

October 18, 2024

## HHS, Baxter Announce Additional Mitigation Efforts to Increase Access, Supply of IV Fluids

The Department of Health and Human Services (HHS) and Baxter officials have [announced](#) additional actions to increase access and supply of IV solutions in response to the effects of Hurricane Helene on Baxter's manufacturing facility in North Carolina. HHS' mitigation efforts include increasing international and domestic supply chains. HHS Secretary Xavier Becerra joined other Administration leaders and officials from Baxter this afternoon for a call with stakeholders to provide updates on the IV solutions supply disruptions.

Baxter along with the Administration for Strategic Preparedness & Response (ASPR), the Food and Drug Administration (FDA) and the Department of Homeland Security established a coordinated effort to import IV solutions starting Oct. 19 to the U.S. from four different Baxter international facilities. In addition, Baxter's more than 2,500 employees at the North Carolina plant are now returning to work and are focused on site remediation and equipment assessment efforts. The building is structurally sound, and phased testing of priority equipment will soon begin, which is necessary before the plant resumes line operations.

### KEY HIGHLIGHTS FROM THE OCT. 18 HHS CALL

- For the imported products, ASPR is working to expedite the process of getting these supplies to Baxter's U.S. customers. This includes preparing paperwork in advance and expediting clearance. When planes arrive in the U.S., the product taken off the plane will receive an expedited customs review and then will be sent to Baxter distribution centers. Baxter will distribute the products through its usual channels.
- Baxter is aware that its initial promise of 100% allocations to children's hospitals did not recognize the health systems that have embedded children's hospitals or large pediatric units. For additional allocations for pediatric use, hospitals and health systems should email [HurricaneHeleneSupport@baxter.com](mailto:HurricaneHeleneSupport@baxter.com) with the subject line "Pediatric Allocation Request." Baxter officials will respond with requests for additional information from hospitals in its attempts to assess the requests and meet the needs.
- For peritoneal dialysis (PD), Baxter announced it will soon accept some new patients for starting PD. The company will coordinate closely with providers on this initiative, initially accepting only a few new patients. Their goal is, by the end of the year, to reach pre-hurricane levels of new PD starts for patients.
- FDA noted that although it has many ways to offer regulatory enforcement discretion, it does not have the authority to issue emergency use authorizations

(EUAs) for IV fluids because EUAs are primarily intended for countermeasures against chemical, biological and radiological agents.

- Hospitals were reminded not to throw out expired medical products as government officials continue to say they will expedite requests to use expired products.

## **ADDITIONAL EFFORTS TO INCREASE DOMESTIC SUPPLY**

- FDA [facilitated](#) expedited approval and temporary importation of IV and dialysis solutions.
- HHS invoked the [Defense Production Act](#) to help Baxter rebuild the North Carolina facility.
- FDA issued temporary [guidance](#) permitting flexibilities for compounding IV solutions.
- The Centers for Disease Control and Prevention (CDC) released an [advisory](#) alerting the field to enact conservation strategies during the supply disruption.
- The Department of Justice, Federal Trade Commission and the Consumer Financial Protection Bureau warned that law enforcement would use every tool available to stop price gouging, price fixing and other illegal scams. They encourage people to report violations at [www.justice.gov](http://www.justice.gov) or [www.reportfraud.ftc.gov](http://www.reportfraud.ftc.gov).

## **BACKGROUND**

The AHA is continuing efforts on multiple fronts to provide updates and assist members related to the supply chain issues resulting from the temporary closure of a Baxter manufacturing plant in North Carolina due to damage from Hurricane Helene. The plant had manufactured approximately 60% — or 1.5 million bags — of the IV solutions used every day in the U.S.

## **ADDITIONAL RESOURCES AND FURTHER QUESTIONS**

Please visit [AHA's webpage](#) for the latest information and resources, including **conservation strategies**. If you have questions, please contact Nancy Foster, vice president for quality and patient safety policy, at [nfoster@aha.org](mailto:nfoster@aha.org), or Roslyne Schulman, director of policy at [rschulman@aha.org](mailto:rschulman@aha.org).