



STATE OF OHIO BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

From the Director's Desk

Dear Ohio Pharmacists,

On May 27, 2023, new rules governing drug repository programs went into effect. Charitable pharmacies, hospitals, and nonprofit clinics can now 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.

For more information about this change, please review the State of Ohio Board of Pharmacy's updated [drug repository guidance document](#).

As part of the new rules, a pharmacy, hospital, or nonprofit clinic that operates a drug repository program that receives donations or dispenses medications to the public must notify the Board within 30 days of establishing a repository program.

The one-page notification form can be accessed [here](#).

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

National Pharmacy Compliance News

A Service of the National Association of Boards
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New COVID-19 Operational Waiver: Authorization for Pharmacy Technician Trainees to Stock Automated Pharmacy Systems and Automated Drug Storage Systems

On June 16, 2023, the Board issued a new coronavirus disease 2019 (COVID-19) operational waiver that authorizes pharmacy technician trainees to stock automated pharmacy systems and automated drug storage systems under certain conditions. The new waiver can be accessed [here](#).

Reminder:

- Certified pharmacy technicians are permitted to stock automated drug storage systems in accordance to rule [4729:3-3-04](#) of the Ohio Administrative Code (OAC).
- Registered pharmacy technicians are permitted to stock automated drug storage systems in accordance to rule [4729:3-3-03](#) of the OAC.

For more information about the Board's COVID-19 waivers, please visit www.pharmacy.ohio.gov/COVID.

DEA Finalizes Rule Changes: Reporting Theft or Significant Loss of CS (Effective July 24, 2023)

Drug Enforcement Administration (DEA) recently finalized changes to rules [21 Code of Federal Regulations 1301.74\(c\)](#) and [1301.76\(b\)](#) that now provide DEA registrants with a 45-day calendar period (instead of the proposed 15-day calendar period) to submit DEA Form 106 upon discovery of the theft or significant loss of any controlled substances (CS). This rule finalizes the other proposed provisions that DEA Form 106 be complete and accurate, and the submission be done electronically through DEA's Diversion Control Division secure network application (available on DEA's Diversion Control Division website). To review the rule change, please visit [here](#).

As a reminder, Ohio has its own theft or significant loss reporting requirements. For more information, please visit www.pharmacy.ohio.gov/theft.

New Federal Training Requirement for Pharmacists With Mid-Level DEA Registrations

On December 29, 2022, the Consolidated Appropriations Act of 2023 enacted a new one-time, eight-hour training requirement for all DEA-registered practitioners on the treatment and management of patients with opioid or other substance use disorders.

For more information on this requirement, visit https://www.dea diversion.usdoj.gov/pubs/docs/MATE_Training_Letter_Final.pdf.

As a reminder, pharmacists can obtain a mid-level DEA registration under a consult agreement. For more information, visit www.pharmacy.ohio.gov/consult.

Note: This training requirement only applies to pharmacists with a mid-level DEA registration obtained under a consult agreement. If you do not have a CS registration with DEA to prescribe CS, you are not required to complete this training.

Board Approves COVID-19 Waivers for Rescission

On June 5, 2023, the Board approved the rescission of the following COVID-19 waivers:

- Authorizes pharmacists, pharmacy interns, and pharmacy technicians licensed in other states to work in Ohio pharmacies under certain conditions.
- Authorizes registered pharmacy technicians to stock automated drug storage systems and send and receive copies of non-controlled prescriptions under certain conditions. Additionally, provides clarification on the positive identification requirements for technicians transferring prescriptions.
- Authorizes expedited licensure of drug distributors.
- Authorizes nurses (LPN, RN, APRN) to stock automated drug storage systems within a terminal distributor of dangerous drugs that has an on-site pharmacy under certain conditions.
- Authorizes an Ohio pharmacy to request a temporary waiver to permit a pharmacist to supervise up to five pharmacy technician trainees at one time (up from the current limit of three).
- Permits registered pharmacy technicians and pharmacy technician trainees to stock automated pharmacy systems and automated drug storage systems at a location licensed as a terminal distributor of dangerous drugs, subject to certain conditions.
- Authorizes the use of support personnel for packaging shipping containers and to package medications for delivery or sale.

For more information on the waivers being rescinded (including the dates of rescission), please visit www.pharmacy.ohio.gov/COVID.

FDA Provides Updated Drug Shortage and Compounding Information for Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss

Food and Drug Administration (FDA) recently provided updated information about FDA-approved semaglutide products, which are marketed for type 2 diabetes or weight loss, and its concerns about compounding semaglutide products.

The full semaglutide update may be viewed [here](#).

As a reminder, Board rules on drug compounding require compliance with all federal regulations, including this guidance.

DEA Issues Guidance on COVID-19 Flexibilities

DEA granted certain flexibilities during the COVID-19 public health emergency (PHE). DEA has determined that some of those flexibilities should remain in place under the ongoing opioid PHE to help respond to the opioid crisis after the COVID-19 PHE expired on May 11, 2023.

The following COVID-19 guidances from DEA were extended as part of the opioid PHE:

- DEA Guidance (Extended to opioid PHE): **Q&A Concerning Administering Certain CS in the Parking Lot of a Healthcare Provider's DEA-registered Location During the COVID-19 Public Health Emergency** (Effective July 28, 2020, DEA-DC-43)
- DEA Policy (Extended via rulemaking): **Exception to Separate Registration Requirements Across State Lines** (Effective March 25, 2020, DEA-DC-18)
- DEA Policy (Extended to opioid PHE): **Use of Unregistered Off-Site Locations in MAT** (Effective April 7, 2020, DEA-DC-25)
- DEA Policy (Extended to opioid PHE): **Use of Unregistered Off-Site Locations in MAT (Buprenorphine)** (Effective April 28, 2020, DEA-DC-30)
- DEA Policy (Extended via rulemaking): **Use of Telephone Evaluations to Initiate Buprenorphine Prescribing** (Effective March 31, 2020, DEA-DC-22)
- DEA Guidance (Extended to opioid PHE): **Exemption Allowing Alternate Delivery Methods for OTPs** (Effective March 16, 2020, DEA-DC-15)
- DEA Policy (Extended to opioid PHE): **Exception to Regulations to Email or Fax DEA Form 222s** (Effective March 26, 2020, DEA-DC-019)

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

Reminder: Performing Remote Pharmacy Services

In 2021, the Board finalized rules permitting pharmacists, pharmacy interns, and pharmacy technicians to conduct remote medication order and prescription processing. This serves as a reminder that any pharmacy personnel residing outside of Ohio who are engaged in providing remote services to patients residing in this state may only do so if authorized in the state where the pharmacist, intern, or technician is licensed and practicing. Pharmacy personnel are strongly encouraged to contact their home-state licensing agency before engaging in remote pharmacy services.

For more information about remote medication order and prescription processing by pharmacists, visit www.pharmacy.ohio.gov/ROEpharm.

For more information about remote order and prescription entry by pharmacy interns and technicians, visit www.pharmacy.ohio.gov/ROEtech.

OARRS Guidance: Reporting Gabapentin Prescriptions From Veterinarians Without a DEA Registration

The Board has been made aware of instances where pharmacies are requesting DEA registration numbers for gabapentin prescriptions issued by veterinarians. As a reminder, gabapentin is not a CS in Ohio, so a veterinarian is not required to have a DEA registration number to prescribe the medication. Additionally, veterinarians do not have National Provider Identifier (NPI) numbers.

As stated in the Ohio Automated Rx Reporting System (OARRS) data submission guide, here are the instructions for submitting gabapentin dispensation data in the event that a prescriber does not have a DEA registration or an NPI number:

- If the prescriber does not have a DEA Number, enter “OH1111119” in PRE02 (Prescriber DEA Number) and populate PRE01 (Prescriber NPI)
- If the prescriber does not have an NPI Number, enter “1234567893” in PRE01 (Prescriber NPI Number) and populate PRE04 (Prescriber State License Number)

Warning: Scammers Posing as Board Staff

The Board would like to remind licensees of an ongoing scam where the scammers claim to work for various governmental agencies (board of pharmacy, DEA, Federal Bureau of Investigation, Department of Justice, etc) to obtain money from the target.

The scam involves phone calls, emails, faxes, and letters purporting to originate from various state and federal agencies and include allegations of drug trafficking and threats of suspension against the target’s license.

Please remember that Board investigators will not ask for fine payment or personal/sensitive information over the phone and will never contact licensees via fax.

If the Board is conducting an investigation 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.

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