



October 10, 2024

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

Dear Dr. Califf:

On behalf of the undersigned medical organizations, the Society of Critical Care Medicine (SCCM) is writing to you to express our deep concern about the significant supply chain disruptions resulting from the damage inflicted by Hurricane Helene on Baxter's North Cove manufacturing site in North Carolina. The undersigned organizations represent hundreds of thousands of clinicians who care for patients in hospital and out-of-hospital settings, emergency medical services (EMS) systems, and other healthcare facilities.

This North Cove facility is crucial to the supply of IV and peritoneal dialysis solutions—essential medical supplies that are widely used across all levels of care. Its closure has the potential to create widespread access issues for EMS providers, hospitals, and healthcare systems, adversely affecting patient care across the nation. It is imperative that everything be done to coordinate efforts to mitigate these supply chain challenges.

We respectfully request the Food and Drug Administration's assistance in coordinating efforts to:

1. Establish a clear communication channel among manufacturers, distributors, and healthcare facilities to share updates on supply availability and timelines for recovery
2. Identify and prioritize the production of critical medical supplies that are currently affected by the plant's closure and expedite import of these products from international suppliers to ensure that EMS providers and healthcare facilities can maintain essential operations
3. Encourage and assist manufacturers to explore alternative production facilities or methods to compensate for the loss of output from the Baxter plant

We also support the American Hospital Association's (AHA) recommendations, attached with this letter, to increase the supply of IV solutions for hospitals, health systems and other healthcare providers. We stand with the AHA in advocating for a stable and sufficient supply of these essential resources to ensure that healthcare providers can continue to deliver safe, effective care to patients, particularly in already overburdened systems.

Thank you for your attention to this urgent matter. The health and safety of patients depend on timely and effective action. Together, we can ensure that our healthcare systems remain resilient in the face of such challenges.

We look forward to your prompt response and to collaborating on solutions that prioritize patient care.

Sincerely,

American Association of Critical-Care Nurses (AACN)
American College of Chest Physicians (CHEST)
American College of Emergency Physicians (ACEP)
American College of Surgeons (ACS)
American Society of Health-System Pharmacists (ASHP)
American Thoracic Society (ATS)
Emergency Nurses Association (ENA)
National Association of Emergency Medical Technicians (NAEMT)
National Association of EMS Physicians (NAEMSP)
Society of Critical Care Medicine (SCCM)
Society of Hospital Medicine (SHM)

October 7, 2024

President Joseph R. Biden
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

Dear President Biden:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the Administration's actions taken to date related to the devastating impact Hurricane Helene has had on individuals, communities and hospitals in the southeast.

The AHA and its members also are deeply concerned about the closure of Baxter's plant in Marion, N.C., due to damage caused by Hurricane Helene. This facility is a critical supplier of intravenous (IV) and peritoneal dialysis solutions, producing approximately 60% — or 1.5 million bags — of the IV solutions used every day in the U.S. We are aware that Baxter is actively working on remediation efforts and exploring alternative production sites to mitigate the impact of the plant closure. We also have learned that Baxter and all other suppliers of these IV solutions have put their customers on strict ordering allocations and are not accepting new customers.

As a result, our members are already reporting substantial shortages of these lifesaving and life-supporting products. Patients across America are already feeling this impact, which will only deepen in the coming days and weeks unless much more is done to alleviate the situation and minimize the impact on patient care.

Therefore, the AHA strongly urges the Administration to take immediate actions to increase the supply of IV solutions for the nation's hospitals, health systems and other health care providers that are already struggling to provide care. Specifically, we urge that your Administration:

- Direct the Food and Drug Administration (FDA) to:



- Declare a shortage of sterile IV solutions, which will permit the use of certain flexibilities not otherwise available to health care providers.
 - Provide flexibilities to allow hospitals and health systems to prepare sterile IV solutions in their own pharmacies and waive the 1-mile rule so that hospitals and health systems can distribute these products among their facilities without a patient specific order.
 - Identify international manufacturers capable of producing sterile IV solutions and their appropriate containers.
 - Extend the shelf-life of all sterile IV and peritoneal dialysis solutions that are beyond or nearing their expiration date.
- Declare a national emergency under the National Emergencies Act and/or the Stafford Act and request that Department of Health and Human Services Secretary Xavier Becerra declare a national Public Health Emergency in order to create the circumstances that will allow for waivers of Medicare/Medicaid rules and regulations.
 - Invoke the Defense Production Act to:
 - Require appropriate manufacturers to prioritize and accept contracts for materials and services necessary to produce sterile IV solutions and their containers.
 - Incentivize appropriate manufacturers to expand the production and supply of the critical materials and goods needed to produce sterile IV solutions and their containers.
 - Direct the Department of Defense to make transportation available for emergency supplies from other international sources identified by the FDA.
 - Remove any barriers to the importation of sterile IV and peritoneal dialysis solutions from abroad that are approved by the European Union.
 - Secure transport to domestic distribution centers for such supplies to be allocated to hospitals and other health care providers in need.
 - Direct the Federal Trade Commission and the Department of Justice to be on alert for and intervene in matters related to price gouging.
 - Appoint a person within the Administration to serve as the point of contact for matters related to the IV solution shortage.

Rest assured that hospitals and health systems have immediately implemented their organization-specific action plans to conserve IV fluids and ensure patient access to care and services. The AHA invites the White House and agency experts to join us in a forum to communicate directly with our hospitals and health systems so that we can

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inform each other in real time on the status of the situation while we work together to mitigate the impact on patients.

Thank you for your consideration of these recommendations. Please contact me if you have questions or feel free to have a member of your team contact Roslyne Schulman, AHA director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Richard J. Pollack
President and Chief Executive Officer

cc: The Honorable Xavier Becerra, Secretary of Health and Human Services
The Honorable Robert M. Califf, M.D., Commissioner, Food and Drug Administration
The Honorable Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services