Collaborative for Evidence-Based Medicines:
Putting Patient Safety First
PROTECTING PATIENTS | ADVANCING SCIENCE | SHAPING POLICY

September 4, 2026

VIA EMAIL

Kayce Shealy, PharmD
Administrator, South Carolina
Board of Pharmacy
110 Centerview Dr.
Columbia, SC 29210
Contact.Pharmacy@llr.sc.gov

Re: Working Draft of Compounding Regulations as of August 18, 2026

Dear Ms. Shealy:

The Collaborative for Evidence-Based Medicines ("CEBM") is a national provider-led organization advancing evidence-backed medicines, safe compounding, and stronger oversight and accountability to protect patients. CEBM brings together providers, patient advocates, academics, consumer groups, manufacturers, and other stakeholders to advance our patient safety mission. The signatories to this letter are pharmacists, physicians, and regulatory professionals who sit on the CEBM Board. CEBM's members bring decades of clinical, scientific, and policy experience to bear on the critical questions presented by these proposed rules.

CEBM offers these comments on the South Carolina Board of Pharmacy's (the "Board") August 18, 2026, working draft of compounding regulations (the "August Draft"). This letter follows CEBM's prior comment letter submitted on May 14, 2026, which addressed the Board's earlier version of its proposed compounding regulations from May 4, 2026. The choices the Board makes in this rulemaking will directly affect the quality and safety of compounded medications provided to South Carolina patients. From the perspective of the clinicians, pharmacists, and patient advocates in our collaborative, the August Draft contains important protections that advance patient safety, but we have recommendations to strengthen the draft regulations in several areas.

In addition to the below recommendations, we urge the Board to take additional action through guidance or other public notices to reinforce that state-licensed pharmacies may not compound versions of investigational drugs. The compounding of the investigational drug retatrutide has expanded dramatically over the past months, a trend that will likely repeat for future drugs after positive clinical data are announced. The widespread compounding of unapproved drugs while they are still under clinical investigation puts patients at risk and threatens the foundation of drug development that depends on the creation of rigorous evidence to assess safety and effectiveness before new drugs reach patients. Patients deserve treatments supported by rigorous evidence—not unauthorized products marketed before the science is complete.

I. The Patient Safety Imperative: Why This Rulemaking Matters Now



To start, we urge the Board to consider the growing body of evidence documenting patient harm from compounded drugs which motivates CEBM's comments. For example, a recent pharmacovigilance study by researchers at Binghamton University found that patients taking compounded GLP-1/GIP receptor agonist drugs were nearly 2.5 times more likely to experience an adverse event requiring hospitalization and over 8.5 times more likely to have an adverse event involving product quality issues compared to patients taking FDA-approved medicines.[1] As of May 31, 2026, the Food and Drug Administration ("FDA") has received 1,720 reports of adverse events associated with compounded GLP-1/GIP drugs alone.[2] Given that compounding pharmacies have no obligation to monitor or report adverse events, this figure captures only a fraction of actual patient harm. From our perspective as providers and patient advocates, these numbers represent real patients who sought treatment and instead received products that put their health at risk.

South Carolina is not insulated from these risks. Recent federal enforcement and inspection activity involving South Carolina compounding facilities has documented unlawful compounding as well as serious deficiencies in sterile-production controls, environmental conditions, and controlled-substance reporting. [3] This is not an abstract, out-of-state problem. It is happening here, and South Carolinian patients deserve the maximum protections that this rulemaking can provide.

II. Section 48(H) — Reinstate the Prior Inspection Requirement for Compounding Pharmacies to Protect Patients

Section 48(H) should give the Board a meaningful opportunity to evaluate a pharmacy's readiness to compound before compounded preparations reach patients. CEBM is therefore concerned that the August Draft replaces the original inspection requirement prior to receiving a license with a notification-based process. Under the revised language, before a pharmacy may begin compounding, all a pharmacy has to do is provide the Board with notice.

For routine pharmacy activities, advance notice may sometimes provide sufficient regulatory visibility. Compounding warrants a different approach. Sterile compounding, in particular, depends on effective environmental controls, validated processes, trained personnel, and consistent adherence to

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[1] Kenneth L. McCall et al., *Safety Analysis of Compounded GLP-1 Receptor Agonists: A Pharmacovigilance Study Using the FDA Adverse Event Reporting System* (2025), https://www.tandfonline.com/doi/full/10.1080/14740338.2025.2499670.

[2] Food and Drug Administration, "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss" current as of June 15, 2026, *available at*: https://www.fda.gov/drugs/drug-alerts-and-statements/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss (last accessed Aug. 19, 2026).

[3] U.S. Attorney's Office for South Carolina, *Upstate Pharmacist Sentenced for Unlawfully Compounding Radioactive Drugs* (July 25, 2024); FDA, *Form 483 to Medi-Fare Drug* (June 6, 2025) ("Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed."); FDA, *Form 483 to Palmetto Isotopes* (Feb. 28, 2025) ("The grid of the HEPA filter appeared dirty and discolored inside the ISO 5 PEC"); FDA, *Form 483 to Carolina Infusion* (Jan. 24, 2025) ("Materials were exposed to lower than ISO 5 quality air."); FDA, *Form 483 to Nephron Sterile Compounding Center* (Sept. 25, 2024) ("we observed visible residue on the floors"); FDA, *Form 483 to Prisma Health* (Mar. 3, 2023) (unreported production of the controlled substance ketamine).

aseptic practices. Deficiencies in any of these areas may not be apparent from a written notice, but they can directly affect the sterility and quality of preparations administered to patients.

CEBM accordingly recommends that the Board require a satisfactory inspection before an in-state pharmacy may begin compounding, or at least before it may begin sterile compounding. Such a requirement would place South Carolina alongside other states that use pre-operational inspections to confirm that sterile-compounding facilities meet applicable safety requirements before receiving authorization to operate.[4]

If the Board elects to not restore a pre-inspection requirement, it should, at minimum, revise Section 48(H) to more clearly require notice no fewer than 10 working days before a pharmacy begins providing compounding services. The phrase "within or no less than 10 working days prior to" is internally inconsistent and may create uncertainty about when notice must be submitted. Although the provision includes the words "prior to," the term "within" could be read to permit notice during the 10-working-day period preceding the start date or even after compounding has begun. A clear advance-notice deadline would eliminate this ambiguity and give the Board a meaningful opportunity to evaluate the proposed operations.

III. Sections 48(L)(2); 49(A)(8) — Resolve BUD Uncertainty in Favor of Patient Safety

A beyond-use date ("BUD") defines the period during which a compounded preparation may be used without jeopardizing its stability and sterility. Because an unsupported BUD can expose patients to contamination, degradation, or loss of potency, the governing rule should require pharmacies to choose the most protective date supported by the available evidence.

The phrase "whichever is lesser for the product's stability and sterility" does not provide a sufficiently clear method for making that choice. It is unclear whether the phrase directs a pharmacy to compare stability and sterility limitations, to choose among different evidentiary sources, or to exercise professional judgment among several potentially supportable dates. Sections 48(L)(2) and 49(A)(8) should instead provide a direct decision rule: when the available information supports more than one BUD, the shortest supported period controls.

IV. Section 48(E) — Prevent Compounding of Essential Copies of Commercially Available Drugs to Reinforce That, Where Possible, Patients Should Receive FDA-Approved Medicines

[4] Massachusetts ("…(4) The Board may require an inspection of a pharmacy before granting final approval of an application." 247 CMR, § 6.04); Texas ("A community pharmacy engaged in the compounding of sterile preparations shall be designated as a Class A-S pharmacy…. A Class A-S license may not be issued unless the pharmacy has been inspected by the board to ensure the pharmacy meets the requirements as specified in § 291.133 of this title (relating to Pharmacies Compounding Sterile Preparation) 22 Tex. Admin. Code § 291.36; and West Virginia ("A pharmacy compounding or mixing prescription orders for sterile solutions or suspensions shall obtain a Sterile Pharmaceutical Compounding Permit from the Board in addition to a pharmacy license. The Board shall issue a permit after a satisfactory inspection of the completed facilities." W. Va. Code R. 15-1-12).

Federal law has long prohibited 503A pharmacies from compounding drugs that are essentially copies of commercially available products.[5] This prohibition exists for a fundamental reason: when an FDA-approved medicine is available, patients should receive that medicine rather than an untested, unregulated copy. Compounding fills a vital role when patients have genuine needs that no approved product can meet. But compounding was never intended to become a pathway for mass-producing cheaper versions of approved drugs without regulatory safeguards that protect patients.

In practice, however, compounding has increasingly been used for precisely this purpose, and the immense (and growing) scale of compounding makes these problems more urgent. The compounding pharmacy market is a five-billion-dollar industry and is projected to approach nine billion dollars by 2035.[6] Growth of this magnitude reflects a market increasingly driven by commercial promotion rather than by the patient-specific clinical needs the framework was built to address. As the NABP recently observed, "the compounded GLP-1 period already showed that demand of this kind blows past the small-scale, patient-specific compounding Congress had in mind when it built the 503A framework."[7] The explosion of the compounded drug market, along with documented adverse events as a result of these products, demonstrates the consequences of failing to enforce the copy prohibition at the state level.

We recommend that the Board take the additional step of defining what it means for a compounded product to be "essentially a copy" of a commercially available drug. Such a definition should require that any drug that contains the same active ingredient as an FDA-approved, available drug be considered a "essentially a copy," unless the compounded preparation includes a change that produces a clinically significant difference for the identified individual patient as determined by the prescribing practitioner and verified by the dispensing pharmacist. Moreover, the combination of multiple active ingredients that could be administered separately should not be allowed to create the pretext to compound copies of approved drugs, and should not constitute a "clinically significant difference."

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For the foregoing reasons, CEBM respectfully urges the Board to adopt the proposed rules with the additional recommendations described above.

As physicians, pharmacists, and regulatory professionals committed to ensuring that patients receive treatments that are safe, effective, and supported by evidence, CEBM stands ready to support the Board in any way that advances that shared goal.

Respectfully submitted,

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[5] 21 U.S.C. § 353a(b)(1)(D).

[6] Towards Healthcare, "503A U.S. Compounding Pharmacies Market Size, Growth and Geographical Insights" last updated Jan. 5, 2026, *available at*: https://www.towardshealthcare.com/insights/503a-us-compounding-pharmacies-market (last accessed June 26, 2026).

[7] NABP, Comment to Docket No. FDA-2025-N-6895; Pharmacy Compounding Advisory Committee Meeting — Consideration of Seven Peptide Substances for the Section 503A Bulk Drug Substances List (Jul. 9, 2026), https://tinyurl.com/32prycjc.

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