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UTAH BOARD OF PHARMACY

Newsletter to Promote Pharmacy and Drug Law Compliance.

Compounding Operating Standards Update

By Matt Higley, PharmD, Utah Board of Pharmacy

Pharmacy Practice Act Rule R156-17b-614e Operating Standards – Compounding updates were approved last summer, with an effective date of December 31, 2025. Details of these approved rules were published in the *Utah State Bulletin* – Number 2025-12 on June 15, 2025, for public comment. These rules incorporate United States Pharmacopeia (USP) requirements for aspects of sterile, nonsterile, and hazardous compounding and outline operating standards for pharmacies engaged in compounding. Pharmacists, pharmacy technicians, and pharmacy interns should read the specific rules and be familiar with their requirements. Below is a brief highlight of the changes for any licensed pharmacy that engages in compounding:

- **Full compliance** with USP <795> Pharmaceutical Compounding—Nonsterile Preparations.
- **Full compliance** with USP <797> Pharmaceutical Compounding—Sterile Preparations, with the **exclusion** of smoke studies unless there is new construction on the facility or physically moving equipment within a cleanroom.
- **Full compliance** with USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging.
- **Full compliance** with USP <800> Hazardous Drugs—Handling in Healthcare Settings if engaging in compounding of sterile or nonsterile **antineoplastic** hazardous drugs.
- **Modified compliance** with USP <800> Hazardous Drugs—Handling in Healthcare Settings

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Compounding Operating Standards Update *(cont)*

for pharmacies engaging in compounding of sterile or nonsterile **non-antineoplastic** hazardous drugs, including the following exceptions:

- Compounding of **nonsterile non-antineoplastic** hazardous drugs is permitted in a double-HEPA filtered or externally vented containment ventilated enclosure, a class II biological safety cabinet, or a compounding aseptic containment isolator.
- Permit risk assessment under USP <800> for compounding **sterile non-antineoplastic** hazardous drugs in a laminar airflow workbench or compounding aseptic isolator.
- **Non-antineoplastic** active pharmaceutical ingredients must be clearly labeled as hazardous and stored in a designated area that is separate from other medications; however, a distinct room is not required.
- Certain parts of USP <800> are exempt and do not need to be followed in the state of Utah as specifically outlined in the rule.

Utah Department of Commerce Division of Professional Licensing (DOPL) has also published new inspection forms for compounding to help to ensure pharmacies are prepared for these new requirements. Links are included below:

- Non-Sterile Compounding Inspection Form
- Sterile Compounding Inspection Form
- Hazardous Compounding Inspection Form (still being created)

Additionally, all DOPL Pharmacy Inspection forms can be found on the DOPL website.

Please email pharmacy@utah.gov with questions or comments specifically for the Utah Advisory Pharmacy Compounding Education Committee, Utah Board of Pharmacy, or DOPL Pharmacy Investigations.

Annual CS Inventory

By DOPL Pharmacy Investigation Team

A controlled substances (CS) inventory must be conducted on the pharmacy's opening day and repeated annually within one year and four days of the previous inventory, per Pharmacy Practice Act Rule R156-17b-605(4). An initial inventory is mandatory even if no CS are currently in stock; in such cases, a "zero inventory" must be recorded. These records must be maintained in a written, typewritten, or printed format for at least five years, filed separately from all other pharmacy records to ensure that they are readily available for inspection.

Annual CS Inventory

(cont)

The inventory must be taken specifically at either the opening or closing of business on the chosen date. The staff members conducting the count and the pharmacist-in-charge (PIC), remote dispensing pharmacist-in-charge (RDPIC), or dispensing-medical-practitioner-in-charge (DMPIC) must sign and date the document, clearly stating the exact time the inventory was taken. If the PIC, RDPIC, or DMPIC delegates the task to another staff member, they must still sign and date the completed inventory within three business days. Finally, Schedule II substances must be listed separately from Schedules III, IV, and V, and the Schedule II perpetual inventory must be reconciled on the same day that the physical count is performed.

If you have any questions regarding the annual CS inventory, please contact DOPL Pharmacy Investigations.

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