Letter to Health Care Leaders and Stakeholders on Impacts of Hurricane Helene from Secretary Becerra

Dear Partner,

Thank you for your work on behalf of individuals and communities around this country every day. As the U.S. Department of Health and Human Services (HHS) continues responding to the impacts of Hurricane Helene, I want to first acknowledge the loss of life and continued search and rescue mission underway in the Southeast. HHS has over 400 personnel on the ground, and that number continues to grow. In addition to our responders supporting the impacted communities, I want to assure you that the Department is working tirelessly to mitigate the sterile solutions supply chain disruptions you may already be experiencing as a result of the storm. The U.S. Government has been working with Baxter at the highest level from the day the storm hit North Carolina, first to ensure Baxter employees and their families are safe. Since then, we have been in constant communication with Baxter and other solutions manufacturers to address gaps in supplies. My Department commits to mitigating the impact of Hurricane Helene and doing all we can to prevent further disruption as a result of Hurricane Milton. Not only do we commit to doing all we can during this supply chain disruption, but we also commit to doing all we can to diversify and build resilience in this supply chain going forward.

This is the status of the current supply chain disruption.

The impacts of Hurricane Helene have led to the temporary supply disruption at the Baxter facility in Marion, North Carolina. The Baxter facility provides a significant portion of IV solutions, irrigation fluids, and peritoneal solutions to the U.S. medical system. There are currently shortages of normal saline IV fluids, normal saline irrigation fluid, sterile water irrigation, and dextrose 5% IV fluids that pre-date Hurricane Helene., The hurricane-related supply disruption at the Baxter facility will likely lead to further constraints for IV fluids. However, compounding of drugs on the FDA shortage list can be done in accordance with current requirements to help alleviate shortages [see Compounding when Drugs are on FDA's Drug Shortages List | FDA]. In the coming weeks, supply may continue to be constrained, and we understand that certain products are on allocation; however, Baxter reported that they have resumed shipments to hospitals and dialysis providers and patients after the temporary hold last week, based on allocations as previously communicated. The inventory will be used to support current allocations in the short term, and they note that several of their global plants are scaling and ramping production to help

meet U.S. needs. Other producers are expected to be able to continue to fulfill domestic orders within their allocation.

This is what you can expect in the coming months.

HHS is coordinating a USG-wide response to address supply chain disruptions. HHS is also working with public and private partners to support the supply chain while the Baxter facility is brought back to full operational capacity. FDA will continue working with Baxter to identify both potential products already in their system and alternative manufacturing sites, including for potential temporary imports. As alternatives are identified, FDA is expediting assessments of those options. FDA will also expedite consideration of any shelf-life extension requests manufacturers submit for short-dated product. FDA will continue to work with Baxter as they bring their plant back online and with other suppliers to increase supply.

ASPR is actively working with Baxter and other USG partners to support infrastructure repairs and ensure the facility can resume operations as quickly as possible. As a result of these efforts, HHS is pleased to report that Baxter does intend to increase allocations to their customers in the coming week. Baxter will be in touch with their customers regarding these increases, and more information is available on Baxter's website [Hurricane Helene Updates | Baxter].

As we work to bring Baxter back to full capacity, ASPR is providing technical assistance and support to increase manufacturing at other domestic sites where possible. As a result of this work with other domestic IV solutions manufacturers, ASPR has identified the possibility of Hurricane Milton further disrupting an already fragile market. ASPR is currently pre-deploying assets to prepare broadly for the impacts of Hurricane Milton and working to move product away from the projected path of this next potentially catastrophic storm.

I commit to keeping you updated on the impact Hurricane Milton may have on this market and continuing to communicate with producers, medical care providers, distributors, and the public in the coming weeks and months.

This is what you might consider doing in light of these challenges.

We understand these circumstances are hard for many providers and health care systems and we ask for your partnership at this critical time. HHS is encouraging manufacturers, wholesalers, and distributors to evaluate product allocation and health care providers to implement product conservation strategies to maintain safe, quality patient care and maximize available supply. HHS is encouraging all providers and health systems, regardless of whether they have experienced a disruption in their supply, to take measures to conserve these critical products. HHS is in communication with stakeholders to reduce disruption and facilitate product allocation. Additionally, HHS and USG partners are monitoring the situation should unforeseen shortages of the affected products arise. When considering impacts from

potential shortages, hospitals and health care providers can modify usual practices for administration to conserve product. Additionally, please take time to review the Baxter Medical Information Letter for Health Care Facilities - PDF; ASHP Small and Large-Volume Fluid Shortages — Suggestions for Management and Conservation.

We will be in close contact in the coming days. My Department stands by to facilitate information sharing and understand further about your needs. You can contact us at HHSIEA@hhs.gov.

Sincerely, Secretary Xavier Becerra U.S. Department of Health and Human Services