

COVID-19 Response Efforts

Updated 5/27/2020

The State of Ohio Board of Pharmacy is committed to protecting the health and safety of Ohioans during the COVID-19 outbreak. This document outlines the Board's COVID-19 guidance and response efforts, including the issuance of waivers to assist our licensees in addressing operational needs, and will be updated regularly.

For more information on the state's efforts to address coronavirus, visit www.coronavirus.ohio.gov or call 1-833-4-ASK-ODH.

Expansion Pharmacist, Pharmacy Intern, and Certified Pharmacy Technician Testing Authority During COVID-19 – UPDATED 5/27/2020

On May 27, 2020, the Board issued an updated guidance on pharmacy personnel conducting COVID-19 testing. Specifically, it clarifies that pharmacists can order COVID-19 testing per guidance issued by the U.S. Department of Health and Human Services. To access the updated guidance, visit: www.pharmacy.ohio.gov/COVIDtest

<u>Additional Delay of ARCOS Review Requirement for Drug Distributors – UPDATED</u> 5/26/2020

The Board has been made aware of certain data issues associated with the Drug Enforcement Administration's ARCOS drug distributor lookup tool, as required by paragraph (G)(1)(d)(iii) of rule 4729:6-3-05 of the Administrative Code.

Therefore, the requirement to check the ARCOS tool as part of the customer due diligence requirements has been further delayed to **November 29**, **2020**. The Board is working closely with DEA and will provide additional updates to licensees when reported data issues have been resolved.

More information on the delay of these requirements can be accessed here.

<u>Drug Compounding Resolutions and Guidance During COVID-19 – UPDATED 5/27/2020</u>

On May 21, 2020, the FDA updated two guidances for the temporary compounding of certain human drugs during the COVID-19 public health emergency. These updates clarify certain policies to address urgent needs for hospitalized COVID-19 patients.

Please be advised that the Board has updated its own guidance to incorporate these policy updates. The Board's compounding resolutions and guidance document can be accessed by visiting: www.pharmacy.ohio.gov/COVIDcompounding



The Board has also updated its outsourcing facility resolution to incorporate FDA's updated temporary policy for outsourcing facilities: www.pharmacy.ohio.gov/osf20.

Responsible RestartOhio Requirements for Board of Pharmacy Licensees – <u>UPDATED</u> 5/26/2020

On April 30, 2020, the Ohio Department of Health issued a Director's Stay Safe Ohio Order. This order permits all businesses, except those specifically <u>listed in the order</u>, to reopen or remain open as long as all workplace safety standards are met. A copy of the order may be reviewed <u>here</u>.

UPDATED 5/26/2020: Please be advised that the order issued on April 30, 2020 is applicable to all Board of Pharmacy licensees. Any additional public health orders issued by the Director of Health since April 30, 2020 are related to the operations of businesses that were not deemed essential by the original stay at home order or easing other restrictions (i.e. out-of-state travel).

The order implements uniform requirements that pharmacies, wholesalers, and other Board of Pharmacy licensees and registrants are required to comply with to remain open. The Board has posted more information about complying with this order and the Responsible RestartOhio requirements here: www.pharmacy.ohio.gov/RestartOhio.

Licensees <u>are strongly advised to review</u> the applicable <u>Responsible RestartOhio Requirements</u>. As a reminder, these requirements include the following:

- Ensure minimum of 6 feet between employees, if not possible, install barriers.
- Businesses must require all employees to wear facial coverings, except for one of the reasons specified in the Responsible RestartOhio Requirements.
- Ensure minimum 6 feet between customers/patients/etc.
- Employees must perform daily symptom assessment.
- Require employees to stay home if symptomatic.
- Require regular handwashing by employees.
- Place hand sanitizers in high-contact locations.
- Clean high-touch items after each use.

IMPORTANT: The above requirements do not represent an exhaustive list and licensees and registrants should consult the Responsible RestartOhio Requirements document for further information.

These requirements replace all previously issued guidance on how licensees are to maintain clean and sanitary conditions during COVID-19.

Automatic Extension of Technician Trainee Registrations - UPDATED 5/18/2020

Technician trainees who are set to have their registrations expire any time between 3/9/2020 through **7/31/2020** (previously 5/31/2020) will be provided an automatic six-month extension to the trainee's registration. More information can be accessed here.

COVID-19 Drug Shortage Guidance - UPDATED 4/23/2020

Due to the COVID-19 pandemic, hospitals and other healthcare facilities may experience shortages of drugs necessary to care for patients. The Board of Pharmacy, in consultation with the Ohio Department of Health, has developed the following guidance to assist hospitals and other healthcare facilities in obtaining drugs that may not be commercially available from manufacturers or wholesalers. This guidance can be accessed by visiting: www.pharmacy.ohio.gov/COVIDshortage.

Emergency Rules for Dispensing Chloroquine and Hydroxychloroquine – UPDATED FAQS 4/16/2020

On March 22, 2020, Governor Mike DeWine authorized the State of Ohio Board of Pharmacy to file emergency rule 4729-5-30.2 of the Administrative Code that places limits on dispensing chloroquine and hydroxychloroquine. **IMPORTANT REMINDER:** The rule only applies to prescriptions that are dispensed for outpatient use.

To address certain questions, the Board has issued two additional FAQs to its guidance document (www.pharmacy.ohio.gov/COVIDrx):

Q4) Am I able to prescribe chloroquine or hydroxychloroquine for other conditions?

Yes, as long as the prescriber includes a diagnosis code on the prescription. The limitations set forth in rule are only for the off-label prescribing of these medications for COVID-19. Other offlabel uses (e.g. dermatomyositis, cutaneous disease, etc.) are still permitted.

Q5) Are urgent cares included in the definition of emergency department?

Emergency department includes emergency departments in hospitals and free-standing emergency departments. It does not include urgent care facilities.

Ohio Launches Toll-Free 'COVID Careline' to Provide Emotional Support for Ohioans: 1-800-720-9616

The Ohio Department of Mental Health and Addiction Services (OhioMHAS) today joined with Governor Mike DeWine and RecoveryOhio to launch a new, toll-free Careline to provide emotional support for Ohioans who are experiencing stress, anxiety, fear, sadness and loneliness amid the COVID-19 pandemic. Ohioans may call 1-800-720-9616 to connect with trained counselors for 24/7 support. The Careline is staffed by credentialed counselors who have been trained to provide free, confidential support for a wide range of needs, including mental health concerns, substance use, problem gambling, and more. Individuals experiencing an acute crisis can still reach out to the Ohio Crisis Text Line (keyword 4HOPE to 741 741) or the National Suicide Prevention Lifeline (1-800-273-8255).



DEA Issues Additional Guidance for Emergency Temporary Sites

The DEA has issued additional guidance for emergency temporary sites, which can be accessed by visiting: https://www.deadiversion.usdoj.gov/coronavirus.html

Licensees that are <u>registering temporary sites</u> with the Board of Pharmacy and the DEA for the use of controlled substances are expected to comply with this guidance.

Board Office Hours

In order to help contain the spread of the coronavirus (COVID-19), the State of Ohio Board of Pharmacy has closed its offices to the general public and Board staff will be working remotely until further notice. Please be advised that it may take longer than usual to receive a response.

If you need to contact the Board for any reason, please use the <u>Contact Us</u> form on our website. A member of our staff will reply to your email as soon as possible. Licensees may also contact their assigned Board field staff member.

For emergencies during non-business hours (8 am - 5 pm), the Board's emergency line is still available by calling the main office number 614-466-4143.

COVID-19 Waivers and Guidance for Licensees

Waiver Issue Date	Description					
3/13/2020	Authorized the practice of remote order entry for all licensed/registered pharmacy personnel (pharmacists, pharmacy interns, and technicians). The guidance can be accessed here .					
3/14/2020 – UPDATED 3/30/2020	Authorized the compounding and sale of certain alcohol-based hand sanitizer products by Ohio-licensed pharmacies and outsourcing facilities. This guidance can be accessed here .					
3/14/2020 - UPDATED 4/14/2020 & 5/15/2020	Authorized licensees conducting sterile compounding to reuse certain personal protective equipment (PPE). The waiver was updated to align with recently released PPE conservation guidance issued by the FDA. This guidance can be accessed here .					
3/16/2020 – UPDATED 4/23/2020 & 5/15/2020	Authorized automatic exemptions to rule authorizing the compounding of drugs in shortage (4729-16-10) under certain conditions. This guidance can be accessed here .					
3/16/2020	Authorized the extension of emergency refills. This guidance can be accessed here .					
3/16/2020 – UPDATED 3/26/2020	Authorized pharmacists, pharmacy interns, and pharmacy technicians licensed in other states to work in Ohio pharmacies under certain conditions. This guidance can be accessed here .					
3/16/2020 – UPDATED 3/26/2020	Authorized expedited onboarding of pharmacy technician trainees. This guidance can be accessed here .					
3/16/2020 – UPDATED 3/31/2020 & 5/18/2020	Authorized an extension of the renewal date for registered pharmacy technicians and automatic technician trainee extensions. This guidance can be accessed here .					
3/18/2020	Authorized prescribers working in an opioid treatment program licensed as a terminal distributor of dangerous drugs to temporarily delegate personally furnishing of buprenorphine products to nurses licensed under Chapter 4723. of the Revised Code. This guidance can be accessed here .					
3/18/2020	Authorized home delivery of medications by opioid treatment programs under specific conditions. This guidance can be accessed here .					
3/18/2020	Authorized an extension of basic life-support training certifications for pharmacists and pharmacy interns. This guidance can be accessed here .					
3/18/2020 – UPDATED 4/14/2020	Authorized prescribers to delegate personally furnishing non-controlled drugs to nurses licensed in accordance with Chapter 4723. of the Revised Code. This guidance can be accessed here .					

3/18/2020 – UPDATED 3/20/2020	Authorized the temporary expansion of the maximum days' supply permitted under rule 4729-9-23 of the Administrative Code from 31 days to 60 days. This guidance can be accessed here .				
3/20/2020 – UPDATED 4/23/2020	Authorized licensees to perform sterile compounding for another licensee, referred to as central compounding. This guidance can be accessed here .				
3/20/2020	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. This guidance can be accessed here .				
3/24/2020 – UPDATED 5/6/2020 & 5/22/2020	Authorized an extension of drug distributor customer due diligence requirements pursuant to paragraph (G) of rule 4729:6-3-05 of the Administrative Code. This guidance can be accessed here .				
3/24/2020	Authorized expedited licensure of drug distributors. This guidance can be accessed here .				
3/24/2020	Authorized the sale and shipment of non-reportable dangerous drugs that are in shortage by unlicensed, out-of-state facilities. This guidance can be accessed here .				
3/31/2020 - UPDATED 4/29/2020	Authorized the use of temporary satellite locations for the storage and use of dangerous drugs during COVID-19. This guidance can be accessed here .				
3/31/2020	Authorized a temporary extension of the annual controlled substance inventory requirements pursuant to rule 4729:5-3-07 of the Administrative Code. This guidance can be accessed here .				
4/3/2020	Permits the temporary reinstatement of lapsed or expired Ohio pharmacist licenses in Ohio under certain conditions. This guidance can be accessed here .				
4/7/2020	Authorized nurses (LPN, RN, APRN) to stock automated drug storage systems within a terminal distributor of dangerous drugs that has an onsite pharmacy under certain conditions. This guidance can be accessed here.				
4/7/2020 – UPDATED 4/29/2020 & 5/27/2020	Authorized pharmacists, pharmacy interns, and certified pharmacy technicians to conduct FDA-authorized COVID-19 testing under certain conditions. This guidance can be accessed here .				
4/9/2020	Authorized the delegation to an Ohio-licensed APRN who is designated as a certified nurse practitioner (CNP), clinical nurse specialist (CNS), certified nurse midwife (CNM) or physician assistant (PA) the				

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	management of a consult agreement authorized under section 4729.39 of the Revised Code. This guidance can be accessed here .				
4/14/2020	Authorized the sale and shipment of patient-specific, non-reportable dangerous drugs by non-Ohio licensed border state facilities to patients residing in the state under certain conditions. This guidance can be accessed here .				
4/14/2020	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). This guidance can be accessed here.				
4/17/2020 – UPDATED 5/15/2020	Formally adopted FDA's "Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency" for Ohio-licensed outsourcing facilities. This guidance can be accessed <a here"="" href="https://example.com/here/health/healt</th></tr><tr><th>4/17/2020</th><th>Authorized the temporary waiver of the 5 percent limit on the occasional wholesale sales of dangerous drugs by a licensed pharmacy set forth in rule 4729:5-3-09 of the Administrative Code. This guidance can be accessed here .				
4/17/2020	Extends recertification of primary and secondary engineering controls in accordance with guidance issued by USP. This guidance can be accessed here .				
4/23/2020	Formally adopted FDA's "Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID-19 Public Health Emergency" for Ohio-licensed pharmacies, repackagers, and outsourcing facilities. This guidance can be accessed				

Licensees seeking waivers to Ohio laws and regulations governing the practice of pharmacy or distribution of dangerous drugs due to COVID-19 can submit a request to: compliance@pharmacy.ohio.gov. Please include a detailed justification for the waiver request and the expected time period.

Important COVID-19 Reminders

Compounding and Preparing Fit Test Solutions for PPE

The Board has received several inquiries regarding the ability of pharmacies to prepare fittest solutions for personal protective equipment. As these solutions are not considered dangerous drugs, pharmacies are permitted to compound these solutions, as long as they comply with the OSHA requirements set forth in Appendix A to §1910.134, which can be accessed here.

Notification of Closures or Reduction in Hours

As a reminder, pharmacies and other terminal distributors of dangerous drugs are not required to submit notification to the Board for any temporary closures or reduction in operating hours. If modifying hours of operation, a pharmacy is required to update signage to reflect the change in store hours.

Pharmacist Authority to Administer Injectable Drugs

Section 4729.45 of the Ohio Revised Code and rule 4729-5-40 of the Ohio Administrative Code authorizes a pharmacist to administer, by injection, certain dangerous drugs as long as the drug that is to be administered has been prescribed by a physician and the individual to whom the dangerous drug was prescribed has an ongoing relationship with the physician, an advanced practice registered nurse practicing who has entered into a standard care arrangement with the physician, or a physician assistant who has entered into a supervision agreement with the physician. Guidance for pharmacists can be accessed here.

Delivery Services

- Pharmacies are permitted to use couriers, pharmacy staff (including support staff), and other delivery services (i.e. United States postal service or common or contract carrier) to deliver patient medications. Be advised that pharmacies seeking to return drugs to stock shelves that cannot be delivered to the patient are required to have policies and procedures in place pursuant to paragraphs (B)(6) and (B)(8) of rule 4729-5-14 of the Administrative Code.
- Additionally, nothing in rule or law prohibits using technicians, interns or support personnel to deliver medications to patients waiting at the store (ex. for curbside pickup).

Providing Services at Alternate Locations

- Pharmacies and other locations licensed as terminal distributors of dangerous drugs can provide services outside of the pharmacy as long as they are on the physical premises of the licensed location (i.e. setting up temporary drive-thru to limit pharmacy personnel exposure, offering immunizations at another location in the store, etc.).
- Pharmacies are reminded that any drugs removed from the pharmacy to provide additional on-site services must be under the supervision of a pharmacist to deter and detect possible diversion. NOTE: This does not apply to dispensed medications that are being provided to patients by pharmacy technicians, interns or support personnel (for example, for curbside pickup or temporary drive thru).
- If seeking to provide services off-site (except for delivery) involving drugs, please refer to the temporary off-site requirements in rule <u>4729:5-3-13</u> of the Administrative Code.

Use of Signatures for Prescription Pick-Up

Please be advised that the use of signatures for picking up a prescription is not required by Board of Pharmacy rules. For patient counseling, a verbal offer or providing an offer to counsel in writing (i.e. a telephone number where a pharmacist may be reached) is required under the patient counseling rule.

Administration of Testing

Pharmacy personnel guidance for COVID-19 testing can be accessed <u>here</u>.

Combining Refills

Section 4729.40 of the Revised Code authorizes a pharmacist who is filling or refilling a prescription that has one or more refills to dispense the drug in a quantity or amount that varies from the quantity or amount that would otherwise be dispensed. Guidance can be accessed here.

Emergency Refills

 Ohio law authorizes a pharmacist to dispense medications without a prescription under certain conditions. Updated guidance can be accessed here.

Pharmacist Consult Agreements

Ohio law authorizes one or more pharmacists practicing under a consult agreement with one
or more physicians to (1) manage a patient's drug therapy (including authorizing refills) for
specified diagnoses or diseases; and (2) order and evaluate blood and urine tests.
 Guidance can be accessed here.

Boards of Health – Public Health Emergencies

- The Board has issued the following resolutions that apply to local boards of health during public health emergencies:
 - Temporary Removal of Drugs: The Board authorized a board of health, as defined in section 3701.048 of the Revised Code, that is licensed as a terminal distributor of dangerous drugs to temporarily remove dangerous drugs upon the governor's declaration of an emergency that affects public health. A complete copy of the resolution can be accessed here.
 - Waiver of Wholesale Licensure Requirements: Pursuant to section 4729.25 of the Revised Code, the Board finds it is in the public's interest to waive the drug distributor licensure requirements pursuant to section 4729.52 of the Revised Code for a board of health, as defined in section 3701.048 of the Revised Code, that is licensed as a terminal distributor of dangerous drugs (TDDD) for the purpose of distributing dangerous drugs to another TDDD during a declared public health emergency or emergency preparedness incident. A complete copy of the resolution can be accessed here.

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