Alliance for Pharmacy Compounding

Compounding the Joy of Living®

May 28, 2024

Kenneth Cleveland, MD
Executive Director
Mississippi State Board of Medical Licensure
1867 Crane Ridge Drive Suite 200-B
Jackson, MS 39216

Dear Director Cleveland and Members of the Board:

On behalf of the Alliance for Pharmacy Compounding, I am writing to provide accurate information on the essential role that compounding plays in serving patients in your state and to ask that you reconsider your restriction on the prescribing of GLP-1 drugs for weight loss.

We recently became aware of a presentation given to the Mississippi Board of Medical Licensure in July 2023 regarding compounded semaglutide. That presentation unfortunately resulted in the Board withdrawing a waiver that allowed for off-label prescribing of GLP-1 drugs for weight loss.

With 72.8 percent of Mississippi residents categorized as overweight or obese – and with accompanying high numbers of patients with diabetes – limiting patient access to these therapies, both as manufactured drug products and/or compounded preparations, is concerning. Physicians and other prescribers in your state need to be able to use these medications to serve the needs of their patients. The decision has impaired the ability of physicians to treat patients in Mississippi suffering from diabetes and obesity.

We are concerned about some of the information on compounding that was presented to the Board in the July 2023 presentation and want to offer an overview of the regulatory structure for compounding of human drugs.

Compounding of human medications is authorized in federal and state law. When a state-licensed pharmacy receives a prescription for a compounded medication from a licensed provider, a determination must be made as to whether the active ingredients that is prescribed to be used in the human compound meets one of three criteria:

1. Is it an active ingredient in an FDA-approved drug product? (Listed in FDA's Orange Book)
2. Does it have a USP or National Formulary drug monograph?[1]

[1] Semaglutide does not have a USP or NF monograph.

3. Does it appear on the Section 503A Bulks List (or 503A Interim Bulks List, Category 1) published by FDA?[2]

As you know, both semaglutide and tirzepatide are components of FDA-approved drug products.

Statements published by the FDA in 2023 and subsequently by some boards of pharmacy regarded the compounding of semaglutide *sodium,* an unauthorized substance. At present, semaglutide base (the active ingredient in the FDA approved drug products) is readily available from FDA-registered facilities, and thus no pharmacy has any reason to use the sodium form.[3]

During times of drug shortages, compounders, as both 503A and 503B facilities, can work to meet these needs until the shortage can be resolved. Semaglutide injection has been listed continuously on the FDA's drug shortage list since March 2022, making it eligible for compounding under FDA's "essentially a copy" guidance.

Under that FDA Guidance, the ability of compounding pharmacies to prepare copies of FDA-approved drugs in shortage is not a loophole. It's an essential strategy for assuring patient access to necessary medications when drug manufacturers have supply chain interruptions. That ability existed before GLP-1s and has no doubt saved countless lives. For instance, just last year, with amoxicillin suspension in shortage – essential for some pediatric patients – 28% of compounding pharmacies across the nation compounded that drug to assure children could be treated.

We urge the Board to reconsider and reinstate the waiver allowing physicians and other providers in your state to prescribe GLP-1 drugs available as both manufactured drugs and compounded medications for weight loss. In doing so, physicians and prescribers can meet the needs of Mississippi patients.

Thank you for your attention to these matters. APC would appreciate the opportunity to discuss all these topics further with you. We hope to serve as a resource to you on any topic related to compounding in the future.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
scott@a4pc.org

[2] FDA is currently evaluating specific additional substances for inclusion on the 503A bulks list and has stated that compounding with them is acceptable in this interim period until the agency finalizes its review of those substances.

[3] Under state and federal law, pharmacists have a responsibility to make sure that any API used in a compounded preparation meets the criteria for compounding and comes from an FDA-registered supplier with a valid certificate of analysis. Research- or laboratory-grade active ingredients should never be used in a compounded preparation.