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Alliance for Pharmacy Compounding

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August 20, 2024

Donna Yeatman
Executive Secretary
Alabama Board of Pharmacy
111 Village St
Birmingham, AL 35242

Dear Executive Secretary Yeatman and Members of the Board of Pharmacy:

I am writing regarding the draft guidance issued by the U.S. Food and Drug Administration in June 2023 regarding the prohibition on wholesaling for 503B outsourcing facilities and the August 2024 newsletter released by the Alabama Board of Pharmacy.

The Alliance for Pharmacy Compounding (APC) is deeply invested in ensuring that compounding practices meet regulatory standards while also serving the needs of healthcare providers and patients effectively. Our organization aims to promote and protect ethical compounding practices and urges our members to adhere to a Code of Conduct, which can be accessed here.

The FDA's draft guidance clarifies the prohibition on wholesaling for 503B outsourcing facilities under the Federal Food, Drug, and Cosmetic Act. It emphasizes that compounded drugs from 503B facilities must not be sold or transferred beyond the healthcare setting or for purposes other than direct patient care. The Food, Drug, and Cosmetic Act mandates that these products be labeled "not for resale" or "for office administration only" to prevent their distribution in a manner akin to commercial wholesaling.

Despite these restrictions, the FDA recognizes the importance of compounded medications in healthcare. The draft guidance would allow 503B outsourcing facilities to distribute compounded drugs to 503A pharmacies, provided these drugs are dispensed to patients pursuant to a prescription and not resold.

In light of this draft guidance, I urge the Alabama Board of Pharmacy to adopt a position on this matter in line with the FDA draft guidance and taken by most other states. That includes allowing 503A pharmacies to purchase compounded products from 503B outsourcing facilities that are labeled "not for resale" or "for office administration only," provided these products are used within the intended regulatory framework.

This approach has several benefits:

1. **Enhanced access to compounded medications:** By permitting the use of these products, healthcare providers can ensure timely access to necessary compounded medications, especially in situations where commercially available alternatives are not suitable or available.

2. **Alignment with FDA guidance:** Adopting enforcement discretion aligns Alabama with the

FDA's regulatory intent and provides a clear framework for pharmacies to follow, reducing ambiguity and potential compliance issues.

3. **Patient safety and care:** Allowing the use of compounded medications produced by 503B outsourcing facilities to fill patient prescriptions helps provide access to needed medications that are not available otherwise, such as medications on shortage.

It is important to note that this recommendation does not undermine the regulatory authority of the Alabama Board of Pharmacy. Instead, it enhances the Board's ability to oversee the compliant use of compounded medications while respecting the practical needs of healthcare providers.

We believe that Alabama's adoption of this enforcement discretion will provide clarity and support to pharmacies and healthcare providers, ensuring they can continue to deliver high-quality care to their patients without fear of regulatory repercussions.

Thank you for considering this recommendation. We look forward to collaborating with you and the Alabama Board of Pharmacy to promote ethical and compliant compounding practices.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
scott@a4pc.org

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.