100 Daingerfield Road, Suite 100
Alexandria, VA 22314

www.a4pc.org

Alliance for Pharmacy Compounding

Compounding the Joy of Living®

February 20, 2025

Mississippi Board of Nursing
713 Pear Orchard Road, Plaza II
Suite 300
Ridgeland, MS 39157

Subject: Concerns Regarding Temporary Rule on Weight-Loss Treatment Services and Compounded Medications

Members of the Mississippi Board of Nursing:

On behalf of the Alliance for Pharmacy Compounding, thank you for your commitment to patient safety in weight-loss treatment services and the role of compounded medications in addressing patient needs.

We write to express serious concerns with the temporary rule issued on January 30, 2025, specifically Section I.5(E)(i), which imposes additional API verification requirements on pharmacies supplying compounded weight-loss medications. The rule requires that any compounded medication administered or prescribed be sourced from a pharmacy that has either obtained the active pharmaceutical ingredient (API) from a U.S.-based repackager or wholesaler that has performed API verification testing or has independently performed API verification testing to confirm the supplier's certificate of analysis (COA).

While we support measures that promote patient safety and drug quality, this requirement is unnecessary, inconsistent with national standards, operationally impractical, and creates significant barriers to patient access. Compounding pharmacies already follow strict federal and state regulations regarding API sourcing, including compliance with United States Pharmacopeia (USP) standards and FDA oversight of drug supply chains. The additional API testing mandate is not required for any other API and places an unnecessary financial and operational burden on pharmacies that dispense compounded weight-loss medications, and that cost will be passed along to patients.

Neither FDA regulations nor USP standards require independent verification testing of APIs when sourced from registered, compliant suppliers that provide a COA. Your requirement singles out weight-loss medications for additional scrutiny without scientific justification, creating a regulatory precedent that places Mississippi pharmacies at a disadvantage compared to those in other states.

The practical implementation of this requirement presents major workflow challenges that pharmacies are not equipped to manage without significant cost and disruption. There is no

standardized process for independent API verification, and no established industry workflow for compounding pharmacies to conduct independent verification testing for each lot of API before compounding. To comply, pharmacies would need to use a third-party laboratory for each API lot, which would introduce weeks of delay and increase costs significantly. Because compounded medications are often prepared based on immediate patient need, requiring API testing before compounding introduces unnecessary delays that can make timely treatment impossible. Pharmacies unable to comply will be forced to discontinue these compounded medications, limiting patient options and potentially increasing reliance on unregulated online sources in this period of ongoing shortage.

We urge the Mississippi Board of Nursing to remove this additional API verification requirement from the temporary rule and instead align with national regulatory standards that already ensure API safety and quality without imposing unnecessary barriers. If the Board believes further safeguards are necessary, we encourage collaborative discussions with compounding experts to explore feasible, science-based approaches that protect patient safety without disrupting pharmacy workflow or limiting access.

APC welcomes the opportunity to engage with the Board on this issue and provide further insights from compounding professionals who navigate these challenges daily. Please let us know if we can assist in developing policies that balance safety with practical implementation. Thank you for your time and consideration.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
Alliance for Pharmacy Compounding