



# Board of Pharmacy

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## e-News March 2024

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### Outpatient Pharmacy Minimum Standards Rules

Effective 5/1/2024, the following rules on outpatient pharmacy minimum standards go into effect. These rules are the result of the work of the Ohio Pharmacist Workload Advisory Committee and feedback provided by pharmacy professionals through various surveys. For more information on the Pharmacist Workload Advisory Committee, please visit: [www.pharmacy.ohio.gov/PWAC](http://www.pharmacy.ohio.gov/PWAC).

- [4729:5-5-02](#): Minimum Standards for the Operation of an Outpatient Pharmacy.
- [4729:5-5-02.1](#): Provision of Ancillary Services in an Outpatient Pharmacy.
- [4729:5-5-02.2](#): Mandatory Rest Breaks for Pharmacy Personnel.
- [4729:5-5-02.3](#): Requests for Additional Staff and Reports of Staffing Concerns in an Outpatient Pharmacy.
- [4729:5-5-02.4](#): Significant Delays in the Provision of Pharmacy Services.
- [4729:5-5-02.5](#): Outpatient Pharmacy Access Points.

*(Click on the rule number to access the full text of the rule)*

To assist licensees in complying with these new regulations, the Board developed a frequently asked questions document that can be accessed here: [www.pharmacy.ohio.gov/minstandard](http://www.pharmacy.ohio.gov/minstandard)

#### Additional Questions

For questions regarding the rules, please review this [document](#). If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: <http://www.pharmacy.ohio.gov/contact.aspx>.

#### To Report Any Violations

Any violations of these rules should be reported using the Board's online complaint form: <https://www.pharmacy.ohio.gov/complaint>

**REMINDER:** Per section [4729.23 of the Ohio Revised Code](#), the identity of an individual submitting a complaint to the Ohio Board of Pharmacy is confidential.

#### Anti-Retaliation Provisions

Ohio rules (OAC 4729:5-4-01 [B]{25}) prohibit a licensed pharmacy from retaliating against or disciplining an employee for filing a complaint with the Board or other licensing body or reporting a violation of state or federal statute or any ordinance or regulation of a political subdivision that the employee's employer has authority to correct.

Retaliation or discipline of an employee includes, but is not limited to, the following:

1. Removing or suspending the employee from employment;
2. Withholding from the employee salary increases or employee benefits to which the

- employee is otherwise entitled;
- 3. Transferring or reassigning the employee;
- 4. Denying the employee a promotion that otherwise would have been received; and
- 5. Reducing the employee in pay or position.

Further, the following rules have specific employee anti-retaliation provisions:

- 4729:5-5-02.2 Mandatory Rest Breaks for Pharmacy Personnel.
  - 4729:5-5-02.3 Requests for Additional Staff and Reports of Staffing Concerns in an Outpatient Pharmacy.
  - 4729:5-5-02.4 Significant Delays in the Provision of Pharmacy Services.
  - 4729:5-5-02.5 Outpatient Pharmacy Access Points.
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## New Distributor of Dangerous Drugs Inspection Guide Available

The Ohio Board of Pharmacy has posted a new inspection guide for distributors of dangerous drugs. The guide can be found here: <https://www.pharmacy.ohio.gov/DDDinspect>

This guide applies only to locations licensed as drug distributors in accordance with section [4729.52](#) of the Revised Code, which includes the following license types:

- Wholesale distributors of dangerous drugs, including brokers and virtual wholesalers
  - Manufacturers of dangerous drugs
  - Outsourcing facilities
  - Third-party logistics providers
  - Repackagers of dangerous drugs
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## Request for Stakeholder Feedback - OARRS and ASAP 5.0

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 proposing a new version of OAC 4729:8-3-03 (electronic format required for the transmission of drug sales).

The rule provides licensees until May 1, 2025, 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.

Additionally, the Board is conducting a statutorily mandated 5-year review of OAC 4729:8 and includes a new rule governing the reporting of non-fatal drug overdoses to the system (OAC 4729:8-4-05).

To review the proposed rules, visit: <https://pharmacy.ohio.gov/oarrs-and-asap>

Comments on the proposed rules will be accepted until close of business on **Wednesday, May 1, 2024**. Please send all comments to the following email address: [RuleComments@pharmacy.ohio.gov](mailto:RuleComments@pharmacy.ohio.gov).

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## Registered Pharmacy Technician License Renewal Reminder

All registered pharmacy technicians must renew by Sunday, March 31st in [eLicense Ohio](#). Any registered technician who does not renew will have their registration updated to Inactive – Lapsed and will not be able to work in an Ohio pharmacy. Technicians in Inactive – Lapsed

status can file a late renewal application within 90 days and pay the renewal fee plus a \$50.00 penalty. Review more guidance on renewal application requirements [here](#).

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## Upcoming Certified Pharmacy Technician License Renewal

Certified pharmacy technician renewal applications can be submitted beginning August 1, 2024. Each technician must hold an active or valid PTCB or ExCPT certification to renew. A verification of the technician's certification will be required on the renewal application. Any certified pharmacy technician issued on or after June 1, 2024, will receive an expiration date in 2026 and will not be required to renew this year. More information about renewal requirements will be released as the renewal date nears.

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## Certified Pharmacy Technicians with Restricted Status

The Board of Pharmacy actively monitors certified technicians' PTCB and ExCPT certification status. Any certified technician who does not maintain their national certification will receive a sub-status of Restricted on their registration and communication from the Board on how to remedy their registration status. Any technician with a Restricted status will not be eligible to renew. More information on the Restricted status can be found on the Board's website: [www.pharmacy.ohio.gov/TechStatus](http://www.pharmacy.ohio.gov/TechStatus)

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## 2024 Law and Responsible Person Review Virtual Presentations

Join the Ohio Board of Pharmacy for presentations throughout 2024 to learn about the latest developments in pharmacy laws and rules.

2024 Law Review topics will include:

- Minimum standard rules for an outpatient pharmacy
- Updates to state and federal laws and rules
- Scams and drug diversion trends

Responsible Person Roundtable topics will include:

- Minimum standard rules and TDDD responsibility
- Drug diversion trends and safeguard practices
- Updates to state and federal laws and rules - what RPs need to do

Responsible Person 101 topics will include:

- Duties and responsibilities of a responsible person
- General requirements of a terminal distributor of dangerous drugs
- An overview of resources available for a responsible person

For presentation dates and times and a link to sign up, visit:

<https://www.pharmacy.ohio.gov/documents/licensing/ce/rplaw/2024%20law%20review%20communication.pdf>

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## Updated Regulatory Guidance: Hospitals Reporting Sales to EMS

In light of pending DEA regulations for emergency medical services, the Board is issuing updated guidance related to hospitals that sell or transfer OARRS reportable drugs to EMS agencies.

Hospitals that sell or transfer controlled substances and other OARRS reportable drugs to an EMS agency are not required to report these transactions to OARRS.

The OARRS wholesale guide ([www.pharmacy.ohio.gov/wholesalereport](http://www.pharmacy.ohio.gov/wholesalereport)) has been updated to reflect this policy change.

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## Fentanyl Test Strip Educational Handouts Now Available in Spanish

The Ohio Board of Pharmacy has translated the “How to Test Your Drugs – Using Fentanyl Test Strips” [educational handout into Spanish](#) and is offering licensees the opportunity to place orders for these handouts using the following link: <https://www.pharmacy.ohio.gov/FTSorder>

Licensees can also use that link to request the educational handout in English and a maximum of two packs of fentanyl test strips per order (200 strips in total). Please allow 7-10 business days for delivery.

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## Reminder for Licensees Who Also Participate in the Ohio Medical Marijuana Control Program

On March 5, 2019, the State of Ohio Board of Pharmacy released guidance saying a person licensed or registered by the Board will not be subject to professional discipline solely based on participation in any lawful activity authorized under Chapter 3796. of the Revised Code.

The Board recognizes that a licensed pharmacist may engage in the practice of pharmacy outside of a traditional pharmacy setting, such as in a medical marijuana dispensary. The Board reminds all licensed pharmacists that should the practice of pharmacy occur in a setting other than a pharmacy, the licensee remains subject to all relevant regulations in Chapter 4729. of the Ohio Revised Code and agency 4729 of the Ohio Administrative Code.

Additionally, an individual licensed or registered under Chapter 4729. of the Ohio Revised Code who engages in the lawful use of medical marijuana, in accordance with Chapter 3796. of the Revised Code and rules adopted thereunder, is not automatically subject to disciplinary action pursuant to Chapter 4729. of the Revised Code.

To read the guidance in full, visit:

<https://www.pharmacy.ohio.gov/Documents/Pubs/Special/MedicalMarijuanaControlProgram/Participation%20in%20the%20Ohio%20Medical%20Marijuana%20Control%20Program.pdf>

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## National Prescription Drug Takeback Day is April 27, 2024

National Prescription Drug Takeback Day aims to provide a safe, convenient, and responsible means of disposing of prescription drugs while also educating the general public about the potential for abuse of medications. The next National Prescription Drug Takeback Day will be taking place on April 27, 2024, from 10AM-2PM. For more information and to find a collection site locator, visit: <https://www.dea.gov/takebackday#collection-locator>

Ohioans can also dispose of prescription drugs year-round at a local drug disposal receptacle. To find a drug disposal site near you, visit:

<https://www.pharmacy.ohio.gov/Documents/Pubs/Special/DrugRepository/Drug%20Repositories%20Operating%20in%20Ohio.pdf>

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## **DSCSA Compliance Policies Establish 1-Year Stabilization Period for Implementing Electronic Systems**

FDA is announcing two compliance policy guidance documents establishing a 1-year stabilization period to accommodate additional time that trading partners in the pharmaceutical supply chain may need to adhere to **Drug Supply Chain Security Act (DSCSA)** requirements for electronic drug tracing at the package level. This period ends on November 27, 2024.

Under the DSCSA, trading partners – primarily manufacturers, wholesale distributors, dispensers, and repackagers – are subject to certain requirements for enhanced drug distribution security. For more information, visit: <https://www.fda.gov/drugs/drug-safety-and-availability/dscsa-compliance-policies-establish-1-year-stabilization-period-implementing-electronic-systems>

NABP has a resource on how pharmacies can begin preparing for these new requirements here: <https://nabp.pharmacy/news/blog/how-pharmacies-can-prep-now-for-the-2023-dscsa-requirements/>

There is also a resource page to house educational information that dispensers may find useful to assist in implementation of the DSCSA here: <https://dscsa.pharmacy/resources/>

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## **Medications for Opioid Use Disorder: A Message from the DEA**

In 2022, 6.1 million people in the United States had an opioid use disorder (OUD). Among them, only 18.3% received medication-assisted treatment. The removal of the Drug Addiction Treatment Act of 2000 “x-waiver” in December 2022 eliminated a significant barrier to treatment for OUD, dramatically increasing the number of medical professionals who can prescribe buprenorphine from the previously eligible 130,000 prescribers.

The DEA and the Department of Health and Human Services are committed to ensuring safe and ready access to medications for opioid use disorder (MOUD), especially in rural or underserved areas where treatment options have been limited. With the passage of the Consolidated Appropriations act in 2023, there was an immediate and significant increase in the number of practitioners who can prescribe schedule III MOUD products (e.g., buprenorphine combination products containing buprenorphine and naloxone) for patients with OUD.

As access to treatment increases, it is understood that the use of MOUD products will likely increase at the same time. DEA recognizes that there have been recent increases in demand for certain schedule III MOUD controlled substances as compared to years prior to the Opioid Public Health Emergency, and that there may be a corresponding increase in prescriptions for these medications from medical providers. DEA supports collaboration amongst all DEA registrants to ensure there is an adequate and uninterrupted supply of MOUD products when these products are appropriately prescribed. Distributors should carefully examine quantitative thresholds they have established to ensure that individuals with OUD who need buprenorphine are able to access it without undue delay.

For more information, please visit [www.samhsa.gov](http://www.samhsa.gov) and [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov). It is our sincere hope that the remarkable increase in the number of medical professionals who can prescribe this life-saving medication will not only change the lives of individuals with OUD, but will also stem the escalating rate of opioid-related deaths at a population level.

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## **NABP Launches Examination Preparation Videos to Assist Candidates**

The National Association of Boards of Pharmacy has released three new educational videos

designed to enhance candidates' understanding of the North American Pharmacist Licensure Examination (NAPLEX), the Multistate Pharmacy Jurisprudence Examination (MPJE), and the Foreign Pharmacy Graduate Equivalency Examination (FPGEE). The newly released videos include:

1. **NABP's 5 Essential Tips for Test Day**: This video guides candidates on optimal preparation strategies for test day, emphasizing the importance of the testing policies and procedures found in the NAPLEX/MPJE Candidate Application Bulletin.
2. **Avoid Misconduct for NABP Exams**: Aimed at educating candidates on the definition of misconduct and its ramifications, this video reinforces NABP's dedication to the integrity of its examinations.
3. **Performance Report Overview**: In the event of an unsuccessful NAPLEX and/or MPJE attempt, candidates will receive a Performance Report. This video will help candidates learn how to access and interpret their Performance Report. Candidates will also understand each section of the report and assess performance by competency area to support their study efforts for their next exam attempt.

In addition to watching the newly released videos, candidates should review the [NAPLEX/MPJE Candidate Application Bulletin](#) or the [FPGEE Candidate Application Bulletin](#) for comprehensive information about examination processes. Candidates are encouraged to [visit the NABP website](#) for access to additional resources and helpful infographics, including the official [practice exams](#). These resources exemplify NABP's innovative and collaborative efforts to support candidates as they seek licensure from the boards of pharmacy, which is a crucial part of NABP's mission to protect public health.

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## Mental Health and Well-Being Resources from NABP

As health care providers, pharmacists and pharmacy technicians have always felt the need to ensure the safety of their patients. In recent years, however, stress levels for pharmacy personnel have increased exponentially as they have taken on new responsibilities and seen increased workloads, while at the same time providing patients with top-level care.

To help support pharmacists and pharmacy technicians, we have compiled tools and information that can be used to find help. To review NABP's mental health and well-being resources, visit: <https://nabp.pharmacy/initiatives/presidential-initiative/mental-health-and-well-being-resources/>

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## Licensee Scam Warning

The State of 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.

USA Today recently published this article detailing an elaborate scam targeting a pharmacist from Ohio: <https://www.usatoday.com/story/money/2024/03/24/professionals-with-licenses-targeted-scams-online-phone/72094706007/>

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 or by personal service.

If you are contacted by a scammer, please report this information using the Board's online complaint form: [www.pharmacy.ohio.gov/complaint](http://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](mailto:contact@pharmacy.ohio.gov)) the Board to confirm its legitimacy.



*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.*

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Ohio Board of Pharmacy  
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