



E-News August 2023

Ohio Rules on Pharmacy Technician Immunizations Go Live September 1st

Effective September 1, 2023, rule [4729:3-3-06](#) of the Administrative Code authorizes a certified or registered pharmacy technician working under the direct supervision of a pharmacist to administer, subject to a physician protocol, the following immunizations:

- Any immunization for any disease to individuals 13 years old or older without a prescription.
- Any immunization for any disease to individuals ages 7-12 if there is a prescription for the immunization (except as provided below for COVID-19 vaccines and flu shots).
- FDA authorized COVID-19 vaccines and flu shots to individuals starting at seven years old without a prescription.

For more information, the Board developed a guidance document that can be accessed here: www.pharmacy.ohio.gov/techimmunize

Changes to Ohio's Terminal Distributor Licensing Laws Effective July 11th

Effective July 11, 2023, Ohio law will no longer require terminal distributor licensure for the following:

1. An office-based opioid treatment facility licensed in accordance with section 4729.553 of the Revised Code.
2. A person who possesses nitrous oxide (including nitrogen) for use as a direct ingredient in food pursuant to 21 C.F.R. 184.1545 or for testing or maintaining a plumbing or heating, ventilation, and air conditioning system.
3. A person who possesses medical oxygen, sterile water, or sterile saline for direct administration to patients or for the purpose of installation or maintenance of home medical equipment, as defined in section 4752.01 of the Revised Code.

Additionally, the Board updated the following guidance documents to reflect these changes:

[Terminal Distributor Licensure of Prescriber Practices](#)
[Terminal Distributor Licensure for Office-Based Opioid Treatment](#)
[Terminal Distributor Licensure Exemptions for Non-Prescriber Practices](#)

Pharmacists Can Now Administer Long-Acting/Extended- Release Buprenorphine Under Ohio Law

With recent changes to federal law on the prescribing of buprenorphine, the Board recently updated its compliance guidance to allow pharmacists to administer long-acting injectable buprenorphine in accordance with ORC [4729.45](#). For more information on the requirements for pharmacists administering injectables, visit: www.pharmacy.ohio.gov/injections.

Board Issues Clarification Regarding Pharmacies Providing

Controlled Substances for Opioid-Use Disorders to Residential Care Facilities

Over the past several months, the Board has been approached by several crisis stabilization centers in Ohio that are seeking to use pharmacies to provide medications for opioid-use disorder. After a review of state and federal laws and regulations, the Board has determined that a pharmacy may provide controlled substances and other drugs to a residential care facility.

It is the Board's contention that institutional facilities and pharmacies may either obtain an Automated Dispensing System (ADS) registration at the facility, or the pharmacy may provide the controlled substances as emergency kits based on a earlier DEA Notice ([Docket No. DEA-337N](#)).

Further, pharmacies may dispense controlled substances for treatment of opioid-use disorder in accordance with federal regulations and state rules, which requires the pharmacy to receive a valid outpatient prescription issued prior to administration of initial dose of a controlled substance drug contained in the emergency kit or ADS.

DEA Issues Final Rule Allowing for Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances between Pharmacies

The US Drug Enforcement Administration (DEA) issued a final rule scheduled for publication in the Federal Register on Thursday, July 27, 2023. As described in the summary, DEA is amending its regulations to allow the transfer of Schedule II-V electronic prescriptions between DEA registered retail pharmacies for initial filling, upon request from the patient, on a one-time basis. This amendment specifies the procedure that must be followed and the information that must be documented when transferring such electronic controlled substance prescriptions between pharmacies. This rule becomes effective on August 28, 2023.

Please be advised that OAC [4729:5-5-11\(E\)\(8\)](#) specifically authorizes the transfer of unfilled controlled substance prescriptions in accordance with DEA regulations.

A copy of the final DEA regulation can be found [here](#).

Board Now Offering Free Fentanyl Test Strips to All Ohio Licensees

In recognition of Overdose Awareness Day on August 31, 2023, the State of Ohio Board of Pharmacy is partnering with the Office of Governor Mike DeWine, RecoveryOhio, the Ohio Department of Mental Health and Addiction Services, and the Ohio Department of Health to offer no-cost fentanyl test strips to all Ohio pharmacies.

To help save lives, the State of Ohio Board of Pharmacy encourages you to make these important tools available to your patients. The Board is offering each licensee up to two boxes of strips per order (100 strips per box). Strips will be available until supplies last and may be reordered by the same location if running low. Additionally, you may also request copies of the Board's [educational handouts](#) (100 per pack).

Orders must be placed online using the following link: www.pharmacy.ohio.gov/FTSorder.

DUE TO GRANT FUNDING RESTRICTIONS, WE ARE ONLY ABLE TO OFFER STRIPS TO LICENSEES LOCATED IN THE STATE OF OHIO.

Make Your Voice Heard – Comment on the Board's Proposed Workload Rules

In 2020, the Board began the process of reviewing working conditions in pharmacies across Ohio. As a result of these efforts, the Board has developed several draft rules aimed at addressing working conditions in outpatient pharmacies:

- 4729:5-5-02 - Establishes minimum standards in an outpatient pharmacy. Includes

- requirements to ensure sufficient time and personnel.
- 4729:5-5-02.1 - Prohibits the use of quotas in the provision of ancillary services in an outpatient pharmacy.
- 4729:5-5-02.2 - Provides mandatory rest breaks for pharmacy personnel.
- 4729:5-5-02.3 - Requires outpatient pharmacies to develop a process to address staffing concerns.
- 4729:5-5-02.4 - Defines a significant delay in pharmacy services and creates a process whereby an outpatient pharmacy must address such delays.
- 4729:5-5-02.5 - Provides the requirements for managing pharmacy access points in an outpatient pharmacy.

Click [here](#) to review the rule text (starting on Page 21 of the CSI document).

Comments are due by **September 12, 2023**, and should be submitted using the following link: <https://www.surveymonkey.com/r/MINSTAND>

Board Seeks Initial Comments on Continuous Quality Improvement and Error Reporting

In an effort to promote continuous quality improvement, the Board released preliminary draft rules for public comment. These draft rules are an attempt to balance the need for the Board to investigate serious errors, while also ensuring licensees are developing processes to mitigate future prescription errors.

Copies of the rules and instructions for submitting comments can be accessed [here](#).

Comments on the proposed rules are due by **September 8, 2023**.

REMINDER: Ohio Drug Repositories Now Accepting Donations from Patients

Effective May 27, 2023, charitable pharmacies, hospitals, and non-profit clinics are permitted to accept or distribute donated drugs that are not in their original sealed and tamper-evident unit dose packaging. This includes the collection of medications directly from patients and caregivers.

For more information about this change, please review the Board's updated drug repository guidance document: www.pharmacy.ohio.gov/repository.

If you are contacted by a patient or caregiver with leftover medication, please direct them to the Board's directory of existing repository programs: www.pharmacy.ohio.gov/donate.

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