Draft Compounding Regulation: Standards Council Draft as of 5/30/2025

99-50. Compounding Standards Adoption

A. Intent.

(1) In accordance with S.C. Code of Laws Sections 40-43-60(D)(5) and 40-43-86, it is the purpose of this regulation to establish a system for the development and ongoing review and revision of the minimum specifications for various activities related to compounding including but not limited to the physical facilities, technical equipment, environment management, personnel, and procedures for preparation, handling, storage, and dispensing of compounded medications.

(2) Through adoption and periodic review of detailed Compounding Standards ("Standards") tailored to the unique needs of pharmacy practice in the State, the Board will:

(a) Assure, to a reasonable degree, the safety of compounded preparations notwithstanding the location of the patient to whom the preparation is administered or dispensed (e.g. home, hospital, LTHC facility, practitioner's office, etc.);

(b) Provide in clear language the minimum standard of care to ensure the safety of compounded preparations based on a review of available compendia literature, medical and/or scientific literature, and/or practical experience in the art and science of compounding; and

(c) Allow the Board to proactively and timely address advances in techniques and technologies in the art and science of compounding to ensure patients in the State have access to safe and appropriate treatments.

B. Applicability.

(1) The Standards adopted pursuant to this regulation must apply to all persons and entities engaging in compounding within the Board of Pharmacy's purview, as defined in S.C. Code Ann. Section 40-43-30(8), including but not limited to pharmacists, pharmacies, practitioners, outsourcing facilities, etc.

(2) These Standards must apply to all compounding activities occurring within the State and to all compounded preparations compounded, dispensed, or administered in this State, including compounding by appropriately qualified practitioners who may be exempt from obtaining a Board facility permit.

(3) Upon completion of the Standards review and adoption process as described herein, the adopted Standards must become effective immediately, however, compounders will have at minimum one-hundred-eighty (180) days from the date of adoption to fully implement the initial and any later revised Standards so long as they are documenting their efforts to comply and ensure patient safety during any transitional periods.

(4) It is incumbent upon all individuals or facilities engaged in compounding to comply with standards of other accrediting bodies and/or other laws (i.e. federal law and regulations, as applicable) related to compounding as relevant to their pharmacy practice to the degree that those standards or laws may be more stringent than the Standards adopted pursuant to this regulation.

C. Compounding Standards Council.

(1) At minimum, the Board must appoint a Compounding Standards Council ("Council") with relevant experience in the art and science of compounding comprised of representatives licensed and/or permitted by the Board from the following areas of compounding practice:

(a) Non-Sterile Compounding in a Traditional Retail Setting and or Institutional Setting;

(b) Sterile Compounding in a Traditional Retail Setting;

(c) Sterile Compounding in an Institutional Setting (i.e. hospital);

(d) Sterile Compounding in an Alternative Setting (e.g. home infusion);

(e) Compounding of Radiopharmaceuticals;

(f) Compounding of Hazardous Substances;

(g) Compounding by Outsourcing Facilities;

(h) State-Certified Pharmacy Technician Engaged Primarily in Compounding;

(2) To the extent that multiple candidates present themselves from the above compounding practice settings, they should be considered and added to the Council as the Council Chair and Vice Chair deems appropriate to provide a broad perspective of each relevant practice area.

(3) Once appointed to the Council, an appointee must serve indefinitely so long as the appointee attends at least 80% of the Council's scheduled meetings on an annual basis and remains licensed as a pharmacist in good standing in this State

(4) The Compounding Standards Council must be led by a Chair and Vice Chair. These two (2) Council members must be active members of the Board. Additionally, the lay members of the committee should appoint an Advisory Representative. The Advisory Representative will assist the Chair and Vice Chair with stewarding the Council and will also serve as a representative as called upon by the Board to confer on topics related to the Standards and or the Council.

D. Initial Adoption of Compounding Standards.

(1) The Council will, no later than one hundred eighty (180) days following promulgation of this regulation, draft initial Compounding Standards detailing the minimum technical specifications for the following compounded preparations and compounding practice settings with each section being an independent chapter of the Standards:

(a) Low Risk Non-Sterile Compounds;

(b) Non-Sterile Compounds;

(c) Sterile Compounds;

(d) Radiopharmaceutical Compounds;

(e) Compounding by Non-Dispensing Drug Outlet Permit Holders;

(f) Compounding by Outsourcing Facilities;

(g) Compounding of Hazardous Substances;

(h) Compounding of Over-the-Counter ("OTC") Agents;

(i) Glossary of Compounding-Related Terms of Art;

(j) Appendix of Relevant Exhibits;

(k) Application or Form for Board Approval of Variances or Deviations from Applicable Compounding Standards; and

(l) Form for Submission of Public Comment to Proposed Standard Chapter

(2) The Council will publish a draft of each respective chapter on the Board website and disseminate information regarding its publication and consideration of public comments for a period of approximately forty-five (45) days. Such public comment may come from any entity or individual, including members of the Board and or Council. All public comments must be submitted in the manner prescribed by the Council using any required form(s), as applicable.

(3) Approximately sixty (60) days following closure of the comment period, the Council must review and consider all public comments received, providing a detailed report to the Board consisting of:

(a) The Council's recommended Standards;

(b) Copies of all public comments received on the recommended Standards; and

(c) The Council's written response to the public comments received.

(4) At the first Board meeting following the Council's report, the Board must review the Council's report and recommended Standards. The Board may then:

(a) Approve the Council's recommendation on the applicable Standards;

(b) Approve some or all of the applicable Standards and remand sections back for further review and editing by the Council; or

(c) Decline the Council's recommendation in full and remand the applicable Standards back to the Council with detailed guidance on the reasons for remand so that the Council may adequately address these deficiencies in subsequent iterations.

E. Periodic Review of Compounding Standards.

(1) The Board of Pharmacy and the Compounding Standards Council should continuously monitor the state of compounding in South Carolina and the suitability of the Standards relevant to contemporary practice. If it is felt that a Standards chapter requires revision:

(a) The Council should petition the Board if it is felt that changes and or edits are necessary, or

(b) The Board will vote to approve the opening of a chapter or group of chapters to be edited by the Council.

(2) Once the Board has charged the Council to review and consider revising a chapter or group of chapters, the Council will meet to review and revise the applicable sections within a suitable time frame. Meetings of the Council may be convened by the Chair or Vice Chair.

(3) Upon completion of the review and revisions, if deemed necessary, the Compounding Standards Council will publish a draft of each respective chapter on the Board website and disseminate information regarding its publication and consideration of public comments for a period of approximately forty-five (45) days. Such public comment may come from any entity or individual, including members of the Board. All public comments must be submitted in the manner prescribed by the Council using any required form(s) as applicable.

(4) Approximately sixty (60) days following closure of the comment period, the Council must review and consider all public comments received, providing a detailed report to the Board consisting of:

(a) The Council's recommended Standards;

(b) Copies of all public comments received on the recommended Standards; and

(c) The Council's written response to the public comments received.

(5) At the first Board meeting following the Council's report, the Board must review the Council's report and recommended Standards. The Board may:

(a) Approve the Council's recommendation on the applicable standards;

(b) Approve some or all of the applicable Standards and rescind chapters back for further review;

(c) Decline the Council's recommendation in full and remand the applicable Standards back to the Council with detailed guidance on the reasons for remand so that the Council may adequately address these deficiencies in subsequent iterations.