

Anti-Diversion: It's Everyone's Responsibility

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Disclaimer

- Not a tutorial on how to divert drugs
- Not legal advice
- Opinions are not binding
- Reserve the right to change my mind on any opinions I may profess
- Designed to stimulate thought, challenge your assumptions

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Learning Objectives

- Review applicable federal controlled substance regulations
- Understand the regulatory influences on controlled substance distribution
- Understand methodologies for meeting regulatory requirements
- Create an awareness of the underlying societal issues
- Discuss methodologies for detecting and preventing diversion

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Anti-diversion is *everyone's* responsibility

Prescription drug diversion is a societal problem to be addressed by a societal solution involving all participants in the prescription drug supply chain - from manufacturer to patient - with the collaboration and cooperation of professionals and regulatory groups at the state and federal levels.

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Statistics

- Non-medical use of pharmaceutical products is now greater than the abuse of cocaine, hallucinogens or inhalants.
- Among adults 26 or older, 6.3 percent reported non-medical use of prescription medicines in 2005.
- In 2005, one of 20 high school seniors admitted to abusing prescription pain killers such as hydrocodone and oxycodone.

• From USDOJ/DEA

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Statistics

- The U.S. Drug Enforcement Administration says nearly 7 million Americans currently abuse prescription drugs, noting that is "more than the number who are abusing cocaine, heroin, hallucinogens, ecstasy and inhalants combined." The DEA also reports that "opioid painkillers now cause more overdose deaths than cocaine and heroin combined."

Statistics

- Last year alone, at least 485 people died in Kentucky from prescription drug overdoses, according to the state's Cabinet for Health and Family Services. Medical Examiners' records indicate the drugs most commonly found in those death cases were methadone, the painkillers oxycodone and hydrocodone, alprazolam (Xanax), morphine, diazepam (Valium) and fentanyl.

Pharmaceuticals Commonly Diverted

- Hydrocodone
- Oxycodone
- Phentermine
- Alprazolam
- Fentanyl
- Diazepam
- Clonazepam
- Sertraline
- Tramadol
- Carisoprodol
- Varenicline
- Sildenafil
- Tretinoin

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Why are drugs diverted?

- Known quality and potency
- Readily obtained by prescription
- Access in the work place
- Produce desired effects
- Large market if trafficking
- They are not "street" drugs

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When are drugs diverted?

- When procedures are not followed
- When records are not reviewed
- When staff are too trusting or naïve
- During periods of “turmoil”
- During “slow” work shifts
- Anytime!

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Detection

- Prescriptions filled too frequently
- Prescriptions filled concurrently
- Unjustified over-prescribing
- Self-prescribing
- Prescription alteration
- Coworker lifestyle changes

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Other Concerns

- Alteration or loss of records
- Unjustified purchases
- Decline in profit margins
- Patients without pain relief
- Losses of drugs subject to abuse
- Product tampering

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Regulatory Landscape

- Drug Enforcement Administration
- State Board of Pharmacy
- State Law Enforcement Administration
- State Board of Medicine
- State Wholesale Registration Authority
- State Controlled Substance Authority
- State Medicaid Fraud Unit

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DEA Regulations

- Prescription validity
- Section 1306.04 Code of Federal Regulations
 - (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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DEA Regulations

- Corresponding Liability
- Section 1306.04 Code of Federal Regulations
 - 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.
 - An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription.

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Regulatory Foundation

- Interestingly, the foundation of the prior discussion is based upon state law and the individual practice acts for medicine, other prescribers and pharmacy.
- Conflict of law principles apply, however, in most situations they are read complementarily to avoid any conflicts in interpretations.

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DEA Regulations

- Technical requirements
- Section 1306.05 Code of Federal Regulations
 - (a) All prescriptions for controlled substances shall be:
 - dated as of, and signed on, the day when issued
 - shall bear the full name and address of the patient,
 - the drug name, strength, dosage form, quantity prescribed, directions for use
 - the name, address and registration number of the practitioner.
- Mere technical compliance with this regulation does not create a valid prescription.

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DEA Regulations

- Technical requirements
- Section 1306.05 Code of Federal Regulations
 - The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.
 - A corresponding liability rests upon the pharmacist.

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Non-medical prescribing indicators (examples)

- Prescriber who writes
 - significantly more prescriptions (or in larger quantities) compared to other prescribers
 - prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time
- Patients appear simultaneously, or over a short time, all presenting similar prescriptions from the same physician with the same quantities
 - Totality of the circumstances analysis
- Not an exhaustive list

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DEA Regulations

- Registrant obligations
- Section 1301.74 Code of Federal Regulations
 - Before distributing the registrant must make a good faith effort by contacting
 - DEA or state agency to determine that the customer is registered to possess controlled substances
 - The registrant must design and operate a system to disclose to the registrant suspicious orders of controlled substances.

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DEA Regulations

- Registrant obligations
- Section 1301.74 Code of Federal Regulations
 - The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant.
 - Suspicious orders include orders of
 - unusual size,
 - orders deviating substantially from a normal pattern,
 - and orders of unusual frequency
 - Must determine what constitutes “normal”

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Controlled Substance Diversion

- Theft – DEA 106
 - internal – what are your institutional controls?
 - external – what are your security controls?
- Loss – DEA 106
 - size, drug, nature, frequency
 - systems for identifying
- Prescriptions
 - fraud and forgeries
 - Internet

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Controlled Substance Diversion

- Patterns of purchases that deviate from norm
 - Varies by class of trade
- History of disciplinary action
- Single family of purchases
- Unusual percentage of controlled substances compared to total legend drug purchases
- Cash basis for business
- Internet advertisement

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Ryan Haight Online Pharmacy Consumer Protection Act of 2008

- PL 110-425
- Defines an online pharmacy as “a person, entity, or Internet site, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet.”

Ryan Haight Online Pharmacy Consumer Protection Act of 2008

- The definition of online pharmacy explicitly excludes DEA registered pharmacies “whose dispensing of controlled substances via the Internet consists solely of refilling prescriptions for controlled substances in Schedules III, IV and V.
- It also excludes DEA registered pharmacies that solely fill new prescriptions obtained via the Internet where the pharmacist has conducted due diligence and the prescription is for a patient for whom the pharmacist has previously filled controlled substance prescriptions that were not obtained via the Internet.

Internet and Diversion

- It is a communication medium
- DEA policy can be found at:
 - <http://www.deadiversion.usdoj.gov/faq/internetpurch.htm>
- No valid prescriber-patient relationship = no valid prescription = can't legally dispense pursuant to the “prescription”
- Internet has not changed the analysis
 - just jurisdiction and enforcement
- Administrative, civil and criminal

Disciplinary Actions

- Ohio pharmacist license revoked
 - 8,324 online prescriptions for 5,621 patients across the United States
 - Internet Health Enterprise
 - “caught in a con game set up by a Florida doctor”
 - October 17 to February 14 distributed 74,400 doses of narcotics, anti-anxiety drugs, tranquilizers and diet pills.

WHAT MANUFACTURERS ARE DOING TO PREVENT DIVERSION

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Diversion as Counterfeits

- Technologies to validate product
 - 2D Bar Codes
 - RFID Chips
- Obligation to validate product – supply chain
- Drug Product Problem Reporting/MedWatch
 - Label, visual examination of dosage form
 - Compilation of reports leading to pattern analysis and recalls

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WHAT WHOLESALERS ARE DOING TO PREVENT DIVERSION

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Suspicious Order Monitoring

- Everyone will have a program, including pharmacies.
- Components of a program include:
 - People
 - Partners
 - Customer Information
 - IT component
 - Thresholds
 - Account evaluation
 - Communication

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Customer Information

- Key information
 - Ownership
 - Application to Board of Pharmacy
 - History of purchases
 - 12 month history
 - Description of key prescribers in area
 - Business model
 - Compliance agreements

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Suspicious Order Monitoring

- Identify
- Block
- Report
- Foundational principle is to conduct an independent analysis of orders prior to completing a sale
- Secondly to assess whether the product is likely to be diverted

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WHAT COMMUNITY PHARMACY IS DOING TO PREVENT DIVERSION

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Partners in Action

- Organized pharmacy is involving itself in partnerships to educate the public
- Organized pharmacy is engaging in partnerships with manufacturers
 - Partners Against Pain –
www.partnersagainstpain.com
- Enhancing State Recovery Programs for professionals

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WHAT SOCIETY IS DOING TO PREVENT DRUG DIVERSION

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Significant Education and Advocacy

- Partnership for a Drug Free America
 - www.drugfree.com
- Parents. The Anti-Drug
 - www.theantidrug.com
- Substance Abuse & Mental Health Services Administration
 - www.samhsa.gov
- ONDCP
 - www.whitehousedrugpolicy.gov

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Case Studies

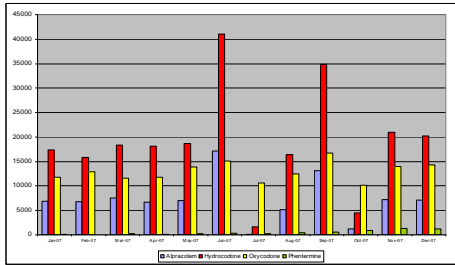
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Pharmacy Practice Issues

- Key employee with responsibility for:
 - Placing orders
 - Receiving orders
 - Putting orders into inventory
 - Paying invoices for orders
- Adjustments
 - Break up of order process
 - Periodic auditing

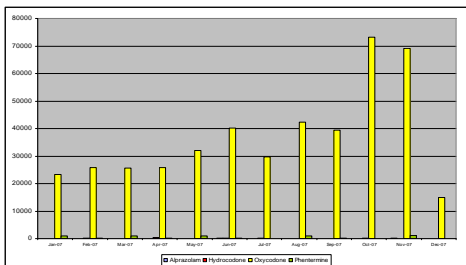
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Case Study #1



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Case Study #2



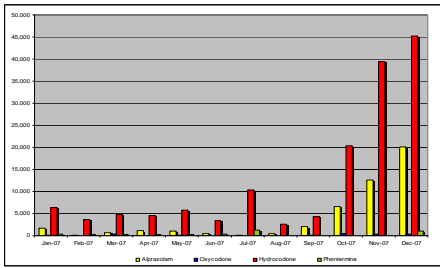
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Evaluation

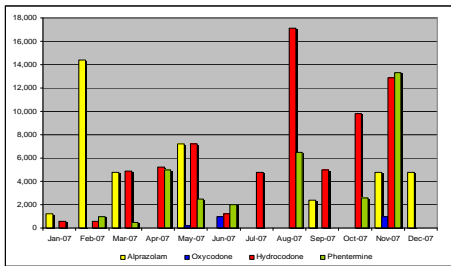
- Balancing of interests
- Identify suspicious orders and report to the DEA
 - How much information is available?
 - How much responsibility does a wholesaler have for physician and pharmacy conduct?
- Preserve legitimate business relationships
- Meet legitimate medical/patient needs
 - Get the right drugs to the right people who administer or dispense the right drugs to the right people who need them

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Case Study #3



Case Study #4



Case Study #5

- Customer gives notice of closure of 1 office
- Investigation discovers
 - 2004 arrest of owner for trading 100 oxycodone and 100 alprazolam for 2 ounces of marijuana
 - License of owner emergency suspended
 - MD’s license acted against by Board of Medicine for Internet transactions involving phentermine and sildenafil

QUESTIONS?

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