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Alliance for Pharmacy Compounding

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Subject: Clarifying Compounding Practices and Prescriber Authority in Response to Eli Lilly's Communication

Director Taylor and Members of the Georgia Board of Nursing:

We write to raise concerns regarding the Eli Lilly letter shared by the Georgia Board of Nursing about compounded tirzepatide products. Disseminating communication from a drugmaker without carefully validating its claims risks lending undue credibility to statements in the letter that are, at best, misleading. It may also inadvertently undermine the authority of licensed prescribers, including nurse practitioners, to make individualized decisions about their patients' treatment plans – decisions about drug therapies that are clearly authorized in law and policy.

Compounding Legality and Prescriber Discretion

Pharmacy compounding is authorized under federal law by Section 503A of the Food, Drug, and Cosmetic Act. It permits state-licensed pharmacies to prepare medications for individual patients based on a valid prescription from a licensed prescriber. These prescriptions may be issued when an FDA-approved product is not commercially available, such as during a drug shortage, or when the prescriber determines that the approved product is not appropriate for a particular patient. In such cases, a compounded preparation may offer a necessary alternative due to differences in strength, formulation, route of administration, or excipients.

Prescribers, including nurse practitioners, are empowered by law to determine when a compounded medication is medically necessary

Compounding plays a well-established role in alleviating supply chain disruptions. When a drug is placed on FDA's drug shortage list, as tirzepatide recently was, certain restrictions on compounding are relaxed to help ensure patient access. Pharmacies and outsourcing facilities may compound shortage drugs in accordance with the applicable provisions of Section 503A or 503B, consistent with FDA policy. As the tirzepatide injection products Mounjauro® and Zepbound® are no longer in shortage, compounding pharmacies can no longer prepare copies of those formulations.

Addressing Mischaracterizations in Lilly's Communication

The letter from Eli Lilly implies that now that the tirzepatide injection shortage has been resolved by FDA, all compounded tirzepatide formulations are unlawful or inappropriate. This is false. While compounded medications are not FDA-approved, that alone does not prohibit their use when prescribed appropriately and prepared by a licensed pharmacist in accordance with applicable standards.

FDA's own guidance on "essentially a copy" clarifies that compounded medications may be prepared when a prescriber determines there is a clinical difference for a patient, even if the active pharmaceutical ingredient is no longer on the FDA's drug shortage list. The agency has stated that it does not intend to question a prescriber's medical judgment in these instances.

Additionally, compounded medications are subject to detailed practice standards under USP <795>, <797>, and <800>, and are regulated by state boards of pharmacy. Licensed pharmacies that follow these requirements are providing customized therapy in accordance with the law and the needs of individual patients.

It is important to recognize that communications like the one issued by Eli Lilly are part of a broader strategy to protect market exclusivity. By forwarding such letters to licensees, regulatory boards may inadvertently convey a one-sided narrative that discounts the legal standing and clinical judgment of nurse practitioners and other licensed prescribers. These actions can have a chilling effect, discouraging appropriate prescribing of compounded medications even when they are both necessary and lawful.

Ensuring Integrity and Accountability in Compounding

Like all areas of health care, compounding must be done responsibly. APC supports appropriate regulatory oversight and disciplinary action when pharmacies or clinics operate outside of legal bounds, such as misrepresenting products or compounding without valid prescriptions.

But this should not be conflated with the legitimate, individualized compounding done in accordance with prescriber instructions and legal requirements. Many patients rely on these services when no suitable commercial option exists, and restricting access can create unintended barriers to care.

Conclusion

We respectfully ask the Georgia Board of Nursing to issue a corrective statement clarifying what law and policy say and disowning misrepresentations of law and policy in the Eli Lilly letter. Statements suggesting that all compounded tirzepatide products are inappropriate or illegal misrepresent the current regulatory framework and may discourage lawful, patient-centered care.

We welcome the opportunity to further engage in constructive dialogue and provide additional educational resources to your members. We encourage boards and agencies to support the rights of prescribers to exercise their clinical discretion under federal and state law. Patients deserve access to individualized treatment options, especially when no FDA-approved alternatives meet their needs.

Sincerely,

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Chief Executive Officer
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The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 600 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.