



**STATE OF
OHIO**
BOARD OF PHARMACY

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 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.

For questions regarding this guidance, the most expedient way to have your questions answered is to e-mail the Board by visiting: www.pharmacy.ohio.gov/contact.

Outsourcing Facilities

Outsourcing facilities are Ohio-licensed businesses that are registered by the U.S. Food and Drug Administration (FDA) to compound sterile and non-sterile drugs for sale to hospitals, physicians, clinics, or other healthcare facilities.

According to the FDA, outsourcing facilities are authorized to compound any drug that is on the FDA's [drug shortage list](#). Specifically, the FDA [states](#):

The agency also does not consider a compounded drug produced by an outsourcing facility as “[essentially a copy](#)” if it is identical or nearly identical to an FDA-approved drug that is on FDA's [drug shortage list](#). The agency also does not intend to take action under this provision if the facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

REMINDER: This provision also applies to patient-specific compounding. For additional information see [FDA guidance](#).

A terminal distributor of dangerous drugs is permitted to buy compounded drugs that are on the FDA's drug shortage list (or that have been discontinued or no longer marketed) from either:

1. An outsourcing facility currently licensed by the Board of Pharmacy (a list of currently licensed outsourcing facilities is available at the [end of this document](#)).
2. An outsourcing facility that is not currently licensed by the Board of Pharmacy but complies with a Board resolution on the use of non-Ohio licensed facilities in the event of drug shortage due to COVID-19. For more information on this resolution, visit: www.pharmacy.ohio.gov/TEMPOOS.

All FDA registered outsourcing facilities are listed on the FDA's website:

<https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities>

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Additionally, outsourcing facilities are required to submit reports to the FDA on the drug products the facilities have produced in a six-month period. This information is intended to assist the public in identifying outsourcing facilities that have produced certain drug products that they need. The most recent list can be accessed [here](#).

Lastly, the FDA recently issued additional [guidance](#) setting forth a temporary policy for outsourcing facilities to compound certain human drugs for hospitalized patients during the COVID-19 public health emergency. This guidance is being issued to help ensure treatment options are available for hospitalized patients with COVID-19 when hospitals experience difficulties accessing certain FDA-approved drugs. A copy of the guidance can be accessed here: <https://www.fda.gov/media/137031/download>

Please be advised that [Board adopted this FDA policy](#) for Ohio-licensed outsourcing facilities and this guidance shall remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)).

Non-Patient Specific Drug Compounding by Ohio Pharmacies for Hospitalized Patients – UPDATED 4/23/2020

An in-state pharmacy intending to compound certain non-patient specific drugs in shortage for use by hospitalized patients pursuant to rule 4729-16-10 of the Administrative Code and the FDA's [temporary policy](#) may do so in accordance with updated [guidance](#) issued by the Board.

For more information on non-patient specific compounding by in-state pharmacies for hospitalized patients, visit: www.pharmacy.ohio.gov/COVIDcompounding.

Occasional Wholesale Sales

Section [4729.51](#) of the Revised Code includes a provision that permits any terminal distributor (not just pharmacies) to engage in the sale (even a no-cost sale) of dangerous drugs that are on the FDA's [drug shortage list](#). This allows the purchase of drugs in shortage from non-pharmacy licensees such as EMS agencies, ambulatory surgical centers, clinics, etc.

Terminal distributors engaged in occasional wholesale sales are required to maintain the following records documenting the sale of drugs:

Records of transfer or sale conducted in accordance with rule [4729:5-3-09](#) of the Administrative Code shall contain the name, strength, dosage form, national drug code, 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.

REMINDER: This applies to sales between licensees that are not commonly owned and controlled. Those that are under common ownership may already transfer drugs between licensees.

Please be advised that limits on pharmacies and other terminal distributors set forth in rule 4729:5-3-09 of the Administrative Code as well as limits imposed by the [Drug Enforcement Administration](#) have been temporarily suspended due to the COVID-19 pandemic. For more information on these waivers [click here](#).

Repackaging or Combining Propofol Drug Products During the COVID-19 Public Health Emergency – [UPDATED 4/23/2020](#)

The FDA has received reports that hospitals are having difficulty obtaining adequate supplies of FDA-approved propofol products that are needed to care for critically ill COVID-19 patients. To address this issue, the agency [issued a temporary policy](#).

On April 23, 2020, the [Board adopted](#) this FDA policy for Ohio-licensed pharmacies, repackagers, and outsourcing facilities.

CDC CHEMPACKs and Strategic National Stockpile

IMPORTANT: This guidance is being issued in consultation with the Ohio Department of Health's Bureau of Health Preparedness.

As a last resort, hospitals and other facilities that have access to the Strategic National Stockpile or [CDC CHEMPACKs](#) may obtain drugs from this supply in order to treat patients during COVID-19. Refer to the [Assistant Secretary for Preparedness & Response memo](#) dated April 2, 2020 for further guidance and a list of medications that may be available in CHEMPACK containers that could be applicable to the care of COVID-19 patients.

For Ohio, the deployment of CHEMPACK supplies to sites will follow the guidance set forth in reference to information contained in the [Ohio CHEMPACK Program Operational Plan](#). Hospitals and other facilities must maintain records documenting the use of drugs obtained from CHEMPACKs of the National Stockpile in accordance with existing Board of Pharmacy record keeping requirements.

Ohio Licensed Outsourcing Facilities – As of 4/23/2020*

License Num.	License Type**	Name
0162000006	Outsourcer - Category 3	American Specialty Pharmacy, Inc.
012481000	Outsourcer - Category 3	ANAZAOHEALTH CORPORATION
012663850	Outsourcer - Category 2	ATHENEX PHARMA SOLUTIONS, LLC
012660150	Outsourcer - Category 3	ATLAS PHARMACEUTICALS
012632100	Outsourcer - Category 3	AVELLA OF DEER VALLEY, INC. #38
012636650	Outsourcer - Category 3	BELMAR SELECT OUTSOURCING
012579850	Outsourcer - Category 2	BROOKFIELD MEDICAL/SURGICAL SUPPLIES, INC.
012644800	Outsourcer - Category 3	CARIE BOYD'S PRESCRIPTION SHOP
012489750	Outsourcer - Category 2	CENTRAL ADMIXTURE PHARMACY SERVICES, INC.
0160000002	Outsourcer - Category 2	Central Admixture Pharmacy Services, Inc.
012536450	Outsourcer - Category 3	CENTRAL ADMIXTURE PHARMACY SERVICES, INC.
012564450	Outsourcer - Category 2	EAGLE, INC.
012646700	Outsourcer - Category 2	Edge Pharma, LLC
012645250	Outsourcer - Category 3	EMPOWER PHARMACY
012656550	Outsourcer - Category 2	EXELA PHARMA SCIENCES, LLC
0162000007	Outsourcer - Category 3	F H Investments, Inc.
012584200	Outsourcer - Category 2	FAGRON STERILE SERVICES, LLC
0162000005	Outsourcer - Category 3	FarmaKeio Outsourcing LLC
012657150	Outsourcer - Category 3	IMPRIMIS NJOF, LLC
012477200	Outsourcer - Category 3	JCB LABORATORIES
012579900	Outsourcer - Category 3	KRS GLOBAL BIOTECHNOLOGY, INC.
012531700	Outsourcer - Category 3	LEITER'S
012665250	Outsourcer - Category 3	LEITERS HEALTH
012649500	Outsourcer - Category 3	NEPHRON SC, INC
012518100	Outsourcer - Category 2	OPS INTERNATIONAL INC. DBA OLYMPIA PHARMACY
012649900	Outsourcer - Category 3	PHARMEDIUM SERVICES, LLC
012514550	Outsourcer - Category 2	PHARMEDIUM SERVICES, LLC
012471950	Outsourcer - Category 2	PINE PHARMACEUTICALS LLC
012649000	Outsourcer - Category 3	PREMIER PHARMACY LABS INC.
012580900	Outsourcer - Category 3	QUALGEN, LLC
012648600	Outsourcer - Category 3	QUVA PHARMA, INC.
0160000001	Outsourcer - Category 2	QuVa Pharma, Inc.
012548400	Outsourcer - Category 3	QUVA PHARMA, INC.
012489700	Outsourcer - Category 2	RC OUTSOURCING
012485200	Outsourcer - Category 3	RXQ COMPOUNDING, LLC
012649850	Outsourcer - Category 3	SCA PHARMACEUTICALS
0162000001	Outsourcer - Category 3	SCA Pharmaceuticals LLC
012659500	Outsourcer - Category 2	SINCERUS FLORIDA, LLC
012645850	Outsourcer - Category 2	STERRX, LLC.
0162000002	Outsourcer - Category 3	STOKES PHARMACY
012472000	Outsourcer - Category 3	US COMPOUNDING, INC.

0162000004

Outsourcer - Category 3

WELLS PHARMACY NETWORK, LLC

*This listed was produced on 4/23/2020. Licensees are required to verify an outsourcing facility's licensure using Ohio's [eLicense system](#) prior to placing an order.

**Category 2 licensees are not permitted to sell compounded drug preparations that are controlled substances.