

# UTAH BOARD OF PHARMACY

Newsletter to Promote Pharmacy  
and Drug Law Compliance.

## Pharmacy Inspection – Self-Audits

By DOPL Investigations Group

**Pharmacies frequently fail to conduct required self-audits during inspections by the Utah Division of Professional Licensing (DOPL).**

**Self-audits are crucial internal evaluations that pharmacies must perform to ensure compliance with all applicable regulations.**

These audits are not just a regulatory requirement; they are a fundamental responsibility of the consulting pharmacist, pharmacist-in-charge (PIC), remote dispensing pharmacist-in-charge (RDPIC), or designated medical practitioner-in-charge (DMPIC).

**The Utah Pharmacy Practice Act Rule R156-17b-603(3)(u) (i-iv) outlines the self-audit requirements:**

(3) The duties of the consulting pharmacist, PIC, RDPIC, or DMPIC shall include:

...

(u) under Subsection 58-17b-103(1), conducting a pharmacy self-audit on a form provided by the Division, in accordance with the following timeframes:

- (i) within 30 days of a change of consulting pharmacist, PIC, DMPIC or RDPIC;
- (ii) within 30 days of the opening of a new facility; and
- (iii) at least 90 days before the end of each renewal cycle; and
- (iv) maintaining each pharmacy self-audit form for two years from the date of the self-audit.

**The DOPL website provides the necessary self-audit inspection forms to assist pharmacies in fulfilling this obligation.** These forms are accessible at <https://dopl.utah.gov/pharmacy/additional-forms/>.

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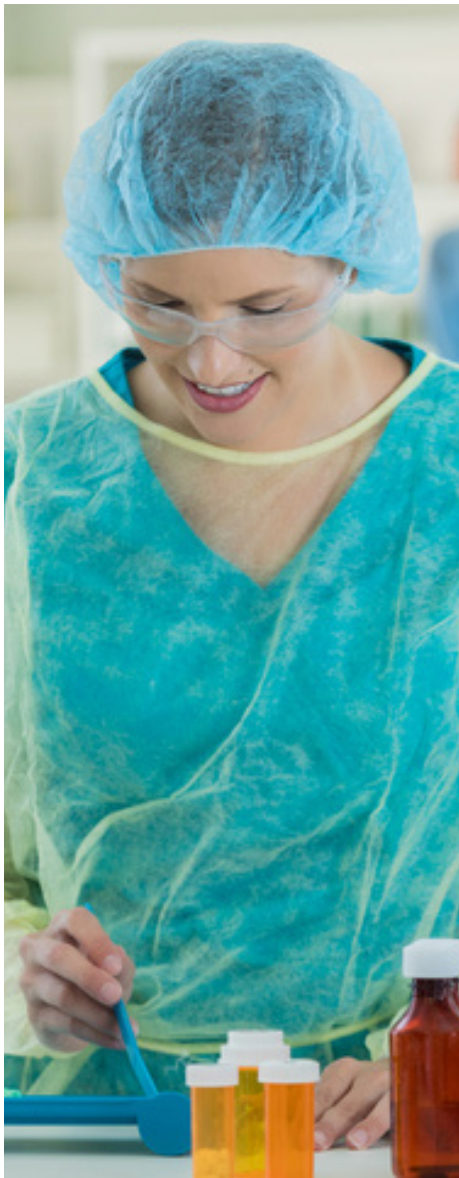
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**It is important to note that pharmacies may be required to complete multiple self-audit forms, depending on their specific activities.** For example, a Class A retail pharmacy that also engages in nonsterile compounding would need to conduct both a Class A

pharmacy self-audit inspection and a separate nonsterile compounding self-audit inspection.

**We urge all pharmacies to prioritize self-audits as an essential component of their quality assurance and risk**

**management programs.** By diligently conducting and maintaining accurate self-audit records, pharmacies can demonstrate their commitment to patient safety and regulatory compliance.



## Compounding Operating Standards Update

*By Hali O'Malley, Vice Chair, Advisory Pharmacy Compounding Education Committee*

### Board Proposes Significant Changes to Compounding Operating Standards

The Utah Board of Pharmacy recently submitted a proposed amendment to Rule R156-17b-614e that outlines new operating standards for pharmacies engaged in compounding.

The proposed rule includes the following changes for any licensed pharmacy that engages in compounding:

- Full compliance with United States Pharmacopeia (USP) <797> Pharmaceutical Compounding – Sterile Preparations, with the exclusion of smoke studies in certain cases.

- Full compliance with USP <795> Pharmaceutical Compounding – Nonsterile Preparations.
- 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 antineoplastic drugs.
- Modified compliance with USP <800> for pharmacies engaging in compounding of non-antineoplastic hazardous drugs.

# Compounding Operating Standards Update

(cont)

## Proposed Compliance

### Date:

Pharmacies will be expected to comply with these updated standards by **December 31, 2025**.

### Public Comment Period:

Following publication, the proposed rule changes will

undergo a public comment period of at least 30 days. This period allows stakeholders, including pharmacists, pharmacy technicians, and other interested parties, to submit their feedback and concerns regarding the proposed amendments.

If you have any questions or comments specifically for the Utah Advisory Pharmacy Compounding Education Committee, please send an email to [pharmacy@utah.gov](mailto:pharmacy@utah.gov).

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