Alliance for Pharmacy Compounding

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July 9, 2024

Nicki Chopski, PharmD
Executive Director
Idaho Board of Pharmacy
1199 Shoreline Lane, Suite 303
Boise, ID 83702

Dear Dr. Chopski,

I am writing to thank you for meeting with me on July 8 to discuss matters related to compounding. During our discussion, we talked about the draft guidance issued by the U.S. Food and Drug Administration in June 2023 regarding the prohibition on wholesaling for 503B outsourcing facilities.

As the Chief Advocacy Officer for the Alliance for Pharmacy Compounding, I am 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The FDA's draft guidance clarifies the prohibition on wholesaling for 503B outsourcing facilities under the Federal Food, Drug, and Cosmetic Act.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. This aligns with what is in the Idaho Code.

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 The draft guidance would allow 503B outsourcing facilities to *distribute* compounded drugs to 503A pharmacies, provided these drugs are *dispensed* to patients pursuant to a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In light of this draft guidance, I urge the Idaho Board of Pharmacy to adopt a position on this matter in line with the FDA draft guidance and taken by most other states.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 Idaho 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 Idaho 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 Idaho'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.

I would like to applaud you and the members of the board for all the work done in Idaho to expand the practice of pharmacy, including prescribing authority, and for understanding that pharmacists are trained medical professionals capable of using their professional judgment to provide patient care.

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

Sincerely,

Tenille Davis
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