October 8, 2024

Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, D.C. 20201

Dawn O'Connell
Assistant Secretary
Administration for Strategic Preparedness and Response
U.S. Department of Health and Human Services
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Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: IV Solutions Shortages Recommendations

Dear Secretary Becerra, Assistant Secretary O'Connell, and Commissioner Califf,

On behalf of our 60,000 pharmacist, pharmacy technician, and pharmacy student members, we thank you for your immediate action to address the aftermath of Hurricane Helene. As you are aware, the storm devastated clinical facilities across its path, including a Baxter manufacturing plant in Marion, NC. Because the Baxter plant, which is now closed indefinitely, produced approximately 60% of the intravenous (IV) and peritoneal dialysis solutions used in our nation's hospitals and health systems, the impact of the closure has been immediate and will continue to be felt in the coming months.

Hospitals and health systems across the country are at 40% allocation of the impacted Baxter products, with concentrated sodium chloride, 5% dextrose solution, and sterile water on FDA's shortage list, and Lactated Ringer's solution in short supply and likely to go into shortage in the near term. These products are the lifeblood of hospitals and health systems, with large organizations requiring 1,000 – 1,500 bags per day. Providers are taking all available actions to stretch scarce supply, utilizing conservation strategies such as those included in ASHP's conservation recommendations, but the shortages will adversely impact patient care over time, potentially delaying certain procedures and jeopardizing hospitals' clinical resources.

Although Baxter is working closely with the Food and Drug Administration (FDA) to find alternate sources of supply, including through importation from its international facilities, additional flexibilities will be necessary. To mitigate the shortages and safeguard patient care, we urge your agencies to take the following steps:

I. Short-Term

- FDA should waive the 24-hour requirement in the hospital and health system 503A compounding guidance. Although this guidance is in draft, hospitals and health systems should be provided with full flexibility to compound IV solutions to the greatest degree possible until supply recovers.

- FDA should provide any requisite flexibility for 503B outsourcing facilities to provide each other with products necessary to manufacture IV products in shortage (e.g., sterile water).

- FDA should provide any requisite flexibilities to 503A pharmacies that can safely compound products necessary to meet the demand created by the Baxter plant closure.

- FDA should extend the expiry dates for IV and peritoneal dialysis solutions at or near the end of their shelf-life.

- Secretary Becerra should declare a national Public Health Emergency in order to create the circumstances that will allow for waivers of Medicare/Medicaid rules.

- HHS should request that insurers suspend audits and compliance reviews for at least 90 days in the areas immediately impacted by Hurricane Helene.

- HHS should work with insurers to remove prior authorization requirements and/or formulary restrictions for alternative therapies that do not require IV solutions (e.g., an oncologic drug that can be injected versus given through IV infusion).

- HHS should monitor marketplace activity and take appropriate action to prevent price gouging and/or market manipulation.

- HHS, ASPR, and FDA should take any action available to help locate and facilitate purchase of ancillary supplies (e.g., bags, empty containers) to compound IV and peritoneal dialysis solutions.

- ASPR should clearly communicate whether tapping the Strategic National Stockpile (SNS) is a viable option for mitigating this shortage. Given that the SNS supply of IV and peritoneal dialysis products is insufficient to meet even a fraction of daily national needs, we do not expect the SNS will realistically provide relief for ongoing shortages.

- FDA should work with manufacturers to waive any Risk Evaluation and Mitigation Strategies (REMS) requirements that are not manageable in the areas directly affected by Hurricane Helene.

- HHS, ASPR, and FDA should appoint one person or office as the main point of contact for addressing the drug shortages associated with Hurricane Helene.

II. Longer Term

To improve the resilience and security of our pharmaceutical supply chains and to mitigate against similar scenarios in the future, we urge your agencies to take the following steps:

- Provide FDA with additional resources for managing shortages and creating a standing set of prospective importation plans for critical medications.

- Revisit the FDA shortage definition and revise it to better reflect the realities of the drug supply on the ground. For example, although three of the products manufactured by the Baxter facility are on FDA's list, Lactated Ringer's solution is not, yet providers cannot access it, and shortage-related flexibilities are not in place.

Hospitals and health systems are taking every possible step to conserve critical IV solutions, but we anticipate that the situation will become more tenuous as shortage duration increases. We urge your agencies to implement our short-term recommendations as quickly as possible to help mitigate these shortages and protect patient care.

We would welcome the opportunity to provide any additional information or assistance necessary as your agencies continue with Hurricane Helene response. We look forward to continuing to work closely with your agencies to safeguard patient care and improve supply chains.

Sincerely,

Tom Kraus
Vice President, Government Relations