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Alliance for Pharmacy Compounding

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February 19, 2026

VIA ELECTRONIC MAIL: pharmbd@dhp.virginia.gov

Caroline D. Juran, Executive Director
Virginia Board of Pharmacy
Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

RE: Compounding of GLP-1 drug products

Dear Ms. Juran:

The Alliance for Pharmacy Compounding ("APC") is a national trade association advocating on behalf of millions of patients who benefit from compounded medications. APC's more than 5,000 members, located in all 50 states, include compounding pharmacists, pharmacy technicians, educators, students, researchers, and suppliers. APC is the voice for state-licensed compounding pharmacies ("503A pharmacies") and registered outsourcing facilities ("503B outsourcing facilities") throughout the country and works to ensure the availability of – and access to – customized medications for patients for whom manufactured drugs are not suited.

It has come to our attention that the Virginia Board of Pharmacy has begun issuing complaints to pharmacies or declining to process their license applications due to concerns they are compounding inordinate amounts of essentially copies of commercially available GLP-1 drug products. This is concerning, as it is our understanding that the pharmacies at issue have provided the Board with patient-specific prescriptions that document the prescribers' determinations that there is a change, made for an identified individual patient, which produces, for that patient a significant difference from the commercially available drug product. As such, the Board's actions appear to depart from the formal guidance issued by the FDA concerning compounding drug products that are essentially copies of commercially available drug products.

In its January 2018 Guidance for Industry, titled, "Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Sections 503A of the Federal Food Drug and Cosmetic Act," the FDA stated that it does not consider a compounded drug product to be essentially a copy of a commercially available drug product if "a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product." The FDA further explained,

> FDA does not believe that a particular format is needed to document the determination, provided that the prescription makes clear that the prescriber identified the relevant change and the significant difference that the change will produce for the patient. . . .
>
> It is not possible to offer exhaustive guidance about when a difference will be "significant" to an identified individual patient. At this time, FDA generally does not intend to question prescriber determinations that are documented in a prescription or notation. However, we do intend to consider whether a prescription or notation relied upon by a compounder to establish that a drug is not essentially a copy documents that the determination was made.
>
> If the compounder produces drugs in anticipation of receiving valid prescriptions for identified individual patients, and the compounder obtains the statement of significant difference from the prescriber when it receives the prescription for the compounded drug, prior to distribution, FDA does not intend to consider the compounded drug that is then distributed to be essentially a copy. [1]

We note that Va. Code § 54.1-3410.2.H, subsection 2, similarly provides as follows:

> H. Pharmacists shall not engage in the following:
> . . .
> 2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include **(i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient,** (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) the compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, or **(v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product**. (Emphasis added).

On behalf of APC and its members, I am writing to obtain clarification of the Virginia Board of Pharmacy's positions with respect to the compounding of GLP-1 products. Specifically,

[1] Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Sections 503A of the Federal Food Drug and Cosmetic Act: Guidance for Industry; January 2018; https://www.fda.gov/media/98973/download.

1. Does the Board follow the FDA's "essentially copies" guidance referenced above, or does it apply a different standard?

2. How does the Board interpret Va. Code § 54.1-3410.2.H, subsection 2? Specifically, how does the Board define the relevant phrases "inordinate amounts" and "essentially copies of commercially available drug products?" What does the Board consider to be an "inordinate amount" and is that standard documented in a Virginia statute, rule, regulation, or guidance document?

3. How does the Board interpret Va. Code § 54.1-3410.2.H, subsection 2(i), especially the relevant phrase "a change in the product ordered by the prescriber for an individual patient?"

4. How does the Board interpret Va. Code § 54.1-3410.2.H, subsection 2(v), especially the relevant phrase "the mixing of two or more commercially available products regardless of whether the end product is a commercially available product?"

5. What is the Board's position regarding compounding of GLP-1 products by pharmacies licensed in Virginia that are not otherwise included in items 1 through 3 above?

Thank you for your attention to the inquiries above, which are important to APC's members as they seek to ensure that they remain fully compliant with Virginia laws and regulations related to compounded medications. We ask that you provide a copy of this inquiry to members of the Virginia Board of Pharmacy.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer