SUPPLEMENTAL GUIDANCE REGARDING
GLP-1 and GIP MEDICATIONS

FROM THE MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE, ISSUED AUGUST 6, 2024

APPLICABILITY

This Supplemental Guidance Regarding GLP-1- And GIP Medications updates the previous Guidance Regarding Semaglutide-Based Medications, issued by the Mississippi State Board of Medical Licensure on August 28, 2023, and supersedes the previous Guidance to the extent any conflict exists.

EXEMPTION FOR CERTAIN COMPOUNDED GLP-1 AND GIP MEDICATIONS APPROVED

Based on updated information, at its meeting on July 17, 2024, the Mississippi State Board of Medical Licensure unanimously voted to grant a request for a limited waiver or exemption from the FDA requirements contained in Part 2640, Chapter 1, Rule 1.5(F) for certain compounded versions of GLP-1 and GIP medications. **The exemption applies only if the following terms and conditions are met:**

1. The FDA approval requirements in Rule 1.5(F) shall not apply to compounded versions of GLP-1 and GIP drug classes in two situations: (1) a patient has a specific clinical need that is not met by a commercially available product or (2) the specific medication is currently on the FDA's Drug Shortages List, AND

2. If ANY compounded GLP-1 or GIP drugs are administered or dispensed, the licensee has a duty to confirm that the pharmacy supplying the compounded medications has either obtained the active pharmaceutical ingredient (API) from a US based re-packager or wholesaler that has performed API verification testing to confirm the supplied certificate of analysis (COA), or the supplying pharmacy has independently performed API verification testing to confirm the supplier's COA

A copy of the Board Order approving the exemption is attached hereto.

The first condition may be met by documenting in the patient's medical records that one of the two circumstances under which a compounded version of a legend drug may be produced (specific clinic need or appearance on the FDA Drug Shortages List) exists. The second condition may be met by a licensee obtaining documentation from the wholesaler or supplying pharmacy confirming that proper chemical analysis and API verification testing has been performed. The Board strongly advises that licensees maintain copies of the COA and verification documentation in their records.

The FDA does not approve any compounded drug products. Therefore, the restriction on off-label use for the purpose of weight loss does not apply to compounded versions of GLP-1 and GIP based medications that qualify for the exemption.

Despite the creation of this exemption, Licensees must remain vigilant, as untested and unsafe APIs will undoubtedly remain available on the black or gray markets. This includes both unconfirmed and untested versions of base APIs as well as salt-forms which are not equivalent to base APIs. The Board cannot and does not condone the use of unproven and potentially unsafe versions of any compounded GLP-1 or GIP medications obtained from a source that cannot provide the requisite verification and documentation.

CONCLUSION

1. Compounded versions of GLP-1 and GIP medications may be used without violating Board regulations if a specific clinical need exists or if the medication appears on the FDA Drug Shortages List; and

2. Licensees obtain and maintain COA and API verification testing documentation for any such compounded medications prescribed, administered, or dispensed;

3. Prescribing, dispensing, or administering any compounded GLP-1 or GIP medication **that does not qualify for the exemption** would violate Board regulations, specifically Part 2640, Chapter 1, Rule 1.5(F).

KENNETH E. CLEVELAND, MD
EXECUTIVE DIRECTOR

MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

BEFORE THE MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

ORDER

THIS MATTER comes before the Mississippi Board of Medical Licensure Board (Board) as a request for a waiver exempting Glucagon-like Peptide-1 (GLP-1) Receptor Agonist and Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Drug Classes from the requirements of Part 2640 Chapter 1: Rules Pertaining to Prescribing, Administering and Dispensing of Medication Rule 1.5(f) under certain circumstances. Board Rule 1.5(f) states:

> A licensee must not utilize a schedule III, IV or V controlled substance or legend drug for purposes of weight loss unless it has an FDA approved indication for this purpose and then only in accordance with all of the above enumerated conditions. The purpose of this rule is to prohibit the use of such drugs as diuretics and thyroid medications for the sole purpose of weight loss.
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> 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. Thyroid hormone, diuretics, vitamin B12, B1, B2, B6, methionine, choline, inositol, chromium picolate and human chorionic gonadotropin are examples of medications that may not be used in this manner. This prohibition does not apply to FDA categories of nutritional supplements sold without prescription.
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> Licensees may request the Board waive the FDA requirements set forth in Rule 1.5(F) on a per-medication or class of medications basis, for good cause. Temporary waiver may be approved by the Executive Director until the request can be heard before the Board
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Edra S. Kimmel, MD (License #15452) personally appeared before the Board and presented the request. Todd Dear, Associate Director of the Mississippi Board of

Pharmacy, also personally appeared and provided information to the Board concerning the use of compounded versions of GLP-1 and GIP medications.

After consideration and discussion, the Board unanimously voted to approve the waiver request and issues the following **FINDINGS OF FACT AND CONCLUSIONS OF LAW:**

Good cause exists for the Board to grant a limited waiver of the FDA requirements set forth in Rule 1.5(F), specifically exempting compounded versions of Glucagon-like Peptide-1 (GLP-1) Receptor Agonist and Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Drug Classes under the following terms and conditions:

1. The FDA approval requirements in Rule 1.5(F) shall not apply to compounded versions of GLP-1 and GIP drug classes in two situations: (1) a patient has a specific clinical need that is not met by a commercially available product or (2) the specific medication is currently on the FDA's Drug Shortages List.

2. If ANY compounded GLP-1 or GIP drugs are administered or dispensed, the licensee has a duty to confirm that the pharmacy supplying the compounded medications has either obtained the active pharmaceutical ingredient (API) from a US based re-packager or wholesaler that has performed API verification testing to confirm the supplied certificate of analysis (COA), or the supplying pharmacy has independently performed API verification testing to confirm the supplier's COA.

SO ORDERED, this the 17th day of July 2024.

MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

BY: Michelle Y. Owens
MICHELLE Y. OWENS, M.D.
PRESIDENT