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STATE OF NEVADA

DEPARTMENT OF BUSINESS AND INDUSTRY
OFFICE OF NEVADA BOARDS, COMMISSIONS AND COUNCILS STANDARDS
STATE OF NEVADA BOARD OF PHARMACY

June 2, 2025

Via Email

Re: Notice of FDA's Declaratory Orders Resolving Shortages of Tirzepatide (Mounjaro and Zepbound) and Semaglutide Injection Products (Ozempic and Wegovy)

Dear Licensees and Registrants:

On December 19, 2024, the FDA issued a Declaratory Order ("December Declaratory Order") removing tirzepatide injection products from the FDA's drug shortage list following an analysis that the product shortage has been resolved. Additionally, February 21, 2025, the FDA issued a Declaratory Order ("February Declaratory Order") removing semaglutide injection products from the FDA's drug shortage list. On March 5, 2025, and April 24, 2025, the district court denied the plaintiff's preliminary injunctions in *Outsourcing Facilities Association v. FDA*, (N.D. Tex.) related to the tirzepatide and semaglutide products, respectively. This letter serves as notice that your pharmacy must comply with both Declaratory Orders and cease the compounding, distributing, and dispensing of compounded tirzepatide injection and semaglutide injection products as of the effective dates below. A copy of the Declaratory Orders are attached to this notice.

Tirzepatide Injection Products

According to the December Declaratory Order, the dates by which 503A and 503B pharmacies must stop compounding, distributing, and dispensing compounded tirzepatide injection products are as follows:

- Consistent with the FDA's latest update and the district court's decision, 503A pharmacies may no longer compound, distribute, or dispense compounded tirzepatide injection products;

- Consistent with the FDA's latest update and the district court's decision, 503B pharmacies may no longer compound, distribute, or dispense compounded tirzepatide injection products.

Semaglutide Injection Products

According to the February Declaratory Order, the dates by which 503A and 503B pharmacies must stop compounding, distributing, and dispensing compounded semaglutide injection products are as follows:

- Consistent with the FDA's latest update and the district court's decision, 503A pharmacies may no longer compound, distribute, or dispense compounded semaglutide injection products;
- After **May 22, 2025**, 503B pharmacies may no longer compound, distribute, or dispense compounded semaglutide injection products.

Compounding pharmacies should consult the FDA's January 2018 industry guidance on essential copies of commercially available drugs to evaluate exceptions and other information regarding the FDA's regulation of compound drug products. *See Compound Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, Food and Drug Administration Guidance Document (Jan. 2018). Additionally, the Board reminds 503A pharmacies that they are not permitted to sell compounded medications to practitioners. The Board further reminds all compounding pharmacies of their limitations and obligations under NAC 639.757 and associated compounding regulations, as recently amended by LCB File No. R053-24 (effective November 15, 2024).

If the Board determines that your facility continued to compound, distribute, or dispense compounded tirzepatide or semaglutide injection products after the effective dates above, or that your facility engaged in the business of wholesaling and/or distributing prescription drugs in Nevada that are restricted by federal law, this will constitute a violation of Nevada law, including, without limitation, NRS 639.100, NRS 639.233, NRS 639.288, NRS 639.310, and NAC 639.593. Violation of the Declaratory Order and Nevada law may result in a citation and/or administrative fine pursuant to NRS 639.2895(2)-(3).

Please send any questions to Pharmacy@Pharmacy.nv.gov.

Sincerely,

Nevada State Board of Pharmacy