



STATE OF OHIO BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

From the Director's Desk

On April 6, 2023, new laws expanding access to overdose reversal drugs (ORDs), such as naloxone, went into effect.

To assist its licensees in understanding these new laws, the State of Ohio Board of Pharmacy developed this comprehensive guide: www.pharmacy.ohio.gov/ORD. The guide is divided into sections based upon the type of entity engaged in the distribution of ORDs.

The Board has several resources to assist pharmacies in distributing this lifesaving medication, including patient counseling brochures that have been translated into five different languages. To access those resources, please visit www.pharmacy.ohio.gov/naloxone.

As a reminder, the state of Ohio developed a dedicated website to order naloxone for personal use and for organizational use. For more information, please visit naloxone.ohio.gov.

On behalf of the Board, thank you for all that you do to help keep Ohioans safe and healthy.

Sincerely,

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

Xylazine Is a Schedule III CS in Ohio

On March 29, 2023, the Board classified xylazine as a Schedule III controlled substance (CS) via emergency rule. To ensure that licensees remain in compliance with Ohio law, the Board issued temporary

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enforcement waivers for veterinary clinics, terminal distributors (including pharmacies), and drug distributors: www.pharmacy.ohio.gov/xylazineCOMP.

Please review the time frame for each enforcement waiver to ensure compliance with Ohio law.

State Medical Board of Ohio Adopts New Rules on CS for Weight Loss Rules

Ohio Administrative Code 4731-11-04 became effective on February 28, 2023. This rule outlines the requirements for prescribing CS for weight loss in Ohio. Pharmacists are recommended to familiarize themselves with the new rules. For more information, please contact the State Medical Board of Ohio at contact@med.ohio.gov.

Pharmacists Now Permitted to Manage Buprenorphine for OUD Under Consult Agreements

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), recent changes to federal law now allow all practitioners who have a current Drug Enforcement Administration (DEA) registration to prescribe buprenorphine for opioid use disorder (OUD) if permitted by applicable state law. Therefore, pharmacists who have a mid-level DEA CS registration under a consult agreement are now able to manage buprenorphine for the treatment of OUD.

Reminder: SAMHSA and DEA have released a separate provision of the Omnibus bill related to [training requirements](#) for DEA registration that becomes effective in June 2023. Visit SAMHSA.gov to learn more.

For more information about obtaining a mid-level DEA CS registration under a consult agreement, visit www.pharmacy.ohio.gov/consult.

2023 Law and Responsible Person Review Virtual Presentations

Join the Board for a presentation to learn about the latest developments in pharmacy laws and rules. These presentations offer free pharmacy jurisprudence continuing education (CE). For more information on these presentations, visit www.pharmacy.ohio.gov/Present2023.

State Medical Board of Ohio Adopts New Telehealth Rules

The State Medical Board of Ohio adopted new telehealth rules, which became effective on February 28, 2023. These rules implement the requirements of the telehealth statute (R.C. 4743.09) for the following medical board health care professionals: physicians (MD, DO, and DPM), physician assistants, dietitians, respiratory care professionals, and genetic counselors.

The medical board recently posted a summary of the new rules, which can be accessed by visiting www.pharmacy.ohio.gov/MedBoardTelehealth.

Cultural Competency CE

To provide effective communication with patients, pharmacy professionals must learn to accurately assess their own level of cultural competency and develop methods to improve those skills. Cultural competency can foster a greater understanding and appreciation of diverse patient populations, giving pharmacy professionals additional information and insight to enrich patient care. The skills developed with cultural competency allow health care providers to understand and respect a patient's cultural identity. This includes effective communication and appropriate interactions with patients from various ethnic and/or cultural groups.

While there is no requirement to complete CE relating to this subject, the Board strongly encourages its licensees to consider these important learning opportunities. More information about CE can be found at www.pharmacy.ohio.gov/cultural.

Removal of DATA-Waiver (X-Waiver) Requirement

On December 29, 2022, with the signing of the Consolidated Appropriations Act of 2023 (the Act), Congress eliminated the "DATA-Waiver Program."

All pharmacies should be aware of the following changes that are now in effect:

- A DATA-Waiver registration is no longer required to treat patients with buprenorphine for opioid use disorder.
- Going forward, all prescriptions for buprenorphine only require a standard DEA registration number. The previously used DATA-Waiver registration numbers are no longer needed for any prescription.
- There are no longer any limits or patient caps on the number of patients a prescriber may treat for opioid use disorder with buprenorphine.
- The Act does not impact existing state laws or regulations that may be applicable.

The Board is in the process of reviewing how these changes will impact its current rules and requirements and will be issuing additional guidance.

EPCS Program Guidance Regarding the Role of the Pharmacy and Pharmacist

As a result of House Bill 193, prescribers are required to issue an electronic prescription when prescribing a Schedule II CS.

As of January 1, 2023, Medicare Part D plans require the use of e-prescribing for all CS prescriptions. The SUPPORT for Patients and Communities Act will require the use of electronic prescriptions for controlled substances (EPCS) for Schedule II-V CS covered under a Medicare Part D prescription drug or a Medicare Advantage prescription drug plan.

Reminder: Compliance actions for prescriptions for beneficiaries in a long-term care facility will begin January 1, 2025.

The Centers for Medicare & Medicaid Services (CMS) recently issued program guidance regarding the roles of the pharmacy and pharmacist, which are outlined below:

1. There are **no** compliance requirements for pharmacists or pharmacies in the CMS EPCS Program, as all compliance requirements are limited to prescribers of controlled substances under Medicare Part D.
2. A pharmacist is **not** required or otherwise obligated to verify that a prescriber has a “waiver” from the CMS EPCS Program prior to dispensing a controlled substance under Medicare Part D.
3. A pharmacist is **not** required or otherwise obligated to verify that a prescriber or prescription qualifies for an exception from the CMS EPCS Program requirements prior to dispensing a controlled substance under Medicare Part D.
4. The CMS EPCS Program does not limit or impede in any way pharmacists or pharmacies from dispensing covered Part D drugs including controlled substances from valid written, oral, or faxed prescriptions that are consistent with current laws and regulations, including state EPCS mandates or [DEA] requirements.

For more information, visit www.pharmacy.ohio.gov/CMSepcs.

New Law Permits Pharmacists to Add Drug Delivery Devices to Prescriptions

Ohio law (4729.391) permits a pharmacist to modify a drug's prescription to also include a drug delivery device, if the pharmacist determines that the device is necessary for the drug's administration.

Here are a few helpful reminders to assist pharmacists in implementing this new law:

- The device should be added to the existing prescription for the drug requiring the delivery device.
- The pharmacy should follow its standard process for amending prescription records to document the addition of a device.
- This is a modification of the current prescription, not the creation of a new prescription.
- The pharmacist should use their professional judgment to determine if adding a device is appropriate and necessary for the administration of the drug.

The law also addresses reimbursement for the device, specifically:

(C) For purposes of reimbursement under the terms of a health benefit plan by a health care insurer, government health care program, pharmacy benefit manager, or other entity that offers health benefit plans, a prescription modified as described in this section, and in accordance with any rules adopted under it, shall be deemed a valid prescription for the drug delivery device.

Board Issues Updated Guidance Due to the End of the Federal PHE

The United States Department of Health and Human Services has planned for the Federal Public Health Emergency (PHE) for coronavirus disease 2019 (COVID-19), declared under Section 319 of the Public Health Service Act, to expire at the end of the day on May 11, 2023 (effectively May 12, 2023).

The Board updated its COVID-19 guidance to reflect the waivers that ended because of the expiration of the PHE. That document can be accessed [here](#).

Changes to the Federal PREP Act

With the end of the federal PHE, here is a summary of the changes under the Public Readiness and Emergency Preparedness Act ([PREP Act](#)) that will impact pharmacists, interns, and technicians in Ohio, effective May 12, 2023:

- **Extending coverage for COVID-19 vaccines, seasonal influenza vaccines, and COVID-19 tests.** PREP Act immunity from liability will be extended through December 2024 to pharmacists, pharmacy interns, and pharmacy technicians to administer COVID-19 and seasonal influenza vaccines (to those individuals ages three and over, consistent with other requirements), and COVID-19 tests, regardless of any US government agreement or emergency declaration.
- **Ending of coverage for routine childhood vaccinations.** Now that there is no emergency in effect, PREP Act coverage will no longer extend to all routine childhood vaccinations by pharmacists, pharmacy interns, and pharmacy technicians.

To reflect these changes, the Board issued the following updated guidance documents:

- [Administration of COVID-19 Vaccines during the COVID-19 Pandemic](#) (pharmacists and interns)
- [Pharmacy Technician Administration of Vaccines during the COVID-19 Pandemic](#) (registered/certified technicians)

The Board also removed guidance from its website related to the administration of childhood vaccines by pharmacists and pharmacy interns under the PREP Act. Pharmacists and pharmacy interns may still administer childhood vaccines under the applicable provisions of [Ohio law](#).

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Steven W. Schierholt, Esq - State News Editor

Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Megan Pellegrini - Publications and Editorial Manager