AUGUST 2025

OHIO BOARD OF PHARMACY

Newsletter to Promote Pharmacy and Drug Law Compliance.

From the Director's Desk

Dear Ohio Pharmacists,

Effective January 15, 2027, amendments to Ohio Administrative Code (OAC) 4729:5-5-04 will require, with limited exceptions, that **all Ohio outpatient pharmacies** adopt electronic positive identification as part of the pharmacy's record-keeping system. This means that the rule, once effective, will not permit the use of hard copy records and manual signatures to capture positive identification, except for the following:

- compounding and the dispensation of compounded drugs; and
- ancillary services, as defined in OAC 4729:5-5-02.1.

This change does not impact institutional pharmacies (except those that operate outpatient pharmacies), nonresident pharmacies, and other terminal distributors (emergency medical services, clinics, opioid treatment programs (OTPs), etc). To review the upcoming amendments to the rule, visit *www.pharmacy.ohio.gov/positiveIDchange*.

A waiver of the requirement for electronic positive identification may be granted by the Board upon written request of an outpatient pharmacy. All requests must be submitted in writing using this form. Please note that waivers will not be considered for review until January 1, 2026. Waiver requests submitted prior to this date will not be reviewed.

Thank you for all that you do to keep Ohioans safe and healthy.

Sincerely,

Steven W. Schierholt, Esq
Executive Director
Ohio Board of Pharmacy

Access the National Pharmacy Compliance News

A Service of the National Association of Boards of Pharmacy Foundation® (NABPF®)

Reconstituted Neurotoxins and Beyond-Use Dates

The reconstitution of neurotoxins (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 (BUD) 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 time frame. If no such BUD or time frame exists on the label, the drug may only be used for up to six hours following preparation.

NOTE: Even if the labeling says, "should," Ohio Board of Pharmacy rules require you to consider that time frame 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 time frame listed on the manufacturer's labeling is considered a violation of Board rules and may subject the terminal distributor of dangerous drugs (TDDD) to administrative action.

As a reminder, all neurotoxins prepared by a TDDD must:

1) be prepared using aseptic technique, and procedures shall be in place to minimize the potential for contact with nonsterile surfaces and the introduction of particulate matter or biological fluids; and
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.

Retatrutide and/or Cagrilintide Cannot Be Used in Compounding

The Board continues to see instances of pharmacies, clinics, and health care providers ordering, compounding, and administering medications containing retatrutide and/or cagrilintide.

Retatrutide and cagrilintide **cannot** be used in compounding under federal and state laws. Additionally, these compounds are not components of a Food and Drug Administration-approved drug and have not been found to be safe and effective for any condition.

Licensees who have been found compounding, selling, ordering, administering, or otherwise facilitating the distribution of these unapproved drugs 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"
- National Association of Boards of Pharmacy®'s Letter: FDA Letter - Retatrutide in Compounded Drug Products

Have Compliance Questions? Consult Your Inspection Guide!

The Board is committed to licensee compliance. As part of this effort, inspection guides were developed for each license type.

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

The following inspection guides are available below and can also be accessed by visiting *www.pharmacy.ohio.gov/inspection*.

- Animal Shelter
- Clinic and Prescriber Office
- Distributor of Dangerous Drugs
- First Aid Department
- Institutional Pharmacy and Facility
- Laboratory
- Limited Facility
- Non-Limited Facility
- Non-Resident Terminal Distributors
- Opioid Treatment Program
- Outpatient Pharmacy
- Pain Management Clinic
- Prescriber Compounding
- Veterinary Clinic

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

In response to the increasing number of retail intravenous (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 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 health care 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*.

Board of Pharmacy Ephedrine Rules Updated

Effective July 7, 2025, all rules on the sale and distribution of ephedrine products in Ohio will be consolidated into a single rule: OAC 4729:9-3-01. This rule combines all the following rules, which will be rescinded, effective July 7, 2025, into a single rule: OAC 4729:9-3-01, OAC 4729:9-3-02, OAC 4729:9-3-03, OAC 4729:9-3-04, OAC 4729:9-3-05, OAC 4729:9-3-06, OAC 4729:9-3-07, OAC 4729:9-3-08. To review the new rule, visit *www.pharmacy.ohio.gov/EphedrineContainingProducts*.

Updated OARRS and ASAP Version 5.0 Rules

Note: Click on the rule number to access the full text of the rule and to familiarize yourself with the changes.

As of August 1, 2025, the following Ohio Automated Rx Reporting System (OARRS) rules are in effect:

- 4729:8-1-01**: Ohio automated Rx reporting system - definitions. (AMEND)** Provides the definition section for the division of OAC. Adds references to central fill and originating pharmacies. Also adds references to dispensaries for the purposes of medical marijuana reporting.
- 4729:8-3-01**: Entities required to submit information. (AMEND)** Lists the entities required to submit data to OARRS. Adds references to medical marijuana dispensaries and exempts OTPs from having to report patient data, as these data are reported via the state's central registry.
- 4729:8-3-04**: Frequency requirements for submitting drug database information. (AMEND)** Includes the requirements for the frequency of reporting patient information to OARRS. Makes minor grammatical updates to the rule.
- 4729:8-3-05**: Corrections to the drug database. (AMEND)** Specifies the process for making corrections to data reported to OARRS. Adds specific requirements for making corrections if a pharmacy utilizes a central fill pharmacy to dispense prescriptions.
- 4729:8-4-01**: Procedures for obtaining drug database information and access by peer review committees and fatality review committees. (AMEND)** Establishes standards for hospital peer review committees to access OARRS. Removes the requirement for patients to notarize a request form and allows Board staff who participate in fatality review committees to access OARRS on behalf of a committee.
- 4729:8-4-03**: Access to opioid treatment program data provided by the Ohio department of mental health and addiction services. (AMEND)** Specifies who can access data provided by the Ohio Department of Mental Health and Addiction

Updated OARRS and ASAP Version 5.0 Rules *(cont)*

Services that are reported to OARRS. Updates the language to reflect statutory changes in Ohio Revised Code 4729.80 and makes one minor grammatical update.

Additionally, on March 6, 2023, the American Society for Automation in Pharmacy (ASAP) released a new version, ASAP Version 5.0, of its standard for prescription drug monitoring program reporting. To ensure the most up-to-date reporting standards, the Board is also making the following rules effective on July 1, 2026:

- **4729:8-3-02: Information required for submission. (AMEND)** Provides the data that are required to be submitted to the Board for outpatient prescriptions that meet the requirements of the rules. The rule is being amended to add additional data fields that are part of the ASAP Version 5.0 data standard to improve data quality.
- **4729:8-3-03: Electronic format required for the transmission of drug sales. (NEW)** Requires all reporting to be conducted in accordance with the ASAP Version 5.0 data standard by July 1, 2026. Permits the Board's executive director to grant extensions to the requirements of this rule. Replaces the current version of the rule.

These rules provide licensees until July 1, 2026, to begin reporting to OARRS using the ASAP Version 5.0 format. The rule also permits the Board's executive director to authorize an additional six-month extension if a pharmacy or prescriber has made all reasonable and prudent attempts to meet the deadline.

Additional Questions

- The most expedient way to have questions regarding the rules answered will be to email the Board office by visiting *www.pharmacy.ohio.gov/contact*.

Licensee Scam Warning

The Board continues to learn that licensees are being targeted by scammers who claim to work for various governmental agencies (the Board, Drug Enforcement Administration, Federal Bureau of Investigation, Department of Justice, etc) in attempts to extort money. The Board strongly encourages licensees to be on alert for suspicious activity.

Scammers may try to initiate contact via phone calls, emails, faxes, and letters purporting to originate from various state and federal agencies that include allegations of drug trafficking and threats of suspension against the target's license.

Board investigators will not ask for fine payment or personal/sensitive information over the phone and will never contact licensees via fax. As a reminder, administrative fines issued by the Board are not paid via gift cards or cryptocurrency. If the Board is investigating and an individual faces action against their license, they will receive an official notice of opportunity for a hearing either via certified mail or by personal service.

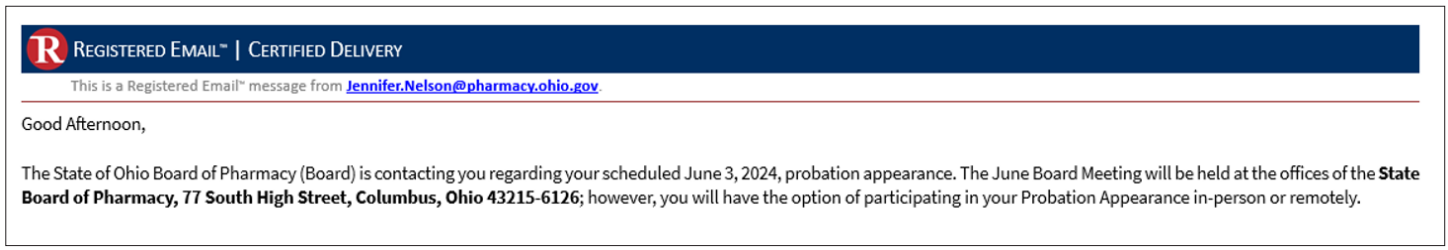
If you are contacted by a scammer, please report this information using the Board's online complaint form. Additionally, reports should be made to your local law enforcement agency.

If you receive any suspicious calls or correspondence purporting to be from the Board, we encourage you to call (614/466-4143) or email (contact@pharmacy.ohio.gov) the Board to confirm its legitimacy.

Licensee Scam Warning

(cont)

As licensees become more vigilant about looking out for scams, the Board would like to remind all licensees that official electronic registered mail from the Board of Pharmacy will sometimes have a **Registered Email | Certified Delivery** banner across the top, like in the image below. Emails with this banner are official correspondence from the Ohio Board of Pharmacy.


REGISTERED EMAIL™ | CERTIFIED DELIVERY

This is a Registered Email™ message from Jennifer.Nelson@pharmacy.ohio.gov.

Good Afternoon,

The State of Ohio Board of Pharmacy (Board) is contacting you regarding your scheduled June 3, 2024, probation appearance. The June Board Meeting will be held at the offices of the **State Board of Pharmacy, 77 South High Street, Columbus, Ohio 43215-6126**; however, you will have the option of participating in your Probation Appearance in-person or remotely.

The Ohio Board of Pharmacy News is published by the Ohio Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Steven W. Schierholt, Esq - State News Editor
Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor
Megan Pellegrini - Publications and Editorial Manager

77 S High St, 17th Floor | Columbus, OH 43215-6126 | Tel: 614/466-4143 Fax: 614/752-4836 | www.pharmacy.ohio.gov