

February 10, 2025

M. Joseph Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700

Dear Executive Director Fontenot and Members of the Louisiana Board of Pharmacy:

I am writing on behalf of the Alliance for Pharmacy Compounding to seek clarification regarding Louisiana's policies on the ability of 503B outsourcing facilities to distribute compounded medications to 503A pharmacies. Recent reports from a pharmacy in your state indicated that an inspector claimed 503Bs are not allowed to sell to 503As in Louisiana. We would appreciate clarification on this matter to ensure pharmacies understand and comply with state policies.

APC represents a wide range of stakeholders in the compounding industry, including 503A and 503B facilities, healthcare providers, researchers, and suppliers. We are dedicated to promoting ethical and compliant compounding practices that meet both regulatory requirements and the needs of patients and providers.

As you may know, the U.S. Food and Drug Administration issued [draft guidance](#) in June 2023 clarifying the prohibition on wholesaling for 503B outsourcing facilities under the Federal Food, Drug, and Cosmetic Act. According to the FDA, compounded drugs from 503B facilities must not be sold or transferred beyond the healthcare setting or for purposes other than direct patient care. These products must also bear the label "not for resale" or "for office administration only" to prevent misuse as commercially distributed products.

However, the FDA guidance recognizes that 503B outsourcing facilities play a critical role in ensuring patient access to compounded medications. Specifically, the guidance permits 503B outsourcing facilities to distribute compounded drugs to 503A pharmacies, provided these drugs are dispensed to patients pursuant to valid prescriptions and are not resold. This arrangement is crucial in facilitating timely access to essential compounded medications, particularly in cases of shortages or when commercially available alternatives are unsuitable.

In light of the above, we ask for clarification on whether Louisiana permits 503A pharmacies to procure compounded medications from 503B outsourcing facilities under these conditions.

We are confident that Louisiana's policy on this matter will balance the need for regulatory oversight with the practical needs of pharmacies and their patients. Ensuring clarity on this issue will support healthcare providers in delivering high-quality care and reduce the risk of regulatory confusion or noncompliance.

We greatly appreciate your time and consideration of this important matter. APC is committed to collaborating with the Louisiana Board of Pharmacy to address these concerns and promote effective and compliant compounding practices. Please do not hesitate to reach out should you have any questions or require further information.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Brunner', with a stylized, cursive script.

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