

October 11, 2024

Dear Partner:

On October 1, the Ohio Department of Health (ODH) was informed of potential shortages of IV fluids caused by Hurricane Helene's flooding of Baxter International's North Cove IV fluid manufacturing plant in North Carolina. ODH immediately and actively began working with partners at the regional, state, and national levels.

This is a fast-developing situation, and I am writing to provide some recent updates from the state's work, as well as updates from Baxter and the federal government.

Within the state, we are coordinating closely with hospital zone leads, regional healthcare coordinators, the Ohio Hospital Association, and the Ohio Pharmacy Services Center, among others, to ensure a statewide approach for situational awareness and information sharing, data collection, and strategy development. Through this collaboration, ODH initiated a data-reporting event through EMResource for IV fluid tracking. EMResource is a web-based, near-real-time, resource management program used by Ohio area hospitals and ODH to maintain awareness of critical hospital impacts during incidents, which can then be leveraged to inform data-driven decisions and strategies at the state, regional, and local levels. The event went live October 4, with a requirement for all Ohio hospitals to report their IV fluid data daily.

We have seen our hospitals engaging in more efficient methods of delivery and conservation measures aimed at responsibly managing IV fluid volume use, while maintaining the same level of care. The partnership has also assisted regional healthcare coalitions to maintain situational awareness and to support individual facilities' requests for critical resources, including resource sharing between hospitals when necessary.

ODH is very encouraged by Baxter's announcement on Wednesday, October 9, that they are making significant increases in allocations of IV solutions across the country; increasing allocations to direct customers from 40% to 60%, and from 10% to 60% for distributors. We look forward to further increases in these allocations, as Baxter has said it anticipates making over the coming weeks. You can see more about this announcement from Baxter, as well as future updates as the situation evolves, at <https://www.baxter.com/baxter-newsroom/hurricane-helene-updates>.

We also have been encouraged by the U.S. Food & Drug Administration's (FDA's) announcement Wednesday that they are lifting some restrictions on organizations that have the ability to compound these vital IV solutions, including the innovative outsourcing facilities regulated by section 503B of the Food, Drug and Cosmetics Act. This clears the way for ODH to work actively with companies who have advanced compounding capabilities to potentially add more supply to healthcare facilities.

In addition, the clarification the FDA provided that hospitals and health systems which prepare sterile IV solutions in their own pharmacies are able to distribute within their own facilities outside of a 1-mile radius, is another tool that will be helpful for hospitals adapting to the Baxter shortage. More information on the FDA announcement is available at https://www.fda.gov/drugs/updates-2024-hurricane-season/hurricane-helene-baxters-manufacturing-recovery-north-carolina?utm_medium=email&utm_source=govdelivery.

Similarly on the state level, the Ohio Board of Pharmacy has issued guidance to hospital pharmacies that it will allow the sale and shipment of IV and peritoneal dialysis solutions by additional out-of-state facilities: <https://www.pharmacy.ohio.gov/documents/pubs/special/drugshortages/purchase%20of%20iv%20and%20peritoneal%20dialysis%20solutions%20from%20unlicensed%20out-of-state%20facilities.pdf>. The Board has also established a mechanism for hospitals to submit proposals that would help alleviate potential shortages, and the Board will consider whether it is able to exercise enforcement discretion to allow those proposals.

These developments should do much to help alleviate the current situation, and we are hopeful the supply will improve soon. In the meantime, I will continue having regular, high-level coordination meetings between our ODH team, hospital leadership, and the Ohio Hospital Association to ensure we maintain strong and consistent levels of collaboration until this situation is resolved.

The disruption in the IV solutions supply chain has caused very real challenges in our state and across the nation. In Ohio, we are fortunate to have developed strong partnerships with our hospitals and other healthcare facilities that we have been able to leverage to respond swiftly and appropriately. While we are hopeful for additional supply to soon provide relief, as a collective statewide healthcare ecosystem, we will continue to closely monitor the situation amid the ongoing shortage. At the same time, we are cognizant of the damage done by Hurricane Helene and Hurricane Milton, and we mourn the loss of life and destruction being experienced by people living in the impacted areas.

Thank you to all of you making sacrifices to ensure that Ohio patients are protected.

Bruce Vanderhoff, MD, MBA
Director, Ohio Department of Health