National Home Infusion Association

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October 10, 2024

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

RE: Shortage of Dextrose 70% Solution

Dear Commissioner Califf:

On behalf of the National Home Infusion Association (NHIA), I am writing to share our appreciation for the prompt attention paid by FDA and other agencies in addressing the IV fluid supply challenges. We specifically appreciate the recent addition of dextrose 5% and sterile water for injection to the list of items on shortage. However, we write today to share our deep concerns regarding the impact of the flood on Baxter's plant in North Carolina on the supply of a critical product – Dextrose 70%, which is a necessary ingredient for parenteral nutrition support. NHIA is a trade association representing providers of infusion therapy to patients in their homes, as well as manufacturers and suppliers of infusion and specialty pharmacy products. Access to home infusion therapies is critically important to patients with disabilities, those who lack transportation, and for patients living in rural areas. Additionally, patients and Medicare beneficiaries who rely on parenteral nutrition (PN) as their sole source of nourishment depend exclusively on home infusion pharmacies to supply these formulations. The availability of Dextrose 70% is being significantly impacted by the Baxter plant closure. This product is currently on allocation and NHIA is hearing from several providers that they are having difficulty securing an adequate supply to meet current patient demand. Unfortunately, there is also no reliable substitute for this product.

As the leading voice for the home and alternate site infusion community, we write to share our concerns and offer recommendations for how FDA can support patients who depend on PN and other home infusion therapies. We understand that FDA is working with Baxter and other suppliers to address the current impacts to the intravenous (IV) fluid supply chain, and we appreciate the proactive communication provided by HHS on Friday, October 4. Since that time, NHIA has developed conservation guidance for home infusion providers to implement immediately to minimize the impacts on Medicare beneficiaries and other patients.

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Despite the current assessment that there is sufficient supply available, NHIA believes additional steps are needed to minimize the impact on patient care and ensure equitable access to life-savings IV therapies.

Specifically, we urge FDA to work with other Agencies to address the following:

- Declare a shortage of Dextrose 70% as this will allow 503B compounding facilities to help fill gaps in the supply chain.
- Incentivize existing manufacturers to expand the production and distribution of sterile IV solutions.
- Fast track the approval process of any IV solutions or parenteral nutrition products such as PN pre-mix solutions currently approved in the European Union for use in the U.S.
- Prioritize allocation/distribution of IV fluids, including those from 503B compounding facilities, to hospitals and pharmacies that use them for lifesaving and medically necessary treatments.
- Incentivize distributors to identify and re-allocate IV fluids being used in IV Spas for non-medically urgent purposes, such as hangovers, athletic performance, and beauty aids.
- Appoint a person within the Administration to serve as the point of contact for matters related to the IV solution shortage and PN policies and hold regular calls with industry stakeholders (including NHIA).

Thank you for your consideration of these recommendations. Please contact me if you have questions at connie.sullivan@nhia.org.

Sincerely,

Connie Sullivan, B.S. Pharm
President and Chief Executive Officer

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cc: The Honorable Xavier Becerra, Secretary, U.S. Department of Health and Human Services