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Newsletter to Promote Pharmacy and Drug Law Compliance.

Drug Interchange Regulations for Pharmacists

By Nirali Patel, University of Utah PharmD Candidate, Class of 2025

Pharmacists in Utah are granted certain authorities to adjust prescriptions under specific circumstances. According to Utah Code Section 58-17b-602.1, pharmacists or pharmacy interns are allowed to dispense prescriptions in quantities or dosage forms different from what was initially prescribed. This also extends to situations where the prescribed quantity or package size is unavailable commercially or when a different dosage form is in the patient's best interest by the pharmacist's professional judgment. This flexibility helps make sure patients get their medications when they need them, even if the exact details are not available or need to be changed.

In addition to the general dispensing allowances outlined in Section 58-17b-602.1, there are specific guidelines regarding the substitution of certain medications, such as albuterol inhalers and diabetic supplies. For albuterol inhalers, addressed in R156-17b-626, pharmacists or pharmacy interns are authorized to make appropriate substitutions with any brand of albuterol product as long as they maintain the same milligram dose per actuation. Similarly, for diabetic supplies, including glucometers, test strips, lancets, syringes, needles, and other designated supplies specified in Section 58-17b-608.2, pharmacists have the authority to dispense therapeutic equivalents, providing patients with access to necessary diabetes management supplies.

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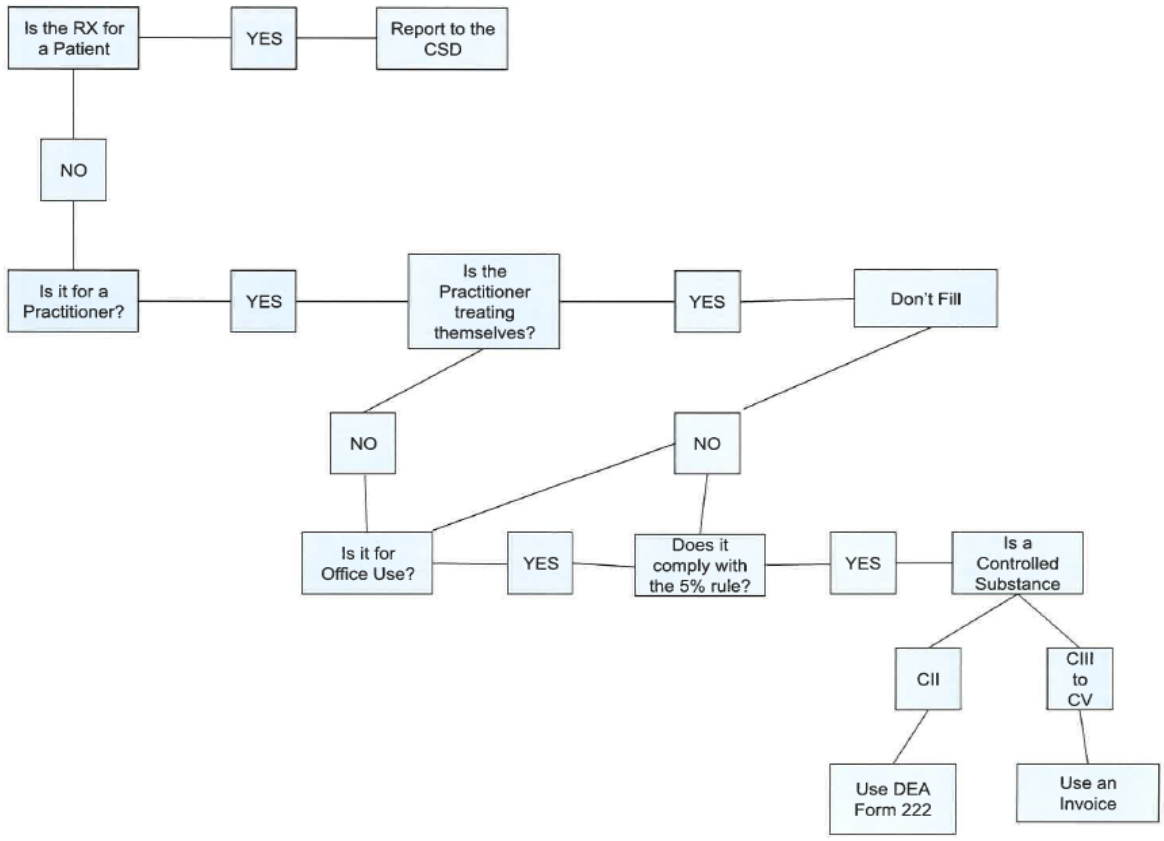
Office Use Distribution

The Utah Division of Professional Licensing (DOPL) has received several questions regarding office use distribution; therefore, the following clarification is provided. Pharmacies may distribute prescription drugs up to 5% of their total prescription drug sales without having to be licensed as a distributor. Each drug sold to practitioners for office use must be labeled "for office use only." Compounded preparations can only be sold for office use from facilities registered with Food and Drug Administration (FDA) as an outsourcing facility and cannot contain a controlled substance (CS). "For office use" drugs can then be administered by the practitioner, but they cannot be dispensed.

Office use distribution to practitioners for CS has further restrictions. First, a practitioner cannot write a prescription for office use for CS per 21 Code of Federal Regulations (CFR) 1306.04(b). As a result, the distribution of CS must not be reported to the Utah Controlled Substance Database, as they are not patient-specific prescriptions. For practitioners to procure CS from a pharmacy for office use, they can complete a transfer or invoice. Second, any transfers of Schedule II CS must be done with a Drug Enforcement Administration (DEA) Form 222. Transfers of Schedule III, IV, and V CS must be documented by invoice. Both the practitioner and the pharmacy must keep a copy of the invoice. All records for CS must be kept for five years.

Further Reading:

- Utah Laws 58-37; 58-17b, 58-37f
- Utah Rules R156-37, R156-17b, R156-37f
- United States Department of Justice DEA Practitioner's Manual - Diversion Control Division, June 7, 2023
- US FDA Registered Outsourcing Facilities
- US Title 21 CFR Part 1306



Allowable Changes to Schedule II Prescriptions

The Medicare Modernization Act of 2003 included the use of electronic prescribing. Since then, the number of e-prescriptions issued has increased and become the standard and, in Utah, the required method for issuing CS prescriptions. E-prescriptions have improved patient safety by providing secure, understandable, and timely prescriptions to pharmacies. Despite the benefits of e-prescribing and the best intentions of prescribers, clarification and corrections are sometimes needed on Schedule II prescriptions.

On October 18, 2022, DEA issued Guidance Document DEA-DC-063, which stated that pharmacists should "adhere to state regulations or policy regarding those changes that a pharmacist may make to a [S]chedule II prescription after oral consultation with the prescriber." In May, DOPL posted a guidance document outlining the approved changes a pharmacist may make to a Schedule II prescription after consultation with the prescriber.

This document can be found under the "Resources" tab of the Pharmacy DOPL website. Below is a summary of the changes permitted by a pharmacist after consulting with the prescribing practitioner:

- Clarification of the patient's name.
- Changes to the patient's information, including date of birth and address.
- Dosage form of the prescribed medication.
- Strength of the prescribed medication.
- Quantity of the prescribed medication.
- Directions for use.

Additionally, a pharmacist is permitted to annotate the prescriber's DEA number on the prescription. It is the dispensing pharmacist's ultimate responsibility to ensure that the prescribing practitioner has a valid DEA number prior to dispensing the medication.

As a reminder, the following elements are required on all CS prescriptions:

- The name, address, and registry number of the prescriber.
- Signature of the prescriber (ink, indelible pencil, or electronic signature).
- The name, address, and age of the person to whom or for whom the prescription is issued.
  - The patient's address shall be a physical address, not a post office box.
- The date of issuance of the prescription.
- The name, quantity, and specific directions for use by the ultimate user of the CS.

Prescription requirements can be found under CFR Title 21 Section 1306.05, 58-17b-602, 58-37-6, and R156-17b-612.

Non-Disciplinary Support for Health Care Professionals With SUDs: UPHP

Health care professionals suffer from substance use disorders (SUDs) at rates similar to the general population. In addition to genetic vulnerabilities, health care professionals have additional risk factors that may further increase their susceptibility to SUDs. When health care professionals find themselves struggling with an SUD, they often feel isolated and ashamed. They are afraid to come forward because of concerns that they will lose their livelihood

Non-Disciplinary Support for Health Care Professionals With SUDs: UPHP

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and their community standing. Inevitably, their disease worsens, and patient care begins to suffer. Recognizing the need for a program where health care professionals can seek help confidentially, DOPL created the Utah Professionals Health Program (UPHP) to assist health care professionals who have SUDs. Providing a "safe harbor" where health care professionals can confidentially self-report provides many benefits to both licensed health care professionals and the public.

When health care professionals find themselves struggling with an SUD, they often feel isolated and ashamed. They are afraid to come forward because of concerns that they will lose their livelihood and their community standing. Inevitably, their disease worsens, and patient care begins to suffer.

Because participation in UPHP is voluntary, the first step is admitting that there is a problem. This is a very difficult step for anyone with an SUD, as their default is denial. Elizabeth Howell, MD, MS, an addiction psychiatrist and associate professor at the University of Utah, said, "The first thing that I think hits most people is that 'This can't be true. I cannot be addicted. I am too smart. I should know better. I should be able to control this,' [but] addiction doesn't care how smart you are."

While admitting you need help is difficult, it is an important step in healing from SUD. The earlier you take this step, the better. As SUDs progress, your health and family life deteriorate, and legal consequences ensue. Your career and your patients are at risk. There is strong evidence that SUDs are linked to "burnout" and even suicide. The aim of UPHP is to provide support before these tragic consequences occur.

If you are a health care professional and are struggling with an SUD, it is important to seek help before your condition becomes serious. If you wait too long, you may have to appear before your professional licensing board, and the proceedings will become public record. This could result in the loss of your job, your board certifications, and your ability to obtain malpractice insurance.

Participation in the program is confidential and takes a non-disciplinary and clinical approach. This approach protects public safety and provides health care professionals with an opportunity to demonstrate in a nonpublic, non-disciplinary manner that they can become, and remain, safe and sober, while retaining their licenses.

UPHP was created to assist health care professionals who have SUD. It provides a safe haven where they can confidentially self-report and seek help. UPHP takes a non-disciplinary, clinical approach and protects public safety while allowing health care professionals to demonstrate that they can become and remain sober while retaining their licenses.

To learn more, visit *UPHP.Utah.gov.*

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