Resolutions to Address Shortages of IV and Peritoneal Dialysis Solutions

Updated 3/9/2025

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

- **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) – Extended to June 1, 2025**

IMPORTANT: The resolution permitting the purchase of IV and peritoneal dialysis solutions from non-Ohio licensed out-of-state facilities expired on January 15, 2025, and was not renewed by the Board. Licensees are reminded to only purchase from Ohio licensed drug distributors.

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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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 3/9/2025

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 June 1, 2025, unless rescinded earlier by the Board.