

For the Pharmacist

CORRESPONDING RESPONSIBILITY – A SHARED OBLIGATION

“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.”¹

CORRESPONDING RESPONSIBILITY – A SHARED OBLIGATION

Information for Pharmacists

Brief History:

In 1970, the United States enacted the federal Controlled Substances Act.² The enabling regulations, as codified in the Code of Federal Regulations, establish a framework for lawful prescribing and dispensing of controlled substances. Those regulations list the *criteria* that make a prescription for a controlled substance *lawful*,¹ describe the *manner*³ in which a prescription shall be issued, and lay out the *corresponding responsibility*¹ of the pharmacist to ensure that a prescription is proper before the medicine is dispensed.

Understanding Corresponding Responsibility:

Every prescription involves at least two responsible health care professionals – the prescriber and the pharmacist. Each has a responsibility to ensure that the prescription is issued a) for a legitimate medical purpose and b) by an individual practitioner acting in the usual course of professional practice.¹

“A pharmacist also needs to know there is a corresponding responsibility for 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 an invalid prescription within the meaning and intent of the Controlled Substances Act. 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. A pharmacist is required to exercise sound professional judgment when making a determination about the

legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin....”⁴

A prescription for a controlled substance may be prepared by an agent of the practitioner for their signature, but the prescribing practitioner is responsible in case it does not conform in all essential aspects to the law and regulations.¹

Interactions With the Prescriber or Their Practice

When calling a prescriber’s office, instead of using the number printed on the prescription, it is best to use a number you have on file or to look up their number. One pharmacy scam involves having an accomplice’s number printed on the prescription or business card who will then impersonate a prescriber when you call to verify some aspect of the prescription content.⁵

When you get the practice on the telephone, tell them you routinely verify prescriptions for opioids when a person presents to them for the first time and you want to work with the prescriber as a member of the healthcare team to ensure patients have access to opioids when it is appropriate, while also working to prevent opioids from getting into the hands of people who don’t have a legitimate reason. That is why you are calling to discuss this particular prescription.

Depending on the issue, you may not even need to speak with the prescriber.

Let whoever you speak with know, similar to a prescriber, a pharmacist also has a corresponding responsibility, which is a legal obligation to

ensure a prescription for a controlled substance is written for a legitimate medical purpose.¹

Begin by verifying the person is, indeed, a patient in their practice, and that the healthcare provider prescribed the opioid named in the indicated strength and quantity on the date on the prescription.

Some prescribers may think you are trying to “second guess” their medical judgment. Be prepared for this and assure them that is not the case, but you are discharging your obligation under federal law and would like to ask them a couple of questions so you can better serve their patient while taking care to dispense opioids only to those with legitimate medical need. Remain professional.

If you speak with the prescriber, you may suggest that next time they have a patient being prescribed an opioid for the first time, they proactively communicate with your pharmacy to let you know about this new patient coming in and discuss any possible issues. Remind the prescriber of the goal that appropriate patients get access to opioids, while you are working together as a team to ensure abusers and diverters are not dispensed opioids.

All prescriptions for controlled substances must include the following:⁴

- ✓ The date of issue
- ✓ Full name of the patient
- ✓ Patient’s address
- ✓ Drug information:
 - ✓ Drug name
 - ✓ Drug strength
 - ✓ Dosage form
 - ✓ Quantity prescribed
 - ✓ Directions for use
 - ✓ Number of refills authorized, if applicable
- ✓ Name of the prescribing practitioner
- ✓ Address of the prescribing practitioner

- ✓ Manual signature of the prescriber on the date of issue (for written prescriptions)
- ✓ A valid DEA registration number of the prescribing practitioner

You may wish to consider the list of “Red Flags” below in discharging your corresponding responsibility obligation.

Red Flags for Pharmacies:^{5,6}

Warning signs of potential abuse, addiction, or attempts to divert controlled substances that might prompt a call to a prescriber to verify the prescription include:

- Ⓜ A group of people presenting prescriptions for the same controlled substance at about the same time.
- Ⓜ A group of people presenting prescriptions that have the same address.
- Ⓜ The same drug and quantity for every person presenting a prescription from the same prescriber.
- Ⓜ Unexplained geographical anomalies, such as great distances between the prescriber and the pharmacy or the pharmacy and the person’s address on the prescription.
- Ⓜ Persons wanting to pay cash for controlled substances, but using insurance for prescriptions for other medicines.
- Ⓜ Prescriptions for “cocktails,” such as an opioid, a benzodiazepine, and a muscle relaxant.
- Ⓜ A mismatch between the stated diagnosis and the medicine on the prescription.
- Ⓜ The specialty or practice of the prescriber doesn’t match the diagnosis or the patient (eg, a pediatrician prescribing a controlled substance for treatment of rheumatoid arthritis in an adult).
- Ⓜ Pharmacy or Prescription Drug Monitoring Program (PDMP) records indicate early refills on controlled substances.
- Ⓜ Pharmacy or PDMP records indicate multiple prescribers of similar drugs for a person.

- Possible state or federal action pending against the prescriber.
- Unexplained signs/behaviors in a person presenting the prescription such as nervous behaviors, slurred speech, excessive talkativeness, unsteady gait, pinpoint pupils, or perspiration.
- Use of street names/slang when referring to medicines.
- Prescriptions for drugs with opposite effects (eg, stimulants and depressants).
- Prescription content differs from typical medical usage.
- Prescription appears “too good” (eg, directions written with no common abbreviations, handwriting doesn’t appear to be the prescriber’s).
- Prescription appears to be photocopied or altered (eg, erasure marks, ink run, bleeding of background patterns).

Definitions: 4.10

Terms used in law and regulation do not always have the same meaning as they do in everyday language. Terms relevant to prescribing and dispensing are defined below:

Controlled Substance: A drug included in schedule I, II, III, IV or V of the Controlled Substances Act.

Dispense: To deliver a controlled substance to an ultimate user by, or pursuant to a lawful order (eg, a prescription) of, a practitioner. The term dispense, therefore, includes both the ordering of (written, oral, electronic, or facsimile, as allowed by law) and the filling of a prescription.

Practitioner: Physician, dentist, veterinarian, pharmacy, etc. permitted to dispense a controlled substance in the course of professional practice or research. Practitioners who lawfully prescribe controlled substances must be licensed by the state in which they practice to do so and also be registered with the federal Drug Enforcement Administration.

References

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- 2 21 USC Chapter 13, subchapter 1, et seq. At: <http://uscode.house.gov/view.xhtml?path=/prelim@title21/chapter13/subchapter1/partA&edition=prelim> Accessed 10/25/2014
- 3 Modified from 21CFR1306.05(a). At: <http://www.gpo.gov/fdsys/pkg/CFR-2014-title21-vol9/pdf/CFR-2014-title21-vol9-part1306.pdf> Accessed 08/07/2014
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For the Prescriber

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when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin....”⁴

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Interactions with the Pharmacy

As a prescriber of controlled substances, you have the primary responsibility to ensure that the medicine is being prescribed for a legitimate medical purpose in the usual course of professional practice. You should be aware, however, the pharmacist receiving the prescription has, under federal law, a corresponding responsibility to ensure medicines are dispensed for a legitimate medical purpose.¹ Therefore, from time to time, a pharmacy may contact your practice to verify some aspects of a prescription, especially if the patient is new to that pharmacy or is presenting a prescription for a new controlled substance.⁵

Welcome these calls from another member of the health care team as a way to protect you, your patients, and your community. Be prepared to have your office provide a brief summary of the history and rationale for the prescription to aid the pharmacist in discharging their duties.

The types of questions a pharmacy may ask include:

- ✓ Did you write a prescription for [PATIENT] on [DATE]?

- ✓ Was it for [DRUG], [STRENGTH], and [QUANTITY], to be taken [DIRECTIONS FOR USE]?
- ✓ Did you authorize any refills (if applicable)?
- ✓ Will you please verify their date of birth?
- ✓ Will you please verify their address?
- ✓ Is this a new patient to your practice?
- ✓ Did your office check the State Prescription Drug Monitoring Program on this person?
- ✓ Is this ongoing therapy?
- ✓ Will you please tell me the patient's diagnosis?
- ✓ Will you briefly describe the patient's medication history?
- ✓ Does your agreement specify selection of only one pharmacy for all controlled substances?
- ✓ Did you counsel the patient/caregiver on the safe use, storage, and disposal of this medicine?
- ✓ Did you counsel the patient/caregiver on a bowel regularity regimen?

While most people seeking pain care do so for legitimate reasons, not every person interacting with you is, in fact, a genuine patient. You can play an important role in protecting your community by being attuned to behaviors that may require further inquiry or could indicate attempted diversion.

Red Flags for Prescribers: 7,8,9

- ✎ Unusual stories about why a particular medicine is needed
- ✎ Reluctance to cooperate with any aspect of the treatment plan, other than medicines
- ✎ Unexplained degree of knowledge of opioid analgesics
- ✎ Reported allergic reactions to medicines other than the one requested
- ✎ Exaggerated, feigned, or "textbook" symptoms
- ✎ Unexplained requests for a specific medicine
- ✎ Prescription Drug Monitoring System report contains surprising information
- ✎ Showing up without an appointment
- ✎ Consistently requesting last appointment of the day or week
- ✎ Calling or arriving after hours when referring physician is unavailable
- ✎ Demanding, insistent, or hurried
- ✎ Refuses physical examination or tests
- ✎ Unwilling/unable to give name of referring or previous treating physician
- ✎ Unable/unwilling to provide previous medical records (eg, clinic burned down)
- ✎ Vague or internally inconsistent medical history
- ✎ Unexpected/unexplainable results on confirmatory urine drug testing

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State: Means a state of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.

Ultimate User: A person who has lawfully obtained, and who possesses a controlled substance for his/her own use or for the use of a member of his/her household or for an animal owned by him/her or by a member of his/her household.

Lawful Prescribing: A prescription for a controlled substance is lawful only if it is issued for a “legitimate medical purpose” by “an individual practitioner acting in the usual course of his/her professional practice.”

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