August 4, 2025

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Re: Letter in Support of Revisions to 30 Code Miss. R. Pt. 3001, Art. XXXI, Section 1(F)

We write on behalf of 5 organizations of public health advocates—including pharmacists, physicians, prescription drug safety experts, patient advocates, and consumer organizations—to express our appreciation for the Mississippi Board of Pharmacy's (the "Board") efforts to address the complex issue of the resale of compounded medications by pharmacies. We respectfully submit this letter of support, along with comments on ways the Board can further strengthen the proposed revisions to 30 Code Miss. R. Pt. 3001, Art. XXXI, Section 1(F).

We thank the Board for its continued leadership in safeguarding the health of Mississippi patients and promoting responsible pharmacy practice. The proposed rule would help address a growing concern: the practice of pharmacies reselling compounded sterile drugs purchased from outsourcing facilities. This issue gained new urgency after the FDA issued draft guidance in June 2023 that, if finalized, would open the door for pharmacies to dispense these compounded sterile products even more broadly.

The risks to patients posed by pharmacies dispensing compounded sterile drugs purchased from outsourcing facilities are significant and real. Across the country, we have seen telehealth companies partner with pharmacies to dispense unprecedented quantities of compounded GLP-1 drugs sourced from outsourcing facilities. Under these arrangements, the compounded drugs are dispensed by the pharmacies into all 50 states with little visibility by state boards of pharmacy. This has allowed for the mass distribution of unapproved drugs with limited safeguards and ability to track problematic drugs in the event of a quality incident, raising serious safety concerns flagged by the FDA, state regulators, and public health organizations like those in our coalition.

FDA's draft guidance, *Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, misinterprets federal law by allowing pharmacies to resell compounded drugs from 503B outsourcing facilities. The draft guidance, which FDA has never finalized, permits such resale despite clear statutory prohibitions and labeling requirements that such drugs are "not for resale." This interpretation blurs the important distinction between outsourcing facilities and conventional manufacturers of FDA-approved drugs and permits mass distribution of unapproved drugs outside of established safety, quality, and oversight

frameworks. Such resales increase patient risk by allowing large-scale compounding to bypass essential protections such as premarket review and inspections, supply chain security, and adverse event reporting.

We appreciate that this issue could put state boards in a difficult position and believe that the Board's proposed rule represents a thoughtful, balanced approach. The proposed rule would adopt nationally recognized quality and safety benchmarks for both compounding pharmacies and outsourcing facilities. 503B facilities would be held to federally established manufacturing protocols, while traditional compounding pharmacies would be expected to meet key United States Pharmacopeia (USP) standards for sterile, non-sterile, and hazardous drug preparation. Additionally, the proposed rule would require each outsourcing facility licensed by the state to designate a licensed pharmacist to serve as its USP Representative and strengthen labeling requirements for the dispensed compounded product. Collectively, these measures would enhance transparency regarding the source of the compounded drugs, reduce the risk of patient exposure to improperly labeled or unsafe products, and support the state's efforts to uphold responsible pharmacy practice.

We further support the proposed rule's effort to restrict the distribution of compounded drugs from outsourcing facilities not licensed to operate in Mississippi. Outsourcing facilities that are not licensed in the state should not be permitted to distribute their compounded sterile drug products through local pharmacies in Mississippi. We also support the requirement for a pharmacy to hold a dispensing outsourcer product certificate. This will provide the Board with critical information to strengthen oversight, enforce safety standards, and ensure accountability.

As a necessary complement to these safeguards, we also urge the Board to require that each compounded drug received by the pharmacy be accompanied by a valid certificate of analysis from the outsourcing facility that identifies the original manufacturer of the active pharmaceutical ingredient. This requirement is essential to protect public health by ensuring transparency in the drug supply chain to prevent the use of unsafe or substandard ingredients. Consumers deserve confidence that the medications they receive are made from verified, high-quality components, especially when those drugs are compounded outside of traditional manufacturing safeguards.

We recognize the Board's efforts to address this complex issue head-on. This rule, if finalized, will represent a step forward to help close dangerous loopholes and protect patients from the risks of unregulated compounded medications.

Thank you for your continued dedication to pharmacy safety and the health of Mississippi patients.

Sincerely,

[Organizations]