



October 16, 2024

The Honorable Xavier Becerra  
Secretary  
Department of Health and Human Services Hubert H. Humphrey Building  
Room 509F  
200 Independence Avenue, SW  
Washington, DC 20201

Robert M. Califf, M.D.  
Commissioner  
Food and Drug Administration  
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Lina M. Khan  
Chair  
Federal Trade Commission  
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Dear Secretary Becerra, Commissioner Califf, and Chair Khan:

On behalf of our nearly 40,000 members, we thank you for your ongoing work to address the aftermath of the recent hurricanes that devastated communities in North Carolina, Florida, and several other states, and significantly disrupted the health care supply chain. As you are aware, Hurricane Helene forced the closure of the Baxter manufacturing plant in Marion, NC, which produced approximately 60% of the intravenous (IV) and peritoneal dialysis solutions used in our nation's health and hospital systems. Routine shortages of critical and life-saving products remain one of the most significant problems emergency physicians across the country deal with on a day-to-day basis and are exacerbated by natural disasters such as Hurricane Helene and Milton, threatening our ability to provide the care our patients need and deserve. We are grateful for the Administration's actions to date, and we urge you to take further immediate action to alleviate the ongoing strain on clinicians and to safeguard patient care.

We request that the Administration immediately take the specific actions detailed below. Given the increasing frequency and intensity of such disasters and potential further strain on the nation's health care supply chain, we additionally encourage the Administration to preemptively refine protocols and procedures that will help federal emergency response entities and affected parties mobilize to more rapidly and effectively mitigate the system-wide impacts of these events on the health care system.

Specifically, we ask that the Department of Health and Human Services (HHS):

- Declare a national public health emergency (PHE) due to the health impacts of the hurricanes and the devastation of vital production facilities. A PHE declaration will allow for waivers of certain Medicare and Medicaid rules and

requirements in which a supply shortage significantly impairs clinicians' ability to fully adhere to them.

- Should the shortages and their impact continue to intensify, consider working with the Administration to invoke additional Defense Production Act authorities to require appropriate manufacturers to prioritize and accept contracts for materials and services necessary to produce sterile IV solutions and their containers and incentivize appropriate manufacturers to expand the production and supply of these materials and services to produce sterile IV solutions and their containers.
- Work with the Administration to appoint a specific person or office as the main point of contact for facilitating cross-agency and cross-divisional coordination to address drug shortages associated with the recent hurricanes and prepare for future scenarios in which there is a significant supply chain interruption.

We ask that the Federal Trade Commission (FTC):

- Continue to monitor marketplace activity, intervene, and take appropriate preventative measures to curtail price gouging and market manipulation.

We ask that the Food and Drug Administration (FDA):

- Use all available authorities to allow for use of sterile IV and peritoneal dialysis solutions beyond their expiration date, as appropriate.

We appreciate the Administration's prompt response in declaring a shortage of certain IV solutions, which permits the use of certain flexibilities and alternatives not otherwise available to health care providers, as well as other administrative and regulatory actions to assist affected pharmaceutical manufacturers, distributors, and other interested parties in restoring the health care supply chain. However, as evidenced by these recent events, regional natural disasters can immediately cause nationwide repercussions, and even relatively "brief" disruptions and delays in response can have immediate impacts on patient care. When a hurricane in Florida and North Carolina results in hospitals and emergency medical services (EMS) agencies in New Hampshire, Washington, or Arizona rationing supplies, changing protocols, and delaying medical procedures, it is clear that our health care system and medical supply chain is ill-prepared to respond to major disasters. This exemplifies the need to develop a more proactive approach to preventing and responding to supply chain disruptions. For instance, so that we do not find ourselves in a situation similar to today or to that in 2017 after Hurricane Maria incapacitated more than 50 pharmaceutical manufacturing facilities in Puerto Rico, incentives should be developed to encourage manufacturers to diversify the geographical distribution of manufacturing sites to ensure redundancy and resiliency of the supply chain, avoiding crises like these in the future.

Emergency physicians across the country are taking every possible step and implementing their organization's specific action plans to conserve critical IV solutions. However, we ask that the Administration take these recommended actions to alleviate the shortages and ensure that our members can provide the highest quality of care to our patients.

Thank you for consideration of these recommendations, and we welcome the opportunity to provide any additional information or assistance necessary to address this critical issue. If you have any questions, please contact Erin Grossmann, ACEP's Manager of Regulatory and External Affairs, at [egrossmann@acep.org](mailto:egrossmann@acep.org).

Sincerely,



Alison J. Haddock, MD, FACEP  
President, American College of Emergency Physicians