

Retratrutide Cannot Be Used in Compounding

The Board continues to see instances of pharmacies, clinics, and healthcare providers ordering, compounding, and administering medications containing retatrutide.

Retatrutide <u>cannot</u> be used in compounding under federal and state law. Additionally, it is not a component of an FDA-approved drug and has not been found safe and effective for any condition.

Licensees who have been found compounding, selling, ordering, administering, or otherwise facilitating the distribution of this unapproved drug may be subject to disciplinary action including immediate licensure suspension (also known as a summary suspension).

For more information, please see the following resources:

- FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss
- FDA Letter Retatrutide in Compounded Drug Products

Compliance Resources Available

Board of Pharmacy licensees are required to comply with all state and federal laws and rules. To ensure compliance, the Board developed inspection guides, which can be accessed here: www.pharmacy.ohio.gov/inspection

These guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to maintain compliance.

The guides also include links to the rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

Additionally, the inspection guide page also includes the following sample forms to assist licensees in maintaining compliance:

- DEA Controlled Substance Inventory Form
- Intracompany Transfer or Occasional Wholesale Sale Form
- Non-Controlled Drug Destruction Form

New Epinephrine Autoinjector Resources Available

To assist licensees in complying with Ohio laws regarding the distribution and sale of epinephrine autoinjectors, the Board recently updated/issued the following resources:

- Pharmacy Laws on Epinephrine Autoinjectors (www.pharmacy.ohio.gov/EPI)
- Procurement of Epinephrine Autoinjectors by Schools, Camps, and Qualified

- Entities (www.pharmacy.ohio.gov/EPIprocure)
- Sample Pharmacy Dispensing for Epinephrine Autoinjectors (www.pharmacy.ohio.gov/EPIsample)

State Medical Board of Ohio, Ohio Board of Pharmacy, and Ohio Board of Nursing Issue Joint Regulatory Statement on Retail IV Clinics

In response to the increasing number of retail IV therapy clinics operating in the state, the State Medical Board of Ohio, Ohio Board of Pharmacy, and Ohio Board of Nursing (collectively the "Boards") issued a joint regulatory statement today highlighting critical patient safety concerns and the importance of regulatory compliance in this emerging sector.

The Boards urge all licensed professionals to review their legal responsibilities and confirm compliance with state laws and rules as outlined in the joint regulatory statement. As the practice of retail IV therapy continues to evolve, it is imperative that Ohio healthcare providers uphold the highest standards of practice to safeguard patient health and safety.

A copy of the joint regulatory statement can be accessed by visiting: www.pharmacy.ohio.gov/IVTherapy

Mandatory Electronic Prescribing of Schedule II Controlled Substances: Safe Harbor Provision

Under current law, prescribers are required to issue an electronic prescription when prescribing a Schedule II controlled substance. However, there are also several exceptions which allow them to issue a written prescription.

Please be advised that current law includes a "safe harbor" provision that does not require a terminal distributor of dangerous drugs or pharmacist to verify any exceptions prior to dispensing a written Schedule II controlled substance prescription.

For additional information, the Board published the following guidance document: www.pharmacy.ohio.gov/C2

People call, text, and chat the 988 Lifeline to talk about a lot of emotional needs—not just thoughts of suicide. Whatever your reason, the #988Lifeline is there to help. There is hope.

Ohio Board of Pharmacy Mike DeWine, *Governor* | Steven W. Schierholt, *Executive Director*

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