100 Daingerfield Road, Suite 100
Alexandria, VA 22314

www.a4pc.org

Alliance for Pharmacy Compounding

Compounding the Joy of Living®

February 6, 2024

Mississippi State Legislature
House Public Health and Human Services Committee
400 High St
Jackson, MS 39201

Dear Members of the House Public Health and Human Services Committee:

I am writing on behalf of the Alliance for Pharmacy Compounding in opposition to HB 648, which allows for sterile compounded preparations prepared outside of a sterile compounding lab to be administered to patients. The proposed bill poses an extraordinary risk to public health.

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 600 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.

HB 648 states "the vitamins administered through IV therapy by a nurse practitioner or registered nurse do not have to be prepared by a compound pharmacy." APC strongly opposes this provision of HB 648. Compounding sterile preparations, including vitamins, outside of the appropriate controls creates a risk of contamination, incorrect strength, and other potential patient harms.

Section 503A of the Federal Food, Drug and Cosmetic Act (FD&C Act) describes the conditions under which compounded human drug products are exempt from approval prior to marketing and from current good manufacturing practice (CGMP) requirements. One of the conditions to qualify for these exemptions is that the drug is compounded by a licensed pharmacist in a state-licensed pharmacy or by a licensed physician.

Sterile compounding pharmacies adhere to standards developed by the United States Pharmacopeia (USP) and regulations set by their respective state board(s) of pharmacy. USP standards set limits on the beyond-use dates for compounded sterile preparations based on the environment in which they are prepared, among other controls. For example, USP Chapter 797 sets a minimum standard for the safe compounding of immediate use compounded sterile preparations. USP chapters are incorporated into law and regulation in Mississippi and compliance is required of pharmacists. However, this bill doesn't apply that same standard to nurse practitioners and nurses. Since these preparations are compounded in uncontrolled environments—such as in a nurse practitioner's office or on a hospital floor, rather than in a cleanroom suite or in a primary engineering control such as a laminar airflow hood—the chapter outlines several requirements that must be met to reduce potential patient harm from contamination:

1. "Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.
2. Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.

3. The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability and compatibility studies).
4. The preparation involves not more than 3 different sterile products.
5. Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.
6. Administration begins within 4 h following the start of preparation. If administration has not begun within 4 h following the start of preparation, it must be promptly, appropriately, and safely discarded.
7. Unless directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the 4-h time period within which administration must begin.

Handling of sterile hazardous drugs (HDs) must additionally comply with ⟨800⟩."[1]

This bill provides no requirements for any of these parameters. As written, sterile drug products could be prepared using any number of products, under any conditions, with no specific training, no standard operating procedures, and stored for any amount of time. Having no structure for how these medications are to be prepared increases the risk that patients could receive contaminated injectable medications or medication that are not of the appropriate strength. This bill creates significant risk to the health of patients in Mississippi.

The FDA issued a memo in October 2021 stating "FDA has become increasingly aware of drug products compounded at medical offices and clinics that were prepared under insanitary conditions. FDA has also become aware of business models, such as intravenous (IV) hydration clinics, medical spas, and mobile IV infusion services, that are compounding drugs that may not meet the conditions of section 503A of the FD&C Act or comply with state regulations."[2] FDA goes further to discuss how preparing drugs intended to be sterile can put patients at risk when they are prepared under insanitary conditions. The memo outlines numerous specific cases in which the practices in these facilities led to serious patient injury or death. HB 648 provides no structure to prevent these medications that are intended to be sterile from being produced under insanitary conditions.

For these reasons, we urge you to reject HB 648.

Thank you for this opportunity to comment on this bill. Please direct any questions to me at scott@a4pc.org.

Best,

Scott Brunner, CAE
Chief Executive Officer

---

[1] U.S. Pharmacopeia General Chapter <797>. https://www.usp.org/compounding/general-chapter-797.
[2] U.S. Food and Drug Adminsitration. "FDA highlights concerns with compounding of drug products by medical offices and clinics under insanitary conditions." October 25, 2021. https://www.fda.gov/drugs/human-drug-compounding/fda-highlights-concerns-compounding-drug-products-medical-offices-and-clinics-under-insanitary