

Compounded Alternatives to Injectable Semaglutide

Below is an explanation as to why we are able to currently dispense compounded injectable Semaglutide when it appears on the FDA's drug shortage list.

Recent Federal Guidance has been released in which smaller 503A Compounding Pharmacies (**Porter's Pharmacy**) are allowed to purchase Compounded Injectable Semaglutide from larger 503B Compounding Pharmacies and dispense it directly to patients pursuant to a prescription when commercial Semaglutide is on the FDA's drug shortage list. **Please refer to the following to differentiate 503A / 503B pharmacies:**

THE DIFFERENCE BETWEEN 503A and 503B COMPOUNDING PHARMACIES

- *The FDA has designated 503A compounding pharmacies as those that compound prescriptions for specific patients and are required by state boards of pharmacy to comply with USP and other guidelines.*
- *The FDA has designated 503B compounding pharmacies as those with outsourcing facilities that may manufacture large batches of compounds with or without prescriptions to be sold to healthcare facilities for office use only.*
- Unlike a 503A pharmacy, 503B compounding pharmacies must validate every process according to CGMP.
- 503A pharmacies must comply with USP <795> and <797> along with state board of pharmacy regulations. Beyond Use Dating (BUD) may be assigned based on internal or external scientific literature showing stability.
- 503B pharmacies must comply with USP <795> and <797> along with state board of pharmacy regulations and 21 CFR Part 210 and 211 (CGMP), among several other regulations and guidelines.

Because Injectable Semaglutide federal guidance is new, Porter's Pharmacy has hired a nationally recognized specialized Pharmaceutical Compounding Attorney to provide us with legal advice on the matter.

With Porter's being a **PCAB Accredited 503A Pharmacy**, his advised counsel is that we could purchase compounded Injectable Semaglutide from larger 503b pharmacies and **dispense it when it appears on the FDA's drug shortage list.**

We can dispense Injectable Semaglutide directly to patients pursuant to a prescription in the three states we are licensed: Pennsylvania /Ohio / West Virginia



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He has also supplied us with a Standard Operating Procedure and process of how to identify and evaluate reputable 503B Compounding Pharmacies that meet all qualifying standards from which we could be able to secure Injectable Semaglutide.

***Porter's Pharmacy has identified a qualified 503B Pharmacy source to provide us compounded Injectable Semaglutide**



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