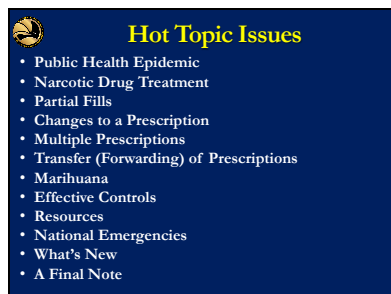
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Slide 3



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Slide 4

 **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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Slide 5

 **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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Slide 6

 **Public Health Epidemic**

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

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Slide 7



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

**Oxycodone**

**Hydrocodone**

**Methadone**

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Slide 8

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

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

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Slide 9



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

**Hydrocodone**

**Oxycodone**

**Fentanyl**

**Buprenorphine**

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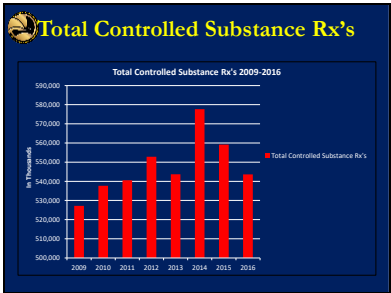
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Slide 10



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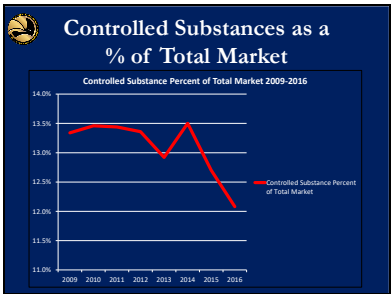
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Slide 11



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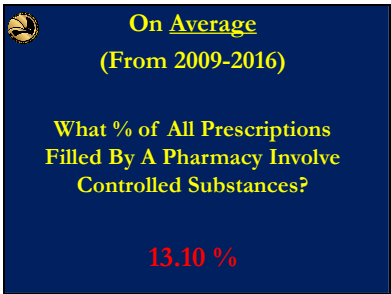
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Slide 12



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Slide 13



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Slide 14



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Slide 15



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Slide 16



### 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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Slide 17



### New Law: C.A.R.A.

“Qualifying Practitioners”  
(Qualifying Physicians)

(Nurse Practitioners/Physician Assistants)

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Slide 18



### 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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Slide 19



### 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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Slide 20



### 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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Slide 21



### 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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Slide 22

**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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Slide 23

**Multiple Prescriptions CII**

Each separate prescription is for legitimate medical purpose issued by practitioner acting in usual course of professional practice

Written instructions on each prescription indicating earliest date it can be filled

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Slide 24

**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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Slide 25



### 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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Slide 26



### 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 the patient

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Slide 27



### 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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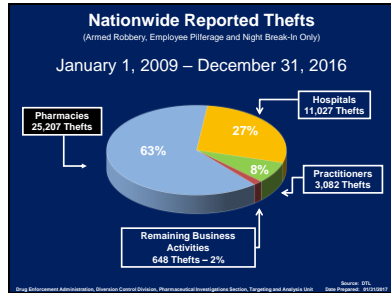
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Slide 28



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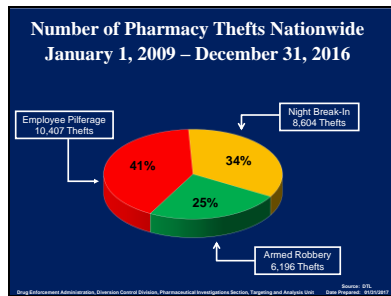
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Slide 29



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Slide 30

 **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.”

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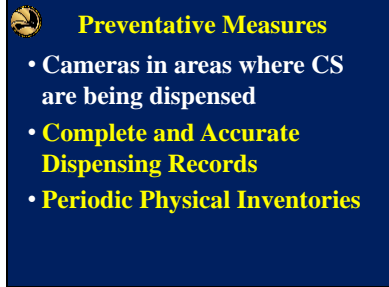
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Slide 31



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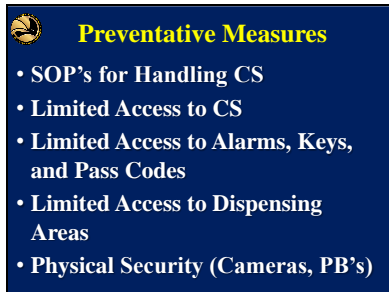
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Slide 32



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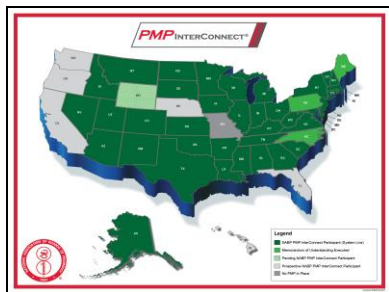
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Slide 33



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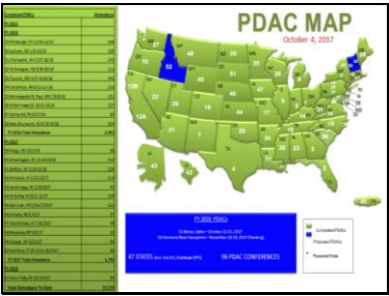
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Slide 34



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Slide 35

 **States with Limits CII**

- Alaska 7 Day Supply (initial prescription)
- Arizona 7 Day Supply (initial prescription)  
7 Day Supply (for minors)
- Connecticut 7 Day Supply (initial prescription)  
7 Day Supply (for minors)
- Delaware Up to 100 dosage units or a  
31 day supply, whatever is greater

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Slide 36

 **States with Limits CII**

- District of Columbia 7 Day Supply  
(emergency situation)
- Florida 72-hour Supply  
(oral prescription)
- Hawaii 30 Day Supply
- Illinois 30 Day Supply: CII  
(Some exceptions under certain conditions)
- Indiana 7 Day Supply (initial prescription)  
7 Day Supply (for minors)

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Slide 37



### 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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Slide 38



### States with Limits CII

Massachusetts	7 Day Supply (unless more in 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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Slide 39



### 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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Slide 40



### 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: CIII-V

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Slide 41



### 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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Slide 42



### 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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Slide 43



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Slide 44

 **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.

Source: <https://www.penmedicine.org/news/news-releases/2016/september/100-million-prescription-opioid>

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Slide 45

 **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

[https://www.nlm.nih.gov/medlineplus/news/fullstory\\_159336.html](https://www.nlm.nih.gov/medlineplus/news/fullstory_159336.html)

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Slide 46



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Slide 47



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Slide 48



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Slide 49



**National Take Back Initiative**  
**NTBI XIII**  
**April 29, 2017**

4,223 Law Enforcement Entities  
5,498 Collection Sites  
450 Tons

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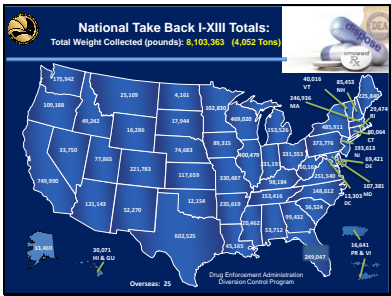
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Slide 50



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Slide 51



**Take-Back of Medications**

- Once a CS has been Dispensed to the Ultimate User it becomes the Legal Property of the Patient.
- It cannot be re-distributed unless otherwise permitted for by Federal Law/DEA Disposal Regulations.

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Slide 52



### Resources for Patients

[www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov)  
[www.rxdrugdropbox.org](http://www.rxdrugdropbox.org) (Police)  
[www.disposemy meds.org](http://www.disposemy meds.org)  
[www.sharpsinc.com/locations](http://www.sharpsinc.com/locations)  
[www.fda.gov](http://www.fda.gov) (Search: Disposal)  
[www.epa.gov](http://www.epa.gov) (Search: Disposal)

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Slide 53



### Resources: DEA

- [www.operationprevention.gov](http://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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Slide 54



### Resources: DEA

- [www.campusdrugprevention.gov](http://www.campusdrugprevention.gov)
  - Publications
  - Information on the 5 Drug Categories
  - Articles offering Federal, national, state, and local perspectives
  - Contacts

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Slide 55



### Resources: CDC

“[Guidelines](#) 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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Slide 56



### National Emergencies

**DEA Registrants** requesting authorization to quickly move controlled substances in response to **domestic disasters** such as **Hurricanes, Earthquakes, Floods, Tornadoes, and Typhoons.**

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Slide 57



### National Emergencies

<http://www.DEAdiversion.usdoj.gov>

At the Above Listed Homepage Click on Tab at the Bottom of the Home Page Titled:



Click on: [Natural.Disaster@usdoj.gov](mailto:Natural.Disaster@usdoj.gov)

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Slide 58



### National Emergencies

At this point you will be given an opportunity to provide your name, DEA registration number, contact information, and the exact details of your emergency request.

Once you send this e-mail, personnel at DEA HQS will be notified automatically and will respond to your request.

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Slide 59



### *A Final Note*

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Slide 60



### Mission

The mission of the Diversion Control Program is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances ... from legitimate channels of distribution...

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Slide 61



### Mission

... while ensuring an adequate and uninterrupted supply of controlled substances ... to meet legitimate medical, commercial, and scientific needs.

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Slide 62



### Mission

The DEA is primarily responsible for Enforcing the CSA

Providing for the Public Health and Safety

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Slide 63



### 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.

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Slide 64



### 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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Slide 65



### 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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Slide 66



### Solutions

Prevention/Detection

Education

Treatment

Enforcement

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Slide 67



*Thank You*



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