Controlled Substances: Understanding The Compliance Challenges

Andrea L. Nelson, Esq.
General Counsel - LDI Integrated Pharmacy Services
What is a controlled substance?

- A legal term referring specifically to substances controlled by federal or state law

- Controlled Substance Act of 1970 - federal law enacted to comply with international treaties and efforts to combat drug trafficking and to assure drug availability for legitimate medical use

- Established five schedules and levels of control, I-V
  - Drug classes: opioids, depressants, stimulants, hallucinogens

- Prescribers and pharmacies must comply with both federal and state laws and regulations

- When federal laws or regulations differ from state laws or regulations, the more stringent rule applies
Controlled Substance Schedules

- **Schedule I (CI)**
  - Most restrictive
  - Reserved for drugs with high abuse potential and no recognized medical use

- **Schedule II-V (CII-V)**
  - Descending abuse potential and restrictions
  - Drugs have medical use in U.S.
The Regulators

**FDA**
- Regulates drug manufacturers
- Reviews and approves drug products for safety and efficacy
- Drug label - primary method for communicating information to prescribers and dispensers
- Post-marketing safety
- FD&C Act does not distinguish between controlled and other drug products

**DEA**
- Registers drug manufacturers
- Establishes quotas
- Registers dispensers and prescribers

**States**
- Boards of Pharmacy and Medicine - primary regulators of physicians and pharmacy practice (some states also have a separate BNDD)
- States may impose additional drug controls
- Authority, regulations, practices, and resources vary across states
Recent DEA Enforcement Actions

**Medicine Shoppe - October 2014**

- The DEA recently revoked the registration of a San Antonio, Texas Medicine Shoppe for violating the CSA in the following ways:
  - Dispensing controlled substances without a prescription
  - Dispensing controlled substances when the prescription was “signed” using a signature stamp
  - Allowing some customers to retain original controlled substances prescriptions
  - Dispensing controlled substances when the prescription contained irregular dosing instructions
  - Dispensing controlled substances when the prescriptions revealed pattern prescribing by physicians
  - Dispensing controlled substances when the prescription lacked a patient’s address and the physician’s DEA registration number
  - Placing a prescription label on the back of the prescription with a physician’s name that was not consistent with the name on the front of the prescription
  - Accepting prescriptions where the refill line was blank
  - Allowing patients with prescriptions containing both controlled and non-controlled substances to fill only the controlled substances’ portion of the prescription
Recent DEA Enforcement Actions

- **Platinum Pharmacy and Compounding - September 2013**
  - The DEA revoked the registration and seized all controlled substances after informants made cash purchases of Schedule II narcotics (oxycodone) from pharmacy employees based on fraudulent prescriptions.

- **Top Rx Pharmacy - May 2013**
  - The DEA revoked registration for multiple CSA/regulatory violations, including:
    - Failure to conduct initial inventory
    - Providing false information to controlled substance distributors
    - Failure to maintain accurate and complete records and/or account for controlled substances
    - Diluting promethazine syrup before dispensing
    - Dispensing controlled substances under circumstances in which it knew or should have known that the drugs were being diverted from non-medical, illegitimate purposes
DEA Enforcement - Retail Chains

CVS

In April of 2013, CVS Pharmacy, Inc. and Oklahoma CVS Pharmacy, L.L.C. agreed to pay $11 million to settle civil penalty claims for record-keeping violations under the CSA and related regulations. Allegations included:

- Creating, entering and maintaining invalid “dummy” DEA registration numbers or numbers other than the valid DEA registration number of the prescribing practitioner on dispensing records, which were at times provided to state prescription drug monitoring programs
- Filling prescriptions for certain prescribers whose DEA registration numbers were not current or valid
- Entering and maintaining CVS dispensing records, including prescription vial labels, in which the DEA registration numbers of non-prescribing practitioners were substituted for the DEA registration numbers of the prescribing practitioners

Walgreens - Largest Controlled Substance Fine In History

On June 11, 2013, Walgreen Co. agreed to pay $80 million in civil penalties to the DEA—the largest ever settlement involving allegations based on the CSA.

The settlement resolves allegations that the pharmacy chain had an “unprecedented” number of record-keeping and dispensing violations under the CSA. Specifically, the DEA alleged that the pharmacy chain negligently allowed controlled substances, such as oxycodone, to be diverted for abuse and black market sale.
DEA Enforcement - Mail Order Pharmacies

- In 2012, Express Scripts, Inc. and Express Scripts Pharmacy Services, Inc. ("ESI") paid $2.75 million to settle a DEA action covering conduct from 2002 through 2009.

- The DEA alleged that ESI employees utilized invalid DEA numbers in ESI’s computerized prescription processing system in order to process certain controlled substances prescriptions at all of its mail order facilities.

- As part of the settlement, ESI developed a comprehensive Controlled Substances Security Compliance Plan that includes diversion protection measures far beyond those required by law, including improved physical security, enhanced inventories, reconciliations and audits, employee background checks, and mandatory training for employees who have contact with controlled substances.
Mail Order Compliance Priorities

- Physical Security
- Inventory
- Loss Reporting
- Prescription Blank Security
- Verification Procedures
- Record Keeping
State Law Compliance Challenges

Requirements for controlled substances vary widely from state to state

- Quantity Limits
- Prescriber Authority (type of prescriber, out-of-state prescriber)
- Method of transmission (fax, oral, electronic)
- Other requirements
State Prescription Drug Monitoring Programs

- Statewide electronic database which collects designated data on controlled substances dispensed in the state
- Proactively provides data to prescribers, dispensers, law enforcement and occupational licensing individuals
Narcotics Monitoring Programs

- PBMs take an integrated approach to managing narcotics and other controlled substances

- These programs rely less on utilization management and more on utilization review
  - Example: quarterly review of narcotics utilization and identification of significantly unusual utilization patterns within members’ claims histories
  - Includes multiple narcotic medications, multiple physicians, multiple pharmacies, or repeated overlap of prescription fills
  - Notification of these patterns to prescribers and, as appropriate, Plan Sponsor, physicians and pharmacies involved in the patient’s health care

- Compliance concerns
  - Fraud and abuse reporting (affirmative obligations under state law)
  - HIPAA
  - Substance abuse confidentiality laws
  - State privacy law considerations
  - ERISA
Narcotics Monitoring Programs - Best Practices

- Do not request or disclose substance abuse treatment information
  - Disclose only factual information necessary to perform a review of narcotic utilization

- Avoid assertions or allegations of narcotic abuse

- Ensure that the individual to whom PBM is disclosing information is authorized to receive that information

- Actions taken in furtherance of the program should be conducted in a non-discriminatory manner
  - It is best if policies are uniform and apply to all plan members for whom similar concerns are raised

- When implementing the program, obtain a clear written request from the Plan Sponsor (could be simply the execution of the service agreement) and obtain written confirmation that the program, as implemented, is not prohibited or limited in any manner under the terms of the relevant benefit plan
Questions?