Compounding of Glucagon-like Peptide-1 Drug Products (GLP-1) in Ohio

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This guidance highlights existing law and is intended for the benefit of practitioners and the public to promote better understanding of the laws governing the compounding and sale of GLP-1 drugs.

For more information on human drug compounding, visit:
https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding

The Ohio Board of Pharmacy (Board) has received inquiries concerning the compounding of GLP-1 medications such as semaglutide and tirzepatide. Semaglutide is available as a commercially available drug product marketed as Ozempic™ and Rybelsus™ for treating diabetes and as Wegovy™ for weight loss. Tirzepatide is available as a commercially available drug product marketed as Mounjaro™ for treating diabetes and as Zepbound™ for weight loss.

The following chart provides the status of GLP-1 drugs and the ability of Ohio pharmacies, prescribers, and outsourcing facilities to compound tirzepatide and semaglutide that are essentially copies of commercially available drug products:

Name of Drug	FDA Shortage?	Compounding Copies Permitted?
Tirzepatide (Mounjaro, Zepbound)	No	No Pharmacy or prescriber compounding: **Ended February 18, 2025** Outsourcing facility compounding: **Ended March 19, 2025**[i]

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Semaglutide (Ozempic, Rybelsus, Wegovy)	No	No Pharmacy or prescriber compounding: **Ended April 22, 2025** Outsourcing facility compounding: **Ended May 22, 2025**[ii]

NOTE: This chart is not exhaustive. Please be advised that other GLP-1 products may be on the FDA drug shortage list.

Retatrutide & Cagrilintide Cannot Be Compounded

Retatrutide and/or Cagrilintide **cannot** be used in compounding under federal and state law. Additionally, they are not a component of an FDA-approved drug, are not listed on the FDA's "bulk drug list", do not have USP/NF monographs, and have not been found safe and effective for any condition.

Licensees who have been found compounding, selling, ordering, administering, or otherwise facilitating the distribution of these unapproved drugs may be subject to disciplinary action including immediate licensure suspension (also known as a summary suspension). For more information, visit: www.pharmacy.ohio.gov/reta.

Have Questions or Need Additional Information?

For questions, please review the following frequently asked questions starting on the next page of this document. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Frequently Asked Questions[iii]

Q1) Can a compounding pharmacy or outsourcing facility continue to distribute or dispense tirzepatide or semaglutide that was compounded prior to the end dates established by the FDA?

No. A compounding pharmacy or outsourcing facility cannot continue to dispense, distribute, or compound an essential copy of an FDA-approved drug after the dates listed.

Q2) Can a prescriber clinic or compounding pharmacy continue to dispense or personally furnish compounded tirzepatide or semaglutide that was previously purchased prior to the end dates listed above?

Yes. A prescriber clinic or compounding pharmacy which previously purchased a compounded GLP-1 prior to the dates listed in the table above may continue to dispense and distribute the compounded drug. However, the prescriber clinic or compounding pharmacy may not engage in the compounding of GLP-1s past the dates listed in the table above.

This does not apply to retatrutide or cagrilintide as these drugs are NOT FDA-approved. All inventory containing retatrutide or cagrilintide must be disposed of immediately.

Q3) Can GLP-1s be compounded if the medication is commercially available?

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act)[iv] and Ohio law[v], compounding "drug products that are essentially copies of a commercially available drug product" is prohibited unless either of the following exceptions occurs:

(1) A drug is not commercially available, including the drug product has been discontinued and is no longer marketed or the drug product appears on the FDA drug shortage list under section 506E of the FD&C Act; **OR**

(2) The compounded drug includes a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the

prescribing practitioner, between the compounded drug and the commercially available product (see Q4 for more information).

Q4) Does a prescriber need to document the specific reason that the compounded drug would produce a significant difference from the commercially available drug product?

Yes. If a compounder (e.g., pharmacy, prescriber, or outsourcing facility) intends to rely on such a determination to establish that a compounded drug is not essentially a copy of a commercially available drug product, the compounder must ensure that the determination is documented on the prescription or order.

A prescription or order that identifies only a patient's name and drug product formulation is not sufficient to establish that the prescriber made the determination that the formulation would produce a significant difference from the commercially available drug product. This is to ensure that compounders do not evade the limits in this section by making relatively small changes to a compounded drug product and then offering the drug to the general public without regard to whether a prescribing practitioner has determined that the change produces a significant difference for the patient.

According to FDA, such documentation does not need to be in a particular format, provided that the prescription or order makes clear that the prescriber identified the relevant change and the significant difference that the change will produce for the patient. For example, the following would be sufficient:

- "No Dye X, patient allergy" (if the comparable drug contains the dye)
- "Liquid form, patient can't swallow tablet" (if the comparable drug is a tablet)
- "6 mg, patient needs higher dose" (if the comparable drug is only available in 5 mg dose)

If a compounded drug is substituted for the commercially available drug product and the prescription or order does not make clear that the prescriber made the determination of significant difference required by federal law, the compounder must contact the prescriber to clarify. If the prescriber confirms it, the compounder shall make a notation on the prescription or order that the compounded drug product contains a change that makes a significant

difference for the patient. The notations should be as specific as those described above, and the date of the conversation with the prescriber should be included on the prescription or order.[vi]

Q5) If and when compounding of GLP-1s drug products is permissible, how must it be performed?

For Pharmacies and Prescriber Clinics

If the compounding of a GLP-1 drug product is allowed (e.g., the drug is listed on the FDA drug shortage list or prescriber makes a determination that the drug would produce a significant difference), pharmacists and prescribers must comply with the United States Pharmacopoeia chapter on sterile compounding (USP 797)[1] as required by federal and state law. In addition, the pharmacy or prescriber must comply with all applicable provisions of the Board's compounding rules:

- Chapter 4729:7-2 | Pharmacy Compounding
    - More information on pharmacy compounding requirements is available here: www.pharmacy.ohio.gov/compound.

- Chapter 4729:7-3 | Prescriber Compounding
    - A prescriber compounding inspection guide is available here: www.pharmacy.ohio.gov/PCinspect.

Further, the pharmacy or prescriber clinic must ensure that all compounded GLP-1 products meet the following, as required by federal and state law:

1) Comply with an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph if one exists;
2) Are components of FDA-approved drug products if an applicable USP or NF monograph does not exist; or

[1] The Board is enforcing the version of USP 797 that went into effect on March 10, 2020. This does not include the newest revisions to the chapter effective November 1, 2023.

3) Appear on FDA's list of bulk drug substances that can be used in compounding (the 503A bulks list) if such a monograph does not exist and the substance is not a component of an FDA-approved drug product.

For Outsourcing Facilities

If the compounding of a GLP-1 drug product is allowed (e.g., not an essential copy or the drug is listed on the FDA drug shortage list – see Q3 for more information), outsourcing facilities must comply with Current Good Manufacturing Practices (CGMP) as required by federal and state law. In addition, the pharmacy or prescriber must comply with all applicable provisions of the Board's outsourcing facility rules (OAC 4729:6-10).

Further, the outsourcing facility must ensure that all compounded GLP-1 products meet the following, as required by federal law:

1) Are used to compound drug products that appear on FDA's drug shortages list at the time of compounding, distribution, and dispensing; or
2) Appear on FDA's list of bulk drug substances for which there is a clinical need (the 503B bulks list).

Q6) If the compounding of GLP-1s is permissible, where do I source the active pharmaceutical ingredient (API)?

Federal Requirements: Pharmacies, clinics, and outsourcing facilities must ensure that the API received is a pharmaceutical-grade product, accompanied by a valid certificate of analysis, and is sourced from an establishment registered with the FDA under section 510 of the FD&C Act. "Research use only" products, or products produced by establishments which are not registered with the FDA, may not be used for compounding in any circumstance. Per federal regulations, investigational new drugs (INDs) used in approved clinical trials must bear a label with the statement "Caution: New Drug—Limited by Federal (or United States) law to investigational use."[vii] Drugs that are labeled "research use only" **are not** approved for use as INDs.

Ohio Requirements: For pharmacies, clinics, and outsourcing facilities in Ohio, all API must be purchased from Ohio licensed drug distributors. Failure to purchase from an Ohio-licensed company is a violation of Ohio law and may subject the licensee to administrative sanctions.

OAC 4729:5-3-04 and 4729:6-3-04 require verification of your seller on an annual basis. Verification may be conducted using Ohio's eLicense system: https://elicense.ohio.gov/

USE OF SALT FORMS PROHIBITED: Ozempic®, Wegovy®, and Rybelsus® contain semaglutide base – not a salt form. Mounjaro® and Zepbound® contain tirzepatide base – not a salt form. Therefore, only the base is a component of an FDA-approved human drug product. The salt forms are different active ingredients than those used in FDA-approved drugs, and do not meet FD&C Act requirements for compounding.

Q7) Is adding another commercially available drug, such as B12, still considered compounding a commercially available drug product?

FDA considers a compounded drug product to be essentially a copy of a commercially available drug product 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 if the commercially available drug products can be used (regardless of how they are labeled) by the same route of administration prescribed for the compounded drug, unless there is documentation as described in Q4 of this document.

Such drug products present the same kinds of concerns as drug products that have a single API and, in some respects, may be more dangerous because of the potential for unintended drug interactions or formulation issues. For example, if drug X and drug Y are commercially available oral drug products, FDA generally intends to consider a compounded oral drug product that combines drug X and drug Y in strengths that are within 10% of the strengths of the respective commercially available products to be essentially a copy of the commercially available drug product, unless a prescriber determination of a significant difference has been documented.[viii]

[i] On March 5, 2025, the district court denied the plaintiffs' preliminary injunction motion in Outsourcing Facilities Association v. FDA, 4:24-cv-00953 (N.D. Tex.).

For a state-licensed pharmacy or physician compounding under section 503A of the FD&C Act until February 18, 2025, or until the date of the district court's decision on the plaintiffs' preliminary injunction motion in Outsourcing Facilities Association (OFA) v. FDA (N.D. Tex.), whichever is longer.

For outsourcing facilities under section 503B until March 19, 2025, or until the date of the district court's decision on the plaintiffs' preliminary injunction motion in OFA v. FDA, whichever is longer. (Source)

[ii] On April 24, 2025, the district court denied the plaintiffs' preliminary injunction motion in Outsourcing Facilities Association v. FDA, 4:25-cv-00174 (N.D. Tex.) regarding compounded semaglutide. Therefore, consistent with FDA's March 10, 2025, update:

For a state-licensed pharmacy or physician compounding, dispensing or distributing semaglutide injection products under section 503A of the FD&C Act, the period of enforcement discretion (described below) has ended.

For outsourcing facilities compounding, distributing or dispensing semaglutide injection products under section 503B, FDA does not intend to take action for violations of the FD&C Act arising from conditions that depend on semaglutide injection products' inclusion on FDA's drug shortage list until May 22, 2025. (Source)

[iii] See Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act: https://www.fda.gov/media/98973/download?attachment

[iv] 21 U.S. Code § 353a

[v] Ohio Administrative Code 4729:7-2, 4729:7-3; Ohio Revised Code 4729.57

[vi] See Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act: https://www.fda.gov/media/98973/download?attachment

[vii] 21 CFR § 312.6

[viii] See Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act: https://www.fda.gov/media/98973/download?attachment