Mike DeWine, Governor Jon Husted, Lt. Governor Steven W. Schierholt, Executive Director

Purchase of IV and Peritoneal Dialysis Solutions from Unlicensed Out-of-State Facilities

Updated 10/9/2024

To address potential shortages IV and peritoneal dialysis solutions due to Hurricane Helene, the Ohio Board of Pharmacy issued the following resolution allowing the sale and shipment of IV and peritoneal dialysis solutions and related non-controlled dangerous drugs by unlicensed, out-of-state facilities.

Resolution Approved 10/9/2024:

An Ohio terminal distributor of dangerous drugs that meets the requirements of this resolution may purchase IV and peritoneal dialysis solutions and related non-controlled dangerous drugs from an unlicensed pharmacy, wholesale distributor of dangerous drugs, third-party logistics provider, outsourcing facility, or manufacturer of dangerous drugs located in another state to alleviate a drug shortage if all the following apply:

- 1. The terminal distributor of dangerous drugs is any of the following:
 - A hospital;
 - An emergency medical service (EMS) organization; or
 - A pharmacy engaged in the compounding of IV solutions.
- 2. The unlicensed location (i.e., the seller) is appropriately licensed in its home state and documentation of the license verification is maintained by the Ohio terminal distributor of dangerous drugs for three years from the date of each purchase.
- 3. The terminal distributor is purchasing any of the following:
 - IV solutions;
 - Peritoneal dialysis solutions; or
 - Any other non-controlled drug intended to mitigate supply disruptions of IV and peritoneal dialysis solutions (ex. concentrated sodium chloride, dextrose, saline flushes, diluent vials for IV push, etc.).
- 4. The terminal distributor is conducting such purchases to minimize supply disruptions of IV and peritoneal dialysis solutions due to Hurricane Helene.



- 5. The terminal distributor complies with all record keeping requirements for each dangerous drug received from any pharmacy, wholesale distributor, third-party logistics provider, outsourcing facility, or manufacturer not licensed in Ohio.
- 6. All documentation and records required above shall be maintained and readily retrievable for three years following purchase.
- 7. The dangerous drug was produced by an authorized FDA registered drug manufacturer or outsourcing facility.
- 8. The terminal distributor submits an Out-of-State Purchase Form (included with this resolution) to the Board of Pharmacy via email (compliance@pharmacy.ohio.gov) prior to purchasing any drugs from the unlicensed seller. Only one form per unlicensed location must be submitted by the terminal distributor during the effective period of this resolution. **NOTE:** If a terminal distributor purchases from multiple unlicensed sellers, the terminal distributor will need to submit a form for each facility.
- 9. An unlicensed pharmacy, wholesale distributor of dangerous drugs, third-party logistics provider, outsourcing facility, or manufacturer of dangerous drugs located in another state shall not be found in violation of Ohio law if they sell to a terminal distributor that meets the requirements of this resolution.

This resolution was authorized by the Board President in accordance with a Board resolution adopted on May 5, 2020. It shall remain in effect until January 15, 2025, unless rescinded earlier by the Board.



OUT-OF-STATE PURCHASE NOTIFICATION FORM

Pursuant to a <u>Board resolution</u> issued on October 9, 2024, this notification form must be submitted prior to the purchase of specified dangerous drugs by a non-Ohio licensed facility. **Completed forms must be submitted electronically to: <u>compliance@pharmacy.ohio.gov</u>**

PART 1 – TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS INFORMATION – Complete all the information for terminal distributor conducting the purchase.

Name of Terminal Distributor of Danger	ous Drugs (TDDD)			
TDDD License Number		Type of I	Facility (select one)	
Address of Facility		City		Zip Code
Full Name of TDDD Contact Person	Contact Person's Ph	none	Contact Person's Ema	il

PART 2 – UNLICENSED SELLER FACILITY INFORMATION – Complete all the information for the unlicensed facility.

Facility Name		Facility's	Home State	
Home State License Number		Type of F	Facility (select one)	
Address of Facility		City		Zip Code
Full Name of Facility Contact Person	Contact Person's Ph	none	Contact Person's Ema	ail

ART 4 - ATTESTATION - To b	e completed by the terminal dist	trihutor's responsible person
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