RUTGERS
THE STATE UNIVERSITY OF NEW JERSEY

Preparing Your Pharmacy for a DEA Inspection

Angelo J. Cifaldi, R.Ph., Esq.
acifaldi@wilentz.com
732-855-6096
Satish V. Poondi, R.Ph., Esq.
spoondi@wilentz.com
732-855-6154
Wilentz, Goldman, & Spitzer P.A.
90 Woodbridge Center Drive
Woodbridge, NJ 07095

Disclosures

- Authors have no disclosures to make

Objectives

- Proposed Learning Objectives for Pharmacists

1. Discuss the common elements of a DEA audit
2. Explain the legal ramifications of a DEA audit, including potential civil, criminal and administrative penalties
3. Discuss the legal rights and responsibilities of the pharmacy undergoing a DEA audit
4. Identify good practices that will help simplify the audit process.

- Proposed Learning Objectives for Pharmacy Technicians

1. Recognize the breadth and scope of the drug diversion problem
2. Describe common types of drug diversion schemes
3. Define good practices that will help secure control substances
4. Explain statutory record keeping requirements

What is Diversion?

- Diversion is best defined as "the unlawful channeling of regulated pharmaceuticals from legal sources to the illicit marketplace"
- Diversion of controlled-substances is a serious matter involving state and federal law.

Inciardi, J. A., Surratt, H. L., Lugo, Y., & Cicero, T. J. (2007). The Diversion of Prescription Opioid Analgesics. Law Enforcement Executive Forum, 7(7), 127–141.

In the News

- Father and Son Charged with Running Prescription Drug Trafficking and Forgery Ring - $1.5 million in painkillers funneled onto black market; March 9, 2016
- From September 2010 to September 2014, the defendants allegedly oversaw an extensive prescription drug trafficking network that acquired blank prescription paper, printed forged prescriptions, and filled them at pharmacies to obtain pills for resale.
- **They allegedly recruited and paid numerous individuals, known as "runners,"** to fill fraudulent oxycodone prescriptions at pharmacies in the Bronx and elsewhere. **The runners consisted primarily of Medicaid patients who lived in the same Bronx neighborhood as the defendants**.
- The runners were paid at most a few hundred dollars per prescription filled in exchange for providing the pills to the defendants. The pills were then bundled for sale on the black market, where the pills from a single prescription could be resold for thousands of dollars.

https://www.deadiversion.usdoj.gov/new.html

In the News cont.

- Essex County, New Jersey, Woman Admits Leadership Role in Oxycodone Distribution Ring ; March 14, 2016
- Using **confidential sources, physical surveillance, and recorded text messages and telephone calls**, investigators with the Drug Enforcement Administration (DEA) discovered that members and suppliers of a drug trafficking organization secured prescriptions for oxycodone and other controlled substances from various doctors in New Jersey, filled them at pharmacies in Belleville and elsewhere, and sold the drugs for a profit.
- She admitted that, between February 5, 2014 and August 13, 2014, she personally went to various doctors' offices and obtained prescriptions for pills containing oxycodone, had the prescriptions filled by various pharmacies, and sold the pills to members of the conspiracy and others. She also drove other conspirators to specific doctors to obtain oxycodone prescriptions, assisted them in getting the prescriptions filled, and helped them sell the pills.

https://www.deadiversion.usdoj.gov/new.html

In the News cont.

- Manhattan U.S. Attorney Announces Conviction of Local Doctor for Unlawfully Dispensing More Than 1.2 Million Oxycodone Pills ; March 17, 2016
- Conviction of a board-certified, state-licensed doctor, for conspiracy to distribute oxycodone. During the period of the charged conspiracy, the doctor wrote more than 13,000 medically unnecessary prescriptions for oxycodone, typically in return for cash payments.
- **Operated out of a sham medical office** located in Manhattan where he typically charged $200 in cash for "patient visits" **that typically involved little, if any, actual examination** and almost always resulted in the issuance of a prescription for a large quantity of oxycodone, typically 90 30-milligram tablets.

https://www.deadiversion.usdoj.gov/new.html

In the News cont.

- NY Pain Doctor Named in a 114 Count Indictment; - April 26, 2016
- The indictment alleges that the defendant attracted and thereafter maintained repeat visits by his patients by operating his pain management clinic in a variety of manners contrary to accepted medical practice.
  - **issuing prescriptions for controlled substances to patients despite obvious indications that the patients were abusing and misusing the medications;**
  - signing blank prescriptions and directing and permitting others who were unqualified to fill out the remaining required information, such as name of patient, drug, and dosage;
  - **creating and utilizing a telephonic patient prescription renewal process which allowed persons to obtain controlled substances prescriptions from individuals not medically trained or certified to do so, and without adequate medical review**;
  - prescribing a highly regulated controlled substance (buprenorphine) under the cover of pain management to circumvent federal regulations limiting the number of patients that any given doctor may treat (100 patients).

https://www.deadiversion.usdoj.gov/new.html

Issues Facing Pharmacists / Top Audit Areas

- Validity of Prescriptions
- Legitimacy of Prescriptions
  - Patient – Physician Relationships
- Theft
- Record Keeping (purchasing/ dispensing)

At Risk Areas

- The pharmacy should review protocols for the following areas:
  - **How are CDS obtained by the pharmacy?**
    - Who is ordering?; Where is it being ordered from?; Who is receiving the medications on delivery?
  - **How are CDS stored in the pharmacy?**
    - Is there free access or limited access?
  - **Is the pharmacy keeping proper records?**
    - Are inventories being conducted?; Who is conducting them?
  - **Does the pharmacy staff properly review CDS prescriptions**?
    - Is the staff trained to look out for fraudulent prescriptions?
  - **Are CDS properly disposed?**

Evaluating the Prescription

- Purpose of Issue
  - For legitimate medical purpose
  - Practices which should alert pharmacist to unauthorized or inappropriate prescribing
    - Larger ***quantities*** prescribed by prescriber as compared to other prescribers of same specialty
    - Dose, quantity, combination drugs ***outside of accepted medical practice***
    - ***Irrational combinations*** frequently prescribed
    - Patients ***travel to pharmacy*** to have prescription filled
    - Erasures, misspellings, hospital Rx's (esp. VAMC = Veterans Administration Medical Center), ***alterations***
    - ***Nonexistent person***

Face of the Prescription

- Board of Pharmacy has issued the following guidance on Making Changes to Schedule II Prescriptions
- Traditionally a confusing issue and led to audits and recoupments by third party insurances
- Board has created three categories:
  - Items that may be changed upon consultation with the prescriber
  - Items that may be added without consultation with the prescriber
  - Items that are NEVER permitted to be changed

Face of the Prescription cont.

- **The following items may be changed upon consultation with the prescriber:**
  - Patient's address
  - Drug strength
  - Drug quantity (both numeric and alpha representations)
  - Drug dosage form
  - Directions for use
  - Date issued
  - DEA number (if omitted)
- **The following items may be added without consultation with the prescriber:**
  - Patient's address
  - Date of birth
  - A notation to correct a misspelled name
- **The following items are NEVER permitted to be changed:**
  - Patient's name (other than as noted above)
  - Controlled substance prescribed (except to substitute a generic)
  - Prescriber's signature

http://www.njconsumeraffairs.gov/phar/Documents/Guidance-for-Pharmacists-on-Making-Changes-to-Schedule-II-Prescriptions.pdf

Manner of Issuance of Prescriptions for Schedule II Substances

- For Schedule II CDS, unless an exception applies, a practitioner may authorize a quantity, not to exceed a 30-day supply, which shall be at the lowest effective dose as determined by the directed dosage and frequency of dosage.
  - Notwithstanding the 30-day supply limitation, a practitioner may prescribe the use of an implantable infusion pump that is utilized to achieve pain management for patients suffering from cancer, intractable pain, or terminal illness. A prescription for such an implantable infusion pump may provide up to a 90-day supply, as long as the physician evaluates and documents the patient's continued need at least every 30 days; and
  - Notwithstanding the 30-day supply limitation, a practitioner may prescribe multiple prescriptions authorizing a patient to receive a total of up to a 90-day supply of a Schedule II controlled dangerous substance

N.J.A.C. 13:35-7.6

Manner of Issuance of Prescriptions for Schedule II Substances cont.

- A practitioner shall not issue an initial prescription for an opioid drug for treatment of acute pain in a quantity exceeding a five-day supply as determined by the directed dosage and frequency of dosage.
- The initial prescription shall be for the lowest effective dose of an immediate-release opioid drug. A practitioner shall not issue an initial prescription for an opioid drug that is for an extended-release or long-acting opioid.
- No less than four days after issuing the initial prescription, upon request of the patient, a practitioner may issue a subsequent prescription for an opioid drug for the continued treatment of acute pain associated with the condition that necessitated the initial prescription if certain conditions are met.

N.J.A.C. 13:35-7.6

Manner of Issuance of Prescriptions for Schedule II Substances cont.

- When a practitioner issues an initial prescription for an opioid drug for the treatment of acute pain, the practitioner shall so indicate it on the prescription.
- The requirements for prescribing controlled dangerous substances set forth above shall not apply to a prescription for a patient who is c**urrently in active treatment for cancer**, **receiving hospice care from a licensed hospice**, **receiving palliative care**, or is **a resident of a long-term care facility**, or to any medications that are being prescribed for use in the treatment of substance abuse or opioid dependence.

N.J.A.C. 13:35-7.6

New Jersey Opioid Law

- On March 1, 2017, the Attorney General and the New Jersey State Boards of Medical Examiners, Dentistry, Nursing, and Optometrists, adopted emergency rules, which include prohibiting a prescriber from issuing an initial prescription for the treatment of acute pain for an opioid drug in a quantity exceeding a five-day supply, and requiring the prescription to be for the lowest effective dose of an immediate-releasing opioid drug specific limitations for opioid drugs.
- Prescribers are also required to indicate on the prescription when it is an initial prescription for an opioid drug for the treatment of acute pain.

New Jersey Opioid Law cont.

- Initial Prescriptions for Opioids
  - The law and rules do not impose any additional requirements for pharmacists to confirm that a prescription must be limited to a five-day supply of medication. However, note that pharmacists are required to perform their corresponding responsibility to ensure that all prescriptions for controlled dangerous substances are being written for a valid medical purpose.
- Beginning with the 2019 biennial renewal of pharmacist licenses, pharmacists must complete one (1) credit of continuing education (CE) programs or topics concerning prescription opioid drugs, including alternatives to opioids for managing and treating pain and the risk and signs of opioid abuse, addiction and diversion. This is not an additional CE credit requirement, and will be part of the existing 30 CE requirement for each renewal period.

New Jersey Opioid Law cont.

- Insurance plans issued in New Jersey will charge co-payments, coinsurance or deductibles for an initial prescription of an opioid drug prescribed pursuant to the law that is either:
  - proportional between the cost sharing for a 30-day supply and the amount of drugs the patient was prescribed; or
  - equivalent to the cost sharing for a full 30-day supply of the opioid drug, provided that no additional cost sharing may be charged for any additional prescriptions for the remainder of the 30 day supply.
- You may need to contact your insurance plans with any questions regarding how this component will be implemented.

http://ipa-rx.org/wordpress/wp-content/uploads/2017/04/Opioid-Guidance-Document.pdf

Emergency Dispensing

- Schedule II Dispensing Requirements (continued)
  - Emergency oral CII prescriptions
    - All 3 determinations must be made to determine if an emergency exists (21 CFR 290.10.)
      a) Emergency administration of CII is needed for patient's care;
      b) No proper alternative available;
      c) Not readily possible for prescriber to present a written Rx prior to dispensing
    - When receiving emergency oral CII (must get from prescriber) RPh must:
      a) Reduce Rx to writing with all required information;
      b) Make reasonable effort to determine prescriber's authority (if not known) (i.e. – call back)
    - Only a **72 hour** supply maximum if taken in accordance with directions can be dispensed

Emergency Dispensing cont.

- Schedule II Dispensing Requirements (continued)
  - Emergency oral CII prescriptions (continued)
    - Prescriber must supply RPh with written Rx covering order within 7 days of oral order
      a) Prescription must have "Authorization for Emergency Dispensing" written on face and dated as of date of oral order
         i. *Original delivered by hand or mail (postmarked within 7 day period)*
         ii. *Upon receipt attach to oral Rx reduced to writing*
      b) If not provided R.Ph must notify DEA

Manner of Issuance of Prescriptions for Schedule II Substances cont.

- Schedule II Dispensing Requirements (continued)
  - Facsimile transmission of CII prescriptions
    - A pharmacist may fill a prescription for a CII transmitted by facsimile provided that the original signed prescription is presented to the pharmacist prior to dispensing N.J.A.C. 13:39-7.10
      - Exception: A prescription for a CII prescribed for pain management to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the practitioner to the dispensing pharmacy by facsimile. The facsimile will serve as the original written prescription.

Requests for Partial Filling

- Schedule II Dispensing Requirements (continued)
  - Partial Filling of CII
    - Must note partial filling on prescription; date and quantity
    - Must complete order within **72 hours** but if not, must notify prescriber and receive new prescription
    - Exceptions for long-term care facilities
    - Only if full quantity is not available

Evaluating the Prescription cont.

- Dispensing Schedule III or IV
  - Prescription may be oral (reduce to writing), written, or faxed
  - Refills – record on back of prescription or on computer
  - Partial filling allowed (same as CII)
- Dispensing Schedule V
  - OTC
  - Prescription

Electronic Prescriptions

- The application requirements are detailed in 21 C.F.R. 1311.205.
- Generally, the application must be able to import, display, and store the required contents of a controlled substance prescription accurately and consistently.
- The application must be able to digitally sign and archive the controlled substance prescription or import and archive the record that the last intermediary digitally signed.
- The application must electronically accept and store all of the information that DEA requires to be annotated to document the dispensing of a prescription.

Electronic Prescriptions cont.

- The application must allow the pharmacy to limit access for the annotation, alteration (to the extent such alteration is permitted by DEA regulations), or deletion of controlled substance prescription information to specific individuals or roles.
- The application must have an internal audit trail that documents whenever a prescription is received, altered, annotated, or deleted.
- The application must conduct an internal audit that identifies any potential security problems daily and generate a report for review by the pharmacy if a problem is identified.
- Many of these requirements are standard functionalities for pharmacy applications

Signs of Invalid of Prescriptions

- The lack of a valid DEA and/or license number,
- Medication names spelt incorrectly
- An improper Sig.,
- Inappropriate erasures or markings
- A suspicious signature
- "Bleaching" prescriptions, meaning that they chemically alter the prescription to erase information and then substitute false information (e.g. number of refills, number of tablets, medication name).

Invalid Prescriptions cont.

- NJ Division of Consumer Affairs adopted new regulations which incorporate print-based security features into all New Jersey Prescription Blanks (NJPBs).
  - Also other features include serially numbered prescriptions
- Effective March 27, 2016, a new law requires nurse practitioners, midwives, dentists, podiatrists, physicians, physician assistants and optometrists in New York State ("prescribers") to issue prescriptions electronically directly to a pharmacy, with limited exceptions.
  - The new law requires electronic prescribing for all types of medications (controlled substances and non-controlled substances) and for syringes and other medical devices dispensed at a pharmacy in New York.
  - Electronic prescribing has the potential to reduce prescription theft and forgery.

Statutory Responsibility

- 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.***

21 C.F.R. 1306.04 (2009)

Statutory Responsibility cont.

- 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. Id.

Statutory Responsibility cont.

- DEA imposes this "corresponding responsibility" on
  - Physicians
  - Pharmacies
  - Pharmacists
  - Wholesalers

Signs of Illegitimate Prescriptions

- Is the identity of the recipient accurate?
  - We are seeing a growing number of cases where an agent approaches pharmacies and presents prescriptions for numerous patients.
  - While there is no prohibition against the use of an agent by a patient, this type of situation should be reviewed critically.
  - Furthermore, a pharmacist should verify that a patient is who he or she claims to be, particularly in the case of new patients presenting prescriptions for controlled dangerous substances.
  - This can be done by keeping a copy of the patient's driver's license on file and periodically checking the patient's phone number/address to ensure that the information provided by the patient is accurate

Signs of Illegitimate Prescriptions cont.

- Is the medication appropriate for the patient's condition?
  - An important question is whether there is a therapeutic purpose for the medication that is being prescribed.
  - Indicators that the medication is not appropriate are extremely high doses, irrational treatment combinations (e.g. two or more extended release products), a physician that writes "cookie-cutter" prescriptions (e.g. the same prescription for all patients), or a physician that is treating a condition that he or she is not normally expected to treat (e.g. a gynecologist treating male patients).

Standard of Care

- When prescribing controlled dangerous substances, a practitioner shall (N.J.A.C. 13:35-7.6):
  - Take a thorough medical history of the patient, which reflects the nature, frequency, and severity of any pain, the patient's history of substance use or abuse, and the patient's experience with non-opioid medication and non-pharmacological pain management approaches;
  - Conduct a physical examination appropriate to the practitioner's specialty, including an assessment of physical and psychological function, and an evaluation of underlying or coexisting diseases or conditions;
  - Access relevant prescription monitoring information as maintained by the Prescription Monitoring Program (PMP)

Standard of Care cont.

- When prescribing controlled dangerous substances, a practitioner shall (cont.):
  - Develop a treatment plan, which identifies the objectives by which treatment success is to be evaluated, such as pain relief and improved physical and psychological function, and any further diagnostic evaluations or other treatments planned, with particular attention focused on determining the cause of the patient's pain; and
  - Prepare a medical record, which reflects the medical history, the findings on examination, any relevant PMP data, and the treatment plan and also includes
    - The complete name of the controlled substance;
    - The dosage, strength, and quantity of the controlled substance; and
    - The instructions as to frequency of use.

Signs of Illegitimate Prescriptions cont.

- Does the patient exhibit suspicious characteristics?
  - The DEA looks to a range or patient characteristics that may indicate the person is engaged in illicit activity. For example, cash payments (especially in situations that a patient has insurance), traveling far distances to utilize a pharmacy, the use of multiple physicians all of whom prescribe controlled dangerous substances, and appearing for refills to soon on a regular basis can all be indicative of diversion.

Applying DEA's "Know Your Customer" Policy to Pharmacies

- "It is fundamental for sound operations that handlers ("pharmacies") take reasonable measures to identify their customers ("patients"), understand the normal and expected transactions typically conducted by those customers, and, consequently, identify those transactions conducted by their customers that are suspicious in nature." *See* DEA Guidance Document

NJ PMP

- In addition to serving as a database for registered users, the NJPMP generates reports on abnormal patterns of prescribing and dispensing related to specific patients. These Patient Threshold Reports are intended to help identify possible abusers of CDS or HGH, and are automatically sent to prescribers and pharmacists when a patient has exceeded certain prescription-related thresholds.
- Prescribers and pharmacists are encouraged to review the Patient Threshold Report to confirm that it, in fact, pertains to their patient or pharmacy customer. Prescribers and pharmacists are urged to discuss with the patient or customer any concerns arising from the report, and to consult with other prescribers and/or pharmacists that may be included in the report.

NJPMP cont.

- Pursuant to N.J.A.C.13:45A-35.9, "...***if a pharmacist has a reasonable belief that a patient may be seeking a controlled dangerous substance for any purpose other than the treatment of an existing medical condition***, such as for purposes of misuse, abuse, or diversion, the pharmacist shall not dispense a Schedule II controlled dangerous substance to any person without first accessing the prescription monitoring information to determine if the person has received other prescriptions that indicate misuse, abuse, or diversion."
- Before dispensing a prescribed drug, pharmacists are able to access the NJPMP website and request the Controlled Dangerous Substances (CDS) and Human Growth Hormone (HGH) history of the patient. The users must certify that they are seeking information for a specific, new or current patient.
- When pharmacists identify a patient as potentially having an issue of concern regarding drug use, they are encouraged to help the patient locate assistance and take any other action the pharmacist deems appropriate.

NJ PMP cont.

- Governor Christie signed bill strengthening opioid abuse prevention program – July 2015
- The bill makes it required by law that all physicians and pharmacists register for access to the state's prescription monitoring program
- It also requires physicians to check the prescription management program when patients return for a second refill on medication

NJ PMP cont.

- Governor Christie: N.J. expanding prescription drug monitoring to thwart 'doctor shopping‘ – April 2016
- Under the program, New Jersey doctors are now able to see a patient's prescription history within the state and to see any written by doctors in seven other states.
- In addition to New York, the program monitors prescriptions in South Carolina, Minnesota, Rhode Island, Virginia, Connecticut and Delaware.

Theft - Actions by Pharmacy

- Awareness
  - Maintain inventory
    - Perpetual inventory
    - Annual Inventory
    - CII, CIII, CIV
  - Monitor employees
    - Activities
    - Mood/ behavior
    - Access to pharmacy area
    - Criminal background checks

Theft - Actions by Pharmacy cont.

- Security
  - Alarms/ Security cameras
  - Limit issuance of keys
  - Locked cabinets
  - Interactions with local law enforcement

Theft - Actions by Pharmacy cont.

- Are there external factors at play?
  - In addition to patient/prescriber specific issues discussed above, DEA also charges pharmacists with knowledge of local events. Thus, one should also be aware of reports of diversion in the area. DEA encourages pharmacies to communicate with each other to obtain this information.

Security Requirements for CDS

- All CDS must be stored in "a securely locked, substantially constructed cabinet." (21 CFR 1301.75(b))
- May DISPERSE the CDS among the non-CDS in such a manner as to obstruct theft (21 CFR 1301.75(b));
- May not employ a person whose registration has been denied, revoked or suspended if that person would have access to CDS stock. (21 CFR 1301.90)

Security Requirements for CDS cont.

- New Jersey Board of Pharmacy issued guidance document in May 2013
  - Where practical Schedule II (C-II) and Schedule III (C-III) medications in solid dosage form, and other dosage forms (e.g. liquid) as space permits, should be stored in a safe or substantially constructed steel cabinet that is locked at all times
  - Only licensed pharmacists should be permitted access to the safe/steel cabinet and locked refrigerator, and at no time should anyone else access the safe or locked refrigerator.
  - Will-call bins for C-II and C-III medications should be located in the secured prescription filling area of the pharmacy department (not on shelves by the cashier) and within unobstructed view of the pharmacist during the hours the pharmacy is open.
  - Maintain a secure area for receiving packages known to contain CDS. No deliveries for prescription drugs shall be accepted during the hours the pharmacy or pharmacy department is closed unless adequate security for the storage of such shipments has been provided

Reporting loss

- Notify the Field Division Office of the Administration in his/her area of any theft or any **significant loss** of CDS immediately upon discovery (21 CFR § 1301.74(c))
  - DEA form 106 is not immediately needed if registrant needs time to investigate loss/theft
  - Should provide initial notification in writing of the event to DEA
    - Fax could be sufficient, but not the only way
  - If investigation of loss/theft last more than 2 months, registrant should provide updates to the DEA
  - DEA for 106 must eventually be filed
  - POLICE REPORTS

Reporting loss cont.

- How Do You Determine a Significant Loss?
  - Factors to consider:
    - Actual quantity lost
    - Specific controlled substance lost
    - Loss associated with access by individuals or unique activities
    - Pattern of loss and results taken to resolve loss
    - Candidates for diversion
    - **Local trends and indicators of diversion potential**
  - "In-transit" losses
    - ALL "in-transit" losses must be reported, not just significant losses

DEA Audits

- Under the CSA and corresponding regulations, DEA has the right to conduct administrative inspections or audits.
- An inspection shall be carried out by an inspector. Any such inspector shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner upon:
  - (a) stating his purpose;
  - (b) presenting to the owner, operator or agent in charge of the premises to be inspected with
    - (1) appropriate credentials, and
    - (2) written notice of his inspection authority under § 1316.06 of this chapter, and
  - (c) receiving informed consent under § 1316.08 or through the use of administrative warrant,

21 CFR 1316.05

Responding to audits

- Creating a process to respond to the audit
  - Who is responsible (RPIC, on duty R.Ph., manager, attorney)
  - What is responsible person's authority (ability to sign statement, produce records)
  - Owner vs. employee (who represents the employee? What rights does an employee have?)

Common DEA Audit Issues

- Record Keeping Violations (e.g. missing prescriptions, data entry errors, missing 222 forms)
- Inventory Discrepancies
  - Each violation carries a maximum penalty of $25,000.00 (21 U.S.C. 842(c)(1)(A))
- Lack of Biennial Inventory
- Suspected drug diversion

Consequences Of DEA Violations

- The Attorney General may deny an application for DEA registration if registration would be inconsistent with the ***public interest.*** See 21 U.S.C. 823(f)
  - The recommendation of the appropriate State licensing board or professional disciplinary authority.
  - The applicant's experience in dispensing, or conducting research with respect to controlled substances.
  - The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
  - Compliance with applicable State, Federal, or local laws relating to controlled substances.
  - Such other conduct which may threaten the public health and safety.

Consequences Of DEA Violations cont.

- Voluntary Surrender of DEA Registration
  - On November 4, 2011 the DEA published a final rule amending **21 C.F.R. §§ 1301.52(a)** and **1301.62(a)**, making it clear that a voluntary surrender of a DEA registration by a practitioner is effective immediately upon a DEA employee's receipt of a signed **DEA Form 104**, or a surrender in any written format.
  - Signing the surrender form will have immediate adverse consequences, including loss of privileges to dispense controlled substances schedules II through V, and collateral consequences (e.g. loss of third party contracts).

Obtaining Controlled Substances

- CII – Hard Copy Order Form: DEA #222
  - Triplicate form
  - Numbered serially (must account for them)
  - Issued with registrant's name, address, registration number, and schedules authorized to handle
  - Batches of 7 or 14 forms

Obtaining Controlled Substances cont.

- CII – Electronic Order Forms
  - An individual enrolls with DEA and, once approved, is issued a personal CSOS Certificate.
  - Requires purchaser's digital signature
  - Unique number assigned by the purchaser to track the order
  - Unique to this type of electronic order is that a purchaser may include controlled substances that are not in Schedule II as well as non-controlled substances.
  - No electronic order may be filled if:
    - Required fields not completed
    - Not digitally signed
    - Digital certificate used had expired or been resolved prior to signature
    - Purchaser's public key will not validate the digital signature

Obtaining Controlled Substances cont.

- CII – Electronic Order Forms (continued)
  - Lost electronic orders:
    - Purchaser must provide to supplier a signed statement with a tracking number and date of the order stating that goods were not received
  - Preservation of electronic orders:
    - Retain all original and linked records for 2 years
    - Retain all copies of unaccepted or defective orders and linked statements

Obtaining Controlled Substances cont.

- CII – Hard Copy Execution
  - All 3 copies of DEA Form 222 completed at once
  - 10 lines per form, 1 item per line, each strength is a separate item
  - Signed by person who signed the most recent annual application (or person to whom ability delegated by power of attorney)
  - No erasures; errors must be voided
    - Keep voided forms
    - Change item: draw single line through item and write "canceled" in space for number of packages
  - Number of lines completed must be noted on form
  - Copy 1 and 2 sent to supplier; copy 3 retained by purchaser
    - Copy 1 retained by supplier, copy 2 sent to DEA
  - Supplier must complete shipment within 60 days

Obtaining Controlled Substances cont.

- CII – Hard Copy Receipt
  - Purchaser must record on copy 3 the number of bulk containers received and the date it was received on
- Additional Uses of Form 222
  - Return of CII
  - Purchase by DEA registered physicians from pharmacies
- CII – Records
  - Executed order forms kept at registered location for 2 years
  - Lost or theft of order forms must be reported including serial numbers of lost/stolen order forms
  - If unfilled order form lost:
    - Fill new form 222
    - Attach a statement with the serial number of the lost form and state that goods were not received
    - Copy 3 of new form retained with copy 3 of the lost form

Maintaining Proper Records

- Records Maintained by Pharmacy
  - On-site and kept for 2 years (NJ 5 years)
  - Central record keeping (must have permission from DEA)
- Inventory
  - **Beginning inventory**
    - All CDS on-hand (including ordered not yet received, and all invoiced) on the date the pharmacy first dispenses a CDS
  - **Biennial Inventory**
    - Must inventory every 2 years on anniversary of beginning/initial inventory date
      - Plus or minus 4 day grace period with notice to DEA
      - Or, if want to inventory on another date, can do so if within 6 months of anniversary date and DEA notified
  - **Newly Scheduled Drugs**
    - Date of inventory specified in Federal Register; thereafter on the biennial date
  - **Must do new inventory when change pharmacists in charge**

Maintaining Proper Records cont.

- Inventory (cont.)
  - Required Information Contained in Inventory Record
    - Date and time of inventory
    - Signature of person(s) responsible for taking inventory
    - Name of CDS
    - Dosage form/unit strengths/concentration
    - Number of units or volume in each commercial container
      - CI or CII: exact count
      - CIII, CIV, CV: estimate, unless container originally held 1000 or more
    - Number of commercial containers
    - Total quantity of substance in all forms to nearest unit weight
    - Inventory, written or typed and if done in oral recording must be promptly transcribed
    - Instructions provided
    - Separate inventories required for each separate location and each separate activity registered for

Maintaining Proper Records cont.

- Records of Acquisition
  - Must be kept in "readily retrievable form"
  - CIIs separate from CIII - CV
  - Controlled orders on invoices highlighted/underlined in red if not on separate invoices

Maintaining Proper Records cont.

- Records of Disposition
  - CII Prescriptions
    - Separate, or with CIII-V
    - Cross out, date, sign, and write "canceled"
  - CIII – CV Prescriptions
    - Red letter "C" in lower right corner no less than 1" height if kept with other Rx's or with CIIs
    - Either maintained separately or with other Rx's in readily retrievable form

Maintaining Proper Records cont.

- Records of Disposition
  - Inventory
  - DEA Form 222 used to return CDS to supplier and dispensing to registered physician
  - DEA Form 106 used for theft, loss, casualty
  - Approved filing methods
    - 3-drawer method
      a) CII
      b) CIII-CV
      c) All other Rx
    - 2-drawer method
      a) CII-CV (CII-cancelled. CIII-CV have red "**C**" in lower right corner no less than 1" height).
      b) All other Rx
    - 2-drawer method
      a) CII
      b) CIII-CV (have red "**C**") with all other Rx's

Maintaining Proper Records cont.

- Boards of Pharmacy recommendations
  - Perpetual Inventories
  - Random manual reconciliation once each month to include at least 5 drugs that are top 10% risk for diversion and 3 that are lower risk for diversion.
  - Each supplier's invoice for Schedule II CDS medications should be stapled to the corresponding DEA -222 Form (or CSOS print-out), on which the pharmacist has recorded the required information for each item received, and should be maintained in a separate file.
  - Inventory for all CDS (Schedule C-II through C-V) should be done once a year on the same day and month that your biennial inventory would usually be completed.

Disposing of Controlled Substances

1. By transfer to person registered under the Act and authorized to possess the substance;
2. By delivery to an agent of the Administration or to the nearest office of the Administration;
3. By destruction in the presence of an agent of the Administration or other authorized person; or
4. By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized person

Ways to Prevent Diversion

- Documentation of each step in the chain of custody
- Occasional rotation of personnel
  - Assign job responsibilities so that a single individual doesn't order and receive of controlled-substances
- Periodically audit and reconcile records of controlled substances received against purchase records

Ways to Prevent Diversion cont.

- Develop policies and procedures regarding:
  - The ordering of control substances
  - The stocking of control substances
  - Filling prescriptions
  - Security measures
- Promote Communication between Staff
- Document Actions
- Be Aware of Local News