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NEW JERSEY STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Statement Concerning Semaglutide Compounding

New Jersey State Board of Pharmacy staff has received inquiries concerning compounding of semaglutide. Semaglutide is, of course, a commercially available drug product marketed as Ozempic® for treatment of diabetes and as Wegovy® for weight loss.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) prohibits pharmacies from compounding "drug products that are essentially copies of a commercially available drug product." (FD&C Act §503A(b)(1)(D)). In general, then, compounding pharmacies may not compound semaglutide, a commercially available drug product.

Board regulations address this topic in New Jersey Administrative Code (N.J.A.C.) 13:39-11.25 Prohibited Compounding:

a) A pharmacist shall not compound preparations that contain drug products that appear on the Federal Food and Drug Administration's List of Drug Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness, codified at 21 CFR 216.24.

b) A pharmacist shall not compound any commercially available drug products unless:

1) The commercially available product is modified to produce a significant difference, in the professional judgment of the prescriber, between the compounded product for the patient and the comparable commercially available product; or

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2) The commercially available product is not available from normal distribution channels in a timely manner to meet the patient's needs, and the dispensing of the compounded product has been approved by the prescriber and the patient.

c) A pharmacist who compounds a commercially available product consistent with the requirements of (b) above shall maintain documentation of the reason for such compounding.

When Is Compounding of Semaglutide Permissible?

Food and Drug Administration (FDA) does not consider a drug to be "commercially available" if it appears on FDA's shortage list. Ozempic and Wegovy have, at times, appeared on the shortage list. On April 27, 2023, FDA officials clarified that a drug is considered in shortage by FDA if it is listed at the above site and its "status" is described as "currently in shortage." As is true of all drug products, pharmacists and pharmacies should regularly monitor FDA's shortage list at the link above to determine semaglutide's shortage status.

The FD&C Act also states that a compounded drug product is not "essentially a copy" of a commercially available drug product if a change is made for an identified individual patient and the prescribing practitioner has determined that the change will produce a significant difference **for that patient.** (FD&C Act §503A(b)(2)). FDA has explained:

> However, if a prescription identifies only a patient name and drug product formulation, this would not be sufficient to establish that the prescriber made the determination described by section 503A(b)(2). Note also that the significant benefit that the prescriber identifies must be produced by the change the compounder will make to a commercially available drug product (i.e., a change in drug product formulation). Other factors, such as a lower price, are not sufficient to establish that the compounded drug product is not essentially a copy of the commercially available drug product.

Source: *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act,* pp. 8-9.

Adding additional substances to a compounded product that is otherwise an essential copy of a commercially available drug product is **not** included in FDA's list of circumstances meeting Section 503A(b)(2)'s requirements.

If/When Compounding of Semaglutide Is Permissible, How Must It Be Performed?

If and when compounding of a semaglutide drug product is allowed under the terms of the FD&C Act, pharmacists should be aware that substances used to compound must: (1) comply

with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, be components of drugs approved by the Secretary [of HHS]; or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary [of HHS], appear on a list developed by the Secretary through regulation. (FD&C Act §503A(b)(1)(A)(i)).

With respect to semaglutide:

(1) There is no USP or NF monograph for semaglutide.

(2) Ozempic and Wegovy contain semaglutide **base.** Hence, only the base is a component of an FDA-approved drug. **No salt form of semaglutide is contained in an FDA-approved drug.**

(3) Semaglutide does not – in any form – appear on FDA's "bulks list" for compounding. (Section 503A Bulks List Final Rule Questions and Answers). So, for this separate and independent reason, no salt form of semaglutide may be used in a compounded drug product.

Even if a pharmacy obtained semaglutide **base** for potential compounding use, the pharmacy must ensure that the active pharmaceutical ingredient (API) received is a pharmaceutical grade product, accompanied by a valid certificate of analysis, and is sourced from an establishment registered with FDA under Section 510 of the FD&C Act. (FD&C Act §503A(b)(1)(A)(ii) – (iii)). Board staff is aware that some "wholesalers" are offering "research use only" products and /or products produced by establishments not registered with FDA. These may not be used for compounding in any circumstance.

The Bottom Line

Compounding of a commercially available product is allowable only in certain narrow circumstances described above. Even when compounding of a semaglutide drug product is allowable under the FD&C Act, the use of semaglutide salts, the use of any non-pharmaceutical grade API, or one not produced by an FDA-registered establishment, is prohibited.

Compounding semaglutide drug product in a way that fails to conform with governing law may lead to enforcement action by FDA and/or the Board.

Pharmacies should be aware that pharmaceutical manufacturers may choose to initiate their own legal proceedings against prescribers and compounders to combat illegal semaglutide drug product compounding.

Criteria for Determining Whether or Not to Fill a Prescription for a Patient

This guidance is intended to advise pharmacists of their professional responsibility to evaluate each individual patient's needs and circumstances when deciding whether to fill a prescription.

On occasion, the Board is asked to respond to inquiries from patients who experienced challenges attempting to get their prescriptions filled. They may not fully comprehend that pharmacists have a "corresponding responsibility" to ensure that a prescription is issued for a legitimate medical purpose by an individual prescriber acting in the usual course of their professional practice, as required by Code of Federal Regulations (CFR) 1306.04, or that pharmacists "have the right to refuse to fill a prescription if, in [their] professional judgment, the prescription is outside the scope of practice of the practitioner; or if the pharmacist has sufficient reason to question the validity of the prescription; or to protect the health and welfare of the patient," per N.J.A.C. 13:39-7.13.

Pharmacists must ensure that when carrying out corresponding responsibility they are both diligent and logical in investigating and determining the legitimacy and medical purpose of a given prescription for a given patient. A pharmacist's exercise of professional judgment must strike a balance between the corresponding responsibility doctrine and the statutory obligation to fill lawful prescriptions without undue delay found in New Jersey Statutes Annotated 45:14-67.1.

A determination to not fill a prescription should be made only after a fair and balanced process of fact-finding so that the health and welfare interests of the patient and your exercise of corresponding responsibility and professional judgment are clearly and truly aligned. While a check of the prescription monitoring program database may preliminarily indicate a possible pattern of questionable medication use, additional fact-finding may be appropriate and necessary, such as:

- speaking with the patient or patient's representative;
- speaking with the physician; and
- obtaining input from other pharmacy staff who may be familiar with the patient.

Inclusion of these elements in your decision making will benefit you and the patient you are serving.

Naloxone Pilot Program Update

The Board-approved New Jersey Department of Human Services **Naloxone365 Pilot Program** made significant progress last year. Started on January 10, 2023, 66 pharmacies submitted agreements to participate in the pilot program by the end of January. As of January 23, 2023, a total of 279 prescriptions had been filled anonymously. The pilot program was initially limited to the prescription version of naloxone nasal spray, but was expanded in September to also include the over-the-counter version of this lifesaving medication, which had recently been approved by FDA. Now, a year after the Naloxone365 Pilot Program launched, the number of participating pharmacies continues to grow. As of January 22, 2024, there were 669 participating pharmacies that had anonymously dispensed 68,024 naloxone nasal spray prescriptions at no cost to patients.

- Participating pharmacies are located here: Department of Human Services (nj.gov).
- Any New Jersey pharmacy wishing to participate in the program may do so by following these instructions: *Naloxone-Pilot-Program-Agreement.pdf (njconsumeraffairs.gov).*

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