

Challenges for Refusals to Fill

Lisa Smith, Pharm.D, MBA

Learning Objectives:

1. Understanding Pharmacists
Corresponding Responsibility
2. Be familiar with the contradictions
between state and federal agencies
as it relates to refusals to fill and
corresponding responsibility
3. Gain perspective on the difficult
position that pharmacists face in
practicing while combatting an
opioid epidemic

I have no financial relationship to disclose

I am an employee of Walmart



(a) 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

[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974; 70 FR 36343, June 23, 2005]

NOTICE: This is an unofficial version. An official version of this publication may be obtained directly from the Government Publishing Office (GPO).

NPPLIS
Publications & Manuals
Questions & Answers
Significant Guidance Documents
Synthetic Drugs
Title 21 Code of Federal Regulations
Title 21 USC Codified CSA

WHAT DOES CORRESPONDING RESPONSIBILITY MEAN?

PHARMACISTS MUST DETERMINE HOW TO EXERCISE THEIR CORRESPONDING RESPONSIBILITY DESPITE DIFFERENT ORGANIZATIONS AND REGULATING BODIES INTERPRETING THIS RESPONSIBILITY DIFFERENTLY

HHS.gov

U.S. Department of Health & Human Services

SAMHSA

Substance Abuse and Mental Health
Services Administration

AMA



CDC



DEA

United States Drug Enforcement
Administration

FDA

**U.S. FOOD & DRUG
ADMINISTRATION**

CMS.gov

Centers for Medicare & Medicaid Services

**PHARMACISTS ARE IN A DIFFICULT
POSITION**



Dispelling Myth

The DEA does **NOT** dictate what tests a practitioner must conduct.

- The DEA does **NOT** require that a practitioner record diagnosis codes on prescription for a controlled substance.

However, some states and insurance providers may choose to impose such limits.

U.S. Drug Enforcement Administration
Diversion Control Division

- The DEA does **NOT** instruct practitioners on what type, or what strength of a Schedule II-V controlled substance they can or must prescribe.
- The DEA does **NOT** dictate how frequently a practitioner must see a patient.

U.S. Drug Enforcement Administration
Diversion Control Division

DEA TRAINING VARIES

✓ If in doubt, DON'T dispense the controlled substances

CDC GUIDELINES AND OTHER ACUTE OPIOID LIMITS

Many states and third parties have adopted guidelines for acute prescribing and dispensing of opioids – many of which align to the CDC guidelines

The CDC has issued statements that the guidelines for chronic pain were not meant to be hard guidelines and they had a narrow scope which did not include pharmacies

The DEA has dropped off copies of these same guidelines to pharmacies.

CDC is raising awareness about the following issues that potentially put patients at risk:

The Guideline does not support abrupt tapering or sudden discontinuation of

opioids. This can result in severe opioid withdrawal symptoms including pain and psychological distress. In addition, policies that mandate hard limits conflict with the **Guideline's emphasis on individualized assessment of benefits and risks considering the circumstances and unique needs of each patient.**





**U.S. FOOD & DRUG
ADMINISTRATION**

Safety Announcement

[4-9-2019] The U.S. Food and Drug Administration (FDA) has received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased. These include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.

While we continue to track this safety concern as part of our ongoing monitoring of risks associated with opioid pain medicines, we are requiring changes to the prescribing information for these medicines that are intended for use in the outpatient setting. These changes will provide expanded guidance to health care professionals on how to safely decrease the dose in patients who are physically dependent on opioid pain medicines when the dose is to be decreased or the medicine is to be discontinued.

Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse. Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances.

Health care professionals should not abruptly discontinue opioids in a patient who is physically dependent. When you and your patient have agreed to taper the dose of opioid analgesic, consider a variety of factors, including the dose of the drug, the duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient. No standard opioid tapering schedule exists that is suitable for all patients.

RECOMMENDATIONS, SEE ADDITIONAL INFORMATION FOR HEALTH CARE PROFESSIONALS.

If you can't dispense if red flags are present, and you can't discontinue therapy – what is a pharmacist to do?

One red flag that has gained a lot of attention in the industry is the trinity – most often the combination of an opioid, benzodiazepine and a muscle relaxer – specifically opioid, Xanax and Soma.

June 17, 2019

James Arnold
Section Chief, Liaison & Policy Section
Diversion Control Division
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, VA 22152

Dear Jim:

Following DEA meeting with industry and associations on June 13, 2019, we would like to bring to DEA's attention two issues for which we request clarification from DEA.

NACDS represents traditional drug stores, supermarkets and mass merchants with a membership rate over 40,000 pharmacies, and NACDS' over 80 chain members include regional chains, with a minimum of four stores, and our members employ nearly 3 million individuals, including 157,000 pharmacists. NACDS members dispense over 3 billion prescriptions yearly, and help patients use their medications safely, while offering innovative services that improve patient care affordability. NACDS members also include more than 70 international members representing 21 countries. For more information, visit nacds.org.

We would like to alert DEA of challenges that our members are encountering with the April 2019 modifications to online DEA Form 106, and to request your assistance in resolving this matter.

Changes to online Form 106 eliminating the option through which registrants could attribute a significant loss that does not fit into one of the loss categories in the drop-down menu. Previously, for which the reason for the loss was not readily apparent, registrants could select "other" to categorize such a loss. However, because "other" is no longer an option in the drop-down menu, registrants are now forced to make a selection that does not accurately address the specific loss-type being reported.

The loss types are now as follows: Break-in/Burglary, Employee Theft, Hijacking of Transport Vehicle, Packaging Discrepancy, Robbery, Customer Theft (or non-employee), Loss in Transit, and Disaster (fire, weather, etc.).

If, as the *Rodriguez* complaint suggests, it is the position of the Justice Department and/or DEA that such prescriptions can never be filled, for any patient, regardless of his or her medical condition and physician's clinical judgement, then it is essential that all pharmacies in the United States—as well as Boards of Pharmacy and Medical Boards throughout the country—be unambiguously advised of this view right away. Given the urgency of the matter, we ask for your immediate clarification.

NACDS SEEKING CLARIFICATION – POTENTIALLY DANGEROUS MEDICATION COMBINATIONS

The logo for HHS.gov, featuring the text "HHS.gov" in a bold, sans-serif font. The "HHS" is in yellow and ".gov" is in white. To the right of the text is a stylized white graphic of a person's head and shoulders, composed of several curved lines.

Caution is needed when using PDMPs as a tool to aid in the proper dispensing of medications. **However, PDMPs are not to be used as tools to stop dispensing medications appropriately to those in need.** For example, it is important for pharmacists to know that doctors often work as teams and to ensure that the conclusion of inappropriate multiple provider use is made only after the pharmacist has communicated directly with the prescribing clinician

Different ways in which pharmacist may refuse to fill a prescription.

1. A pharmacist may refuse to fill an individual prescription based on the inability to clear red flags or clinical concerns
2. A pharmacist may see a pattern of concerns from a patient or prescriber and may make the decision to no longer fill controlled medications from that prescriber or for that patients
3. Pharmacies may make a decision that collectively they will no longer fill for a certain prescriber or patient

WORKING TO BE PART OF THE
SOLUTION THROUGH NALOXONE AND
MEDICATION ASSISTED TREATMENT

FOR IMMEDIATE RELEASE
April 5, 2018

Contact: ASH Media Office
202-205-0143
ashmedia@hhs.gov

Surgeon General Releases Advisory on Naloxone, an Opioid Overdose-Reversing Drug

Urges more individuals to carry life-saving medication

Today, U.S. Surgeon General Jerome M. Adams, M.D., M.P.H., urged more Americans to carry a [lifesaving medication that can reverse the effects of an opioid overdose.](#)

Notes To Prescriber : NARCAN IS RECOMMENDED FOR THIS PATIENT. INSURANCE WILL ONLY COVER WITH A PRIOR AUTHORIZATION. WOULD YOU CONSIDER WRITING RX FOR THIS

NO
And this is our second request that you
Stop Prescribing medication for
Patients. 9/26/18

Prescriber response to request for prior auth for Narcan: “No And this is our second request that you stop prescribing medication for patients.”

SAMHSA

Substance Abuse and Mental Health
Services Administration

The **SUPPORT** for Patients and Communities Act of 2018

Certain physicians can treat up to 100 patients if they satisfy one of the following two conditions:

1. Board certification in addiction medicine or addiction psychiatry by the American Board of Preventive Medicine or the American Board of Psychiatry and Neurology; or
2. Provides medication-assisted treatment (MAT) in a "qualified practice setting." A qualified practice setting is a practice setting that:

1. provides professional coverage for patient medical emergencies after hours
2. provides access to case-management services for patients including referral and follow-up services for programs that provide, or financially support, the provision of services such as medical, behavioral, social, housing, employment, educational, or other related services;
3. uses health information technology systems such as electronic health records;
4. registered for State prescription drug monitoring program (PDMP) and
5. accepts third-party payment for costs in providing health services, including written billing, credit, and collection policies and procedures, or Federal health benefits.

FierceHealthcare

HOSPITALS & HEALTH SYSTEMS TECH PAYER FINANCE PRACTICES REGULATORY

Hospitals & Health Systems

DOJ raids could be making opioid crisis worse: report

by Mike Stankiewicz | May 11, 2018 8:21am

MEDICATION-ASSISTED TREATMENT: CDC recommends never refusing a MAT script while DEA continues to investigate validity of prescriptions

HOW CAN WE BE PART OF THE SOLUTION TO HELP OUR PROFESSION NAVIGATE THESE CHALLENGES

1. Support our pharmacists in using their clinical judgement
2. Advocate for clarity amongst agencies that regulate the practice
3. Create collaboration between pharmacists and other members of the health care team in the community setting to combat the epidemic while meeting regulatory requirements and providing patient care

Questions?