THE OPIOID CRISIS AND ITS EFFECT ON PATIENTS, DOCTORS, PHARMACISTS AND NURSES: A WEBINAR

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WDAA027617

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THE OPIOID CRISIS AND ITS EFFECT ON PATIENTS, DOCTORS, PHARMACISTS AND NURSES

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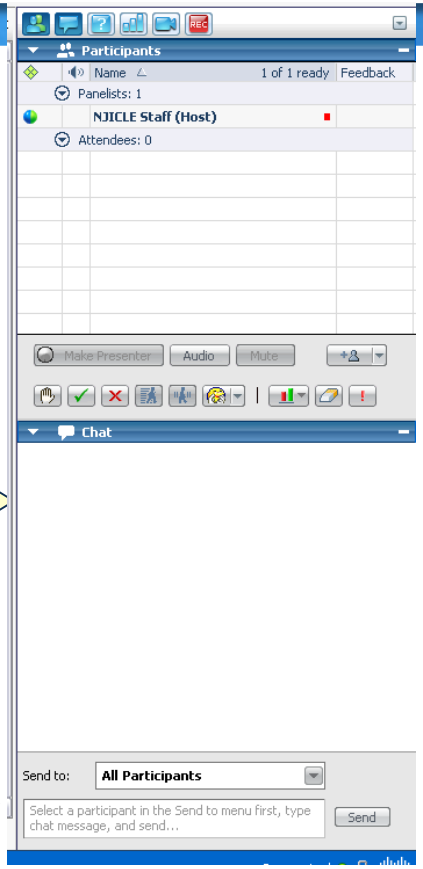

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The Opioid Epidemic & Its Impact on Pharmacy Practice

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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

Williamsville Doctor Pleads Guilty to Prescription Drug Charge; January 09, 2017

- Dr. Yusuf Siddiqui, 72, of Williamsville, NY, pleaded guilty to obtaining controlled substances by fraud before U.S. District Judge Lawrence J. Vilardo.
  - The charge carries a maximum penalty of four years in prison and a $250,000 fine.
- The physician wrote prescriptions for hydrocodone, a Schedule II controlled substance, and clonazepam, a Schedule IV controlled substance, to a patient that he had not examined.
- The physician wrote the prescriptions with the expectation that he would receive a portion of the prescribed medication for his personal use.
- The physician wrote the prescriptions at the request of the patient's daughter whom the physician knew was addicted to pain medication. The patient's daughter was also a former employee of the physician.
- On October 13, 2016, the physician picked the patient's daughter up from her residence and gave her seven hydrocodone and seven clonazepam pills. Later that same day, the physician drove the patient's daughter to a pharmacy where she had the prescriptions filled.
- When the patient's daughter returned to the car, the physician asked her to return the hydrocodone pills that he had given her earlier in the day. The patient's daughter asked the defendant if he wanted more pills and he responded, "Yes" and took 30 hydrocodone pills

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

In the News cont.

Seven Arrested in Major New York City Prescription Forgery Ring; January 23, 2017

- Bivona, 45, And Keller, 53, allegedly employed "runners" to fill **forged oxycodone prescriptions** at pharmacies in Queens and Brooklyn. The forged prescriptions bore the name of a physician who operates a pain management practice in Astoria, Queens.
- During the course of the scheme, runners were directed to fill over 930 prescriptions for oxycodone, leading to the dispensing of more than 160,000 pills with a street value of nearly $3 million. The ring scaled back its criminal activity and altered its methods beginning in August of 2013, at approximately the same time that **"I-STOP," New York State's enhanced Internet System for Tracking Over-Prescribing, tightened restrictions on the prescribing of controlled substances**.
- Since at least 2011, Bivona and Keller allegedly hired family members and friends as runners and **paid cash in exchange for filling prescriptions**. Despite never having been to see the Astoria doctor, the runners' names appeared on prescriptions that originated from the clinic. Bivona and Keller sometimes drove the runners to the pharmacies and waited outside as the prescriptions were filled.
- At the outset of the charged conspiracy, it was not unusual for an individual runner to fill up to eight oxycodone prescriptions in a single month. In general, each prescription was written for 180 pills of 30 mg oxycodone. However, in 2013 the number of prescriptions filled by members of the forgery ring fell to a single prescription per runner each month. This shift coincided with the implementation of New York State's I-STOP regulations.

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

In the News cont.

New Jersey Doctor Indicted on Charges He Sold Oxycodone Prescriptions to Patients with No Legitimate Need for the Drug ; March 02, 2017

- Dr. Byung Kang, 77, of Little Falls, N.J, was **indicted for selling prescriptions of oxycodone to patients, including those he knew to be addicts and drug dealers**
- From June 2010 through April 2016, Kang allegedly sold 90-count prescriptions for oxycodone 30 milligrams pills to patients for $150 or $200 when there was no medical need. Kang's own records allegedly revealed he was aware that many of those patients were addicted or were reselling the pills.
- Charges include strict liability for drug-induced death (1st degree), money laundering (1st degree), conspiracy (2nd degree), unlawful distribution of oxycodone (2nd degree), unlawful distribution of oxycodone within 1,000 feet of a school (3rd degree), filing a fraudulent state tax return (3rd degree), and failure to pay state income tax (3rd degree).
- Kang's wife, Soo Kang, 73, who acted as the receptionist for Kang's medical practice, was also charged in the money laundering, conspiracy and tax-related counts of the indictment
- The state seized $564,304 in U.S. currency during the execution of a search warrant and seized $869,777 from bank accounts of the Kangs

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

In the News cont.

Former Health Minister of Guyana, Dr. Noel Blackman, Sentenced for Running "Pill Mill" in Long Island ; May 12, 2017

- Noel Blackman, who practiced as a medical doctor and was the former Health Minister of Guyana and Executive Member of the World Health Organization, was sentenced to 50 months' imprisonment, three years of supervised release for illegally distributing oxycodone, and ordered to forfeit $536,200 in illegal proceeds
- Between 2015-2016 Blackman prescribed more than 365,000 30 milligram oxycodone pills from "pain management" clinics that he worked out of in Elmhurst, Queens, Franklin Square, Long Island and Cypress Hills, Brooklyn
- In his guilty plea, Blackman admitted that in exchange for $300 cash payments, he wrote oxycodone prescriptions to **persons whom he knew had no legitimate medical need for that highly-addictive drug**
- Following his arrest, Blackman **admitted that he believed that some of his patients were addicted to oxycodone**
- Blackman has **forfeited his medical license** and will no longer be allowed to practice medicine in the United States

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

In the News cont.

New Jersey Man Sentenced for Role in Oxycodone Distribution Ring ; July 24, 2017

- A man from Belleville, New Jersey was sentenced to 41 months in prison and 3 years of supervised release for his role in a conspiracy to illegally obtain and distribute oxycodone in New Jersey
- Using **confidential sources, physical surveillance, and recorded text messages and telephone calls**, investigators with the 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
- He admitted that from February 5, 2014 to August 13, 2014, he personally went to various doctors' offices and obtained prescriptions for pills containing oxycodone, had the prescriptions filled, and sold the pills to members of the conspiracy and others
- Of the 16 people that have been charged in this conspiracy, 13 have been convicted

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

In the News cont.

- Massive Fentanyl Seizure in Bronx ; August 01, 2017
- DEA seized 18 kilograms, nearly 40 pounds of fentanyl, from a vehicle and a hotel in the Melrose neighborhood of the Bronx
  - Colorado resident, Carlos Ramirez, 25, was arrested on June 19 in connection to the seizure.
  - His duffel bag was found to contain 17 packages of what authorities originally suspected was heroin. DEA laboratory tests determined the narcotics inside the packages were not heroin, but rather fentanyl
  - Based on the lab results, Ramirez's bail was increased from $50,000 to $200,000.
  - This is the largest seizure of fentanyl to date by DEA New York Division
- **Fentanyl is approximately 50 times stronger than heroin**. Given that a fatal dose is only 2 to 3 milligrams, officials say the seizure could have yielded over **7 million lethal doses**

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

NEW JERSEY'S OPIOID ABUSE PREVENTION AND TREATMENT ACT OF 2017

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

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 YORK'S LAWS FOR OPIOIDS

New York Opioid Law

- No more than a thirty day supply or, pursuant to regulations of the commissioner enumerating conditions warranting specified greater supplies, no more than a three month supply of a schedule II, III or IV substance, as determined by the directed dosage and frequency of dosage, may be dispensed by an authorized practitioner at one time
- Notwithstanding the provisions of paragraph (a) of this subdivision, a practitioner, within the scope of his or her professional opinion or discretion, may not prescribe more than a seven-day supply of any schedule II, III, or IV opioid to an ultimate user upon the initial consultation or treatment of such user for acute pain. Upon any subsequent consultations for the same pain, the practitioner may issue, in accordance with paragraph (a) of this subdivision, any appropriate renewal, refill, or new prescription for the opioid or any other drug.
- For the purposes of this subdivision, “acute pain” shall mean pain, whether resulting from disease, accidental or intentional trauma, or other cause, that the practitioner reasonably expects to last only a short period of time. Such term shall not include chronic pain, pain being treated as part of cancer care, hospice or other end-of-life care, or pain being treated as part of palliative care practices.

- Public Health Law § 3331 [McKinney]

New York Opioid Law cont.

- Although pharmacists may continue to use all of the tools at their disposal when dispensing opioid prescriptions, pharmacists are not required to verify with the prescriber whether an opioid prescription written for greater than a 7-day supply is in accordance with statutory requirements. Pharmacists may continue to dispense opioids as prescribed, consistent with current laws and regulations.
- Within the scope of the practitioner's professional opinion or discretion, the limited quantity for opioid prescribing affects the initial consultation or treatment for acute pain only. Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill or new prescription for the opioid or any other drug.

https://www.health.ny.gov/professionals/narcotic/laws_and_regulations/docs/combat_heroin_legislation_faq.pdf

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

MCLE CODE

- PLEASE RECORD THIS CODE ON YOUR AFFIRMATION FORMS:

DRUGS199

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).

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.

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.

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

U.S. Department of Justice

United States Attorney
District of New Jersey
Civil Division

WILLIAM E. FITZPATRICK
ACTING UNITED STATES ATTORNEY
[redacted]
Assistant United States Attorney

[redacted]

main: [redacted]
direct:
fax:

April 3, 2017

Via Certified Mail

[redacted]

Dear Mr. [redacted]:

As you are aware, the United States Department of Justice, Drug Enforcement Administration ("DEA") conducted an audit of [redacted] in May of 2016. The period used for the audit was June 1, 2014 (BOB) through May 2, 2016 (COB).

The DEA's audit revealed numerous violations of the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-904, and the applicable sections of the Code of Federal Regulations ("CFR"). This matter was referred to the United States Attorney's Office for the District of New Jersey to initiate a civil penalty action. This letter describes the DEA's findings and the significance of the violations so that you may have the opportunity to address them with us prior to any decision concerning further action by our office.

The deficiencies revealed during the DEA's May 2016 audit of [redacted] include the following:

1. Complete and accurate records of several controlled substances were not maintained in accordance with law and regulation, specifically:

- Oxycodone 30 mg (Schedule II) – shortage of 7,216 pills
- Oxycodone APAP 10-325mg (Schedule II) – shortage of 259 pills
- Endocet 10/325 mg (Schedule II) – shortage of 52 pills
- Oxycodone 15 mg (Schedule II) – overage of 473 pills
- Hydrocodone 7.5/200mg (Schedule II) – overage of 4 pills

- Alprazolam 2 mg (Schedule IV) – shortage of 86.5 pills
- Diazepam 10 mg (Schedule IV) – overage of 86 pills

Each overage and shortage is subject to a maximum $14,739 civil penalty as a negligent record keeping violation in accordance with 21 U.S.C. §§ 842(a)(5) and 842(c)(1)(B), and 28 C.F.R. § 85.5.

2. [redacted] did not have DEA Form 222s available for inspection, as required by law. Pursuant to 21 C.F.R. § 1304.04(a), "every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the [DEA]." We understand [redacted] relied on [redacted] to maintain its DEA Form 222s, even though Mr. [redacted] is not registered with the DEA. Mr. [redacted]'s handling of DEA Form 222s on [redacted]'s behalf is a violation of 21 CFR § 1305.04(a), which states that "[o]nly persons who are registered with DEA . . . may obtain and use DEA Form 222 (order forms)[.]" Failure to properly maintain DEA Form 222 is a violation of 21 U.S.C. § 842(a)(5), and each violation is subject to a maximum $14,739 civil penalty under 21 U.S.C. § 842(c)(1)(B) and 28 C.F.R. § 85.5.

3. [redacted] utilizes [redacted], owned by [redacted] is not a DEA registrant nor is he a common or contract carrier. Accordingly, Mr. [redacted]'s handling of controlled substances on [redacted]'s behalf is a violation of the CSA, which makes it unlawful for a "registrant to distribute or dispense a controlled substance not authorized by his registration to another . . . authorized person." 21 U.S.C. § 842(a)(2); *see also* 21 C.F.R. § 1317.05 (setting forth the requirements for registrant disposal). Each violation of 21 U.S.C. § 842(a)(2) is subject to a maximum $63,523 civil penalty under 21 U.S.C. 842(c)(1)(A) and 28 C.F.R. § 85.5.

In addition to the deficiencies outlined above, we understand you failed to timely notify DEA that your state license was suspended in 2007 and you falsified your DEA renewal registrations in 2008 and 2011 by omitting your suspension. In fact, you waited to disclose your state license suspension to the DEA until October 2014. Your failure to timely notify the DEA of your license suspension, as well as your discrepancies in record keeping, raise serious concerns.

Prior to commencing suit concerning the above-referenced conduct, we would like to provide you with the opportunity to come into our office, with legal counsel if you so desire, to discuss this matter. Please contact me within 20 days of the date of this letter to indicate whether you would like to appear in my office to discuss these allegations. If we do not hear from you within that time period, we will assume that

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).

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

Legislative Update on Combating the Opioid Epidemic

By Joann L. Downey, Esq.
Assemblywoman
New Jersey Eleventh District

Biography

- Elected in 2015; serving first term in the New Jersey General Assembly.
- Represents the 11th Legislative District, which is composed of the following municipalities: Allenhurst, Asbury Park, Colts Neck, Deal, Eatontown, Freehold Borough, Freehold Township, Interlaken, Loch Arbour, Long Branch, Neptune City, Neptune Township, Ocean Township, Red Bank, Shrewsbury Borough, Shrewsbury Township, Tinton Falls, and West Long Branch.
- Currently serves on the Assembly Regulated Professions Committee and the Financial Institutions and Insurance Committee.
- Trial Attorney with J.D. from New York Law School

Background

- What prompted the legislature into action?
  - From the New Jersey Medical Examiner's office, between 2014 and 2015 overdose deaths increased by 22 percent in New Jersey. In 2015, 6,000 people lost their lives to narcotics in the State.
  - The Attorney General's office reports that in 2014 there were 5,174 total naloxone administrations, and the number increased to 7,222 in 2015. In 2016 the number escalated again to 10,000 Narcan deployments. According to the New Jersey Division of Mental Health and Addiction Services, in 2014 there were 28,653 patients in treatment for opioids, and that number increased to 35,529 in 2015. Experts agree that treatment figures are no longer reliable indicators as the need for treatment far outpaces what is available in the State.

Response from the Legislature

- The following legislation for combating opioids was signed into law:
  - S3 / A3: Five-pill limit on initial prescriptions; coverage for inpatient and outpatient treatment; and coverage for detoxification and medication assisted treatment (Signed into Law on 2/15/17)
  - A3744 / S2330: Establishing law enforcement assisted addiction and recovery referral programs (Signed into Law on 10/26/2016)
  - S295 / A2334: Allowing pharmacists to dispense opioid antidotes to any person, without a prescription (Signed into Law on 6/9/2017)
  - S2156 / A3424: Requiring prescribers to discuss the addiction risk prior to issuing a prescription minor. (Signed into Law on 2/6/2017)
  - S2844 / A4425: Eliminating certificate of need requirement for hospital beds being used for treatment of substance abuse. (Signed into Law on 7/3/17)
  - A3944 / S2402: Requires DOE to develop educational fact sheet for student-athletes and cheerleaders concerning use and misuse of prescription opioids. (Signed into Law on 7/21/17)

S3 / A3

- Reduces the amount of opioids that can be dispensed for acute pain on an initial prescription to just five pills.
- Requires coverage by insurance companies for 180 days of treatment for inpatient and outpatient treatment as determined by a physician.
- Would also mandate that detoxification and medication assisted treatment are covered by insurance companies for a minimum of 28 days without prior authorization and without increased cost sharing by the insured. This bill would apply to the State health benefits programs for teachers (SEHBP) State employees (SHBP). This bill does not mandate coverage under Medicaid or NJ Family Care.

A3744 / S2330

- Establishes law enforcement assisted addiction and recovery referral programs throughout the state.
- Specifically, the bill requires the Director of the Division of Mental Health and Addiction Services in the Department of Human Services, in consultation with the Attorney General, to prescribe regulation requirements for county and municipal law enforcement departments throughout the state to:
  - establish or authorize the operation of a program within their departments;
  - develop and implement guidelines for the recruitment and training of law enforcement officers, volunteers, and treatment providers to participate in the program
  - support and facilitate the linkage of law enforcement assisted addiction and recovery programs -to facilities and programs that provide appropriate substance abuse recovery services and health care services;
  - coordinate with law enforcement officials and program volunteers to ensure that individuals seeking to participate in the program are treated with respect, care, and compassion, and are reassured that assistance will be provided;
  - establish requirements for an individual to be eligible for participation in the program; and
  - develop and implement procedures for determining eligibility requirements for the program

S295 / A2334

- Expands public access to opioid antidotes, such as naloxone hydrochloride, in order to allow pharmacists to dispense naloxone to any person, without a prescription, pursuant to a standing order issued by a prescriber or, upon request by the pharmacist, pursuant to a standing order issued by the Commissioner of Health or the Deputy Commissioner for Public Health Services.
- The bill, which amends the OPA, stipulates that a licensed pharmacist may dispense an opioid antidote to any patient who is deemed to be capable of administering the same, regardless of whether that patient presents an individual prescription for the antidote. Protocols would have to be consistent with the provisions of the OPA, and must require a pharmacist to determine that the patient seeking the antidote is capable of administering the same to an overdose victim in an emergency. Any pharmacist who acts in good faith, and in accordance with the bill's requirements, in supplying an opioid antidote to a patient without a prescription, will be immune under the OPA from any civil or criminal liability or any professional disciplinary action stemming from such act.

S2156 / A3424

- Would require health care professionals with prescribing authority to discuss the addiction potential of any opioid drug that is a Schedule II controlled dangerous substance prior to issuing a prescription for the medication to a patient who is under 18 years of age. The prescriber would be required to have this discussion with the patient, along with the patient's parent or guardian, if the patient is not an emancipated minor.
- The prescriber will specifically be required to discuss the risks of developing a physical or psychological dependence on the medication and, if the prescriber deems it appropriate, any alternative treatments that may be available. Finally, the prescriber will also be required to include a note in the patient's medical record indicating that the discussion took place.

S2844 / A4425

- The bill would eliminate the requirement that a health care facility obtain a certificate of need from the Department of Health (DOH) to develop inpatient treatment beds used solely for the treatment of patients who have co-occurring mental health and substance use disorders.

A3944 / S2402

- Requires the Commissioner of Education, in consultation with the Commissioner of Health, to develop an educational fact sheet that provides information concerning the use and misuse of opioid drugs in the event that a student-athlete or cheerleader is prescribed an opioid for a sports-related injury. The law requires school districts and nonpublic schools that participate in interscholastic sports or cheerleading programs to distribute the fact sheet annually to the parents or guardians of student-athletes and cheerleaders, and to obtain a signed acknowledgement of the receipt of the fact sheet by the student and his parent or guardian.

Future Issues

- Continue increasing access to opioid antidotes
- Monitor the impending transfer of the Division of Mental Health and Addiction Services to the Department of Health.
- Pursuing Social Innovation loans and other types of financial incentives

Continue increasing access to opioid antidotes

- We sponsored legislation (A4177) that would require high schools to maintain a supply of opioid antidotes, and permit the school nurse to administer the antidote to a student or staff member who is experiencing an overdose. We also sponsored legislation (A2183) that would require county health departments to obtain and maintain a healthy stock of opioid antidotes for first responders and hospital pharmacies.
- Both bills have only been approved by the committees. They could be taken up in the lame duck session, but they could also be held until next year.

Transfer of DMHAS to DOH

- Governor Christie's Reorganization Plan No. 001-2017, issued on June 29, 2017, will transfer the Division of Mental Health and Addiction Services (DMHAS), and all of the state's mental health and addiction prevention and treatment functions, powers, and duties from the Department of Human Services (DHS) to the Department of Health (DOH).
- Administration argued that integrating physical and behavioral health care is the most effective way to treat the "whole person."
- Stakeholders expressed concerns regarding the content, potential effects, and timing of the planned reorganization
- Assembly approved a concurrent resolution (**ACR254**) to block Gov. Christie's plan, but the Senate failed to act. Hence, the plan will go forward.

Social Innovation loans

- We introduced legislation (A4379) that establishes a five-year social innovation loan guarantee pilot program for the purpose of encouraging private investment in health care services for the treatment and prevention of opioid and other substance use disorders to lower public expenditures related to those services.
- The bill is based on the concept of Social Innovation loans -- which are also known as Social Financing, social impact bonds or Pay for success (PFS) contracts.
- Social Innovation loans shifts financial risk from a traditional funder—usually government—to a new investor, who provides up-front capital to scale an evidence-based social program to improve outcomes for a vulnerable population.
- Will encourage innovation and creative problem solving in combating the opioid abuse

Thank you

- Thanks to our speakers for presenting today's program.
- Please remember to sign your affirmation form and either fax or e-mail it to ICLE:
- Fax: 732-249-1428
- E-Mail: smilek@njsba.com

Angelo J. Cifaldi

Phone: 732.855.6096 **Fax:** 732.726.6614 **Email: acifaldi@wilentz.com**

Bar Admission:

New Jersey and the United States District Court for the District of New Jersey, 1984

Education:

J.D., Seton Hall, *magna cum laude*, 1984
B.S., Rutgers College of Pharmacy, *magna cum laude*, 1981

Biographical Information:

Angelo Cifaldi is a shareholder with Wilentz, Goldman and Spitzer P.A., where he is Co-chair of the Mass Tort/Class Action Team, a member of the management committee and the firm's Vice President. He has been with the firm since he graduated *cum laude* from Seton Hall Law School in 1984. Before law school he graduated from Rutgers College of Pharmacy with high honors in 1981 and became a licensed pharmacist in New Jersey, a license that he still maintains. Mr. Cifaldi has two primary areas of practice: mass tort litigation and pharmacy administrative law.

During the past 30 years, Mr. Cifaldi, in conjunction with his Mass Tort/Class Action Team, has collected over one billion dollars for his clients. Mr. Cifaldi has successfully represented clients who have been the victims of:

- Asbestos exposure, including asbestosis, lung cancer and mesothelioma
- Defective prescription drugs and medical devices
- Chemical exposure
- Environmental pollution, including ground water and air contamination

Notably, Mr. Cifaldi has been on the forefront of asbestos and environmental litigation, and has achieved several successful single case recoveries. He achieved $38.5 million and $17.5 million resolutions for the victims of a ground water contamination. He has also handled various pro bono matters, the most notable being the representation of widows and relatives of the 9/11 terrorist attack on the World Trade Center.

As to his pharmacy administration practice Mr. Cifaldi represent hundreds of pharmacies, pharmacists, pharmacy technicians, wholesalers, and other healthcare providers in New Jersey, New York and Pennsylvania. He is considered a leading authority on pharmacy law in New Jersey and has handled numerous matters and hearings before the New Jersey Board of Pharmacy, DEA, FDA, Medicare and New Jersey Medicaid.

A few of the many services he provides:

- New Jersey Board of Pharmacy Hearings
- Regulatory compliance audits, including site inspections
- Sale/purchase of pharmacy
- Licensing issues
- Medicaid/3rd party audits
- Federal and state compounding
- Mail order pharmacies
- HIPAA compliance
- DEA regulatory compliance/hearings
- Defend Against Medicaid/Medicare Fraud Charges, including criminal charges
- Wholesale licensing

Mr. Cifaldi is also an adjunct associate professor of Pharmacy Law and Bioethics at Rutgers College of Pharmacy. He has been teaching Pharmacy Law at the school for over 25 years. In addition Mr. Cifaldi presents numerous continuing education seminars on pharmacy law related issue for groups such as Rutgers University, New Jersey Pharmaceutical Association, Garden State Pharmacy Owners Association, Indo American Pharmaceutical Society, New York State Department of Health-AIDS Institute, New Jersey Institute of Continuing Legal Education and others.

Mr. Cifaldi is also involved in civic activities as the chairman for the North Haledon Recreation Commission. He has held that position since 1983. He serves as the regional vice president of the American Amateur Baseball Congress. He also coaches a team of college and ex professional baseball players (over 25 years) in the Met League, a summer baseball league in Northern New Jersey. He is a former Councilman and Council President of the Borough of North Haledon and continues to be active politically in Passaic County.

Area of Emphasis:

Asbestos Litigation
Defective Drug Litigation (i.e. Fen-Phen, Rezulin)
Ground Water
Surface Water
Soil and Air Contamination Litigation

Practice Area(s):

- Asbestos and Mesothelioma
- Chemical Exposure
- Class Actions
- Drug / Medical Device Litigation
- Environmental Contamination
- Healthcare
- Mass Tort
- Pharmacy Law
- Railroad Injuries
- Unsafe Products / Product Liability
- Welding Rod Injuries

Lawyer Publications:

- Asbestos Disease - The Problem That Will Not Go Away
- New Jersey Healthcare Regulatory Update - April 2014

Lawyer Videos:

- Dealing With Medicare & Medicaid
- NJ Board of Pharmacy - How to Deal with Various Licensing Issues You May Encounter
- Pharmacy Compounding
- The Anatomy of a DEA Case - Your Rights, Responsibilities, & Potential Liabilities

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Heavy Metal Litigation (i.e. Chromium, Beryllium, Lead, Mercury)
Miscellaneous Toxic Tort Litigation
Pharmacy Administrative Law
Toxic Tort Class Action Litigation

Assemblywoman Joann Downey (D)

EDUCATION:	B.A. Rutgers University (Political Science/English) M.S.W. Boston University School of Social Work J.D. New York Law School
OCCUPATION:	Trial Attorney, Dimian & Masterpalo
LEGISLATIVE SERVICE:	General Assembly 2016-present
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Satish V. Poondi

Phone: 732.855.6154 **Fax:** 732.726.4752 **Email: spoondi@wilentz.com**

Bar Admission:

New Jersey, 2008

Education:

J.D., Rutgers University School of Law, Newark, 2005-2008
Pharm. D., Ernest Mario School of Pharmacy – Rutgers University, 1999-2005

Biographical Information:

Satish Poondi is a shareholder and a member of the Mass Tort/Class Action Team. Mr. Poondi is also a registered pharmacist, having received his Doctor of Pharmacy degree from Rutgers University. Mr. Poondi's unique combination of knowledge and experience in law and science allows him to provide his clients with strategies that address both the legal and commercial aspects of each matter.

Mr. Poondi's clients come from all sectors of the pharmacy industry, including: independent pharmacies, pharmacists, pharmacy technicians, retail chains, wholesalers, hospitals, and compounding pharmacies. He represents healthcare professionals, as well as healthcare entities, before licensing boards, including: the New Jersey Board of Pharmacy, New Jersey Medicaid, Medicare, the Drug Enforcement Administration and the Office for Civil Rights. He provides guidance on the regulatory requirements associated with the sale and purchase of pharmacies, as well as:

- Licensing concerns
- Medicaid/third party audits
- Defense against Medicaid/Medicare fraud charges
- HIPAA compliance
- DEA regulatory compliance/hearings
- Mail order pharmacies

Mr. Poondi is a guest lecturer at the Ernest Mario School of Pharmacy at Rutgers University and an advisor to multiple pharmacy organizations. Mr. Poondi understands the importance of educating lawyers and healthcare providers alike by regularly lecturing at continuing education seminars and programs sponsored by academic institutions, professional organizations and retail chains on relevant, topical pharmaceutical legal issues.

In addition to his administrative law practice, Mr. Poondi also advocates for patients injured by defective products against large pharmaceutical companies. He also represents clients with lung cancer and mesothelioma caused by their exposure to asbestos.

Mr. Poondi is a member of the firm's Cyber State Legal Resource Group. In that capacity, he consults with pharmacies and other healthcare providers on a variety of issues relating to the transmission and receipt of patient records, including: developing policy manuals, drafting privacy notices and related documents, conducting employee training regarding HIPAA compliance and data sharing, regulatory filing requirements and business associate agreements related to Medication Therapy Management.

Mr. Poondi is also an active member of the community. He is the legal advisor for the Indian Business Association, and advisory board member for the New Leaders Council. He previously served on the Mayor's Advisory Committee on Community Relations for the township of Edison. In addition, Mr. Poondi is on the Executive Board of various Middlesex County based community associations.

Area of Emphasis:
Defective Drug Litigation
Toxic Tort Class Action Litigation
Miscellaneous Toxic Tort Litigation
Pharmacy Administrative Law

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- Pharmacy Law

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- Pharmacy Compounding
- The Anatomy of a DEA Case - Your Rights, Responsibilities, & Potential Liabilities

News:

- Wilentz, Goldman & Spitzer, P.A. Promotes Four Associates in the Woodbridge, New Jersey Office