



Compounding for Drug Shortages

Updated 11/18/2017

IMPORTANT NOTICE: Due to reports of critical drug shortages, the State of Ohio Board of Pharmacy has postponed the rescission of rules [4729-16-10](#) and [4729-16-07](#) of the Ohio Administrative Code to a date to be determined later.

In-State Compounding Pharmacies

- [Rule 4729-16-10 of the Ohio Administrative Code](#) allows an in-state compounding pharmacy to obtain an exemption from the Board of Pharmacy in order to provide non-patient specific compounded drugs to an in-state health care facility in the event of a drug shortage. The exemption request can be found on the next page of this document.
- The drugs provided are to be used for direct administration to patients **ONLY** within the in-state health care facility that receives the exemption. The drugs may not be transferred or sold to another facility (even within the same company).
- The request for any compounded drug that is experiencing a drug shortage must be made by a medical director of an in-state health care facility.
- The drugs provided to the in-state health care facility must be listed on the U.S. Food and Drug Administration's (FDA) drug shortage list:
<http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>
- An in-state health care facility is any of the following facilities that are licensed as a terminal distributor of dangerous drugs in the state of Ohio:
 - a) A hospital registered with the department of health under section 3701.07 of the Revised Code;
 - b) Ambulatory surgical facility as defined in section 3702.30 of the Revised Code; or
 - c) Emergency medical service (EMS) organization as defined in section 4765.01 of the Revised Code.
- For drugs compounded by an in-state pharmacy that are on the FDA Drug Shortage List, the drug must be compounded after the drug is placed on the drug shortage list and may not be administered to a patient after it has been removed from the drug shortage list.
- In-state compounding pharmacies are advised to place shorter beyond use or expiration dates on such products to ensure that they will be used within this period and compounders

77 South High Street, 17th Floor, Columbus, Ohio 43215



and purchasers will not be left with inventory of drugs that cannot be used because they are no longer in shortage.

Outsourcing Facilities

- Outsourcing facilities that are licensed by the State of Ohio Board of Pharmacy can also provide drugs in the event of a drug shortage. For more information please visit: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm389118.htm#16>
- The FDA has recently developed a product report that lists drug products that outsourcing facilities produce. This report can be accessed here: <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm393571.htm>
- Visit www.pharmacy.ohio.gov/list to download a spreadsheet of current licensed outsourcing facilities (download the drug distributor spreadsheet, then filter the "Business Type Code" column by OSC).



Drug Shortage Exemption Form

**Please complete the following and submit via email to:
contact@pharmacy.ohio.gov**

Date:

IN-STATE COMPOUNDING PHARMACY

| | |
|-------------------|----------------------------------|
| Pharmacy Name: | TDDD License No: |
| Street Address: | Name of Responsible Person (RP): |
| City: | RP Pharmacist License No: |
| Zip Code: | RP Contact Phone: |
| RP E-Mail Address | |

IN-STATE HEALTH CARE FACILITY

| | |
|---------------------------------|---------------------------------|
| Health Care Facility Name: | TDDD License No: |
| Street Address: | Name of Medical Director: |
| City: | Medical Director License No: |
| Zip Code: | Medical Director Contact Phone: |
| Medical Director E-Mail Address | |

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Signed Statement by Responsible Person for In-State Pharmacy:

I FULLY UNDERSTAND THAT:

- All drugs compounded by the in-state pharmacy shall comply with all federal and states laws and regulations.
- The drugs requested on this form shall only be compounded after the drug is placed on the drug shortage list and may not be dispensed or administered after it has been removed from the drug shortage list.
- The Board may place restrictions on the quantity and a limit on the time the exemption shall be in effect.

I DECLARE UNDER PENALTIES OF FALSIFICATION AS SET FORTH IN CHAPTERS 2921., 3715., 3719. AND 4729. OF THE OHIO REVISED CODE THAT I AM AUTHORIZED TO PURSUE THIS REQUEST ON BEHALF OF THE ENTITY LISTED IN THIS APPLICATION AND THAT THIS REQUEST IS TRUE, CORRECT, AND COMPLETE.

| | | |
|--|--------------------|---------------------------|
| SIGNATURE of Responsible Person | Date Signed | PRINT OR TYPE NAME |
| Facility TDDD License No. | | |

Signed Statement by the Medical Director for In-State Health Care Facility:

I FULLY UNDERSTAND THAT:

- The drugs requested on this form shall only be compounded after the drug is placed on the drug shortage list and may not be dispensed or administered to a patient after it has been removed from the drug shortage list.
- The Board may place restrictions on the quantity and a limit on the time the exemption shall be in effect.
- Drugs made by compounders are NOT FDA-approved and do not adhere to the current good manufacturing practices applied to drug manufacturers. This means that they have not undergone the same premarket review as approved drugs. They lack an FDA review of safety and efficacy and of manufacturing quality. Therefore, when an FDA-approved drug is commercially available, or an alternative FDA-approved drug can be used, the Board recommends that the Medical Director obtain the FDA-approved drug rather than a compounded drug unless the Medical Director has determined that a compounded product is necessary and would provide a significant difference as compared to the FDA-approved commercially available drug product.

I DECLARE UNDER PENALTIES OF FALSIFICATION AS SET FORTH IN CHAPTERS 2921., 3715., 3719. AND 4729. OF THE OHIO REVISED CODE THAT I AM AUTHORIZED TO PURSUE THIS REQUEST ON BEHALF OF THE ENTITY LISTED IN THIS APPLICATION AND THAT THIS REQUEST IS TRUE, CORRECT, AND COMPLETE.

| | | |
|--------------------------------------|--------------------|---------------------------|
| SIGNATURE of Medical Director | Date Signed | PRINT OR TYPE NAME |
| Facility TDDD License No. | | |