NABP
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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Andrew Funk, PharmD, Member Relations/Government Affairs Director

DATE: April 9, 2026

RE: FDA Reminder: Certain Conditions Must be Met for Compounded Drugs to Qualify for Exemptions under Section 503A and 503B of the FD&C Act

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On April 1, 2026, the FDA issued an updated Drug Alert and Statement reminding compounders that certain conditions must be met for compounded drugs to qualify for the exemptions under sections 503A and 503B of the FD&C Act.

503A Pharmacy and Prescriber Compounding

For pharmacies and prescribers to qualify for the exemptions under 503A, the drug product must be compounded for an individual patient based on receipt of a prescription, and the compounder does not compound, regularly or in inordinate amounts, any products that are essentially copies of commercially available drugs.

Pharmacies and prescribers may not regularly compound drug products that are essentially copies of commercially available drugs. In guidance, the FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if the compounded drug has:

- The same Active Pharmaceutical Ingredient (API).
- The same, similar, or easily substitutable strength.
- The same route of administration.

This is unless a prescriber determines and documents that the compounded drug product contains a change that produces a significant difference from the commercially available drug product for a specific patient.

The FDA also intends to consider a compounded drug product to be essentially a copy of a commercially available drug if:

- The compounded drug product contains the same APIs as two or more commercially available drug products in the same, similar, or easily substitutable strength and
- The commercially available drug product can be used (regardless of how it is labeled) by the same route of administration prescribed for the compounded drug product, unless there is documentation of a prescriber determination of a significant difference.

The FDA does not intend to take enforcement action against a pharmacy or prescriber who fills **four or fewer** prescriptions for an "essentially a copy" product per calendar month.

503B Outsourcing Facility Compounding

Outsourcing facilities are restricted from compounding drugs using bulk drug substances (or API) unless:

- The bulk drug substance appears on a list identifying bulk drug substances for which there is a clinical need, which is referred to as the 503B bulks list or

- The drug compounded from the bulk drug substance is on the FDA's drug shortage list at the time of compounding, distribution, and dispensing.

Tirzepatide and semaglutide do not currently appear on the 503B bulks list or on the FDA's drug shortage list.

cc: NABP Executive Committee
Lemrey "Al" Carter, Executive Director/Secretary