

## Bob's Pharmacy, DEA Corresponding Responsibilities: Dispensing Controlled Substances

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THE DRUG ENFORCEMENT ADMINISTRATION (DEA) establishes regulations to lessen the risk or prevent drug diversion. The Diversion Control Division detects, investigates, and prevents the diversion of controlled substances from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical needs. To accomplish this mission, the DEA sets forth regulations designed to prevent any such diversion.

### DUE DILIGENCE

Bob, a conscientious and congenial neighborhood pharmacist, is the proprietor of Bob's Pharmacy in Small Town, USA. His wife Sally, who is also a pharmacist, joins Bob in serving their community as reliable health care providers. Their helpful advice over the years has reinforced their good reputation.

Bob's Pharmacy, like any other, should initiate measures to determine that a prescribed narcotic regimen is being used for legitimate medical purposes. Let's suppose, for example, that a new patient who has a prescription for a cocktail of drugs—oxycodone (Oxycontin), Soma (carisoprodol), and Xanax (alprazolam)—appears in Bob's Pharmacy.

Bob is alert to his responsibilities as a pharmacist under DEA regulations, which state that<sup>1</sup>:

*"[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."*

Once Bob has determined that the prescription is for

a controlled substance, he knows that he must:

*"carefully review all purported controlled-substance prescriptions to ensure that the prescription meets all of the legal requirements for a valid prescription. The pharmacist has a duty to inquire further as to any question surrounding the satisfaction of any or all of the legal requirements for a valid prescription, depending on the particular circumstances, including the requirement that the prescription be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice."*<sup>2</sup>

### VERIFICATION

By undertaking the requisite due diligence, Bob knows he will be complying with DEA requirements.

"Why are you taking this medication?" he asks.

"My doctor prescribed it to me for pain management, due to a lumbar herniation in my lower back," the new patient replies.

Bob asks to see the patient's driver's license. This new patient has driven 200 miles out of his home state to have this prescription filled, which triggers a red flag in Bob's mind.

"You're a long way from home," Bob says.

"I forgot to have the prescription filled before I left to visit my aunt," the patient says.

DEA regulations require Bob to take steps to verify that the prescription for the controlled substances has the patient's name and address. The drug and its directions, quantity, and strength must be specified. The law requires the name, address, and DEA number of the issuing practitioner. Bob must also verify that the prescription was dated and signed on the date of its issue.

**EDITOR'S NOTE:** The characters in this article are a work of fiction. Names, characters, businesses, places, events, locales, and incidents are either the products of the author's imagination or used in a fictitious manner. Any resemblance to actual persons, living or dead, or actual events is purely coincidental.

Bob also knows that the DEA, when analyzing a possible drug diversion, may ask the following questions:

- Are patients who come to the pharmacy to have prescriptions for controlled substances filled paying predominantly in cash?
- Did Bob's Pharmacy monitor and document the physical residential proximity of a patient who sought to have a prescription for a controlled substance filled?
- Does the patient seeking controlled substances have a history of or is there evidence of so-called doctor or pharmacy shopping?
- Is the number of a pharmacy's dispensations of controlled substances reasonably proportionate to the total number of prescriptions dispensed or do controlled substances make up the majority of prescriptions it dispenses?
- Is the pharmacy complying with DEA regulations that govern pharmacist and physician responsibilities when it determines the legitimacy of patients who seek to have their prescriptions for controlled substances filled?
- Does the pharmacy adhere to other DEA regulations in relation to record-keeping and security requirements?

The DEA may enlarge the scope of its inquiry at any time.

#### WRITTEN AGREEMENTS

Written patient agreements among or between pharmacies and physicians might help the pharmacy verify the legitimacy of a prescription for narcotics. Additionally, federal- and state-controlled substances registries may shed light on a patient's propensity for frequently seeking controlled substances.

Bob examines the new patient's prescription more closely. He sees that the prescribing doctor's address is also 200 miles from the patient's residence, which is in a third state. Finally, the prescribing doctor is a gynecologist, and pain management is not her area of expertise. These salient details invite new layers of scrutiny and lines of questioning.

Should Bob go ahead and fill this prescription? Would you fill this prescription? ♦

#### REFERENCES

1. Purpose of Issue of Prescription, 21 CFR §1306.04.
2. Drug Enforcement Administration. Practitioner's manual; an informational outline of the Controlled Substances Act. DEA Office of Diversion Control website. [dea-diversion.usdoj.gov/pubs/manuals/pract/pract\\_manual012508.pdf](http://dea-diversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf). Published 2006. Accessed September 5, 2018.



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