Board of Pharmacy

e-News June 2025

Electronic Positive Identification Requirements Effective January 15, 2027

Effective January 15, 2027, amendments to 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 once effective, the rule will not permit the use of hardcopy 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 rule **4729:5-5-02.1** of the Administrative Code.

IMPORTANT: This change does not impact institutional pharmacies (except those that operate outpatient pharmacies), non-resident pharmacies, and other terminal distributors (EMS, clinics, OTPs, etc.).

To review the upcoming amendments to the rule, visit: **www.pharmacy.ohio.gov/positiveIDchange**.

Waiver Request Process

IMPORTANT: Waivers will not be considered for review until January 1, 2026. Waiver requests submitted prior to this date **will not** be reviewed.

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: **www.pharmacy.ohio.gov/waiver**.

NOTE: The Board reserves the right to request additional information and documentation to render a decision as to whether to grant a waiver. Waivers will be granted on a limited basis and requests that do not include all the required information will not be reviewed by Board staff.

In making a determination to grant a waiver, the Board is required to consider all of the following:

(1) Whether the requirement to implement electronic positive identification will be cost prohibitive so as to impact the continued viability of the business;

(2) The average number of dangerous drugs dispensed at the pharmacy to determine the reliability of a non-electronic method of positive identification;

(3) The results of an inspection authorized in accordance with OAC **4729:5-3-03**; and

(4) A review of past disciplinary actions taken against the pharmacy, or against an individual while employed by the licensee, that are based, in whole or in part, on drug security, record

keeping violations, errors in dispensing, and/or any other disciplinary actions deemed relevant to the board's analysis.

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.

Have Compliance Questions? Consult Your Inspection Guide!

The Ohio Board of Pharmacy is committed to licensee compliance. As part of this effort, the Board developed inspection guides 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 the rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

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

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

Board of Pharmacy Ephedrine Rules Updated Effective July 7, 2025

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 7/7/25, into a single rule: 4729:9-3-01, 4729:9-3-02, 4729:9-3-03, 4729:9-3-04, 4729:9-3-05, 4729:9-3-06, 4729:9-3-07, 4729:9-3-08. **Click here to review the new rule**.

Updated OARRS and ASAP 5.0 Rules

Effective August 1, 2025, the following OARRS rules go into effect:

- **4729:8-1-01: Ohio automated Rx reporting system - definitions. (AMEND)** Provides the definition section for the division of the OAC. Adds references to central fill and originating pharmacy. 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 this data is 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 requirement to have patient notarize a request form and allows Board of Pharmacy staff who participate on fatality review committees to access OARRS on behalf of the 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 Services that is reported to OARRS. Updates the language to reflect statutory changes in ORC 4729.80 and makes one minor grammatical update.

(Click on the rule number to access the full text of the rule and to familiarize yourself with the changes)

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 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 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 be conducted in accordance with the ASAP 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.

(Click on the rule number to access the full text of the rule and to familiarize yourself with the changes)

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

- **For questions regarding the rules, the most expedient way to have them answered will be to e-mail the Board office by visiting: www.pharmacy.ohio.gov/contact**

2025 Pharmacist & Intern Renewals Begin in July

All active pharmacists and pharmacy interns with an expiration date of September 15, 2025, will need to file a renewal application and submit the required renewal fee by the expiration date. Renewal applications open on Thursday, July 17. For information on renewal continuing education requirements, please review **this guidance document on the Board's website**. More information will be sent to licensees in the coming weeks.

FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss

FDA is aware that some patients and health care professions may look to unapproved versions of GLP-1 (glucagon-like peptide-1 (GLP-1) receptor agonists) drugs, including semaglutide and tirzepatide, as an option for weight loss. This can be risky for patients, as unapproved versions do not undergo FDA's review for safety, effectiveness, and quality before they are marketed.

Concerns with Compounded Versions of These Drugs

A **compounded drug** might be appropriate if a patient's medical need cannot be met by an FDA-approved drug, or the FDA-approved drug is not commercially available. However, compounded drugs are not FDA approved. This means the agency does not review compounded drugs for safety, effectiveness or quality before they are marketed.

The agency has identified some areas of concern for compounded GLP-1 drugs. FDA is working with its state regulatory partners and will continue to communicate with compounders regarding these concerns.

For more information, visit: **https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss**

Reminder: 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

Follow the Board on Social Media

The Ohio Board of Pharmacy is now active on X (formerly Twitter) and Bluesky. Follow us for updates and reminders from the Board by clicking the icons below.

Be Vigilant - Watch Out for Scammers!

BOARD STAFF DO NOT ASK FOR MONEY OVER THE PHONE OR VIA EMAIL TO RESOLVE PENDING INVESTIGATIONS. WHEN IN DOUBT, PLEASE CONTACT THE BOARD IF YOU BELIEVE YOU ARE THE TARGET OF A SCAM.

The Ohio Board of Pharmacy continues to learn that licensees are being targeted by scammers who claim to work for various governmental agencies (Board of Pharmacy, DEA, FBI, Department of Justice, etc.) to obtain money from the target. The Board strongly encourages licensees to be alert to avoid scammers.

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 of Pharmacy 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 of Pharmacy is conducting an investigation and that individual faces action against their license, they will receive an official notice of opportunity for a hearing either via certified mail, personal service, or electronic registered mail.

If you are contacted by a scammer, please report this information using the Board's online complaint form: **www.pharmacy.ohio.gov/complaint**. 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 of Pharmacy, we encourage you to call (614-466-4143) or email (**contact@pharmacy.ohio.gov**) the Board to confirm its legitimacy.

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988 SUICIDE & CRISIS LIFELINE Ohio

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.
