Resolutions to Address Shortages of IV and Peritoneal Dialysis Solutions

Updated 10/11/2024

To address potential shortages IV and peritoneal dialysis solutions due to Hurricane Helene, the Ohio Board of Pharmacy issued the following resolutions:

- **Purchase of IV and Peritoneal Dialysis Solutions from Non-Ohio Licensed Out-of-State Facilities (Approved 10/9/2024)**
- **Non-Patient Specific Drug Compounding by In-State Pharmacies for Hospitals and EMS (Approved 10/11/2024)**
- **Extension of IV Fluid Hang Times Inside an ISO Class 5 PEC (Approved 10/11/2024)**

For questions regarding these resolutions, please e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

For more information from the U.S. Food and Drug Administration about these shortages, please visit: Hurricane Helene: Baxter's manufacturing recovery in North Carolina | FDA

FDA has also issued its own guidance: Temporary Policies for Compounding Certain Parenteral Drug Products

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Purchase of IV and Peritoneal Dialysis Solutions from Non-Ohio Licensed Out-of-State Facilities

Updated 10/11/2024

Resolution Approved 10/9/2024 (Updated 10/11/2024):

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.

10. The dangerous drugs purchased shall be either of the following:

- FDA approved or, if imported by another country, listed on the FDA's temporary importation list; or
- A compounded drug product prepared by a pharmacy or outsourcing facility.

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 Board resolution 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: compliance@pharmacy.ohio.gov***

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

Name of Terminal Distributor of Dangerous Drugs (TDDD)		
TDDD License Number	Type of Facility (select one) Hospital	
Address of Facility	City	Zip Code
Full Name of TDDD Contact Person	Contact Person's Phone	Contact Person's Email

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 Facility (select one) Wholesaler	
Address of Facility	City	Zip Code
Full Name of Facility Contact Person	Contact Person's Phone	Contact Person's Email

PART 3 – DESCRIPTION OF DRUGS INTENDED TO BE SHIPPED – *Provide a description of the types of drugs that will be shipped into the state by the unlicensed facility.*

PART 4 – ATTESTATION – *To be completed by the terminal distributor's responsible person. Electronic or digital signatures **are** acceptable.*

I DECLARE UNDER PENALTIES OF FALSIFICATION AS SET FORTH IN CHAPTERS 2921. AND 4729. OF THE OHIO REVISED CODE THAT THE INFORMATION PROVIDED IN THIS FORM IS TRUE, CORRECT, AND COMPLETE. I FURTHER ATTEST THAT THE TERMINAL DISTRIBUTOR LISTED IN PART 1 THIS FORM WILL COMPLY WITH THE RESOLUTION ISSUED ON OCTOBER 9, 2024, AND ANY SUBSEQUENT UPDATES ISSUED BY THE BOARD OF PHARMACY.		
Signature of the Terminal Distributor's Responsible Person		Date Signed
Print or Type Full Name	Contact Email	Contact Phone (inc. area code)

Non-Patient Specific Drug Compounding by In-State Pharmacies for Hospitals and EMS

Updated 10/11/2024

Resolution Approved 10/11/2024:

1. An in-state pharmacy may engage in the compounding of non-patient specific drugs, as specified in this resolution, in accordance with the FDA's Temporary Policies for Compounding Certain Parenteral Drug Products.

2. An in-state pharmacy may also engage in the compounding of non-patient specific drugs products, as specified in this resolution, to an emergency medical services (EMS) organization if the EMS organization is unable to obtain IV solutions to meet the demand of its own patients.

3. As used in this resolution, a compounded non-patient specific drug means any of the following on the list authorized by the FDA's temporary policy.

4. All pharmacies shall comply with the beyond-use dating and all other requirements listed in Appendix A of FDA's temporary policy.

5. All pharmacies shall maintain all required records of the transfer or distribution of these compounded drug products in accordance with OAC 4729:5.

6. In accordance with the FDA temporary policy, the Ohio Board of Pharmacy does not object to an in-state pharmacy providing the drug product without first obtaining a patient-specific prescription.

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 rescinded by the FDA, unless rescinded earlier by the Board.

Extension of IV Fluid Hang Times Inside an ISO Class 5 PEC

Updated 10/11/2024

Resolution Approved 10/11/2024:

This resolution extends the time of a punctured conventionally manufactured product in an ISO Class 5 PEC for Ohio hospitals licensed as terminal distributors of dangerous drugs.

1. As used in this resolution, "a conventionally manufactured pharmacy bulk package" means a container of a sterile product for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program that are restricted to the sterile preparation of admixtures for infusion or, through a sterile transfer device (i.e., closed system transfer device or iv spike adapters with needle-free connection) for the filling of empty sterile containers.

2. The conventionally manufactured pharmacy bulk package must be entered or punctured only in an ISO Class 5 PEC and maintained within the PEC.

3. The conventionally manufactured pharmacy bulk package may be used up to 24 hours after initial entry or puncture, unless the manufacturer's instructions specifically permit a timeframe longer than 24 hours.

4. An Ohio hospital utilizing this resolution shall only do so to minimize supply disruptions of IV and peritoneal dialysis solutions.

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.