



**STATE OF
OHIO**
BOARD OF PHARMACY

Drug Compounding Resolutions and Guidance During COVID-19

Updated 6/11/2020

In recent weeks, the Board has issued several resolutions on drug compounding. To further assist licensees, all compounding resolutions and guidance have been consolidated into a single document.

Licensees are advised that several of the Board's compounding resolutions have been updated to comply with temporary compounding policies issued by the United States Food and Drug Administration (FDA).

For more information on addressing drug shortages during COVID-19, visit:
www.pharmacy.ohio.gov/COVIDshortage.

The following resolutions have been incorporated into this document:

- [Non-Patient Specific Drug Compounding by In-State Pharmacies for Hospitalized Patients](#)
(Previously Titled: Automatic Exemptions to Rule 4729-16-10 and Expanded Definitions of Drug Shortages)
- [Central Compounding for Compounded Sterile Products](#)
- [Reuse of Personal Protective Equipment \(PPE\) for Compounding Activities](#)
- [Authorizing Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products](#)
- [Recertification of Primary and Secondary Engineering Controls During COVID-19](#)



Non-Patient Specific Drug Compounding by In-State Pharmacies for Hospitalized Patients

Updated 5/15/2020

(Previously Titled: Automatic Exemptions to Rule 4729-16-10 and Expanded Definitions of Drug Shortages)

To promote patient access to needed medications during the COVID-19 outbreak, the State of Ohio Board of Pharmacy has adopted the following updated resolution regarding the compounding of drugs in shortage as authorized by rule [4729-16-10](#) of the Administrative Code and by a [temporary policy](#) issued by the FDA.

NOTE: This resolution has been updated to reflect a [temporary policy](#) adopted by the U.S. Food and Drug Administration (FDA). Please be advised that due to the issuance of the FDA policy, the Board can no longer recognize drug shortages that exist on the American Society of Health-System Pharmacists' drug shortage list.

This guidance is being issued in accordance with a Board resolution adopted on May 4, 2020 and a [temporary policy](#) issued by the FDA.

An in-state pharmacy intending to compound drugs in shortage pursuant to rule 4729-16-10 of the Administrative Code and the FDA's [temporary policy](#) may do so without first obtaining an exemption from the Board's Executive Director, if the pharmacy complies with the following:

1. The in-state compounding pharmacy maintains documentation of a request for the compounding of drugs in shortage by a medical director of a hospital or Ohio licensed pharmacist who is authorized by the hospital to act on behalf of the medical director. The documentation of a request is not required if the hospital owns and operates the compounding pharmacy.

NOTE: For the purposes of this guidance, hospital includes free-standing emergency departments and any satellite location of a hospital that is being used to treat COVID-19 patients.

2. The in-state compounding pharmacy maintains documentation of a drug shortage for three years in a readily retrievable manner (i.e. must be produced for review no later than three business days to an agent, officer, or inspector of the Board).

IMPORTANT: Now that the FDA has issued guidance for compounding of drugs in shortage, the Board has narrowed its definition of a drug in shortage to be those listed in Appendix A of the [FDA's temporary policy](#) (see page 7). **On 5/9/2020, the FDA updated the list to include morphine sulfate and epinephrine.**

3. If the compounding pharmacy is not owned or operated by the hospital, it shall maintain the following records of any non-patient specific drug provided to the hospital: The name, strength, dosage form, expiration date and quantity of the dangerous drug transferred or

sold, the address of the location where the drugs were transferred or sold, and the date of transfer or sale.

4. The pharmacy complies with the requirements set forth in the FDA's [Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency](#) and any subsequent updates to this policy, including the updated policy issued on May 8, 2020.
5. Per the FDA's policy, submit notification via email (compliance@pharmacy.ohio.gov) to the Board of Pharmacy of the intent to provide non-patient specific drugs in shortage to hospitals. The notification email must include the following:
 - Name and address of the compounding pharmacy and the name and address of the hospital who will receive the compounded drugs;
 - Contact telephone number of the compounding pharmacy;
 - Ohio license number of the compounding pharmacy; and
 - A complete list of non-patient specific drugs that the pharmacy will be compounding (if the pharmacy intends to compound additional drugs after submission, a new notification email is required).

It is the Board's position that an in-state pharmacy providing a drug product to a hospital in accordance with the provisions of this resolution without first obtaining a patient-specific prescription is deemed appropriate. Therefore, a pharmacy is not required to wait for a response from the Board to begin compounding. However, the Board reserves the right to order the pharmacy stop any non-patient specific compounding activities that do not comply with the requirements of this resolution and/or pose a safety risk to the public.

IMPORTANT: Pharmacies may also engage in non-patient specific central compounding for the drugs listed in listed in Appendix A of the [FDA's temporary policy](#) (see page 7). The central compounding resolution (starting on page 4) has been updated to reflect this change.

This guidance is in effect for no longer than the duration of the public health emergency related to COVID-19 declared by HHS, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)).

Central Compounding for Compounded Sterile Products

Updated 4/23/2020

In order to mitigate reported shortages of personal protective equipment (PPE) and address staffing concerns, the State of Ohio Board of Pharmacy has adopted the following guidance to permit licensees to perform sterile compounding for another licensee, referred to as central compounding.

NOTE: This resolution has been updated to reflect a [temporary policy](#) adopted by the U.S. Food and Drug Administration (FDA).

This guidance is being issued in accordance with a Board resolution adopted on March 2, 2020.

As used in this guidance “originating facility” means the facility where compounded medication administration occurs and “compounding facility” means the facility where drugs are compounded for the originating facility.

For a terminal distributor of distributor drugs (TDDD) to compound for another licensee, the TDDD must comply with all the following:

1. The compounding facility is responsible for compliance with chapters USP 797 and 795 and rule 4729-16-04 of the Administrative Code.
2. The compounding facility and the originating facility (i.e. where the medication administration occurs) are under common ownership.
3. Except for drugs listed in listed in Appendix A of the [FDA's temporary policy](#), only patient-specific compounded sterile products (CSPs) are permitted. No batch compounding of CSPs shall be provided to the originating facility. Unless the pharmacy
4. All CSPs must comply appropriate labeling of CSPs in accordance to OAC 4729-17-10. In addition, the label must with also include the name and address of the compounding facility. This may be achieved by affixing an auxiliary label on the CSP.
5. All areas where dangerous drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Transportation and storage of the CSPs shall be maintained at temperatures which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise directed by the board.
6. Unused, patient-specific CSPs may be returned to the compounding facility for appropriate disposal only. Returned CSPs to the compounding facility shall not be reused or redispensed.
7. Unused, patient specific CSPs may be reused at the originating facility if stored under appropriate conditions.

8. The compounding and originating facility must maintain appropriate recordkeeping for each licensee in accordance to OAC 4729-16-06, 4729-9-22, 4729-9-14, 4729-17-04.

This guidance shall remain in effect until rescinded by the Board.

Reuse of Personal Protective Equipment (PPE) for Compounding Activities

Updated 5/15/2020

This guidance replaces previous PPE compounding guidance issued on March 14, 2020.

In order to mitigate reported shortages, the State of Ohio Board of Pharmacy has adopted the following resolution to permit licensees conducting sterile compounding to reuse certain personal protective equipment (PPE).

This guidance is being issued in accordance with a Board resolution adopted on May 4, 2020.

The Board hereby adopts the following FDA guidance for the reuse of PPE for compounding activities **and any subsequent updates to this policy, including the updated policy issued on May 14, 2020:**

- [Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency](#)

IMPORTANT: As stated in the FDA guidance, personal protective equipment used to compound hazardous drugs (as listed in the [NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings](#)) **cannot** be reused.

Authorizing Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products

Updated 6/11/2020

In order to reduce opportunities for the transmission of COVID-19 and mitigate possible shortages, the State of Ohio Board of Pharmacy has adopted the following guidance to permit the compounding and sale of certain alcohol-based hand sanitizer products by Ohio-licensed pharmacies and outsourcing facilities (referred to collectively in this guidance as compounders).

This guidance is being issued in accordance with a Board resolution adopted on March 2, 2020 and section 4729.25 of the Revised Code. This document serves as the formal notice required pursuant to section 4729.25 of the Revised Code.

Compounders must adhere to the requirements and recommendations set forth in the [FDA's Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency](#) (Updated June 1, 2020)

IMPORTANT REMINDER: Per the [FDA policy](#) (see page 6), compounder **ARE NOT PERMITTED** to add other active or inactive ingredients, such as ingredients to improve the smell or taste due to the risk of accidental ingestion in children (examples include the use of essential oils). Different or additional ingredients may impact the quality and potency of the product.

Licensees that produce alcohol-based hand sanitizer products that contain inactive/active ingredients not authorized in the FDA policy must adjust their formulas accordingly and discontinue the sale of hand sanitizer that does not comply with the policy. Additionally, licensees are not permitted to sell any compounded hand-sanitizer that does not comply with the FDA policy. Failure to adhere to these requirements may subject a licensee and the licensee's responsible person to disciplinary action.

UPDATED 3/30/2020 – Due to the public health emergency posed by COVID-19, the FDA has issued [additional guidance](#) permitting the use of alcohol (i.e., ethanol or ethyl alcohol) produced by alcohol production firms to be used as the Active Pharmaceutical Ingredient (API) in alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020. Therefore, compounding pharmacies may utilize ethanol or ethyl alcohol to compound hand sanitizer products that is consistent with this [guidance](#). Additionally, the [pharmacy compounding guidance](#) has been updated to include the use of denatured alcohol (see page 3 of [guidance](#)).

This guidance is in effect until rescinded by the Board or the United States Food and Drug Administration.

For questions regarding this guidance, please e-mail the Board office by visiting: <http://www.pharmacy.ohio.gov/contact.aspx>.

Recertification of Primary and Secondary Engineering Controls During COVID-19

Updated 4/17/2020

In order to address resource constraints, the State of Ohio Board of Pharmacy has adopted the following resolution on the recertification of primary and secondary engineering controls:

- Licensees may delay recertification of primary and secondary engineering controls if they are served by a continuous monitor. The continuous monitor should help to assure that a state of control is established and maintained from the previous certification. The interval between certification shall not exceed 12 months.
 - If delaying certification, licensees should also consider increased environmental monitoring and applying shorter beyond-use dates (BUDs) if certification is delayed.
- **IMPORTANT:** Primary and secondary engineering controls shall not be used without initial (i.e., startup) certification.

This guidance is being issued in accordance with a Board resolution adopted on March 2, 2020 and shall remain in effect until rescinded by the Board.