

GUIDANCE REGARDING SEMAGLUTIDE-BASED MEDICATIONS FROM THE MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

The Board recognizes that Type 2 Diabetes and obesity are two of the most serious public health problems facing our state. The potential benefits for many Mississippi patients of new semaglutide-based medications like Ozempic® and Wegovy® are obvious.¹ However, because these drugs are in high demand and short supply, some providers have turned to the use of compounded versions that are represented to be safe substitutes for the patented drugs, but which are unproven. Public safety requires that the Board emphasize three points concerning this issue:

1. The off-label use of semaglutide-based legend drugs is prohibited by Board regulation;²
2. Compounded semaglutide products likely use as Active Pharmaceutical Ingredients (APIs) salt forms of semaglutide, chemically synthesized versions, or research-grade ingredients not intended for human use. Such APIs have not been proven to be safe and effective substitutes or equivalents for the patented drugs;
3. The Board strongly advises medical licensees to refrain from prescribing, dispensing, or administering any compounded semaglutide until further notice.

Ozempic® and Wegovy® are currently listed on the Food and Drug Administration (FDA) "shortage list." Generally, when a drug appears on the shortage list, compounded drugs can be made and distributed with fewer restrictions. However, the listing of Ozempic® and Wegovy® does not change the high standards for quality of ingredients and sanitary manufacturing conditions with which compounders must comply.

Board regulations prohibit off-label use of any non-FDA-approved medication solely for the purpose of weight loss. On March 22, 2023, the Board passed an emergency rule to permit waivers to be granted for the off-label use of diet medications on a per-medication or class of medications basis. The Board then granted an emergency waiver or exemption for Semaglutide-based legend drugs until July 1, 2023.³ However, since that time the Board has received additional information on this issue from various sources, including the Food and Drug Administration (FDA) and the Mississippi Board of Pharmacy. Therefore, on July 27, 2023 the Board RESCINDED the exemption permitting off-label use

¹ Saxenda® (liraglutide) is also FDA-approved for weight loss. Other non-semaglutide based medications showing promise for these conditions are also becoming available, such as Mounjaro™ (tirzepatide).

² See Part 2640, Chapter 1, Rule 1.5(F). "Off-label use of any medication that does not have Food and Drug Administration approval for use in the treatment of weight loss is prohibited if administered solely for the purpose of weight loss."

³ On April 18, 2023, after the Board received information from the Mississippi Board of Pharmacy expressing concerns about the safety of compounded semaglutide based on FDA publications, the Executive Director emailed to all Board licensees a memorandum prepared by the Pharmacy Board and distributed to Mississippi pharmacists. That memo outlined problems with the use of semaglutide salt forms as APIs for compounding purposes.

of semaglutide-based medications, and REJECTED a new request for a waiver specifically authorizing the use of compounded semaglutide.⁴

Ozempic®, Wegovy®, Mounjaro™ and similar medications are already becoming important tools for treating and managing Type 2 Diabetes and obesity. However, the use of unproven and potentially unsafe compounded versions of these patented medications cannot be condoned by the Board under current circumstances.

CONCLUSION

1. Currently Wegovy® (semaglutide) and Saxenda® (liraglutide) are the only peptides approved by the FDA for weight loss. The off-label use of peptide-based legend drugs solely for weight loss is prohibited;
2. Compounded semaglutide products have not been proven to be safe and effective substitutes or equivalents for the patented drugs;
3. Licensees are advised to refrain from prescribing, dispensing, or administering compounded semaglutide at this time.



Kenneth E. Cleveland, M.D.
Executive Director
MISSISSIPPI STATE BOARD
OF MEDICAL LICENSURE



CC: All Board Licensees

⁴ On July 27, 2023, the Board was asked to grant a waiver for compounded semaglutide. Susan McCoy, the Executive Director of the Mississippi Board of Pharmacy, appeared and provided current information concerning compounded semaglutides. The available compounded versions are likely being made with salt forms of semaglutide, chemically synthesized versions, or research-grade ingredients not intended for use in humans. Research-grade materials are not subject to the same strict manufacturing regulations as pharmaceutical-grade APIs, nor are they intended for human use. Director McCoy advised that the substitute ingredients, manufactured in China, have not been proven to be legitimate, effective, or manufactured under sanitary conditions. At least some such products appear to have been originally labeled as research-grade drugs and then relabeled as pharmaceutical grade after they were imported into the United States. Further, some compounding pharmacies appear to be using misleading or inaccurate information in their advertising. At least one out-of-state pharmacy actively marketing compounded semaglutide to Mississippi physicians has ever had a Mississippi compounding certificate, and therefore cannot legally sell any compounded products in this state. The video from July 27 Board meeting is available at: <https://www.youtube.com/live/PaXqYWd2In0?si=G0LwcbzHHr3W1ve4&t=1976> The waiver request, comments, and discussion of this issue begin at the 21:20 mark.