Draft Compounding Regulation: Standard of Care Model as of 5/30/2025

99-50. Compounding.

A. These regulations are applicable to all individuals and facilities engaged in the compounding, administration, sale, transfer, distribution, or dispensing of compounded preparations for use by humans or animals, including but not limited to compounding by practitioners who may otherwise be exempted from facility permitting by the Board.

B. Engaging in the practice of compounding constitutes the practice of Pharmacy, and upon receipt of a complaint by the South Carolina Board of Medical Examiners, the South Carolina Board of Nursing, the South Carolina Board of Veterinary Medical Examiners, or any other licensing board against a licensed practitioner related to pharmaceutical compounding, the Board of Pharmacy has the jurisdiction to inspect the location where the compounding occurred and to otherwise fully investigate the complaint to the extent the practice of Pharmacy is reasonably implicated. If a violation of the Pharmacy Practice Act is found, the Board may, as it deems appropriate, refer the completed investigation to the relevant licensing board for discipline along with a recommendation for appropriate sanctions.

C. The Board acknowledges that the compounding standards published by the private nonprofit organization known as the United States Pharmacopeia (USP) are utilized by federal authorities and regulatory bodies in many other states. However, the Board has determined that in furtherance of South Carolina's citizens' access to compounded preparations, as deemed appropriate by licensed prescribers in the context of a patient-prescriber relationship, South Carolina is well-served by not adopting the USP-NF standards outright. Instead, the Board shall issue its own Compounding Standards that will include recommended minimal standards for Low Risk Non-Sterile Compounds; Non-Sterile Compounds; Sterile Compounds; Radiopharmaceutical Compounds; Compounding by Non-Dispensing Drug Outlet Permit Holders; Compounding by Outsourcing Facilities; Compounding of Hazardous Substances; and Compounding of OTC (Over-The-Counter) agents

D. The Board's Compounding Standards will be considered the reasonable standard of care for pharmaceutical compounding in the State of South Carolina. "Standard of care" is defined as the accepted standard of care that would be provided in a similar setting by a reasonable and prudent individual with similar education, training, and experience. The Compounding Standards will serve as persuasive authority in any disciplinary matter heard by the Board relating to the practice of compounding. However, the Board must consider a documented deviation from these Compounding Standards if such deviation meets the following criteria:

(1) the deviation is documented in the standard operating procedures of the facility where the compounding is performed;

(2) the deviation is safe and as least as effective as the Board's Compounding Standards as indicated by compendia literature, medical or scientific literature, and/or practical experience of Pharmacy professionals in the art of compounding as supported by third-party testing data; and

(3) the evidence supporting the deviation is maintained along with the relevant standard operating procedures and is readily available for Board review upon request.

While the Board must consider such evidence, the Board retains independent judgment in deciding disciplinary matters before it so long as those decisions are not arbitrary and capricious.

E. The Board's Compounding Standards will also serve as the basis for the inspection forms utilized by the Board in conducting facility inspections in accordance with the Pharmacy Practice Act.

(1) If in conducting an inspection, a Board inspector identifies a deviation from the Board's Compounding Standards, the inspector must consider an appropriately documented deviation prior to recommending issuance of a citation or making an Unsatisfactory finding in the inspection report if such deviation meets the following criteria:

(a) the deviation is documented in the standard operating procedures of the facility where the compounding is performed;

(b) the deviation is safe and as least as effective as the Board's Compounding Standards as indicated by compendia literature, medical or scientific literature, and/or practical experience of Pharmacy professionals in the art of compounding as supported by third-party testing data; and

(c) the evidence supporting the deviation is maintained along with the relevant standard operating procedures and is readily available for inspector review at the time of the inspection.

(2) While the inspector must consider such evidence, the Chief Drug Inspector retains independent judgment in deciding whether a deviation from the Compounding Standards is appropriate.

(3) An inspection finding may be appealed to the Board or its duly authorized designee upon written notice requesting such appeal within fifteen (15) days of receipt of the Inspection Report. If a request for appeal is not timely made, the Inspection Report becomes final, and the facility must take corrective action as required by the inspector or be subject to disciplinary action in accordance with S.C. Code Ann. Section 40-43-150.

F. If a facility or individual engaged in compounding is held to the higher standard of another governmental agency or body, such as an accrediting body, the facility or individual should comply with the more stringent standard.

G. Bulk drug substances may only be used in compounding when such bulk drug substances:

(1) Comply with the standards of an applicable United States Pharmacopoeia or National Formulary ("USP-NF") monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA; or are manufactured by an establishment that is registered by the FDA; and

(2) Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the Board and the FDA to distribute bulk drug substances if the compounder can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source. Documentation of this determination and any supporting documents must be maintained with the compounding record.

H. Compounding may be conducted using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

I. The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases constitutes the manufacturing of drugs and appropriate federal and State permits are required. Such compounding conducted without the appropriate Board-issued permit constitutes unpermitted practice of Pharmacy.

J. Facility design must be appropriate for the risk level of compounded preparations prepared by the facility.

K. Personnel engaged in compounding or assisting in compounding must be trained and demonstrate competency initially and annually thereafter. Four (4) hours of continuing education in compounding appropriate for the risk level of compounded preparations the staff member encounters must be completed annually. Proof of training and competency must be maintained on-site and be readily available for inspection upon a request by the Board.

L. Pharmacy technicians, both state certified and non-state certified, with the appropriate training and demonstrated competency may compound under the direct, in-person supervision of a South Carolina-licensed pharmacist at a South Carolina-permitted facility. Pharmacy technicians may not compound under the supervision of a physician, physician assistant, nurse, or any other practitioner.

M. A final check of a compounded preparation must be conducted by a South Carolina-licensed pharmacist to confirm identity, accuracy, packaging, and label prior to dispensing.