Learning Objectives

• Describe the mission of the Office of Diversion Control
• Discuss the legal requirements of a prescription
• Identify primary drugs of concern to DEA
• List current DEA rulemaking actions
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
Controlled Substances Act of 1970

• Established system for U.S. compliance with international treaties.

• Serves as the legal foundation of the Federal government’s authority over controlled substances and listed chemicals.

• Consolidated over 50 laws regulating the manufacture, distribution, import / export, and dispensing of controlled substances and listed chemicals.
The CSA’s
Closed System of Distribution

Importer

Manufacturer

Practitioner

Distributor

Patient

Pharmacy
Maintaining the CSA’s Closed System of Distribution

Cyclic Investigations

Established Schedules

Recordkeeping Requirements

Registration

Security Requirements

Established Quotas

ARCOS
CSA Registrant Population

Current Number of DEA Registrants

1,338,027
04/12/2010

480,000
1973

Provisional registrations in effect at the time CSA was passed (relative to the Harrison Narcotics Act of 1914)
Active DEA Registrants
(as of 04/12/2010)

- Practitioners: 171,591
- Mid-Level Practitioners: 65,714
- Pharmacies: 15,625
- Hospitals/Clinics: 8,385
- Researchers: 5,914
- All Others: 1,070,622
Prescription Drug Abuse

• 2008 National Survey on Drug Use and Health estimates there are 6.2 million Americans who are current non-medical users of psychotherapeutic drugs.
• More than the number of those abusing cocaine, hallucinogens, and heroin COMBINED.
• Non-medical use of prescription drugs ranks second only to marijuana as the most prevalent category of drug abuse.
Scope and Extent of Problem

Source: 2004 and 2008 National Survey on Drug Use and Health

- **Sedatives**
  - 2004: 0.3 million
  - 2008: 0.35 million

- **Stimulants**
  - 2004: 1.2 million
  - 2008: 1.0 million

- **Tranquilizers**
  - 2004: 1.6 million
  - 2008: 1.8 million

- **Narcotic Pain Relievers**
  - 2004: 4.4 million
  - 2008: 4.8 million
Methadone Initial Aggregate Quotas

2000 - 2010

300% increase 2000-2010

Kilograms
Hydrocodone
Initial Aggregate Quotas
2000 - 2010

272% increase
2000-2010

Kilograms
Number of Prescriptions Dispensed

Source: IMS Health
Number is in Thousands
NFLIS 2008 Data

• National Forensic Laboratory Information System

• Nationwide partnership with state and local forensic laboratories
  • Database of drug intelligence

• From calendar year there were 1,472,625 drug items analyzed
### NFLIS National Data - 2008
#### Narcotic Analgesics

<table>
<thead>
<tr>
<th>Narcotic Analgesic</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone</td>
<td>36,625</td>
<td>37.92%</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>32,194</td>
<td>33.33%</td>
</tr>
<tr>
<td>Methadone</td>
<td>8,314</td>
<td>8.63%</td>
</tr>
<tr>
<td>Morphine</td>
<td>5,366</td>
<td>5.56%</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>4,291</td>
<td>4.44%</td>
</tr>
<tr>
<td>Codeine</td>
<td>3,148</td>
<td>3.26%</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>1,773</td>
<td>1.84%</td>
</tr>
<tr>
<td>Propoxyphene</td>
<td>1,256</td>
<td>1.30%</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>1,149</td>
<td>1.19%</td>
</tr>
</tbody>
</table>
NFLIS Narcotic Analgesics  
2008 Regional Distribution
## NFLIS National Data - 2008
### Benzodiazepines

<table>
<thead>
<tr>
<th>Medication</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alprazolam</td>
<td>31,414</td>
<td>65.62%</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>7,771</td>
<td>16.23%</td>
</tr>
<tr>
<td>Diazepam</td>
<td>6,287</td>
<td>13.13%</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>1,846</td>
<td>3.86%</td>
</tr>
<tr>
<td>Temazepam</td>
<td>395</td>
<td>0.82%</td>
</tr>
<tr>
<td>Chlordiazepoxide</td>
<td>90</td>
<td>0.19%</td>
</tr>
<tr>
<td>Triazolam</td>
<td>52</td>
<td>0.11%</td>
</tr>
<tr>
<td>Midazolam</td>
<td>13</td>
<td>0.03%</td>
</tr>
<tr>
<td>Flunitrazepam</td>
<td>6</td>
<td>0.01%</td>
</tr>
</tbody>
</table>
NFLIS Benzodiazepine
2008 Regional Distribution
DATA-Waived Practitioners

*DW30 - 13,684
*DW100 - 3,315
Buprenorphine Prescriptions
CY 2002-2007 and 1st Quarter 2008

Source: IMS National Prescription Audit

Thousands

From 2004 thru 2007 there was a 500% increase in buprenorphine prescriptions, and a 628% increase in Suboxone prescriptions.
Buprenorphine Distribution to Retail Registrants
January 1, 2008 – March 31, 2008

Subutex and Suboxone 8mg Tablets
18,099,622 dosage units
78%

Subutex and Suboxone 2mg Tablets
4,984,560 dosage units
21%

Buprenex and Buprenorphine Injectable
183,189 units (i.e., vials, and syringes)
1%

Source: ARCOS
Date Prepared: 6/10/2008
Buprenorphine
Top 10 States
2008* ARCOS Distribution DATA

GRAMS PER 100K POPULATION

• 01/01/2008 – 03/31/2008
Subutex and Suboxone 8mg Tablets
Distribution Per 100,000 Population
(Pharmacies Only)

Numbers in parenthesis represents number of Data Waived Doctors

U.S. Average: 6,132 Dosage Units

Above Average = 7,666 Dosage Units or more
Average = 4,599 – 7,665 Dosage Units
Below Average = 4,598 Dosage Units or less

Source: ARCOS
Date Prepared: 6/10/2008
Prescription Requirements

In order to be legal, 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)
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.
CSA and CFR Citations

• Controlled substances have useful and legitimate medical purposes. 21 U.S.C. § 801(1)
• Practitioners are not limited in their ability to prescribe, administer, or dispense narcotics to persons with intractable pain. 21 C.F.R. § 1306.07 (c)
• Prescription must be for legitimate medical purpose by a practitioner acting in usual course of professional practice. 21 C.F.R. § 1306.04 (a)
Pharmacist’s Corresponding Responsibility

- Corresponding responsibility rests with the pharmacist who fills the prescription.

  21 CFR § 1306.04 (a)
Multiple CII Prescription Rule

Issuance of Multiple Prescriptions for Schedule II Controlled Substances


• Rule became effective on December 19, 2007.

• Amend DEA regulations to permit practitioners to issue multiple prescriptions for Schedule II substances to allow patients up to a 90-day supply.

• Provide greater control over prescribing Schedule II medications by physicians.
Pain Management
DEA’s Policy Statement

Dispensing Controlled Substances for the Treatment of Pain

• Policy Statement published 09/06/2006.
• Reiterates DEA policy to prevent abuse and diversion without adversely impacting the legitimate need of patients to have full access to pain relief prescribed by their physician.
Pain Management
DEA’s Policy Statement

Dispensing Controlled Substances for the Treatment of Pain

• To reassure physicians that DEA does not apply a greater scrutiny to the prescribing of controlled substances to treat pain.

• Discussed the phrase “legitimate medical purpose.”

• Addressed requests for a guidance document on treating patients for pain.
Methods of Diversion

• Practitioners / Pharmacists
  – Illegal distribution
  – Self abuse
  – Trading drugs for sex

• Employee pilferage
  – Hospitals
  – Practitioners’ offices
  – Nursing homes
  – Retail pharmacies
  – Manufacturing / distribution facilities

• Pharmacy / Other Theft
  – Armed robbery
  – Burglary (Night Break-ins)
  – In Transit Loss (Hijacking)
  – Smurfing

• Patients
  – Drug rings
  – Doctor-shopping
  – Forged / fraudulent / altered prescriptions

• Internet availability
Electronic Prescriptions for Controlled Substances
Electronic Prescriptions for Controlled Substances

- On March 31, 2010, DEA published an Interim Final Rule with Comments.
- Informal interagency review was completed with HHS, GSA, VA, NIST.
- Effective date: June 1, 2010.
Electronic Prescriptions for Controlled Substances

• The rule revises DEA regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically.
• The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions.
• These regulations are an addition to, not a replacement of, the existing rules.
• The regulations provide pharmacies, hospitals, and practitioners with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances.
Electronic Prescriptions for Controlled Substances

• Processes and procedures include:
  – Initial identity certification
  – Two-factor authentication
  – Use of HHS transmission standards
  – No alteration of prescription during transmission
Electronic Prescriptions for Controlled Substances

- DEA has sent letters/e-mails on the new rule to the following:
  - All DEA registered practitioners
  - Associations that represent medical and pharmacy boards, practitioners and pharmacies
  - State Attorney’s General
  - Vendors
Electronic Prescriptions for Controlled Substances

- DEA has posted several Q&A documents on its website.
- DEA HQ and Field Office staff are being trained on the regulation.
Disposal of Controlled Substances
CSA Definitions

• An “ultimate user” is a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

• To distribute means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical.
Registration Requirement

- Ultimate users are not permitted to distribute controlled substances without being separately registered.
- Because of registration requirement, it is unlawful for ultimate users to give their controlled substances to pharmacies, reverse distributors, etc., for destruction.
Controlled Substance Waste

Proper Disposal

• DEA does not specify the manner of destruction.

• “Waste” not defined in CSA.

• No distinction between expired, contaminated controlled substances and saleable product.

• Accountability required of all controlled substances.
ANPRM Ultimate User Disposal

• ANPRM published on January 21, 2009 in the Federal Register.
• Entitled *Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration.*
• Seeking options for the safe and responsible disposal of patient owned controlled substances consistent with CSA.
• Comment period ended March 23, 2009.
ANPRM Ultimate User Disposal

- Solicited information on the disposal of controlled substances dispensed to ultimate user from:
  - Ultimate users
  - Law enforcement
  - Interest groups
  - Long-term care facilities
  - Hospices
  - In-home care groups
  - Pharmacies
  - Reverse Distributor
  - State regulatory agencies
  - Other interested parties

158 Comments Received
ONDCP Guidelines

• ONDCP guidelines for the disposal of ultimate user medications, including dispensed controlled substances (Feb. 20, 2007).

• Advise public to flush medications only if the prescription label or accompanying patient information specifically states to do so.

• ONDCP recommends a minimal deactivation procedure, and disposal in common household trash.
Law Enforcement Involvement

• Law enforcement officers, acting to enforce laws regarding controlled substances, may receive controlled substances from ultimate users.
• Must safeguard the controlled substances and ensure that they are destroyed properly.
• Law enforcement must be present during the destruction of the controlled substances.
Safe Disposal Act of 2009

• House Resolution 1191
  • Introduced on 2/25/2009 by Rep Inslee (WA)
  • Amend the CSA to allow states to operate disposal programs
  • Direct the Attorney General to create 5 models for implementation

• Companion Senate Bill 1336
  • Introduced on 6/24/2009 by Sen Murray (WA)
Secure and Responsible Drug Disposal Act of 2009

- House Resolution 1359
  - Amend the CSA to permit ultimate user to deliver drugs for destruction
  - Grants the Attorney General discretion to promulgate regulations

- Companion Senate Bill 1292
  - Introduced on 6/18/2009 by Sen Klobuchar (MN) and Sen Grassley (IA)
Internet Legislation
An Internet Pharmacy
Ryan Haight Online Pharmacy Consumer Protection Act

• Amends the CSA adding new provisions to prevent the illegal distribution of controlled substances by Internet.

• Enacted on 10/15/08, effective on 4/13/09.

• As of 9/8/2009, only 6 pharmacies had requested modification to online pharmacy.

• New DEA registration requirements for all Internet pharmacies.
  – Modification of existing Retail Pharmacy registration.
Ryan Haight Online Pharmacy
Consumer Protection Act

• Reporting requirements.
  – Monthly basis
  – All controlled substances dispensed (total of each)
  – Thresholds
    ▪ 100 or more CS prescriptions
    ▪ 5,000 or more total dosage units

• Disclosure requirements on home page.
  – Identify servicing pharmacies, pharmacist in charge, and physicians
Other Rulemakings and Scheduling Actions
DEA Registration Suffix

Identification of Institution-Based Practitioners


• Seeking comments regarding standardizing suffix numbers issued to staff using the facility’s DEA registration.

• Comment to E-prescribing NPRM.

• Comment period closed November 9, 2009.
Locum Tenens Practitioners
Registration Requirements

Advanced Notice of Proposed Rulemaking

• CSA requires separate DEA registration for each principal place of business.
  – Limited exception provided for multiple locations within one state

• No CSA or CFR definition of locum tenens.

• Seeks industry input into current business practices.

• Cleared to publish.
Long-Term Care Facility Issues

- Emergency Kits
- ADS machines
Emergency Kits in LTCFs

- Policy Statement – Controlled Substances in Emergency Kits for Long Term Care Facilities. (FR Vol. 45, No. 70) 4-9-1980
- Placement of kits subject to state authorization and state requirements.
- Improve health care services and decrease quantities of controlled substances on hand.
- Emergency kits cannot be used to fill routine prescriptions.
Automated Dispensing Systems

- ADS machines must hold DEA Registration.
- Pharmacy is responsible for stocking and recordkeeping requirements.
- Transfer of Schedule II controlled substances must be on DEA Official Order Form (DEA Form 222).
- Dispensing must be pursuant to a valid prescription.
- Records are maintained by the home pharmacy.
Scheduling Actions
Three Steroids Rule

- First administrative scheduling of steroids.
- Boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione.
- Schedule III controlled substances.
Carisoprodol

• NPRM published on 11/7/2009.
• Proposal to place in Schedule IV based on recommendations from HHS and evaluation by DEA.
• Objection filed by commenter, request for a hearing.
• Hearing scheduled for May 2010.
Other Scheduling Actions

- Proposal to place fospropofol into Schedule IV.
  - Effective on November 5, 2009
- Placement of lacosamide into Schedule V.
  - Effective on June 22, 2009
- Placement of tapentadol into Schedule II.
  - Effective on June 22, 2009
Other Scheduling Actions

Petitions currently being reviewed by DEA

- Propofol – (for Schedule III)
- 6-Beta-Naltrexol (for decontrol)
Comments / Questions?