Current Trends in DEA Compliance

National Association Chain Drug Stores

August 24, 2015

Ruth A. Carter, Chief Liaison and Policy Section Office of Diversion Control
What People Are Abusing
Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)

- Similarities:
  - Structurally related to codeine
  - Equal to morphine in producing opiate-like effects

- Brand Names: Vicodin®, Lortab®, Lorcet®

- Currently, combination products are Schedule III

**October 6, 2014 moved to SCHEDULE II**

- “Cocktail” or “Trinity”
  - Hydrocodone
  - Soma® / carisoprodol
  - Alprazolam / Xanax®

- Street prices: $2 to $10+ per tablet depending on strength & region
67 countries reported an estimated need requirement for hydrocodone to the International Narcotics Control Board.

20 countries reported an estimated need of 1 kilogram or greater.

4 countries reported an estimated need between 500 grams and 999 grams.

10 countries reported an estimated need between 100 grams and 499 grams.

6 countries reported a need between 25 grams and 99 grams.

27 countries reported a need of less than 25 grams.


U.S. Drug Enforcement Administration Office of Diversion Control
Of the 20 Countries that reported an estimated needs requirement for hydrocodone at one kilogram or more

- 8 countries reported an estimated need of 1 kilogram to 5 kilograms

- 4 countries reported an estimated need over 5 kilograms to 10 kilograms

- 8 countries reported an estimated need over 10 kilograms

Top 10 List

- **10 Guatemala**: 10 kilograms
- **09 India**: 10 kilograms
- **08 Vietnam**: 20 kilograms
- **07 China**: 20 kilograms
- **06 Denmark**: 25.5 kilograms
- **05 Columbia**: 30 kilograms
- **04 Syrian Republic**: 50 kilograms
- **03 Canada**: 115.5 kilograms
- **02 United Kingdom**: 200 kilograms
- **01 United States**: 79,700 kilograms (99.3%)
The Trinity

Hydrocodone

Opiate

Carisoprodol

C-IV as of 1/11/2012

Muscle Relaxant

Alprazolam

Benzodiazepine

U.S. Drug Enforcement Administration
Office of Diversion Control
Commonly Abused Controlled Substances

- Carisoprodol
- OxyContin 80mg
- Oxymorphone
- Oxycodone 30 mg
- Hydrocodone
- Alprazolam

C-IV as of 1/11/2012

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.
Prescription Opiates vs. Heroin
The Circle of Addiction & The Next Generation

Oxycodone Combinations
Percocet®
$7-$10/tab

OxyContin®
$80/tab

Roxicodone®
Oxycodone IR
15mg, 30mg
$30-$40/tab

Hydrocodone
Lorcet®
$5-$7/tab

Heroin
$15/bag
Heroin: No Longer Confined to Urban Areas
The CSA: Checks and Balances
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.

U.S. Drug Enforcement Administration
Office of Diversion Control
Cutting off the Source of Supply
Law: 21 USC 822 (a) (1) Persons Required to Register:
“Every person who manufactures or distributes any Controlled Substance or List I Chemical or who proposes to engage in ..”

Law: 21 USC 822 (a) (2) Persons Required to Register:
“Every person who dispenses, or who proposes to dispense any controlled substance ..”
Closed System of Distribution

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

U.S. Drug Enforcement Administration
Office of Diversion Control
The DEA is responsible for:

- the **oversight** of the system
- the **integrity** of the system
- the **protection** of the public health and safety
Distributor Initiative

Educate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances.

August 1, 2005 – August 21, 2015: Briefings to 85 firms with 280 registrations
Pharmacy Diversion Awareness Conference

This conference is designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity.
Completed PDACs

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<th>Year</th>
<th>City</th>
<th>Date</th>
<th>Attendance</th>
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<td>Total Attendance To Date</td>
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Approved FY 2015 PDACs

28-Portland, ME September 12-13, 2015

Proposed FY-2016 PDACs

29-Little Rock, Arkansas November 2015
30-Jackson, MS January 2016
31-Charleston, WV February 2016
32-Wilmington, Delaware March 2016
33-Charleston, South Carolina April 2016
34-Minneapolis/St. Paul, Minnesota July 2016
35-Towson, Maryland August 2016
36-New Brunswick, New Jersey September 2016
“Stakeholders’ Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances”

- Represents the medical, pharmacist, and supply chain spectrum highlighting the challenges and “red flag” warning signs related to prescribing and dispensing controlled substance prescriptions

- The goal was to provide health care practitioners with an understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose, as well as to provide guidance on which red flag warning signs warrant further scrutiny

- NABP along with 10 national associations and 6 major pharmaceutical firms were the coalition of stakeholders of this document.
The Federation of State Medical Boards (FSMB) promotes excellence in medical practice, licensure, and regulation on behalf of 70 state medical and osteopathic Boards across the country in their protection of the public.

DEA and FSMB are currently working on developing strategies to work more effectively and jointly on indiscriminate prescriber investigations in order to facilitate the administrative process to take action against those that are a threat to the public health and welfare quickly, and at the same time not jeopardize a criminal investigation.
Scheduled Investigations

- Increase in the number of DEA registrants that are required to be investigated to ensure compliance with the Controlled Substances Act and its implementing regulations

- Increase in the frequency of the regulatory investigations

- Verification investigations of customers and suppliers
“All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.”
21 CFR § 1301.71(a)

In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.
Suspicious Orders

21 CFR § 1301.74(b)

*Non-practitioners* of controlled substances

“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances...Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”
Prescriptions

21 CFR § 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.

United States v Moore  423 US 122 (1975)
Pharmacists – The Last Line of Defense

“The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”

(21 CFR § 1306.04(a))

U.S v. Hayes 595 F. 2d 258 (5th Cir 1979)
U.S. v. Leal 75 F. 3d 219 (6th Cir 1996)
U.S. v. Birbragher 603 F. 3d 478 (8th Cir 2010)
East Main Street Pharmacy 75 Fed. Reg. 66149 (Oct. 27, 2010)
Pharmacists – The Last Line of Defense

“An order purporting to be a prescription issued not in the course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the act (21 USC 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” (21 CFR § 1306.04(a))

U.S v. Hayes 595 F. 2d 258 (5th Cir 1979)
U.S. v. Leal 75 F. 3d 219 (6th Cir 1996)
U.S. v. Birbragher 603 F. 3d 478 (8th Cir 2010)
East Main Street Pharmacy 75 Fed. Reg. 66149 (Oct. 27, 2010)
The Last Line of Defense
21 CFR § 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.
A pharmacist, by law, has a corresponding responsibility to ensure that prescriptions are legitimate.

Just because a prescription is presented by a patient or demanded to be filled for a patient by a doctor’s office, a pharmacist is not obligated to fill the prescription!!!
DEA Legal Resources

- Administrative
  - Immediate Suspension Order (ISO)
  - Memorandum of Agreement (MOA)
  - Order to Show Cause (OTSC)

- Civil
  - Fines

- Criminal
  - Arrests
  - Criminal fines
National Take Back Initiative
September 26, 2015

Got Drugs?
Turn in your unused or expired medication for safe disposal
Saturday

Click here for a collection site near you.

10:00 AM – 2:00 PM
DEA Web-Based Resources

Office of Diversion Control
www.deadiversion.usdoj.gov
DEA Web-Based Resources

www.JustThinkTwice.com