

E-News June 2023

Board Approves COVID Waivers for Rescission

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

- Authorized pharmacists, pharmacy interns, and pharmacy technicians licensed in other states to work in Ohio pharmacies under certain conditions.
- Authorized 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.
- Authorized expedited licensure of drug distributors.
- Authorized 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.
- Authorized 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For more information on the waivers being rescinded (including the dates of rescission), please visit: www.pharmacy.ohio.gov/COVID.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

The U.S. 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 at https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss.

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

Reminder: Performing Remote Pharmacy Services

In 2021, the Board finalized the 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.

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

On December 29, 2022, the Consolidated Appropriations Act of 2023 enacted a new onetime, eight-hour training requirement for all Drug Enforcement Administration (DEA)registered practitioners, including pharmacists, on the treatment and management of patients with opioid or other substance use disorders.

For more information on this requirement visit: https://www.deadiversion.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.

Drug Enforcement Administration Issues Guidance on COVID-19 Flexibilities

The Drug Enforcement Administration (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 expires at the end of the day on May 11, 2023.

For more information, the DEA issued a guidance document which can be accessed by visiting: https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-072)(EO-DEA277) Dear Registrant Letter PHE Exceptions Ending and Continuing HHS Comment s - Fina2.pdf

The following COVID-19 Guidance from DEA was extended as part of the Opioid Public Health Emergency:

- 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: https://www.deadiversion.usdoj.gov/opioid phe.html

On May 9, 2023, the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) <u>issued the "Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications"</u> – a temporary rule that extends telemedicine flexibilities adopted during the COVID-19 public health emergency (PHE).

In summary, this temporary extension does the following:

- The full set of telemedicine flexibilities regarding the prescription of controlled medications that were in place during the COVID-19 PHE will remain in place through November 11, 2023.
- Additionally, for any practitioner/patient telemedicine relationships that have been or will be established on or before November 11, 2023, the full set of telemedicine flexibilities regarding prescription of controlled medications as were in place during the COVID-19 PHE will continue to be permitted via a one-year grace period through November 11, 2024.
- In other words, if a patient and a practitioner have established a telemedicine relationship on or before November 11, 2023, the same telemedicine flexibilities that have governed the relationship to that point are permitted until November 11, 2024.

The full text of the temporary rule may be found here.

Additionally, the Board of Pharmacy issued guidance in its May 2023 newsletter about flexibilities in state and federal law regarding controlled substance prescribing and dispensing in light of recent drug shortage. The newsletter can be accessed here.

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 controlled substance in Ohio and so a veterinarian is not required to have a DEA registration number to prescribe the medication. Additionally, veterinarians do not have NPI numbers.

As stated in the <u>OARRS data submission guide</u>, here are the instructions for submitting gabapentin dispensation data in the event a prescriber does not have a DEA registration or an NPI:

- 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 of Pharmacy Staff

The State of Ohio Board of Pharmacy would like to remind licensees of an on-going scam where the scammers claim to work for various governmental agencies (Board of Pharmacy, DEA, FBI, Department of Justice, etc.) to obtain money from the target.

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

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

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. Additionally, reports should be made to your local law enforcement agency.

Please note that if you choose to unsubscribe from receiving emails, this unsubscribes you from all emails that are sent by the State of Ohio Board of Pharmacy, including renewal reminders. If you believe you have unsubscribed in error, you may subscribe by visiting: www.pharmacy.ohio.gov/subscribe. If you would like to change your email address, please log into your <a href="https://example.com/elicense/