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Alexandria, VA 22314

www.a4pc.org

July 17, 2023



Alabama Board of Pharmacy
111 Village Street
Birmingham, AL 35242

RE: USP <800>

Dear Board Members:

Thank you for the opportunity to share input in advance of your open forum regarding USP <800> implementation in Alabama.

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.

It is our understanding that Alabama state law requires that the Alabama Board of Pharmacy to adopt USP chapters, as published by USP, by reference, which leaves little room for the board to question provisions of the chapter or exercise any judgment about the suitability of those provisions for Alabama pharmacies that compound hazardous drugs. Though it is a conversation for another time, we question whether it is prudent for a state agency to be unable to exercise discretion and judgment about the regulations and standards that the licensees it oversees must adhere to. We'd like to see "adoption by reference" changed in Alabama law so that the board actually has a voice in such matters.

Regarding the issue at hand: Alabama law seems to require that USP <800> be implemented. Where we believe the board *does* have flexibility is the timing of that implementation. APC strongly recommends that the board allow a 12-to-18-month period beyond USP's November 1, 2023, effective date for the chapter. It is not an unprecedented action to delay enforcement; We understand that Kentucky, for instance, has announced a 24-month delay in enforcement of USP <800> to allow licensees to bring their pharmacies into compliance.

The fact is, many pharmacies in Alabama simply will be unable to be compliant with USP <800> by USP's November 1 date, which will result in pharmacies being unable to compound any hazardous medication for patients until their labs are built-out to the new USP <800> specs. Patients of those pharmacies who rely on compounded medications listed on the NIOSH list and are considered hazardous suddenly will be unable to access those medications from those pharmacies where they've long been having those prescriptions filled and will either need to look elsewhere or go without the medication.

We urge the board to formally delay adoption of USP <800> in Alabama for those reasons. Please direct any questions to APC's Savannah Cunningham at savannah@a4pc.org.

Best,

A handwritten signature in blue ink, appearing to read "S. Brunner".

Scott Brunner, CAE
Chief Executive Officer