MAY 2024

UTAH BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

2024 Legislative Session

By Lisa Martin, Pharmacy Bureau Manager

The following bills from Utah's 2024 legislative session will have an impact on the Utah Pharmacy Practice Act, the Utah Controlled Substances Act, or the Utah Controlled Substance Database Act.

Controlled Substances Amendments

House Bill (HB) 260

This bill adds gabapentin to the list of controlled substances (CS) as a Schedule V drug.

Each pharmacy that dispenses gabapentin will need to ensure that they also have an active Utah Dispensing Controlled Substance License in connection to the Utah pharmacy license.

The Utah Division of Professional Licensing (DOPL) has provided additional information concerning this change. If you did not receive the information or have additional questions, you may request the letter by contacting DOPL via email at b3@utah.gov. Effective May 1, 2024.

Pharmacy Amendments

HB 132

This bill will allow pharmacists and pharmacy interns to substitute prescribed drugs under certain circumstances. DOPL, in consultation with the Utah Board of Pharmacy and the Medical Licensing Board, will be responsible for developing a therapeutically similar drug list and corresponding rules. Effective May 1, 2024.

National Pharmacy Compliance News
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Pharmacy Practice Act Amendments

Senate Bill 207

In addition to technical corrections, this bill defines "written communication," amends provisions concerning patient counseling, and modifies requirements related to pharmacy audits. Additionally, this bill updates the notification requirements for pharmacies with changes in address. Rule clarification and changes will be required for several aspects of this bill. Effective May 1, 2024.

Compounded Semaglutide – Cautions and Concerns

By Karen Gunning, PharmD, BCPS, BCACP, FCCP, Member – Utah Board of Pharmacy

DOPL and the Board have received numerous questions regarding the compounding of semaglutide, particularly for weight loss. Due to significant shortages of commercially available products (Wegovy® and Ozempic®), and high demand for weight loss indications, compounding has increased in frequency for these products.

Although the practice of compounding products that are on the Food and Drug Administration (FDA) shortage list is legal while the products are on the shortage list, the Board and DOPL would like to remind pharmacists of some points of concern. DOPL has issued citations for several concerns surrounding compounding and distribution of these products. They include:

- Unlicensed practices – particularly medical spas dispensing compounded semaglutide in individual syringes.
- Dispensing medical practitioners practicing out of scope by dispensing these drugs. Dispensing these agents is not allowed by the rules for dispensing medical practitioners.
- Compounding with semaglutide salts. This is not allowed by FDA as the salt formulations are not the FDA-approved version of semaglutide.
- Compounding by 503A pharmacies for office use. This is not allowed by law. To compound products for office use, the pharmacy would need to be a 503B outsourcing facility.

From a safety perspective, FDA has received many reports of adverse drug events with compounded semaglutide. The Utah Poison Control Center has published a case series detailing adverse effects with semaglutide associated with dosing errors in patients using compounded products. Dispensing semaglutide in insulin syringes or with insufficient counseling on administration and use can result in large overdoses that cause serious gastrointestinal adverse effects and emergency room visits for rehydration and care. These symptoms may last for days. Pharmacists compounding semaglutide during the shortage should carefully counsel patients on how to measure doses, how to administer doses, and what to do if the patient has serious gastrointestinal problems. **The dose of semaglutide should be labeled as their milligram dose, and a corresponding dose in milliliters should be included on the label.** Pharmacists should avoid the use of insulin syringes and labeling of doses in units for all medications that are not insulin. Demonstration of appropriate use and measurement of the product should be a part of patient counseling.

Finally, it is important for any pharmacist compounding semaglutide to understand that this practice is legal only while FDA-approved drugs are on the FDA shortage list. Once these are removed from FDA's list, compounding these products will no longer be legal.

References:

FDA. Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss. Updated on January 10, 2024. Accessed on March 29, 2024.

FDA. Drug Shortages. https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages. Accessed March 29, 2024.

FDA letter to NABP regarding semaglutide compounding; semaglutide salt compounding not allowed. https://www.fda.gov/media/173456/download?attachment. October 10, 2023. Accessed on March 29, 2024.

Lambson J, Flegal S, Johnson A. Administration errors of compounded semaglutide reported to a poison control center – Case series. *J Am Pharm Assoc.* 2023;63:1643-1645. https://doi.org/10.1016/j.japh.2023.06.017

Update: Required Electronic CS Prescriptions

By Chris Sheard, Board Chairperson

As of January 1, 2024, most providers are required to issue prescriptions for CS electronically. The Utah Controlled Substances Act (58-37-22) requires most prescriptions for CS to be issued electronically.

Utah pharmacies may still receive and can accept nonelectronic CS prescriptions in accordance with R156-37-609(2). **The expectation is not on pharmacists or pharmacies to determine if the provider meets the exceptions.** If the prescription is determined to be valid, and meets the standards to dispense, pharmacists are permitted to fill the prescription (even if not issued electronically). Patient care should not be delayed when filling legitimate CS prescriptions simply based on the format the prescription was issued (ie, written, telephone, e-prescribed). The pharmacy needs to submit the correct "origin code" for all CS prescriptions when providing data to the Utah Controlled Substance Database.

Per Utah law, each prescription issued for a CS must be transmitted electronically as an electronic prescription unless any of the following situations apply.

The prescription is:

- issued for a patient residing in an assisted living facility (as defined by Section 26B-2-201), a long-term care facility (as defined by Section 58-31b-102), or a correctional facility (as defined by Section 64-13-1);
- issued by a veterinarian;

- dispensed by a Department of Veterans Affairs pharmacy;
- issued in an emergency situation as defined in R156-37-605; or
- issued during a temporary technical or electronic failure at either the prescriber's or the pharmacy's location, as defined in R156-37-102(9).

Supporting rules are located in R156-37-609; the rule also includes instruction for any pharmacist who receives written, oral, or faxed CS prescriptions. Additional exemptions have been proposed; please watch for further rule changes in the future.

Exemptions to the requirement include:

- The prescribing practitioner is licensed in a jurisdiction other than Utah with oral confirmation from the prescribing practitioner.
- The prescriber and dispensing pharmacy are the same entity.
- The federal FDA requires the prescription to contain elements that cannot be included in an electronic prescription.
- The prescription drug is under a research protocol.
- The prescription is for a medication that requires compounding two or more ingredients.

The prescribing practitioner or pharmacy should document the exemption in the prescription's hard copy; **however, it is not required for the pharmacy to seek this if missing from the hard copy prescription.**

If the originating pharmacy cannot fill the electronic CS prescription, the following protocol is required in accordance with R156-37-609(5).

- If the pharmacy can electronically transmit the prescription, the pharmacy shall:
  - contact the ultimate user to determine the pharmacy that is to receive the forward prescription; and
  - document in the . . . pharmacy system the identity of the pharmacy receiving the forward prescription.
- If the pharmacy cannot electronically transmit the prescription, the pharmacy shall:
  - contact the prescribing practitioner;
  - document . . . the individual contacted at the prescribing office; and
  - void the prescription.

R156-37-605. Emergency Verbal Prescription of Schedule II Controlled Substances

1) Under Subsection 58-37-6(7), in an emergency situation a prescribing practitioner may give an oral prescription for a Schedule II controlled substance if:

(a) the quantity dispensed is only sufficient to cover the patient for the emergency period, not to exceed 72 hours;

(b)

(i) the prescribing practitioner has examined the patient within the past 30 days;

(ii) the patient is under the continuing care of the prescribing practitioner for a chronic disease or ailment; or

(iii) the prescribing practitioner is covering for another practitioner and has knowledge of the patient's condition; and

(c) a written prescription is delivered to the pharmacist within seven business days of the oral order.

(2) Under Subsection 58-37-6(7), in an emergency situation a pharmacist may fill an oral prescription from a prescribing practitioner for a Schedule II controlled substance if:

(a) the amount does not exceed a 72 hour supply; and

(b) the pharmacist reasonably believes, or makes a reasonable effort to determine, that the prescribing practitioner is licensed to prescribe the controlled substance.

All applicable laws and rules are located on DOPL's website at *https://dopl.utah.gov/pharmacy/laws-and-rules/*.

Electronic CS Prescription Transfer Requirement

In 2021, Utah legislative session HB 265 was introduced, and the bill subsequently passed. This bill amended provisions relating to an electronic prescription for a CS. This provision requires a pharmacy's software system that receives electronic prescriptions for CS to allow an unfilled prescription to be transferred to a different pharmacy. The implementation date for a software system requirement of electronically transferring prescriptions to a different pharmacy is July 1, 2024.

This requirement is located in the Utah Controlled Substances Act.

58-37-22. Electronic prescriptions for controlled substances.

(3) Beginning July 1, 2024, a pharmacy software program for receiving an electronic prescription for a controlled substance shall be capable of electronically transferring a prescription to a different pharmacy:

(a) upon the request of the patient or the practitioner;

(b) with the approval of a pharmacist at the originating pharmacy; and

(c) if the prescription is unfilled.

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1. recorded audio;
2. written minutes; and
3. handouts associated with discussion items from that meeting.

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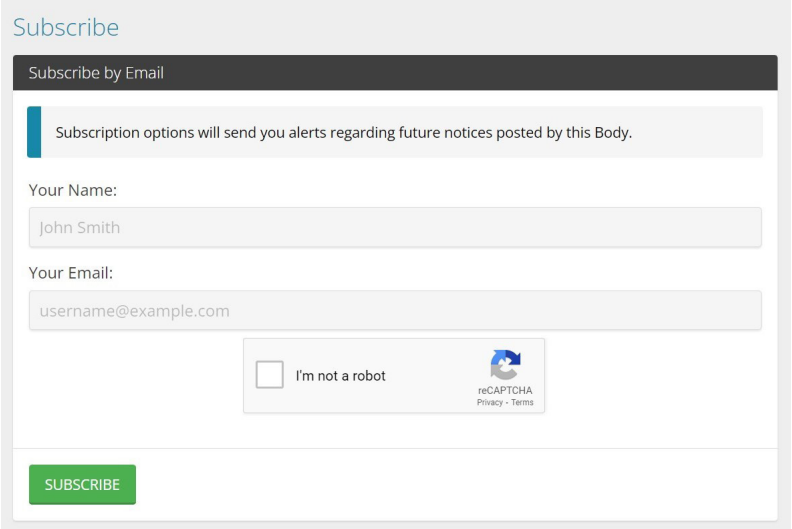

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