National Home Infusion Association

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October 8, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Imminent Intravenous Solution Shortage

Dear Secretary Becerra:

On behalf of the National Home Infusion Association (NHIA), I am writing to share our deep concerns regarding the impact of the flood on Baxter's plant in North Carolina, particularly on the supply of two critical products – dextrose 70% and large volume bags of sterile water for injection. 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, which are compounded from as many as 20 different sterile ingredients. The two ingredients described above are critical ingredients of parenteral nutrition and are being significantly impacted by the Baxter plant closure. These products are currently on allocation at 50 percent or less of previous purchase volume, and some providers are reporting difficulty securing additional supply to meet current patient demand.

As the leading voice for the home and alternate site infusion community, we write to share our concerns and offer recommendations for how HHS can support patients who depend on PN and other home infusion therapies. We understand that HHS 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 the Department 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 HHS to work with other Agencies to address the following:

- Declare a shortage of sterile IV solutions, specifically Dextrose 70% and Sterile Water for injection USP, large volume (1000ml, 3000ml and 5000ml) bags as this will allow 503B compounding facilities to 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.

- Temporarily suspend the following additional documentation requirements in the Parenteral Nutrition LCD (L38953) to allow clinicians to adjust formulations based on individual patient needs, and/or supplement calories with fat to conserve dextrose if clinically appropriate. (Note: All formulation changes are made with the approval of the ordering physician.)
  - *A total caloric daily intake of 20-35 calories/kg/day is considered reasonable and necessary to achieve or maintain appropriate body weight. The treating practitioner must document the medical necessity for a caloric intake outside this range in an individual beneficiary.*
  - *The treating practitioner must document the medical necessity for protein orders outside of the range of 0.8-2.0 gm/kg/day (B4168, B4172, B4176, B4178), dextrose concentration less than 10% (B4164, B4180), or lipid use per month in excess of the product-specific, FDA-approved dosing recommendations (B4185, B4187).*

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- Temporarily suspend all supplier audits regarding the additional documentation requirements above.

- 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

cc:
The Honorable Robert M. Califf, M.D., Commissioner, Food and Drug Administration
The Honorable Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services