Ten Common Prescriber Clinic and Medical Spa Violations

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Since the beginning of 2025, the Ohio Board of Pharmacy has summarily suspended more than 30 clinics and medical spas (med spas) after determining there is clear and convincing evidence they pose a danger of immediate and serious harm to others.

To educate current and future licensees, the Board developed this guidance, which highlights ten common violations identified at prescriber clinics and med spas. These examples come directly from citations issued by the Board. To review these citations in detail, visit: www.pharmacy.ohio.gov/Suspend.

This guidance is intended to supplement existing compliance documents including, but not limited to, the following:

- Clinic and Prescriber Office - Inspection Guide
- Prescriber Compounding - Inspection Guide
- Joint Regulatory Statement on the Operation of Retail IV Therapy Clinics in Ohio
- Steps for Detecting Counterfeit Drugs
- Compounding of GLP-1 Drug Products in Ohio
- Reconstituted Neurotoxins & Beyond-Use Dates

Have Questions?

If you have any questions about the operation of your med spa or prescriber clinic, please do not hesitate to reach out to the Ohio Board of Pharmacy by email (contact@pharmacy.ohio.gov) or by phone (614-466-4143). We have a pharmacist on duty Monday-Friday during normal business hours to assist you with any questions or concerns.

Current licensees are also encouraged to contact their local Board inspector. If you do not have that contact information, please call the Board office (614-466-4143) and ask to speak with the Compliance and Enforcement Department.

Common Violation	Compliance Guidance
1. Purchasing from Unlicensed Sellers: All pharmacies, clinics, and other healthcare facilities, even those not licensed by the Ohio Board of Pharmacy, are required by law to purchase from licensed drug distributors (such as wholesalers, manufacturers, and outsourcing facilities) and, with limited exceptions, pharmacies. As a reminder, licensees cannot purchase drugs from the following sources: ▪ Facebook and other social media sites. ▪ Internet sellers, unless they are appropriately licensed with the Ohio Board of Pharmacy. ▪ Other clinics or prescribers, unless both clinics are under the same ownership (this is an intracompany transfer – see OAC 4729:5-3-09) or under specific circumstances, such as the discontinuation of business (see OAC 4729:5-2-04).	To ensure that a terminal distributor of dangerous drugs (TDDD) is purchasing from an authorized seller, OAC 4729:5-3-04 requires the TDDD to verify the seller is licensed by the Ohio Board of Pharmacy prior to initial purchase and then annually thereafter. Verification should be conducted using Ohio's eLicense system and must be documented by the licensee (e.g., saving the license verification electronically from eLicense).
2. Purchasing Medications Marked "For Research Purposes Only (RUO)": No clinic should order, possess, or administer any drugs labeled "for research purposes only" or "not for human or animal consumption of any kind," as these have not been approved for human or animal consumption by the U.S. Food and Drug Administration (FDA).	Any medication indicating "for research purposes only" or other similar statement is unlawful to possess by prescriber clinics and med spas and is both a violation of state and federal law, regardless if the patient "consents." Some common RUO drugs identified by Board inspectors include GLP-1s such as

	retatrutide and cagrilinitde that are not approved for use by the FDA and commercially available GLP-1s, such as semaglutide and tirzepatide. These medications cannot be used in compounding under federal and state law. Additionally, they are not a component of an FDA-approved drug and have not been found safe and effective for any condition. Any drug labeled "for research purposes only" must be disposed of immediately and patients advised to discontinue the medication.
3. Insanitary Preparation of Medications Marked "Unfinished Drug Products" or Active Pharmaceutical Ingredients (API): Some clinics and med spas have been found "reconstituting" unfinished drug products or APIs (e.g., adding bacteriostatic saline) without complying with federal and state laws on drug compounding.	All preparation of unfinished drug products or API is considered compounding and must comply with OAC 4729:7-3 and the applicable USP compounding chapters. This includes, but is not limited to, environmental monitoring, primary engineering controls (e.g., a hood), regular cleaning and disinfection, and personnel and training requirements.
4. Purchasing Non-FDA Approved Medications Including Foreign-Sourced Drugs or Drugs Not Permitted for Compounding: Board inspectors have discovered prescriber clinics and med spas with medications labeled in foreign languages or with labeling indicating the drug is only approved for use in other countries (such as the UK, European Union,	Any medication that is labeled in a foreign language (some case examples include Turkish, Korean, and Chinese) or is labeled "for export only" or "UK only" is a clear indication the drug was purchased outside of legitimate supply chains and is a violation of state and federal law.

Turkey, or South Korea). This is particularly true for neurotoxins such as botulinum toxin. Hyaluronidase (Liporase) is **not** authorized by the Food and Drug Administration (FDA) for use in the United States. Additionally, peptides such as BPC-157 and other bulk drug substances in category 2 and 3 (see FDA guidance) cannot be compounded because it violates federal and state law. Mistletoe extract for injection is **not** authorized by the Food and Drug Administration (FDA) for use in the United States.	Any drugs with foreign labeling or any indication they are intended for foreign markets must be disposed of immediately. This also applies to drugs, devices, and cosmetic products, such as Liporase and peptide injections, which have not been approved for use by the FDA.
5. Failure to Comply with Compounding Standards: Clinics and med spas have been cited for failure to comply with the Board's prescriber compounding requirements. These regulations ensure that compounded drugs are prepared in a sterile environment to prevent bacterial contamination. Some common violations include drawing up or repackaging syringes of compounded or reconstituted drugs for at home administration and failure of a prescriber to verify a compounded drug product prior to administration.	All prescribers engaged in both sterile and non-sterile compounding must comply with the Board's prescriber compounding regulations (OAC 4729:7-3). For more information about prescriber compounding, please review the following inspection guide: Prescriber Compounding - Inspection Guide

6. Failure to Secure Controlled Substances: Licensees have been cited for allowing unlicensed staff (e.g., office assistants, medical assistants, etc.) access to controlled substances maintained by the clinic or med spa.	OAC 4729:5-19-03 prohibits unlicensed persons from having access to controlled substances (both patient-specific and inventory), this includes testosterone. For specific security requirements, see page 24 of the Clinic and Prescriber Office Inspection Guide.
7. Inadequate Record Keeping: Licensees are required to keep records on drugs maintained at the clinic or med spa. Some common examples include failure to implement temperature monitoring for all refrigerators/freezers used to store drugs and inadequate drug inventory records (e.g., drugs received, disposed, or administered).	OAC 4729:5-19-03 requires a licensee to maintain the following for drugs stored in refrigerators and freezers: ▪ Temperature logs with, at a minimum, daily observations; or ▪ A temperature monitoring system capable of detecting and alerting staff of temperature excursions. **NOTE:** Daily observations are required even if the clinic or med spa is closed. This can be achieved via an automated temperature monitoring system. A clinic or prescriber office shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold or transferred pursuant to OAC 4729:5-19-04 For general record keeping requirements, see the Clinic and Prescriber Office Inspection Guide. For compounding record keeping requirements, see page 39 of the Prescriber Compounding - Inspection Guide

8. Patient-Specific Drugs Used as Office-Stock (Pick-Up Station): Clinics and med spas have been cited for using patient-specific drugs dispensed by a pharmacy as office-stock. One such common example includes having pharmacies dispense medications to the clinic in the name of a clinic employee or patient that is then administered to other patients. Other violations include clinics acting as a prescription pick-up station without meeting the requirements in OAC 4729:5-5-14. This includes compounding pharmacies repeatedly shipping patient-specific doses to a clinic or med spa for the same patient without any clear justification as to how this meets the requirements of the rule.	Patient-specific drugs dispensed by a pharmacy are the property of the patient and cannot be administered to other persons. This is a violation of both federal and state law. OAC 4729:5-5-14 states there must be clear and convincing evidence that delivery of a prescription medication directly to the patient would result in danger to public health or to the patient without increased involvement by a health care professional.
9. Labeling Multi-Dose Vials: Inspectors have cited licensees for failure to properly label multi-dose vials with the date opened and/or the beyond-use date. The 28-day limit is based on the tested effectiveness of the antimicrobial preservative in the vial to prevent bacterial growth after repeated needle punctures. Using a vial beyond this date increases the risk of contamination and infection.	OAC 4729:5-19-03 states that upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated. Any unlabeled multi-dose vials must be disposed of immediately.

10. Expired/Adulterated Drugs in Active Drug Stock: Inspections of clinics and med spas found expired and adulterated drugs comingled in the active drug stock. Expired or adulterated drugs must be removed from inventory to prevent administration to patients.	OAC 4729:5-3-06 requires adulterated or expired drugs to be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding, and administration.

IMPORTANT REMINDER: Reconstituted Neurotoxins & Beyond-Use Dates

The reconstitution of neurotoxins (e.g., Botox®, Dysport®, XEOMIN®, etc.) is not considered prescriber compounding under OAC 4729:7-3-02(B)(1) if done in accordance with the manufacturer's labeling.

The beyond-use date for all neurotoxins is determined by the manufacturer's labeling. If the label says, "use within 24 hours," then the product must be used within that timeframe. If no such beyond use date or timeframe exists on the label, the drug may only be used for up to six hours following preparation.

NOTE: Even if the labeling says "should," Board of Pharmacy rules require you to consider that timeframe as a requirement. For example, a label that says "this drug should be used within 24 hours of preparation" means that the drug cannot be administered after that period.

Any neurotoxin administered past the timeframe listed on the manufacturer's labeling is considered a violation of Board of Pharmacy rules and may subject the terminal distributor of dangerous drugs to administrative action.

As a reminder, all neurotoxins prepared by a terminal distributor of dangerous drugs must:

1. Be prepared using aseptic technique and procedures shall be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids.
2. Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug (if not legible), date, and time prepared.