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October 17, 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
200 Independence Avenue SW
Washington, D.C. 20201

Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

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

On behalf of over 200 children's hospitals across the country, the Children's Hospital Association (CHA) thanks you for your collaboration and immediate action with Baxter to address the impacts of Hurricane Helene on the North Cove, NC facility and resulting intravenous (IV) and peritoneal dialysis solutions supply shortages. We appreciate that you are facilitating the importation of products from international facilities, expedited shelf-life extension requests, and provided additional compounding flexibility for 503A and 503B pharmacies. We ask that you continue to prioritize pediatric needs and identify solutions for children's hospitals that are experiencing persistent challenges accessing these IV fluid products.

During this IV fluid supply chain disruption, Baxter has been working closely with CHA to try to meet the 100% allocation commitment and establish hospital access, and our hospitals have deployed significant fluid conservation measures to continue to provide critical care for children. Despite these mitigation efforts, children's hospitals are not yet able to consistently gain access to the approved allocation or sufficient quantities of Baxter shortage product. Some hospitals are experiencing a lower success rate with accessing the needed IV solutions. As a result, our hospitals are making difficult decisions on who most needs the scarce IV fluids that they can obtain. This is a particularly critical situation for premature infants who require significant nutritional support.

To safeguard pediatric patient care during these critical supply shortages, CHA respectfully calls upon your agencies to take decisive action to:

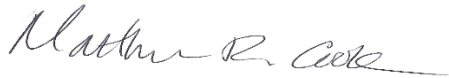
- Ensure manufacturer transparency throughout the IV solution supply chain, including the location of production and storage, as well as an immediate and clear timeline on imported and domestic product availability so children's hospitals can appropriately assess clinical protocols and plan effectively to best care for children.

Champions for Children's Health

- Increase and expedite importation of IV solution products from other manufacturing sites, including global locations, to ensure children's hospitals can provide quality care in a timely manner.
- Work with Baxter to secure extended dating for expired and nearly expired products.

Please let us know how we can work with you to support our pediatric patients that are impacted by this ongoing shortage. We appreciate the dedicated efforts to ensure our hospitals continue providing safe and effective care to children.

Sincerely,

A handwritten signature in cursive script that reads "Matthew R. Cook". The signature is written in black ink and is positioned above the typed name.

Matt Cook
President and Chief Executive Officer
Children's Hospital Association