

Special Bulletin

October 24, 2024

Baxter Provides Updates on Efforts to Increase Access to and Supply of IV Solutions

Among other updates addressed are restarting manufacturing line at N.C. plant, allocations and importation of products

Baxter this week shared <u>updates</u> on its efforts to increase access to and supply of IV solutions in response to the effects of Hurricane Helene on Baxter's manufacturing facility in North Carolina. Among these are:

- Baxter today said that barring any unanticipated developments, it anticipates
 restarting the highest-throughput IV solutions manufacturing line at the impacted
 North Carolina plant within the next week. "Initial batches will be manufactured
 concurrently with ongoing quality activities and would only be released in
 accordance with applicable regulatory requirements to ensure the quality and
 safety of the products," Baxter said. It is important to note that the earliest that
 new North Cove products could begin entering the distribution channel is mid-tolate November; however, that is ahead of Baxter's original expectations.
- The Food and Drug Administration has authorized temporary importation for a variety of product codes from two additional Baxter manufacturing facilities in Thailand and Singapore. This brings the total number of facilities authorized for temporary importation to seven — including Canada, China (two sites), Ireland and the UK. Baxter sites in Mexico and Spain were previously FDA-approved and shipments from these sites began the week of Oct. 7.
- Additional shipments of products authorized for temporary importation arrived in the U.S. this week. There is a range of times when providers may begin receiving this product. Baxter will communicate distribution plans for this product with customers, including direct communication to support any associated set-up and training needs.
- Baxter has begun posting on its Hurricane Helene Clinical Resources <u>portal</u>
 "Dear Healthcare Professional" letters containing information about the imported
 products that have already arrived in the U.S. The letters contain important
 product-specific information intended to inform and assist health care
 professionals in appropriately assessing and using the imported product.
 Additional letters will be posted on a rolling basis as more products arrive in the
 U.S.

 On Monday, Oct. 21, Baxter said that allocation levels for both direct customers and distributors remain as previously communicated by the company on Oct. 9.
 Baxter said it recognizes that not all customers are yet experiencing the increase in allocation. This may be due to a variety of factors, including the typical 1-to-2-week lag time for products to flow through the full distribution network, according to Baxter.

For more details on these and other updates, see Baxter's Oct. 24 and Oct. 21 updates on their webpage.

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 <u>AHA's webpage</u> 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, or Roslyne Schulman, director of policy at rschulman@aha.org.