

Drug Enforcement Administration

**What DATA Waived
Physicians Need to
Understand About
DEA Requirements**

Cathy A. Gallagher
Section Chief
Regulatory Section
Office of Diversion Control

October 2014
1

Disclosure

- I have no financial disclosure.

2

Office of Diversion Control

Mission

To prevent, detect, and investigate the diversion of controlled substances from legitimate sources

while



Ensuring an adequate and uninterrupted supply for legitimate medical and scientific purposes

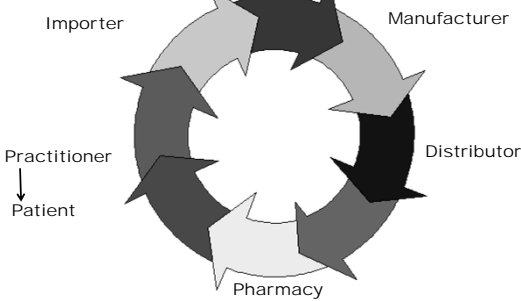
3

Controlled Substances Act of 1970

- Established system for U.S. compliance with international treaties.
- Consolidated over 50 laws regulating the manufacture, distribution, import / export, and dispensing of controlled substances.
- Serves as the legal foundation of the federal government's authority over controlled substances and listed chemicals.

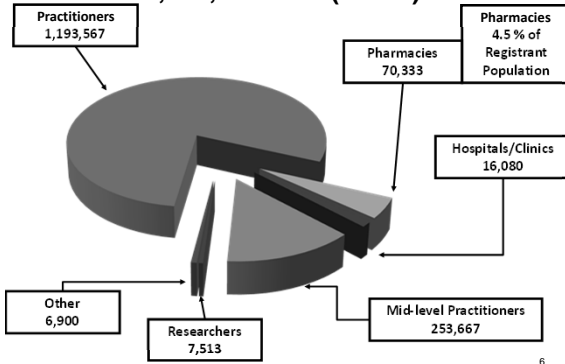
4

The CSA's Closed System of Distribution



5

Active Registrants 1,548,060 total (8/8/14)



6

Active DEA Registrants

as of 10-07-2014

- MLP – Nurse Practitioners 143,919
- MLP – Physician Assistants 79,265

7

Active DATA Waived Physicians

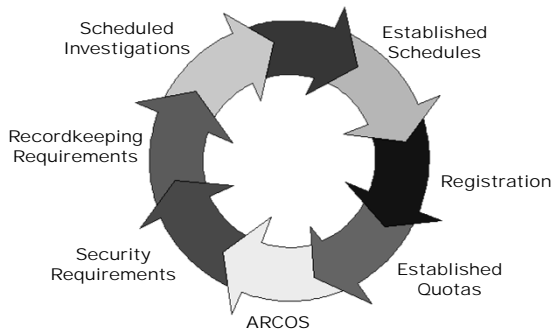
as of 10-07-2014

- DW 30 17,832
- Military DW30 95
- DW 100 7,742
- Military DW100 4

- Total: 25,732

8

Maintaining the CSA's Closed System of Distribution



9

Prescription Drug Monitoring Programs

Please Use

10

Prescription Requirements

In order to be valid, a prescription must:

- Be issued by a registered practitioner.
- For a legitimate medical purpose.
- In the usual course of professional practice.



21 CFR §1306.04(a)

11

Prescription Requirements

- DEA does ***NOT*** define nor regulate medical practice standards.
- There are no federal laws or regulations that put limits on the quantity of controlled substances that may be prescribed.
- Some states or insurance providers may limit the quantities of controlled substances prescribed or dispensed.

12

Pharmacist's Corresponding Responsibility

- Corresponding responsibility rests with the pharmacist who fills the prescription.
21 C.F.R. § 1306.04 (a)

13

DATA Waived Physicians

14

Patient Limits

- A qualified physician must first apply via notification to Center for Substance Abuse Treatment (CSAT) prior to dispensing or prescribing controlled substances approved for drug treatment.
- Initial patient limit: 30
- After a year, a physician may submit a second notification to CSAT of the need and intent to increase the patient limit to 100.
- CSAT will forward requests to DEA.

15

Unique Identification Number

- DEA issues physicians a Unique Identification Number (UIN).
- It will appear on the DEA certificate.
- This UIN lets the pharmacy know that a physician is authorized to prescribe approved controlled substances for drug treatment.
- The UIN is required to be on the prescription.
- A physician is only provided one UIN.
- One UIN can be used with multiple DEA #s.

16

Hospital/Clinic Registration and Drug Treatment

- The activity of treating opioid dependence is an independent business activity from that authorized by a hospital registration.
 - 21 C.F.R. § 1306.07(a).
- To treat opioid dependence, a hospital can register as a Narcotic Treatment Program or employ the services of a DATA-Waived physician who can then write prescriptions.

17

Exceptions

- A DEA registered hospital may maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction.
 - 21 C.F.R. § 1306.07(c).
- Hospital can administer/dispense to persons with intractable pain in which no relief or cure is possible or none is found after reasonable efforts.
 - 21 C.F.R. § 1306.07(c).

18

Prescription Requirements

- All prescriptions for controlled substances must be dated as of, and signed on, the day when issued and must have 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.
 - 21 C.F.R. § 1306.05(a)

19

Prescription Requirements

- A prescription for a schedule III, IV or V narcotic drug approved by FDA specifically for “detoxification treatment” or “maintenance treatment” must include the unique identification number issued by DEA.
 - 21 C.F.R. § 1306.05(b)

20

Recordkeeping Requirements

- A registered individual practitioner is not required to keep records of controlled substances in schedules II-V which are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual.
 - 21 C.F.R. § 1304.03(c)

21

Recordkeeping Requirements

- All records required to be kept, must be available for inspection by DEA
 - 21 U.S.C. § 827(b) and 21 C.F.R. § 1304.03(a)
- What needs to be kept?
 - Records of prescriptions issued
 - Dispensing records

22

Recordkeeping Requirements

- What should the record look like?
 - The regulations only require that a record of the prescriptions be kept.
 - It does not stipulate in what form the record must be.
 - Suggestions:
 - Can be a copy of prescription
 - Can be a log of prescriptions issued
 - Can be noted in patient chart

23

Recordkeeping Requirements

- A registered individual practitioner is required to keep records of controlled substances in schedules II-V which are dispensed.
21 C.F.R. § 1304.03(b)
- Need to account for stock ordered and dispensed. For example:
 - Inventories (Initial and Biennial)
 - Receiving and dispensing records
 - Theft or loss reports

24

Recordkeeping Requirements

- All records required to be kept must be kept by the practitioner and be available for a minimum of 2 years for inspection and copying by authorized employees of the Administration.
 - 21 C.F.R. § 1304.04(a)

25

Storing Required Records

- Records that are required to be kept must be kept at the registered location.
- If you are registered at your residence because you have determined this to be your principal place of business, that is where the records have to be maintained.
- It is also the location DEA will inspect since the address on the DEA Registration is the registered location.

26

Storing Required Records

- Do prescription records have to be maintained where the UIN is tied to the DEA Registration?
 - The X# indicates that the practitioner is authorized to prescribe those controlled substances approved for drug treatment.
 - A practitioner only gets one UIN, but he/she can practice at multiple locations in one state or in numerous states. Use UIN on all prescriptions for drug treatment.
 - The records must be maintained at the DEA registered location.

27

Storing Required Records

- One state with multiple practices:
 - Records of prescriptions for drug treatment must be maintained at the DEA Registered location.
- Multiple states:
 - Records of prescriptions for drug treatment must be maintained at the DEA Registered location in each state from where the prescription was written.

28

DEA Inspection

- DEA is mandated to protect the public's safety.
- DEA is required to ensure that DEA Registrants comply with the Controlled Substances Act and its implementing regulations.
 - Inspections (Unannounced) – Maintains the integrity of the inspection process
 - DEA issues a Notice of Inspection to inspect records required to be kept/Giving consent to inspect records
 - Audit of dispensing records to ensure accountability
 - Verify patient limit compliance

29

DEA Inspection

- Authorized DEA personnel will:
 - Present their credentials
 - Issue a Notice of Inspection
 - Conduct inspection and audit if applicable
 - Conduct a close-out discussion with management
- DEA Action
 - Letter of Admonition
 - Administrative Hearing
 - Order to Show Cause

30

DEA Inspection

- No record of what was prescribed.
- No record maintain at the DEA registered location.
- No dispensing records.
- No UIN (X#) on prescription.
- Treating more than the legal patient limit.

31

WHAT PEOPLE ARE ABUSING

Prescription Drug Abuse

More Americans abuse prescription drugs than the number of:

Cocaine, Hallucinogen, Methamphetamine &
Heroin abusers

COMBINED!!

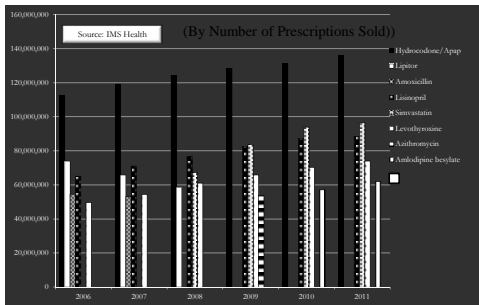
U.S. Drug Enforcement Administration/Operations Division/Office of Diversion Control

**Most commonly prescribed
prescription medicine?**

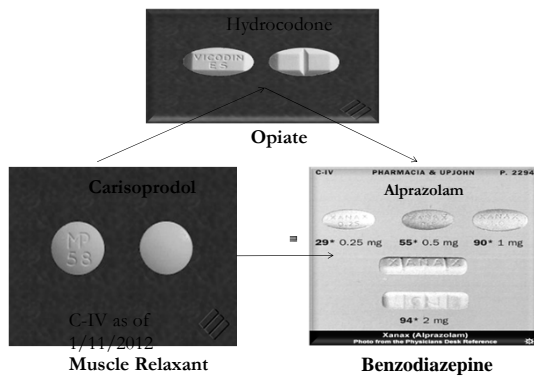
Hydrocodone/acetaminophen

(Schedule II Controlled Substance effective October 6, 2014)

**Top Five Prescription Drugs Sold in the U.S.
(2006-2011)**




The Trinity






Single Entity Extended Release Hydrocodone




10 mg • 15 mg • 20 mg • 30 mg • 40 mg • 50 mg

Manufactured by Alkermes Gainesville LLC for Zogenix, Inc. (San Diego, CA)







FDA Approval October 2013



U.S. Drug Enforcement Administration
Office of Diversion Control



How Supplied

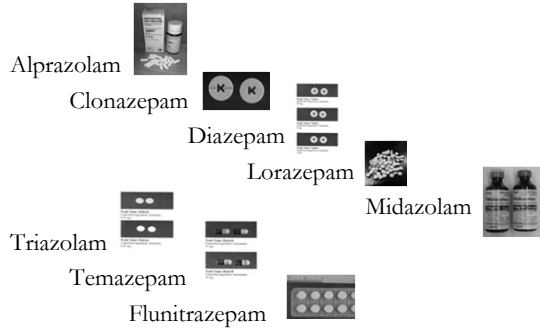
Strength	Image	Capsule color(s)	Capsule Text	NDC Number
10 mg		White opaque	"Zogenix 10 mg" in black ink	43376-210-10 100 ct bottles
15 mg		Light green and white opaque	"Zogenix 15 mg" in black ink	43376-215-10 100 ct bottles
20 mg		Light green opaque	"Zogenix 20 mg" in black ink	43376-220-10 100 ct bottles
30 mg		Dark blue and white opaque	"Zogenix 30 mg" in black ink	43376-230-10 100 ct bottles
40 mg		Dark brown and white opaque	"Zogenix 40 mg" in black ink	43376-240-10 100 ct bottles
50 mg		Dark brown opaque	"Zogenix 50 mg" in black ink	43376-250-10 100 ct bottles

U.S. Drug Enforcement Administration
Office of Diversion Control

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 ® / carisoprodol, Alprazolam / 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.

Benzodiazepines



Ritalin® / Concerta® / Adderall®

- Used legitimately to treat ADHD
- Abuse prevalent among college students; can be snorted, injected or smoked; nicknamed “College Crack”
- \$5.00 to \$10.00 per pill on illicit market
- Adderall® Abusers are 5 times more likely to also abuse prescription pain relievers, 8 times more likely to abuse Benzodiazepines

Source: NSDUH Report: Non-Medical Use of Adderall Among Full-Time College Students, published April 2009

41

Dextromethorphan (DXM)

- Cough suppressant in over 125 OTC medications (e.g., Robitussin and Coricidin)
- Bulk form on the Internet
- At high doses, has Ketamine- and PCP-like effects
- Produces physical and psychological dependence
- Deaths associated with DXM abuse



Cough Syrup Cocktails

- “Syrup and Soda”
- “Seven and Syrup”
- “Purple Drank”



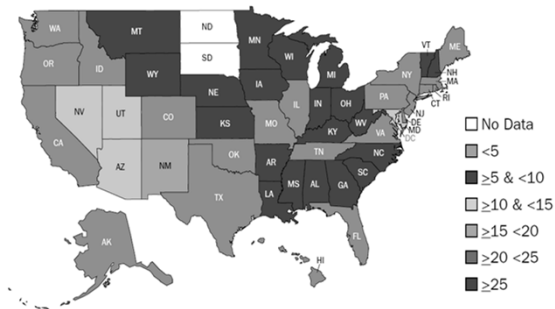
PURPLE DRANK
ima grip and sip



Tramadol

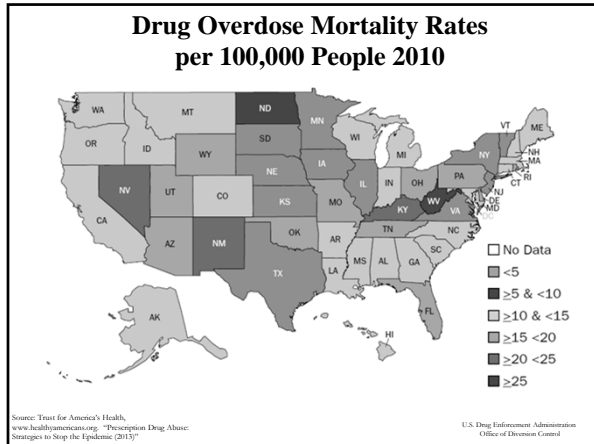
- Analgesic:
 - Tramadol (Ultram®, Ultracet®)
 - Notice of Proposed Rulemaking to place Tramadol into Schedule IV issued November 4, 2013.
 - Effective August 18, 2014, Schedule IV controlled substance
- Muscle Relaxant:
 - Cyclobenzaprine (Flexeril®)

Drug Overdose Mortality Rates per 100,000 People 1999



Source: Trust for America's Health, www.healthreform.com, "Prescription Drug Abuse: Strategies to Stop the Epidemic" (2013)

U.S. Drug Enforcement Administration
Office of Diversion Control





**Most Frequent Method of Obtaining a
Pharmaceutical Controlled Substance for
Non Medical Use**

Friends and Family...For Free!!

The Medicine Cabinet: The Problem of Easy Access



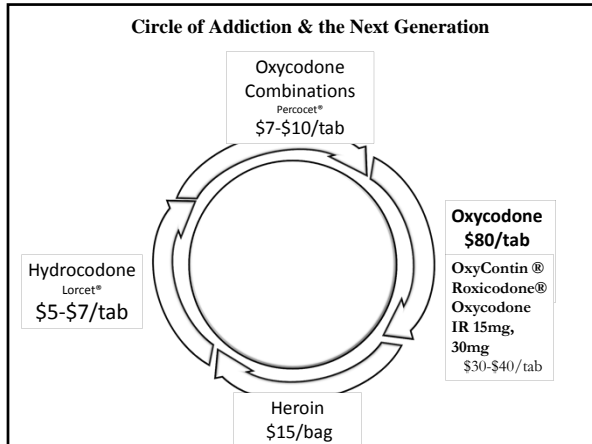
So Many Drugs in the Household – Why?

- Unreasonable quantities being prescribed
- Insurance rules

Prescription Opiates v. Heroin

Unintended Consequence



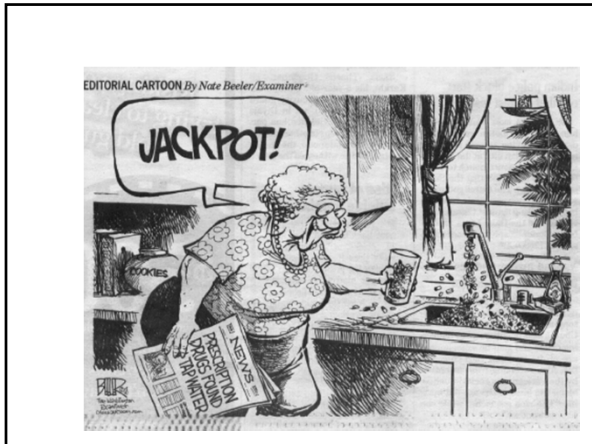


We will not arrest our way out of this problem!!!!

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

Prescription Drug Abuse Prevention Plan

- Coordinated effort across the Federal government
- Four focus areas
 - 1) Education
 - 2) Prescription Drug Monitoring Programs
 - 3) Proper Medication Disposal
 - 4) Enforcement



Take-Back Event



Boxed, Sealed, Counted, Weighed,
Consolidated, Secured, and
Incinerated

Secure and Responsible Drug Disposal Act of 2010

- 12/21/2012 – Proposed Drug Disposal Regulations are published in Federal Register
- 2/19/2013 – Comment period on proposed regulations
- Final Rule Published: September 9, 2014
- Effective: October 9, 2014

Authorized to Collect

Registrants authorized to collect:

- Manufacturers
- Distributors
- Reverse Distributors
- Opioid Treatment Programs
- Hospitals/clinics with an on-site pharmacy
- Retail Pharmacies

21 CFR § 1317.40

Collection Receptacle Location

- Registered location – immediate proximity of designated area where controlled substances are stored and at which an employee is present.
- LTCF – located in secure area regularly monitored by LTCF employees.
- Hospital/clinic – located in an area regularly monitored by employees--**not** in proximity of where emergency or urgent care is provided.
- OTP – located in a room that does not contain any other controlled substances and is securely locked with controlled access.

21 CFR § 1317.75(d)

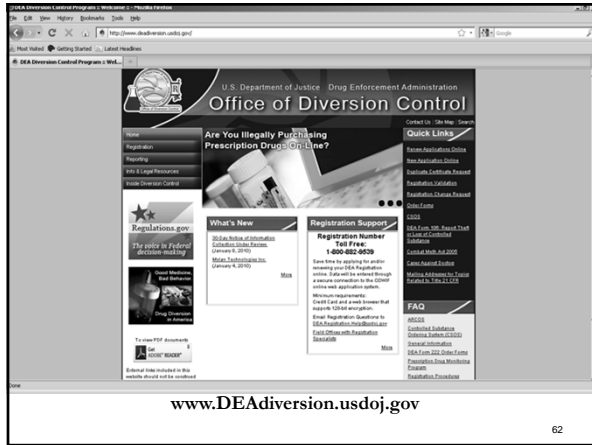
What to Do?

- Take the time and talk to your patients about abuse and dependence potential for medications that have been prescribed;
- Securing their medications in their homes;
- Discuss how to properly dispose of expired or unused medications.

Comments / Questions?



61



62
