Alliance for Pharmacy Compounding

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April 22, 2024

David Sencabaugh, R.Ph.
Executive Director
Massachusetts Board of Registration in Pharmacy
250 Washington Street
Boston, MA 02108

Dear Executive Director Sencabaugh and Members of Board of Registration in Pharmacy:

I am writing to provide perspective to the Board on two compounding issues about which we understand the Board has recently expressed concern.

1. The compounding of sublingual forms of semaglutide.
2. 503B outsourcing facilities providing compounded medications to 503A pharmacies for dispensing.

As you may know, the Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 500 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.

Compounding sublingual forms of semaglutide

Massachusetts Board of Registration Policy 2020-02 states that the Board intends to follow FDA Guidance regarding circumstances under which a 503A compounding pharmacy can compound "essentially a copy" of an FDA-approved product. The guidance provides three criteria for determining if a human compounded medication is a copy of a commercially available drug product:

- The compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product;
- The API(s) have the same, similar, or an easily substitutable dosage strength; and
- The commercially available drug product can be used by the same route of administration as prescribed for the compounded drug.

Compounding a semaglutide sublingual formulation via the crushing of Rybelsus tablets is not creating essentially a copy of an FDA-approved medication, as defined by the FDA guidance; therefore, the guidance is not germane to that practice.

Rather, the compounding of sublingual semaglutide – based on the judgment of the prescriber that a commercially available dosage form and/or dosage strength will not achieve the desired

clinical effect for a patient – is a legitimate compounding practice rooted in the Food, Drug and Cosmetic Act.

In this instance, the commercially available drug product is not indicated for and cannot be used via a sublingual route of administration. The strength of the formulation, which is expressed as mg/ml, is not the same, similar, or easily substitutable dosage strength. The doses written for by prescribers as described to us by our members are not within 10 percent of the dosages offered by the commercially available products. Moreover, following FDA's 503A copies guidance would not result in deeming a sublingual formulation as a copy of the commercially available product.

We also note that although the sublingual formulations in question are not essential copies, the pharmacies that compound a very limited number of these sublingual formulations would not be outside the bounds of FDA's "essentially a copy" guidance in the event that these sublingual preparations were deemed to be copies. FDA's 503A copies guidance discusses the fact that Section 503A of the FDCA prohibits compounding "regularly or in inordinate amounts' of essential copies. The guidance provides enforcement discretion for up to 4 copies compounded in a month*.

503B distributions to 503A for dispensing pursuant to a prescription

In email communication, the Board has recently indicated that resident 503A pharmacies may not order compounded medications for dispensing from 503B outsourcing facilities, even though recent clarifying DRAFT FDA Guidance has signaled that the agency may allow the practice. It is our understanding that the Board does not currently permit non-resident 503A pharmacies, which could order compounded medications from 503B outsourcing facilities for dispensing, to Massachusetts-based patients. The Massachusetts Board permits and inspects resident pharmacies, and in keeping with the Board's mission to protect the public, are better positioned to serve the public by having 503B medications come through those pharmacies that the board regulates.

The interpretation of federal law is another issue too. FDA's draft guidance simply restates what the Federal law has stated since it was first passed in 2013:

> (8) Prohibition on wholesaling. The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. This paragraph **does not prohibit** administration of a drug in a health care setting or **dispensing** a drug pursuant to a prescription executed in accordance with section 503(b)(1). (emphasis added)

In light of these considerations, I wish to request request clarification from the Massachusetts Board regarding the compounding of sublingual semaglutide formulations. I also ask that the Board reconsider its stance on resident 503A pharmacies' ability to dispense compounded preparations sourced from 503B outsourcing facilities so that the medications provided to patients are from facilities and pharmacists that are regulated by this board.

Thank you for your attention to these matters. If APC can serve as a resource on these topics or others related to compounding we would be happy to assist.

I await your response.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
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* From the FDA's Essential Copy Guidance: "To focus enforcement on the most significant cases, as a matter of policy, at this time FDA does not intend to take action against a compounder for compounding a drug product that is a copy of a commercially available drug product regularly or in inordinate amounts if the compounder fills four or fewer prescriptions for the relevant compounded drug product in a calendar month."