

**The Role of the
Drug Enforcement Administration
in Oversight and Enforcement
over Registered Health Care Providers**

**Pennsylvania Pain & Addiction Summit
Wilkes University**

Friday - April 28, 2023

Presenters:

**Carlos M. Aquino,
Compliance Consultant & Founder
PharmaDiversio**n** LLC**

**James R. Schiffer, R.Ph. Esq.
Partner
Allegaert Berger & Vogel LLP**

NOTICE ON CONFLICT OF INTEREST

There are no conflicts of interest with today's speakers regarding this presentation.

This presentation is not intended to provide legal advice but is intended to inform the attendees of current issues involving compliance with the Controlled Substance Act (“CSA”) including: (i) record keeping; (ii) prescribing of a controlled substances; (iii) the need for a fully documented patient chart and (iv) the importance of maintaining a well define patient treatment plan.

Learning Objectives

1. - Review administrative and civil actions by the Drug Enforcement Administration (“DEA”) on a registrant who prescribes or dispenses a controlled substance.
2. - Review the responsibility of a prescribing practitioner who prescribes a controlled substance and what a practitioner needs to do to maintain their DEA registration including the effect of the recent Supreme Court decision that determined the prosecution of the prescribers charged with improper ordering of abusable controlled drugs to be successful, the government **“must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner.”**
- 3.- Review the actions of DEA when they proceed with an Order to Show Cause a DEA registration based on allegations that controlled substance prescriptions were prescribed or dispensed without a legitimate medical purpose.

Learning Objectives (Cont.)

- 4.- Understand the severity of DEA administrative actions when evaluating improper behavior by a DEA registrant.
- 5.- Recognize the steps to be taken by a practitioner to follow federal laws and regulations pertaining to the prescribing and/or dispensing of controlled substance for a legitimate medical purpose.
- 6.- The necessity by a practitioner to prepare and maintain, either electronically or manually by hand, complete and accurate patient records, especially electronic medical records with a detailed and full explanation of a treatment plan for each patient that in the practitioner's medical judgement requires the prescribing of a controlled substance.

DRUG ENFORCEMENT ADMINISTRATION (“DEA”) DIVERSION CONTROL DIVISION (“DIVERSION”)

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 Assigned
to the DEA Tactical Diversion Squad
- On-Site Audits and Inspections of Controlled Substances and
Regulated Chemicals Assigned to the Diversion Compliance
Group

(www.deadiversion.usdoj.gov)

DEA ACTIONS

DEA REGISTRANTS

Administrative Action

- Letter of Admonition (LOA)
- Memorandum of Agreement (MOA)
- Voluntary Surrender of DEA Registration
 - Order to Show Cause (OTSC)
 - Revocation

Civil Actions Fines

- \$18,170.00 per DEA record keeping violation
- \$78,312.00 per controlled substance prescription violation

DENIAL, REVOCATION, OR SUSPENSION OF A DEA REGISTRATION

- **Materially falsified any application or renewal registration
(Review of the Four Liability Questions)**
- **Conviction of a felony relating to controlled substances or List I
chemicals**
- **State license registration suspended, revoked, or denied and no longer
authorized by the state**
- **Committed an act that would render registration to be inconsistent with
the public interest**
- **Exclusion from participation in a program under Title 42, Section
1320A-7(a)**

Title 21 United States Code Part 824 (a) - Grounds

DEA

Definition of a Prescription

“means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription)”.

PURPOSE OF ISSUE OF 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.”

MANNER OF ISSUANCE PRESCRIPTION

“All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, direction for use, and the name, address and registration number of the practitioner.”

**Title 21, Code of Federal Regulations Section
1306.05(a)**

ALLEGATIONS THAT TRIGGER A DEA INSPECTION

- Allegations from State regulatory entities that focus on the prescribing or dispensing of controlled substances.
- A complaint from a family members that a patient became addicted to controlled substances prescribed or dispensed to them.

A complaint from a family member that a patient is diverting their prescribed and dispensed controlled substance medications.

- The arrest of patients who diverted their controlled substance prescriptions who now will cooperate with law enforcement.
- A community complaint or allegation that a medical clinic or pharmacy is a “Pill Mill”

FOCUS OF A DEA INSPECTION (Prescriber)

- Patients**
- Prescriptions**
- Patient Medical Charts**
- Necessity for Prescriptions**

**Revocations of DEA Registrations are
Posted under the “What’s New” section
on the DEA Diversion website**

FOCUS OF A DEA INSPECTION (Pharmacist)

- Pharmacist Corresponding Responsibilities**

- Pharmacy Due Diligence Policy to Determine the Necessity of Prescriptions**

Revocations of DEA Registrations are Posted under the “What’s New” section on the DEA Diversion website

FOCUS OF A DEA INSPECTION (PRESCRIBERS AND PHARMACISTS)

- Prescriptions written or filled earlier from the previous prescription for the same controlled substance
 - A patient profile done through the State Prescription Monitoring Program
- The necessity of prescriptions written that includes an opioid and a benzo
- Prescribing of Buprenorphine for opioid use disorder with a benzo
 - A review of the 90 Morphine Milligram Equivalent (“MME”) requirements for opioid prescriptions (Check with your state 90 MME regulations)
- The prescribing or dispensing of more than one immediate release opioid to the same patient (Break Through Pain)

RECENT DEA PUBLICATIONS

- Chemical Handlers Manual 2022
- Narcotic Treatment Program Manual 2022
 - Pharmacist's Manual 2022
 - Researcher's Manual 2022

WHERE TO FIND THEM

<https://deadiversion.dea.gov>

- Click on RESOURCES
- Click Publications & Manuals

RECENT DEA ACTIONS “DATA WAIVE PROGRAM”

LETTER FROM DEA ADMINISTRATOR ANNE MILGRAM DATED JANUARY 12, 2023

- Eliminates the need for a Data Waive Registration (“X Number”) (The Consolidated Appropriations Act of 2023)
- All prescriptions for buprenorphine requires a standard DEA registration number
 - No limits on number of patients for opioid use disorder
- The Act does not impact existing state laws and regulations that may be applicable
- The Act introduced new training requirements for prescribers (“Target Date June 21, 2023”)

“REMEMBER”

PURPOSE OF ISSUE OF 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.

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

“A practitioner is required to determine the legitimacy of prescribing controlled substances and the pharmacist has a corresponding responsibility to determine the legitimacy of a prescription written for legitimate medical purpose. There is a need for a practitioner and a pharmacist to speak to each other. Don't rely on the receptionist.”

Carlos M. Aquino April 28, 2022

Questions?

Thank you for your attendance

Carlos Aquino

PharmaDiversio**n** LLC

Phone 610 487 4663

Email: carlos@pharmadiversion.com

Jim Schiffer

Allegaert Berger & Vogel LLP

phone 908 228 7520

Email: jschiffer@abv.com