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Alliance for Pharmacy Compounding

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2/28/2024

Maryland State Legislature
Environment and Transportation Committee
Room 251
House Office Building
Annapolis, Maryland 21401

Dear Members of the Environment and Transportation Committee:

I am writing on behalf of the Alliance for Pharmacy Compounding to express our opposition to HB1099. This bill presents numerous conflicts with compounding regulations and best practices. It introduces risks to patient safety should it be adopted as it is currently written.

Our concerns:

Office-use definition: MD HB 1099 states that veterinarians and veterinarian technicians can prepare "office-use products approved by the U.S. Food and Drug Administration." Though FDA provides a guidance document with a list of products that in the opinion of the FDA can be compounded for office-use from bulk drug substances (https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-office-stock-drugs-use-nonfood-producing-animals), no office-use compounded products exist that are explicitly approved by the FDA. Also, this bill refers to "at-home treatment," which could include dispensing for home visits and does not equate to "office-use."

- **Quality standards:** Pharmacies licensed in Maryland are required to adhere to USP chapters <795> and <797> (compliance standards for nonsterile and sterile compounding), as the chapters are incorporated by reference and discussed in Maryland code. (https://health.maryland.gov/pharmacy/docs/Sterile/COMAR%2010.34.19%20June%202016.pdf) However, HB 1099 does not require veterinarians and veterinarian technicians who are compounding to adhere to USP standards. Instead, it is written with significant generalizations that leave the ability for wide variability from one office to another – for example, stating that veterinarians and veterinarian technicians "may not compound a drug if the complexity of compounding the drug is beyond the veterinary practitioner's or veterinary technician's knowledge, skill, expertise, or available facilities or equipment." Adherence to USP requires specific knowledge and competency requirements in order to compound at all, and would be more appropriately referenced here. In addition, the proposed bill does not discuss sterile versus nonsterile compounds (**non-sterile** means that the medications are used in or on parts of the body where sterility is not essential, such as on the skin or in the mouth. **Sterile** medications must be sterile when introduced into the body and include IV, injections, and irrigation products). These two types of compounding differ vastly in the training requirements and equipment needed, but the proposed bill does not reflect that.

- **Beyond-use-dates (BUDs):** The bill erroneously refers to “expiration dates” instead of “beyond-use-dates (BUDs) for compounded medications. Moreover, it lacks criteria for establishing BUDs, instead imposing arbitrary storage limits unrelated to the actual BUDs of the drugs. This approach risks unnecessary waste and disposal of drugs that remain within their BUDs, potentially depriving patients of crucial treatments.

- **Safety:** The bill also requires “the State Board of Veterinary Medical Examiners to establish certain *safety* standards and guidelines.” In compounding, safety and efficacy are terms with legal meanings and are reserved for manufactured FDA-approved drugs and cannot be used in reference to compounded medications.

In light of these concerns, we urge you to reject HB1099.

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

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 500 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.