



Sale and Shipment of Non-Reportable Dangerous Drugs from Unlicensed Out-of-State Facilities

Updated 8/31/2020

In order to address any drug shortages during the COVID-19 outbreak, the State of Ohio Board of Pharmacy issued the following guidance on the sale and shipment of non-reportable dangerous drugs that are in shortage by unlicensed, out-of-state facilities.

As used in this guidance:

- "Non-reportable dangerous drug" means a dangerous drug, as defined in section [4729.01](#) of the Revised Code, that is not required to be reported to the Ohio Automated Rx Reporting System for the purposes of reporting wholesale transactions. Therefore, a non-reportable dangerous drug includes all dangerous drugs except for:
 - Controlled substances dangerous drugs; and
 - Dangerous drugs containing gabapentin.

- "Drug in shortage" or "drug shortage" means any of the following:
 - A drug on the United States Food and Drug Administration's [drug shortage list](#) that is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler.
 - A drug on the American Society of Health-System Pharmacists [drug shortage list](#) that is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler.

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

An Ohio terminal distributor of dangerous drugs may receive non-reportable dangerous drugs from an unlicensed pharmacy, wholesale distributor of dangerous drugs, third-party logistics provider, or manufacturer of dangerous drugs located in another state in order to alleviate a drug shortage if all the following apply:

1. The unlicensed location is appropriately licensed in its home state and documentation of the license verification is maintained by the Ohio terminal distributor of dangerous drugs.
2. The terminal distributor maintains documentation of the shortage of any dangerous drug received from any pharmacy, wholesale distributor, third-party logistics provider, or manufacturer not licensed in Ohio.



3. The terminal distributor complies with all record keeping requirements for each dangerous drug received from any pharmacy, wholesale distributor, third-party logistics provider, or manufacturer not licensed in Ohio.
4. All documentation and records required above shall be maintained and readily retrievable for three years following the end of the declared public health emergency.
5. The dangerous drug was produced by an authorized FDA registered drug manufacturer.
6. The pharmacy, wholesale distributor, third-party logistics provider, or manufacturer submits an [Out-of-State Shipment Notification Form](#) to the Board of Pharmacy prior to shipping any drugs to an Ohio terminal distributor of dangerous drugs. Only one form per unlicensed location must be submitted during the effective period of this guidance.

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