

Quick Reference Guide for Pharmacists: Answering Questions About Compounded GLP-1s

AUDIENCE: PHARMACISTS IN RETAIL, HOSPITAL, AND COMPOUNDING SETTINGS

PURPOSE: EQUIP PHARMACISTS TO RESPOND PROFESSIONALLY TO PRESCRIBERS, NURSES, AND PATIENTS ASKING ABOUT LEGALITY, SAFETY, AND APPROPRIATENESS OF COMPOUNDED GLP-1s



Common Question #1:

Can I prescribe compounded GLP-1s like semaglutide or tirzepatide for my patient?

The FDA ended its enforcement discretion for compounding GLP-1s earlier this year. This means routine compounding of semaglutide or tirzepatide that copies Ozempic®, Wegovy®, Zepbound®, or Mounjaro® is no longer permitted. However, patients may find compounding facilities preparing it.

Compounding is only allowed for patient-specific medical needs—such as documented allergies to excipients or unique dosing requirements. In these cases patients should obtain a prescription from their doctor and fill the prescription at a state-licensed pharmacy or visit FDA's [BeSafeRx](#) campaign for resources to safely fill prescription medicines online.

Key Points to Emphasize:

- 503A pharmacies: Enforcement discretion ended April 22, 2025
- 503B outsourcing facilities: Enforcement discretion ended May 22, 2025
- Medical necessity for compounded GLP-1s must be documented and justified when prescribed

Common Question #2:

Is it safe to use compounded GLP-1s?

Compounded GLP-1s are not FDA-approved and may carry risks. They do not undergo FDA's review for safety, effectiveness and quality before they are marketed. The FDA has reported over 1,000 adverse events—including hospitalizations and deaths—linked to compounded GLP-1s. Safety depends on the source, formulation, and compounding practices. Only pharmacies following strict safety and sterility protocols should be considered. Unfortunately, the general public and even health care professionals do not know if these compounding pharmacies are compliant with US compounding standards making

it difficult to differentiate between compliant facilities and non-compliant compounding facilities.

Additionally, understanding all the compounding standards to make an informed decision about a facility is complex. Below we have provided a safety & legality checklist, and as you will see, some of the items are difficult to evaluate.

Key Safety Risks to Mention:

- Improper cold storage during shipping
- Use of salt forms (e.g., semaglutide sodium) instead of base
- Counterfeit or contaminated APIs from unregistered foreign suppliers
- Incorrect dosing or absence of active ingredient
- No FDA oversight or standardized labeling

Common Question #3:

Can we compound GLP-1s for weight loss patients who can't afford branded drugs?

Cost alone doesn't justify compounding. The FDA now considers the shortages resolved, so compounding for affordability or convenience is not permitted. Patients should be directed to manufacturer savings programs or alternative therapies. The cost of these medications have significantly decreased within the past year.

Tips for Pharmacists

- Stay factual and calm — avoid speculation or emotional responses
- Refer to FDA guidance when in doubt: [FDA GLP-1 Policy Update](#)
- Educate prescribers and nurses on the risks of non-FDA-approved GLP-1s





Compounded GLP-1 Safety & Legality Checklist

Use this checklist to assess whether compounded GLP-1s are appropriate, compliant, and safe for use.

Legal & Regulatory Compliance

- [] Is the GLP-1 being compounded for a documented medical need (e.g., allergy, non-standard dose)?
- [] Is the shortage officially resolved (FDA says yes as of 2025)?
- [] Is the prescriber aware that routine compounding is no longer permitted?
- [] Is the pharmacy 503A or 503B compliant and following FDA guidance?

Ingredient Verification

- [] Is the GLP-1 in its base form (not salt form like semaglutide sodium or acetate)?
- [] Is the API sourced from an FDA-registered supplier and on the [FDA Green List](#)?
- [] Has the pharmacy verified purity, potency, and sterility of the ingredient?

Compounding Process

- [] Is the formulation prepared using a validated MFR (Master Formula Record)?
- [] Are dose calculations independently verified?
- [] Is the product clearly labeled with concentration, expiration, and patient-specific instructions?
- [] Is the compounding environment certified and monitored (e.g., ISO Class 5 PEC)?
- [] Are CAPA procedures in place for deviations or out-of-spec results?

Prescriber & Patient Communication

- [] Has the prescriber been informed of FDA restrictions and risks?
- [] Has the patient been counseled that this is not an FDA-approved product?
- [] Are patients aware of potential risks (e.g., dosing errors, contamination)?
- [] Is documentation of the conversation included in the patient record?

Documentation & Audit Readiness

- [] Is the compounding batch traceable to source materials and personnel?
- [] Are certification reports available and interpreted correctly?
- [] Is the pharmacy prepared for FDA or state board inspection?