Disclaimer: This presentation is not intended to provide legal advice but is intended to inform the attendees of current issues affecting the handling and dispensing of controlled drugs as these drugs are regulated by the Drug Enforcement Administration and the New York State Department of Health Bureau of Narcotic Enforcement.

PHARMA COMPLIANCE GROUP LLC
DISCLAIMERS
- We Do Not Represent DEA
- We Do Not Speak on Behalf of DEA
- Familiarize Yourself with NYS DOH BNE and DEA Regulations on CS
- Not Intended to Provide Legal Advice

Mr. Aquino’s Experience
2 Year with Pharma Compliance Group LLC as a DEA compliance consultant
5 Years as PharmaDiversion, LLC as a DEA compliance consulting firm
12 Years with PFD DEA Diversion (8 as an Investigator & 4 as a Supervisor)
24 Years with Philadelphia Police (Last 10 years assigned to DEA Task Force)
LEARNING OBJECTIVES

- Discuss the Role of DEA Diversion
- Review DEA Actions
- Discuss NYS DOH & DEA Regulations
- Discuss the Red Flag Indicators
- Review the Prescriber’s Role
- Discuss the Questions to Ask
- Discuss Prescription Trends

INFO & LEGAL RESOURCES

- Title 21 Regulations & Codified CSA
- Questions & Answers
- Significant Document Guidance
- Pharmacist Manual 2010

Title 21, United States Codes
Section 829 – Prescriptions

Title 21, Code of Federal Regulations
Section 1306 - Prescriptions
DEFINITION OF A PRESCRIPTION

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. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Title 21, Code of Federal Regulations Section 1306.04(a)

ROLE OF DEA
DRUG ENFORCEMENT ADMINISTRATION (DEA)
OFFICE OF DIVERSION CONTROL

Responsible to Prevent, Detect, and Investigate Diversion of Pharmaceutical Controlled Substances & Regulated Chemicals While Ensuring an Adequate Supply for Legitimate Medical and Scientific Purposes

- Enforcing the Federal Laws & Regulations relating to Schedules I to V Controlled Substances and Regulated Chemicals (Tactical Diversion Squad)
- On-Site Audits and Inspections of Controlled Substances and Regulated Chemicals (Diversion Compliance Group)

AUTHORIZATION TO INSPECT

PURPOSE – To inspect, copy, verify correctness of records, reports, or other documents required to be kept or made under the Act or regulations including inventory (excludes financial data, sale data other than shipping data, and pricing data).

- Notice of Inspection (DEA Form 82)
- Administrative Inspection Warrant
- Search & Seizure Warrant

Title 21, United States Codes Section 880 & 965
Title 21, Code of Federal Regulations Section 1316

ACTIONS BY DEA

- Criminal Investigation
- Civil Action through USAO
- Administrative Actions
- Referral to State Regulatory Agency
DEA ADMINISTRATIVE ACTIONS
- Letter of Admonition
- Memorandum of Understanding
- Voluntary Surrender of DEA Registration
  (Repeat After Me – “I Will Never Surrender”)
- Immediate Suspension
- Order To Show Cause

CROSS-HAIRS OF BNE & DEA
- Oxycodone 30 mg Tablets
- Hydromorphone 8mg Tablets
- Hydrocodone 10 mg Tablets
- Methadone 10 mg Tablets
- Morphine IR 30 mg Tablets
- Out-of-State Prescribers
- Out-of-State Patients

REMEMBER
“NO PATIENT TRAVELS 100 MILES OR MORE BECAUSE OF YOUR PHARMACY SERVICES”

“DON’T LET WILLFUL BLINDNESS & DELIBERATE IGNORANCE STOP YOU FROM DOING YOUR DUE DILIGENCE”
EVIDENCE QUESTION

Did the pharmacist dispensed the controlled substance which he/she knew, or had reason to know, lacked a legitimate medical purpose and were issued outside of the usual course of professional practice?

Title 21, United States Codes

Section 846 – Attempt and Conspiracy

Any person who attempts or conspires to commit any offense defined in this subchapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.
EVIDENCE IN ANY CRIMINAL CASE

Dispensing was not for a legitimate medical purpose

KEY ELEMENT OF KNOWLEDGE

That the prescriber and/or pharmacist deliberately closed their eyes to the true nature of the Rx

Willful Blindness
Deliberate Ignorance

A Famous Quote, “I'll fill anything as long as you got paper. After all, who am I to tell you, you are not in pain”

CRIMINAL ACTIONS

- Dispensing Without a Legitimate Medical Purpose
- Exchange Controlled Substances for Money
- Exchange Controlled Substances for Sex
- Fabricating a Bogus Prescription Using a Patient’s Personal Information

Violation of Title 21, United States Code 841(a)(1)
ROLE OF A PHARMACIST

CORRESPONDING RESPONSIBILITY
- Determine that there is a legitimate medical purpose for the prescription
- Perform patient drug utilization review
- Dispense medications as noted on the written prescription
- Should perform a patient PMP verification for every C-II and C-III Narcotics

STATEMENTS OF PHARMACY THAT LOSE YOUR DEA REGISTRATION
“The doctor has a DEA registration and that's good enough for me.”
“DEA & BNE should do their job.”
“It's not my job to second guess the doctor.”
“Our volume of prescriptions is so great that we can’t screen each prescription.”
“The pharmacy is not responsible for what the customer does with their drugs.”
THE BIG QUESTION

How do I know that the prescription is for legitimate purpose?

LOOK FOR THE
“RED FLAGS”

FIRST FLAG

Cash vs. Medical Insurance

Due Diligence Questions

“Do you have a medical card?”

“Where did you get your last Rx filled?”

“We only accept insurance for that prescription.”
OTHER FLAGS
- An Out-of-State Prescriber
- An Out-of State Patient
- Location of Your Pharmacy vs. Physician
- A Patient Driving a Long Distance
- Multiple Patients Arrive in the Same Car
- All Patients Received the Same Drug
- Physician has No Pain Management Training

OTHER FLAGS
- Lack of Individual Therapy
- Cursory or No Patient Examination
- Unscrupulous Clinic Owners
- All Patient MRIs Coming from Same Place
- Paying Large Amounts for Prescription
- Large Volume in the Highest Dosage Form
- Other Pharmacies Refused to Fill the Rx
- Patients Exhibit “High” Behavior (Slurred Speech, Stumbling & Drooling)

OTHER FLAGS
Every Patients Received Same Prescription
- Two Narcotics
  (30 Day Supply of 30mg of Oxycodone and 10mg Percocet for Breakthrough Pain)
- One Benzo (Xanax 2mg)
- One Muscle Relaxer (Soma)
ANOTHER FLAG
Prescriptions Written by Dentist
Look For
- Percocet 10mg x 40 Tablets
- Anti-Biotic x 10 Days
(Patient Refuse Anti-Biotic Rx)

BIG QUESTION
What can I do to assure myself that the prescription is for legitimate medical purpose?

ANSWER
- Ask Questions
- Accept Only Insurance for Rx
- Document on Back of Prescription
- Establish a Written Pharmacy Policy

PATIENTS
- Determine Medical Purpose for Prescription
- Identify Other Physicians Used by Patient
- Ask for Their Medical Card
- Identify the Last Pharmacy Used by Patient
- Obtain Drivers’ License or Picture ID
- Verify Patient Information with PMP
- Advise Patient of Pharmacy Policies

Reminder: “If you have doubts about the prescription, don’t fill it” CMA
PHYSICIANS
- Verify with the Physician or Office Manager
- Verify the Listed Phone Number on Rx
- Ask Information on Treatment Plan
- Document on Back of the Prescription
- Fax Prescription to Physician
- Verify Patient Information (Name & Address)
- Verify Method of Payment for Visit by Patient
- Google the Physician

Reminder: “Use caution with first time customers. They can wait or take back their prescription” CMA

STREET VALUES
- Hydrocodone $1 - $10
- Xanax/Valium $1 - $5
- Oxycodone $25 - $80
- Fentanyl - $25 - $40
- Methadone - $2 - $10
- Cough Syrup - $250 - $600 @ PINT

HOLY TRINITY OF PAIN DRUGS
- Oxycodone
- Xanax
- Soma
Title 21, United States Codes
Section 842. Prohibited Acts B

(a) (5) to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter;

(a)(10) negligently to fail to keep a record or make a report under section 830 of this title;

c) Penalties

(B) In the case of a violation of paragraph (5) or (10) of subsection (a) of this section, the civil penalty shall not exceed $10,000

YES - $10,000 per Violation
LATEST ACTIONS BY DEA
Controlled Substances Ordering System “CSOS”

PURPOSE OF CSOS
- Eliminate the cost of mailing order requisitions
- Reduce the time to get you the Schedule II orders
- Does not replace the paper DEA Forms 222
  - Not to make your life easier

CSOS CIVIL ACTIONS
- Failure to provide executed order forms
- Unauthorized sharing of CSOS password
- Failure to confirm CSOS orders
- Failure to maintain a signed POA

NOTE: C-II invoices or packing slips is not a substitute for a DEA Form 222
Availability of DEA Required Records

DEA Administrative – Up To 2 Years
DEA Civil Action – Up To 5 Years
NYS DOH BNE – Up To 5 Years

ORDER FORMS (DEA Form 222)

“Must be Available for Inspection”
Electronic vs. Paper DEA 222

Proper notation includes:
- Date Drugs were Received
- Quantity Received
- Initials of Person Receiving the Drugs

Title 21 CFR 1305.22 – Procedure for filling electronic orders

“(g) When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived.”
Title 21 CFR 1305.27 – Preservation of electronic orders

“(a) A purchaser must, for each order filled, retain the original signed order and all linked records for that order for two years.”

“(c) If electronic order records are maintained on a central server, the records must be readily retrievable at the registered location”

Remember: NY State requires 5 Years of Records

Title 21 CFR 1311.60 – Recordkeeping

“(a) A supplier and purchaser must maintain records of CSOS electronic orders and any linked records for two years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records.”

Remember: New York State requires 5 Years

Title 21 CFR 1311.60 – Recordkeeping

“(b) Electronic records must be easily readable or easily rendered into a format that a person can read. They must be made available to the Administration upon request.”

Administration = DEA
Title 21 CFR 1311.45 – Requirement for Registration

“(a) A registrant that grants power of attorney must report to the DEA Certification Authority within 6 hours of either of the following (advance notice may be provided, where applicable):

(1) The person with power of attorney has left the employ of the institution.
(2) The person with power of attorney has had his or her privileges revoked.

(b) A registrant must maintain a record that lists each person granted power of attorney to sign controlled substances orders.”

POWER OF ATTORNEY
- DEA Form 251 - Registrant
- DEA Form 252 - CSOS Coordinator
- DEA Form 253 – Any Person Being Granted POA

Title 21 CFR Section 1305.05 – Power Of Attorney

Moving onto other pharmacy issues…..
HIPAA BASICS

• MUST ISSUE NOTICE OF PATIENT PRIVACY ON FIRST VISIT (NOPP)
• MUST DESTROY SENSITIVE DOCUMENTS WHICH CONTAIN PROTECTED HEALTH INFORMATION (PHI)
• MUST NOT SHARE PHI WITH UNAUTHORIZED INDIVIDUALS. BE CAREFUL NOT TO BE TRAPPED INTO UNAUTHORIZED PHI. DEMAND PROPER AUTHORIZATION FORM FOR RELEASE OF PHI
• UTILIZE SHREDDER OR SERVICES OF A DATA DESTRUCTION COMPANY
• OBTAIN BUSINESS ASSOCIATE AGREEMENTS WITH ANY VENDOR WITH ACCESS TO PHI

MEDICARE & MEDICAID COMPLIANCE

• ALL PHARMACY STAFF MUST COMPLETE FRAUD, WASTE, AND ABUSE TRAINING ANNUALLY
• MUST COMPLY WITH ANNUAL CERTIFICATION WITH NY OMIG IN DECEMBER OF EACH YEAR
• MUST CHECK MONTHLY BOTH THE OIG & OMIG WEBSITES FOR DISBARRED/EXCLUDED PROVIDERS/STAFF/PRESCRIBERS

WEBSITES TO CHECK:

• www.omig.ny.gov
• https://www.sam.gov/portal/public/SAM/#1
• www.oig.hhs.gov
• FOR HIPAA DISCLOSURES:
• www.nycourts.gov/forms/hipaa_fillable.pdf
Other current pharmacy compliance issues

- There is an intense push to conduct integrity audits of Pharmacy Providers who are handling Medicaid Managed Care patients and Medicare Parts C/D Prescription Plans.
- These integrity audits go far beyond the basic show me the prescription record and patient signatures...these audits require documentation of sufficient purchases to justify billings to the various MCO’s and Medicare Part C/D prescription drug plans.

Examples of Common Audit findings

- Pharmacy owners purchasing drugs off of street “bag men”
- Pharmacy owners conducting automatic refilling of medications without patient consent nor patient pick up
- Infrequent reversals of medications never picked up
- Failure to have adequate inventory to justify billings of various pharmaceuticals
- Switching pharmaceuticals to satisfy patient requests without billing properly and without prescriber authorization, i.e. dispense ProAir but receive rx for Ventolin and bill for Ventolin violation of federal law for purposes of federal rebate collections
- Failure of pharmacy owner to update proper NDC of generic and brand name drugs

Thank You

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Questions?? Comments??