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

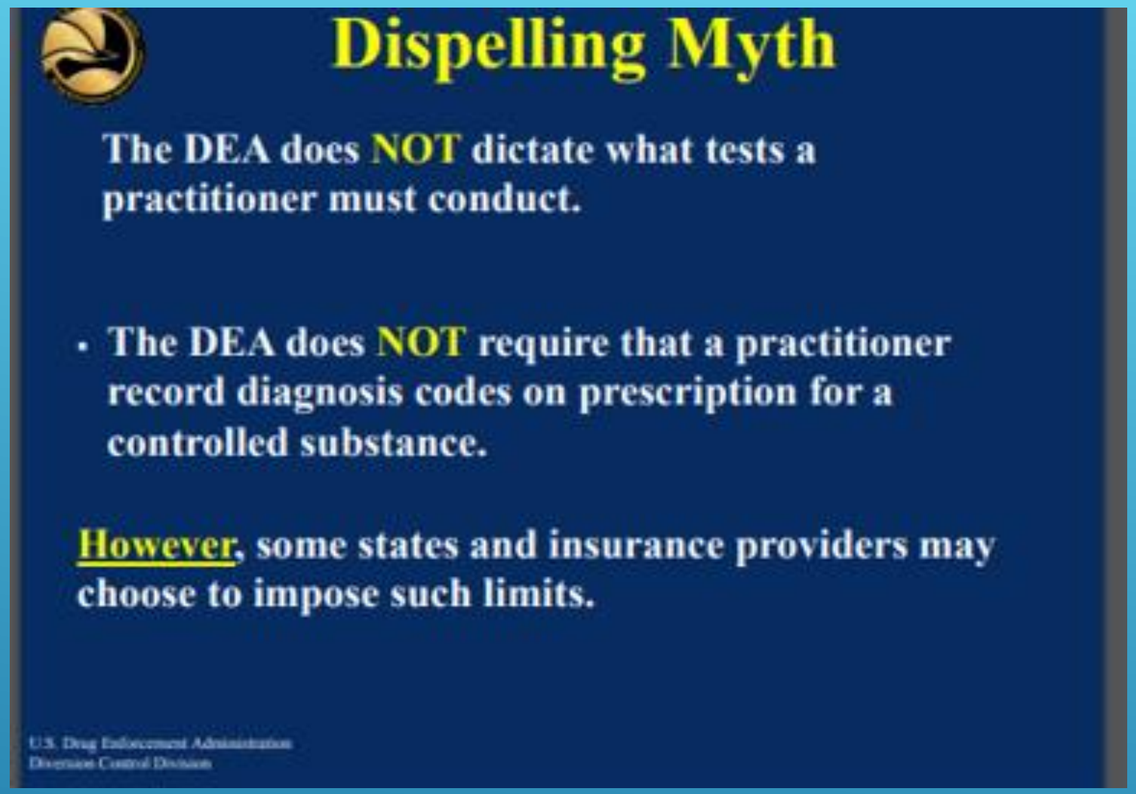
I have no financial relationship to disclose

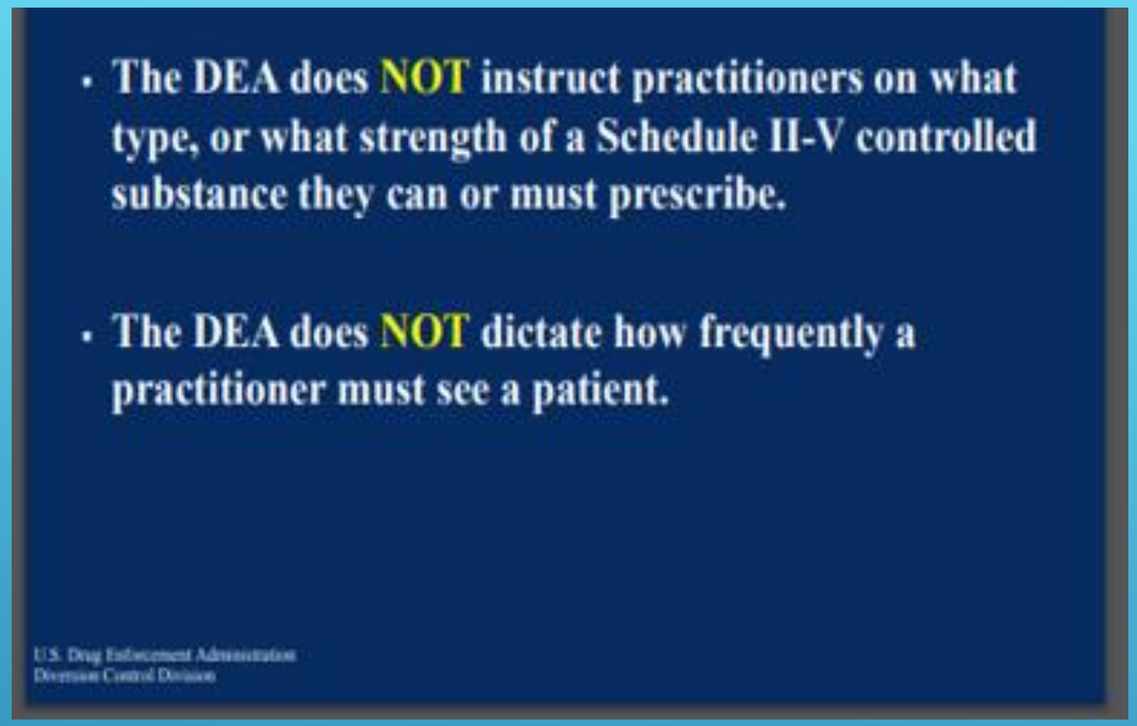
I am an employee of Walmart

WHAT DOES CORRESPONDING RESPONSIBILITY MEAN?

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

PHARMACISTS ARE IN A DIFFICULT POSITION





DEA TRAINING VARIES

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

“When in doubt, don’t dispense”

What does this mean for pharmacists?

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 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.**

FDA 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.

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 NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 17, 2019

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

Dear Jim:

...coming DEA meeting with industry and associations on June ...o bring to DEA's attention two issues for which we request ...on from DEA.

...itional drug stores, supermarkets and mass merchants with ...rate over 40,000 pharmacies, and NACDS' over 80 chain ...lude regional chains, with a minimum of four stores, and ...ains employ nearly 3 million individuals, including 157,000 ...ver 3 billion prescriptions yearly, and help patients use ...l safely, while offering innovative services that improve ...thcare affordability. NACDS members also include more than ...nd over 70 international members representing 21 ...acds.org.

...lert DEA of challenges that our members are encountering ...April 2019 modifications to online DEA Form 106, and to ...a resolving this matter.

...changes to online Form 106 eliminating the option through ... attribute a significant loss that does not fit into one of the ...oss categories in the drop-down menu. Previously, for ...ich the reason for the loss was not readily apparent, ..."other" to categorize such a loss. However, because "other" ...a the drop-down menu, registrants are now forced to make a ...ccurately address the specific loss-type being reported.

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

NACDS SEEKING CLARIFICATION – POTENTIALLY DANGEROUS MEDICATION COMBINATIONS

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

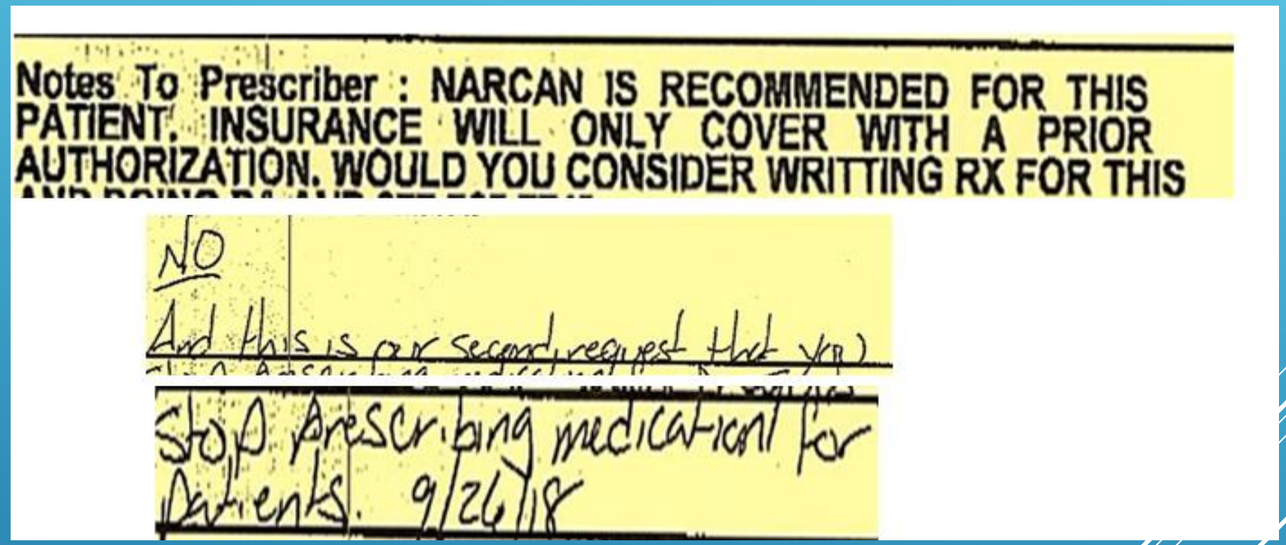
FOR IMMEDIATE RELEASE
April 5, 2018

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 WRITTING 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."

U.S. Department of Health & Human Services

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?