

Charles N. Kahn III President and CEO

October 8, 2024

The Honorable Secretary Xavier Becerra U.S. Department of Health and Human Services Hubert H. Humphrey Building 200 Independence Avenue, SW Washington, DC 20201

## Dear Secretary Becerra:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities access to high-quality, affordable care in urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services. The FAH expresses gratitude for the Administration's prompt response to the devastating effects of Hurricane Helene, particularly the impact on vulnerable communities and patients.

Today, we urgently request that the Department of Health and Human Services (HHS) immediately provide relief from the critical shortage of IV solutions that significantly hinder hospitals nationwide. This shortage, largely driven by the shutdown of Baxter's North Cove facility in North Carolina and the subsequent reduction in supply from Baxter and other manufacturers due to the devastating effects of Hurricane Helene, has left hospitals struggling to maintain essential patient care, including hydration, medication administration, and wound care.

This dire situation is expansive and growing. Baxter is a significant supplier, and current reports suggest that over 60% of the market relies on its production. While other manufacturers are taking steps to increase production, none have definitively communicated additional supply

capacity to the market. Hospitals nationwide are receiving far below their historical allocations of IV solutions from Baxter, creating unsustainable conditions and jeopardizing patient safety. We respectfully urge the HHS to declare this a national public health emergency under the National Emergencies Act and/or the Stafford Act to expedite actions to mitigate the shortage.

We also respectfully urge HHS to declare this a formal drug shortage and take any necessary actions to expedite the support of Emergency Use Authorizations (EUAs) for alternative saline solutions. This classification is essential to ensuring that the EUA process is expedited, that products are authorized for importation from other countries, and that they are distributed to hospitals as soon as possible to provide relief. It also allows for immediate regulatory relief to facilitate the use of medical countermeasures, such as approving the use of expired products under public health emergency protocols.

Moreover, we request an extension of the shelf-life of IV Solutions and Peritoneal Dialysis solutions that are beyond or nearing their expiration date and to establish clear guidelines for providers on using expired saline products, as many hospitals are considering this option due to the severity of the shortage. The lack of timely access to saline endangers patients and strains an already overwhelmed health care system.

Last, we request that any barriers to importing IV solutions and peritoneal dialysis solutions from abroad be removed, particularly those already approved by the European Union, to ensure timely access to critical medical supplies and support patient care.

We remain committed to collaborating with HHS and other stakeholders to resolve this crisis and welcome the opportunity to engage in further discussions on potential solutions. Thank you for your attention to this critical issue.

Sincerely,

cc: The Honorable Robert M. Califf, M.D., Commissioner, Food and Drug Administration The Honorable Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Service