NASCSA
National Association of State Controlled Substances Authorities

Annual Conference
October 25-28, 2021

The Pharmacist's Corresponding Responsibility: Evolving Legal and Regulatory Requirements

John A. Gilbert, Jr., Director
Hyman, Phelps & McNamara, P.C.
jgilbert@hpm.com

Corresponding Responsibility

- Not a new concept but has it evolved?
- Prevent fraud by both the doctor and the patient
- Pharmacist training and education: “Who am I to second guess the doctor?”
- Pharmacists subject to state licensing but not federal, why not?
- Not defined in the CSA or state statutes
- No definition of Red Flags in any federal statute or regulation, not aware of definitions under state law.

21 USC § 829

- (a) Schedule II substances - Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without the written prescription of a practitioner, . .
- (b) Schedule III and IV substances - Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 U.S.C. 353(b)]

The Pharmacist's Corresponding Responsibility

- **21 C.F.R. § 1306.04(a) Purpose of issuance 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. (Emphasis added.)

DEA Regulations:
Definition of "Persons entitled to fill prescriptions

- **§1306.06 Persons entitled to fill prescriptions.**
- A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner.

East Main Street Pharmacy, 75 Fed. Reg. 66149 (Oct. 27, 2010)

- Development of the "red flags." Egregious facts that make bad law?
- Pharmacist repeatedly dispensed "cocktailed" prescriptions; no individualization prescribing; refilling prescriptions of patients or doctors located hundreds of miles away; an overwhelming proportion (95%) of prescriptions filled were cs prescriptions and filling prescriptions of patients that travelled to the pharmacist in groups.
- Pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.
- DEA did not focus on whether the pharmacist had "actual knowledge" that the prescriptions were not issued for a legitimate medical purpose, but instead whether the pharmacist had "reason to know [they] were not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice." Id.
- DEA stated that even if the pharmacist had verified with the physician "each and every" prescription, the evidence showed he still violated his corresponding responsibility because many of the prescriptions "patently served no legitimate medical purpose."

Holiday CVS, LLC, d/b/a CVS Pharmacy Nos 219 and 5195, 77 Fed Reg. 62316 (Oct 12, 2012)

- Failure to resolve Red flags
- To show a violation under 1306.04(a), the Government must establish that:
  - (1) the Respondent dispensed a controlled substance;
  - (2) a Red Flag was or should have been recognized at or before the time the controlled substance was dispensed; and
  - (3) the question created by the red flag was not resolved conclusively prior to dispensing the controlled substance.

JM Pharmacy Group Inc. d/b/a Farmacia Nueva & Best Pharma Corp., 80 Fed. Reg. 28667, 28685 (May 19, 2015).

- Is it the pharmacy or pharmacist that is responsible?
- Do you need to identify a specific pharmacist?
- DEA found:
  - Considering whether a pharmacy has violated its corresponding responsibility, DEA will consider whether the entity, not the pharmacist can be charged with the requisite knowledge.
  - Knowledge obtained by pharmacists and other employees acting with the scope of their employment may be imputed to the pharmacy
- Is a showing that a pharmacist filled red flag prescriptions without investigating whether the prescription was legitimate basis to impute knowledge to the pharmacy?

DEA Decisions and Orders for pharmacies show same of similar “red flags” of diversion

- Looking at the 27 DEA “Decision and Order” documents (26 pharmacies, 1 distributor) published between 2015 and 2020, including “Masters Pharmaceuticals”
- Of the 26 pharmacy documents, 13 discussed common red flags of diversion, including doctor shopping, pharmacy shopping, cocktail/drug combination prescriptions, patients traveling far distances, cash prescriptions, etc.
- Most often cited, pattern prescribing, traveling long distances, forged prescriptions, drug combinations , same households, cash, and therapeutic duplication
- In almost all cases, the pharmacy’s DEA certificate was revoked or application for DEA certificate was denied.

How Does a Pharmacist Evaluate the Context Around Red Flags

- When are combinations valid and when are they red flags?
- What distances should be used to determine if a pharmacy is too far from a patient or a patient too far from a doctor?
- What percent of cash payments are inappropriate?
- How many occurrences of a red flag should be considered in whether a pharmacy has violated its corresponding responsibility?
- Is a pharmacist required to have all of this information? What tools should be required?
- Should the PDMP be the standard?

Continued Evolution of Corresponding Responsibility Cases

- "New" DEA enforcement tool includes use of the civil injunction action.
- ***Oakley Pharmacy, et al.*** (ex parte DEA/DOJ Temporary Restraining Order entered against offending pharmacy and its pharmacists): Feb. 2019
- Part of a coordinated effort by the Department's Prescription Interdiction & Litigation (PIL) Task Force to deploy all available criminal, civil, and regulatory tools to reverse the tide of opioid overdoses in the United States.
- Dispensing, and billing Medicare for, prescriptions in violation of the Controlled Substances Act and the False Claims Act.
- According to the United States' complaint, the defendants' unlawful dispensing of opioids has been tied to the deaths of at least two people and numerous others have been treated at hospitals for serious overdoses within a short time of obtaining controlled substances from the pharmacies.

And the Trend Continues

- December 16, 2020*: **Seashore Drug Company*** and two pharmacists entered into consent judgment of permanent injunction permanently enjoining the pharmacists from distributing controlled substances, and/or serving as manager/owner of PIC of an entity that handles controlled substances. Also imposed a shorter suspension on one of the pharmacists, and a monitoring period.

- January 6, 2021: ***Shaffer Pharmacy***, its pharmacist owner Thomas Tadsen, and pharmacist Wilson Bunton (Toledo, Ohio) repeatedly dispensed opioids and other controlled substances in violation of the Controlled Substances Act.

- January 29, 2021: ***WeCare Pharmacy***, its pharmacist owner Qingping Zhang, and pharmacy technician Li Yang, and another related corporate entity, L&Y Holdings LLC, repeatedly dispensed opioids in violation of the Controlled Substances Act.

But, More Cases leading to More Scrutiny of Standards

- In *US v. Shaffer Pharmacy*, the District Court reversed course.
- District Court ultimately denied government's motion for preliminary injunction.
- Restrictions put in place by ABC (declined to continue selling) and new supplier Cardinal reduced "dramatically" number of opioids prescribed to the rate of a "typical" pharmacy
- Although calling defendants' explanations for filling controlled substance prescriptions as "Johnny-come-lately," explanations, they resolved certain red flags identified by government
- "Best practices" would have required more by the pharmacists, but that would be determined as the case progresses

US v. Shaffer Pharmacy (cont.)

- District Court concluded:
- Danger of recurrent violations is minimized; with certain practices, further violations are either reduced or eliminated.
- Defendants must supplement recordkeeping to identify and document red flag resolutions,
- Fully conform to written policies and procedures
- Documentation must be available for immediate inspection by DEA on a bi-weekly basis
- Suspected failures will be brought to the court's attention.
- "Defendants are now required to address the legitimacy of a prescription in a contemporaneous writing prior to dispensing to meet a 'legitimate medical purpose'"

Push back from Patients?

- National class action lawsuits have been filed against the largest pharmacy chains in the country for discrimination in refusing to fill legitimate prescriptions for opioid medication. Class Actions by patients against pharmacies: Smith v. Walgreens Boots Alliance, Inc., et al., Case No.: 20-cv-05451 and Fuog v. CVS Pharmacy, Inc., et al., Case No.: 20-cv-00337
- As alleged in the lawsuits, CVS, Walgreens and Costco have implemented nationwide policies that have resulted in their pharmacies treating patients who presents a valid prescription for opioid medication as if they are a drug abuser, interfering with the customer's relationship with his or her treating doctor and improperly refusing to fill legitimate prescriptions for opioid pain medication or imposing medically unnecessary limitations or other requirements before agreeing to fill the prescriptions.
- In a June 16, 2020 letter to the CDC, the American Medical Association stated that guidelines issued by the CDC in 2016 "included multiple arbitrary dosage and quantity limitation recommendations that have been consistently misapplied by State legislatures, national pharmacy chains, pharmacy benefit management companies, health insurance companies and federal agencies."

Closer look at CR Regulatory Standard

- *United States v. Ridley Family Markets*, ND Utah, Case No. 1:20-CV-173-TS-JCB
- US filed a complaint in federal court seeking penalties against Ridley's Family Market, Inc. (Ridley's) for alleged violations of filling 160 invalid prescriptions for two individuals married to each other. Allegations of red flags including cash payments, high doses and long duration, early refills, etc.
- US seeks civil penalties and injunctive relief because the pharmacy filled prescriptions without resolving red flags that indicated the prescriptions were not for a legitimate medical purpose or written in the usual course of professional practice.
- Ridley filed a Motion to Dismiss on several grounds including challenging penalties on the grounds of 1306.04(a) and 1306.06.

United States v. Ridley Family Markets, (cont.)

- Court noted that ;
  - Section 1306.04(a) prohibits pharmacists from filling prescriptions they know are not legitimate. A person filling a prescription he know is not legitimate he is subject to penalties.
  - Section 1306.06 requires pharmacists to fill prescriptions only in the course of their professional practice. Absent a penalty provision.
- Court noted that unlike 1306.04; 1306.06 does not have a knowledge requirement and does not provide for penalties.
- When interpreting regulations courts will apply general rules of statutory construction and look at the plain meaning of the language, the context of the regulatory scheme and the administrative intent.

United States v. Ridley Family Markets, (cont.)

- Court noted that neither the regulations nor the CSA define "usual course of professional practice.
- Because 1306.06 does not explicitly provide for penalties, the Court found the Government could not seek penalties under this regulation.
- Court also found that the Government's argument that Ridley's violated 1306.06 as the same basis for the claim that it violated 1306.04(a) would render 1306.04(a) and the knowledge requirement meaningless. Meaning that if the government could bring the same claim under 1306.06 even if there was not evidence to show the pharmacist knew that it was legitimate would run contrary to rules of statutory construction.
- Finally, the Court cited to comments filed when DEA promulgated the regulations in 1971, finding that DEA included the knowledge requirement in 1306.04(a) so that pharmacists would not be responsible to determine the legitimacy of the prescription. Nullifying the "knowledge" requirement would create a fear for the pharmacist whenever they filled a controlled substance prescription.

Resources

- FDA Law Blog, www.fdalawblog.net (frequent posts on DEA legal matters and FDA matters).
- Administrative Actions Against Registrants, DEA Office of Diversion Control, https://www.deadiversion.usdoj.gov/crim_admin_actions/(archive of DEA administrative cases published in Federal Register).
- DEA website for general and specific information: https://www.deadiversion.usdoj.gov/

NASCSA
National Association of State Controlled Substances Authorities

Annual Conference
October 25-28, 2020

QUESTIONS?

THANK YOU!

John A. Gilbert, Jr., Director
Hyman, Phelps & McNamara, P.C.
Visit our HPM BLOG: www.fdalawblog.net