Refusing to Dispense: Considerations and Consequences

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CPE Information

• Target Audience: Pharmacists and Pharmacist Technicians
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• Activity Type: Knowledge-based
Disclosures and Disclaimers

Neither Dr. O’Neil or Dr. Melton have any financial conflicts of interest or other potential conflicts of interest in relation to this program/presentation.

Any information provided in this presentation should not serve as legal advice regarding any potential case and should serve only as a framework to direct pharmacists to appropriate resources regarding key considerations when refusing to dispense a prescription.

*State regulations and boards of pharmacy regulations vary considerably regarding this topic.* This presentation will address *general considerations* regarding pharmacists refusal to dispense prescriptions.
At the completion of this knowledge-based activity, participants will be able to:

1. Describe the categories of prescriptions that are frequently refused to be dispensed by pharmacists and the common rationales for refusal.

2. Cite laws that support or require pharmacists to refuse to dispense.

3. Discuss potential consequences to patients, prescribers, and pharmacists for refusing to dispense.

4. Explain rationales for refusing to dispense a prescription to patients and prescribers.
Assessment Question

1. Which of the following classes of medications is one of the most common “refused to be dispensed prescription” by pharmacists and has been associated with the most controversy?

A. Stimulants for weight loss
B. Emergency contraceptive products
C. Antipsychotics in pediatric patients
D. Controlled substances used for sleep
2. Which of the following laws, regulations, or guidelines holds the pharmacist responsible for failure to practice due-diligence because of the pharmacist’s corresponding responsibility?

A. Omnibus Budget Reconciliation Act (OBRA ’90)
B. Pharmacy Practice Act as delineated in each state
C. Corporate Human Resource policy regarding dispensing
D. Code of Federal Regulations (CFR) Title 21 Part 1306.04
Assessment Question

3. Which of the following is a common consequence for a pharmacist who speaks inappropriate comments to a patient when refusing to dispense a prescription for a prescriber that may be under investigation by law enforcement or a medical board?

A. Sued by the prescriber for slanderous statements or defamation of character of the prescriber
B. Sued by the patient for slanderous statements or defamation of character of the prescriber
C. Prosecuted by the Drug Enforcement Agency (DEA) for slandering the prescriber
D. Terminated because of violating a Health Insurance Portability and Accountability Act (HIPAA) statute
4. Which of the following rationales is a reasonable consideration when refusing to dispense a controlled substance where a clinically significant concern exists about a prescriber’s prescribing practices?

A. “It’s reckless for any medication to be prescribed this way!”
B. “Your prescriber is under investigation so I can’t dispense this prescription.”
C. “I am not comfortable dispensing this prescription based on current practice guidelines and clinical circumstances.”
D. “I am not comfortable dispensing this medication under these circumstances since the prescriber operates a known pill-mill.”
• How common is the dilemma of refusing to dispense in your practice?
• What key points do you hope to leave this session with that will help you with your daily practice?
A variety of lawsuits *from patients* *against* pharmacies and pharmacists

- Moral beliefs, religious beliefs, practice “standards”

Lawsuits from *prescribers* against pharmacies and pharmacists

- Defamation of character, slander

Difficult and frustrating working environments for pharmacists because of lack of support or direction from *employers*

- Front store manager dealing with patient complaints that try to influence pharmacist dispensing

Confusion about pharmacists rights versus “*agreed upon*” job responsibilities with corporate employers contracts

- Failure of employer to understand work contracts or policy
Caution-One Size Doesn’t Fit All!

Requirements for pharmacists to dispense prescription medications *vary significantly* from state-to-state because of overriding state government regulations, boards of pharmacy regulations, and individual corporate pharmacy policies *regardless of personal beliefs.*
Prescription Classes Commonly Refused to be Dispensed

• Oral contraceptives (acute-Plan B and chronic)
• Controlled substances (opioids, benzodiazepines, stimulants)
• Weight loss or weight gain medications (stimulants, human chorionic gonadotrophin (hCG) or growth hormone)
• Medications for transgender transition (hormonal therapy)
• Combinations of medications (carisoprodol, benzodiazepines, opioids)
• Syringes to patients with Substance Use Disorders (SUDs)
What is the Role / Responsibilities of the Pharmacist?

Protect and support patients, prescribers, their employers, and themselves from harm
Patient Common Expectations, Beliefs.....and Fallacies

• The pharmacist **MUST** dispense every prescription a prescriber writes

• Prescribers are always right and know what is best for the patient

• Patients *think* they CAN have it both ways
Prescriber Common Expectations, Beliefs....and Fallacies

• Pharmacists **MUST** dispense every prescription prescribers write

• Prescribers know the most/everything about their patients
Pharmacist Common Expectations, Beliefs....and Fallacies

• We can refuse to fill any prescription for any reason without any negative consequences to patients, prescribers, ourselves.
Board of Pharmacy and Law Enforcement Expectations

• Follow all laws and regulations
• Perform our “due diligence”

‘Due Diligence’ may be defined as……..

“This care that a reasonable person exercises to avoid harm to other persons or their property”

Common Rationales for Pharmacists Refusing to Dispense Prescriptions

• Religious beliefs
• Moral / ethical beliefs
• Patient safety concerns
• Standards-of-care / “guideline” deviations
• Public safety
• Personal/licensure protection
• The decision is *emotional or personal*
Potential Consequences of Pharmacist Refusal to Dispense

Harm to patient (Restricting healthcare to patients?)
  • Physical
  • Emotional
  • Embarrassment

Loss of pharmacist’s employment
  • Policy violations

Lawsuit from prescribers
  • Slander/defamation of character
Laws and Regulations “Supporting” Pharmacist Refusal to Dispense

1. Drug Enforcement Agency (DEA) Law and Regulations

2. Omnibus Budget Reconciliation Act of 1990 (OBRA ’90)

3. State Board of Pharmacy Regulations- “Pharmacy Practice Acts”
According to 21 C.F.R. 1306.04, pharmacists are required to ensure that prescriptions for controlled substances are issued for a legitimate medical purpose. The regulation states, in pertinent part, the following:


“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.”

OBRA ‘90

Mandates the offer to counsel patients about their prescriptions, and also specifies the components of patient counseling.

If the patient accepts the offer to counsel, the following items should be addressed:

• Name of drug
• Intended use and expected action
• Route, dosage form, dosage, and administration schedule
• Common side effects that may be encountered, including their avoidance and the action required if they occur

OBRA ’90 (cont’d)

• Techniques for self-monitoring of drug therapy
• Proper storage
• Potential drug-drug or drug-food interactions or other therapeutic contraindications
• Prescription refill information
• Action to be taken in the event of a missed dose

RULES OF THE TENNESSEE BOARD OF PHARMACY
CHAPTER 1140-3 STANDARDS OF PRACTICE

(Rule 1140-3-01)

• In order to effectively counsel patients, the pharmacist or a person designated by the pharmacist shall, through communication with the patient, caregiver, or agent make a reasonable effort to obtain, record, and maintain the following information for each patient of the individual pharmacy practice site.

• 3. An individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

Drug Regimen Review.

(a) A pharmacist shall be responsible for a reasonable review of a patient’s record prior to dispensing each medical or prescription order. The review shall include evaluating the medical and prescription order for:

1. over-utilization or under-utilization;
2. therapeutic duplication;
3. drug-disease contraindication;
4. drug-drug interactions;
5. incorrect drug dosage or duration of drug treatment;
6. drug-allergy interactions;
7. clinical abuse/misuse.

(b) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem.

A reasonable appropriate step to resolve the problem may be refusing to fill the prescription.
Right to Refuse with Patient Protection

• **Cal. Bus. & Prof. Code § 733** (2009)- A licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient.

• **Delaware Code Regs. 24 2500 §3.1.2.4** (Regulations 2009)- Allows the refusal to dispense pharmaceuticals based on the religious, moral, or ethical beliefs of the dispensing pharmacist, however these procedures shall include proper supervision of supportive personnel and delegation of authority to another pharmacist when not on duty.

• **New York Policy Guideline Concerning Matters of Conscience** (Regulation 2009) – In the case of a pharmacist who realizes they have a moral objection to providing a certain medication, the pharmacist has a professional obligation to take appropriate steps to avoid the possibility of abandoning or neglecting a patient. When a pharmacist begins practice in a professional setting, they should take steps that may include notification to the owner and supervising pharmacist if their beliefs will limit the drug products they will dispense.

Right to Refuse with Patient Protection

- **North Carolina Board of Pharmacy** (Regulation 2005)- A pharmacist has the right to avoid being complicit in behavior that is inconsistent with his or her morals or ethics, however it is unacceptable for pharmacists to impose their moral or ethical beliefs on the patients they serve. Pharmacists cannot obstruct a patient’s right to obtain such medication.

- **The Oregon Board of Pharmacy** (Regulation 2005) – Requires the Pharmacist-in-Charge (PIC) to adopt written policies and procedures that address the issues of pharmacists' moral, ethical and professional responsibilities. Pharmacy policies and procedures could allow a pharmacist to exercise his or her choice to not participate, and at the same time not interfere with the patient's right to receive appropriate and lawfully prescribed drug therapy or drugs.

- **Pennsylvania Cons. §27.103** (2009) – Pharmacists may decline to fill or refill a prescription if, in the pharmacist’s professional judgment exercised in the interest of the safety of the patient, the pharmacist believes the prescription should not be filled or refilled. When a pharmacist recognizes that religious, moral or ethical beliefs will result in the refusal to fill a prescription that is otherwise available in a pharmacy, the pharmacist has a professional obligation to take steps to avoid the possibility of abandoning or neglecting a patient.

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Right to Refuse without Patient Protections

• **Georgia Admin. Code § 480-5-.03** (2001) – Provides that a pharmacist shall not be required to fill a prescription for an emergency contraceptive drug; provides that such refusal shall not be the basis for any claim for damages; provides for the duration of the effectiveness of the written objection.

• **Arizona Rev Stat § 36-2154** (2009) – Allows a pharmacist to refuse to participate in abortion, abortion medication or emergency contraception.

• **Arkansas § 20-16-304** (1973) – Physicians, pharmacists and private institutions cannot be required to fill a prescription if their refusal is based on religious or conscientious objection.

Right to Refuse without Patient Protections

• **Idaho Code § 18-611** (2010) – Provides that no health care professional shall be required to provide any health care service that violates his or her conscience.

• **South Dakota Codified Laws § 36-11-70** (1998) – Allows pharmacists the right to refuse to provide services.

• **Missouri RS 191.724** (2012) – No employer, health plan provider, health plan sponsor, health care provider, or any other person or entity shall be compelled to provide coverage for, or be discriminated against or penalized for declining or refusing coverage for, abortion, contraception, or sterilization in a health plan if such items or procedures are contrary to the religious beliefs or moral convictions of such employer, health plan provider, health plan sponsor, health care provider, person, or entity.

• **Texas Insurance Code § 1271.007** (2003) – Allows a health maintenance organization, physician, or provider to refuse to recommend, offer advice concerning, pay for, provide, assist in, perform, arrange, or participate in providing or performing any health care service that violates the religious convictions of the health maintenance organization, physician, or provider.

Consequences of Management Trying to Influence Professional Judgment of a Pharmacist

“The customer is always right...especially when management is backing them up.”

Title 56; Title 63, Chapter 1; Title 63, Chapter 1 0; Title 67 and Title 68, relative to certain duties of pharmacists. .........Tennessee Code Annotated, Title 53, Chapter 10, Part 1, is amended by adding the following language as a new section: 53-10-112.

(c) A pharmacist shall, by utilizing education, skill, experience and professional judgment, make every reasonable effort to prevent the abuse of drugs which the pharmacist dispenses. In doing so, a pharmacist may decline to dispense to a patient a legend drug which in that pharmacist's professional judgment, lacks a therapeutic value for the patient or which is not for a legitimate medical purpose.
Consequences of Management Trying to Influence cont’d

(d) A pharmacist shall not be subject to any penalty or fine when fulfilling their obligation to uphold the health and safety of a patient which results in their decline to dispense any legend drug.

(e) It shall be a Class A misdemeanor, punishable by fine only, for the owner, manager or operator of a pharmacy to knowingly restrict or interfere with, or knowingly require a protocol or procedure that restricts or interferes with, a pharmacist's professional duty to counsel with patients and to evaluate the patients' appropriate pharmaceutical needs and the exercise of the pharmacist's professional judgment as to whether it is appropriate to dispense a legend drug to a patient. SECTION 2. This act shall take effect July 1, 2013, the public welfare requiring it.
Common “Approaches” to Refuse to Dispense

To patient:
• “I am not comfortable dispensing the prescription under these circumstances”
• “I do not think it is in your best interest to dispense this prescription”
• “I do not think it is my best interest to dispense this prescription”

To prescriber:
• “This prescription appears to be outside the current standards of practice or guidelines and I am not comfortable dispensing this prescription unless you can provide better literature or support”
Considerations for Pharmacists

• You **MUST** know state laws, boards of pharmacy regulations, corporate policies and human resource work agreements wherever you practice.

• Make every effort to be positive. Show a caring, supportive and helpful attitude towards the patient (“protect the patients health, dignity and safety”).

• Avoid stereotyping patients and lying to patients

• Educate your prescribers about pharmacy laws and regulations. They are not taught these.
Considerations for Pharmacists

• Communicate directly with prescribers regarding your concerns.

• Avoid any negative or inflammatory terminology when explaining why you are refusing to dispense to the patient or prescriber.

• Do not overexplain the situation to patients. Direct patients where they can be accommodated when possible (some company policies require this).
Considerations for Pharmacists

- Do not make major decisions based on hearsay comments from other patients or staff.
- Do not make inflammatory comments to other patients or staff.
- Use evidence-based medical information whenever possible.
- Document interactions / conversations in the patients record.
- Leave feelings and emotions out of the decision process.
- Recognize your patient’s fears when you refuse to dispense.
- Use, refer to, or recommend another pharmacist whenever possible.
- Evaluate each situation on a case-by-case basis.
Closing remarks/conclusion

- Decisions to “Not Dispense” vary widely across the country for a variety of reasons.

- Pharmacists should show to the patient their concern for the patients health, dignity and safety.

- Pharmacists should avoid any negative or inflammatory verbiage regarding the patient or prescriber.

- Referral to another pharmacist is often required by law or store policy and may alleviate a significant amount of avoidable stress and law suits.
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Audience Sharing

• What experience have you had where you refused to dispense?
• What was your rationale?
• How did you handle the situation?
• What was the outcome?
Refusing to Dispense: Considerations and Consequences Questions and Discussion

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