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Independent Pharmacy Owners and Pharmacists Beware

You may not know it, but you are being watched. The U.S. Drug Enforcement Administration (DEA) and U.S. Department of Justice (DOJ) are watching you and many other independent pharmacies and pharmacists across the country.

Under the Controlled Substances Act (the “Act”), physicians write prescriptions for their patients, but pharmacists must serve as second gatekeepers. It is their job to make sure that powerful, highly addictive drugs like opioids are dispensed and sold only for legitimate medical purposes. In short, the DEA and DOJ want pharmacists to second-guess prescriptions written by a DEA-registered physician who has examined the patient and knows the patient’s medical history.

According to [21 CFR 1306.04 of the Act](#), “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.” Section 21 CFR 1306.04(a) of the Act “prohibit[s] a pharmacist from filling a prescription for a controlled substance when she either knows or has reason to know that the prescription was not written for a legitimate medical purpose.” *Wheatland Pharmacy*, 78 Fed. Reg. 69,441, 69,445 (2013). Additionally, 21 CFR 1306.04(a) “expressly requires pharmacists to identify and resolve suspicions that a prescription is illegitimate.” *Trinity Pharmacy II*, 83 Fed. Reg. 7,304, 7,331 (2018) (emphasis added).

In addition to federal law, Texas law provides that “[a] pharmacist may not dispense a controlled substance if the pharmacist knows or should have known that the prescription was issued without a valid patient-practitioner relationship.” [Tex. Health & Safety Code § 481.074\(a\)](#). It is unlawful in Texas for any “registrant or dispenser” to deliver a controlled substance in violation of sections [481.070–481.075](#) of the Texas Health and Safety Code. *Id.* at [§ 481.128](#) (emphasis added). How do these laws and regulations affect a small independent pharmacy? As described in more detail below, the DEA

and DOJ put the onus on you, the owner, and the pharmacist-in-charge (PIC) to apply a three-prong litmus test to every prescription for a controlled substance.

The DEA uses “red flag” indicators to determine which pharmacies, and its owner(s) or pharmacists, should be the subject of increased scrutiny, undercover visits, or potentially a raid. A greater number of these DEA red flags increases the likelihood of further scrutiny. Circumstantial evidence can be enough to prove that a registrant ignored red flags, even if there is no witness testimony that he or she had “personal knowledge” of drugs being diverted.

If there is any indicator of suspicious activity or an attempt at diversion, the pharmacist cannot simply ignore those indicators and fail to investigate further. Under the law, PICs are required to second-guess the prescribing physician and conduct their own independent investigation to (1) confirm the prescription is for a legitimate medical purpose; (2) identify and resolve suspicions, if any, that a prescription is illegitimate; and (3) verify the existence of a valid patient-practitioner relationship.

If the PIC does not conduct this research and maintain a record of doing so, the DEA and DOJ will use this “red flag” and argue that the pharmacy’s DEA certificate of registration is inconsistent with the public interest. This would then trigger the issuance of an Order to Show Cause as to why the DEA should neither revoke the pharmacy’s registration pursuant to [21 U.S.C. § 824\(a\)\(4\)](#) nor deny any pending applications for renewal or modification, or for additional DEA registrations.

Fortunately, there are steps that every pharmacy and PIC should take to protect themselves and their licenses. The obvious steps are good recordkeeping—detect and report suspicious orders and red flags, and *always* review the prescription for fraud, waste, and abuse. It is important to remember that the pharmacy’s role is to protect the public. Following simple steps will help accomplish this goal.

Frost Brown Todd has handled, and currently handles, matters before the DEA and DOJ. For more information or questions relating

to this subject, please contact [Derek Staub](#) (214.580.5826; dstaub@fbtlaw.com) or any attorney from Frost Brown Todd's [Health Care Innovation Team](#).

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