



October 11, 2024

The Honorable Joseph R. Biden
President
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear President Biden:

On behalf of the more than 37 million Americans living with kidney diseases and the over 21,000 nephrologists, scientists, and other kidney healthcare professionals who are members of the American Society of Nephrology (ASN), I write to express the kidney community's concern regarding the impact of Hurricane Helene on the production of peritoneal dialysis (PD) fluid (dialysate) and intravenous (IV) fluids, with life-threatening effects on people receiving dialysis.

Currently, more than 800,000 Americans have kidney failure, including over 550,000 Americans who receive dialysis and more than 200,000 living with a kidney transplant. Kidney failure rates are 3.5 times greater in Black and African Americans, 2.7 times greater in Native Hawaiians and Pacific Islanders, 1.5 times greater in Hispanic or Latino people, and 1.4 times greater in American Indian and Alaska Native populations when compared to White Americans¹.

On Friday, September 27, 2024, Hurricane Helene damaged the Baxter manufacturing plant in Marion, NC, the largest plant in the United States for both peritoneal dialysate and intravenous (IV) fluids. This facility is a critical supplier of IV and PD solutions, producing approximately 60%—or 1.5 million bags—of the IV solutions used every day in this country. To mitigate the impact of the plant closure, Baxter is actively working on remediation efforts with federal and state authorities as well as exploring alternative production sites. Baxter representatives announced that beginning Wednesday, October 9, IV fluid allocations were increased to a 60% allocation for highest demand solutions. They continue to deliver PD solutions to current peritoneal dialysis patients, but there is a lack of clarity of allocation of solutions and the ability to start new patients on peritoneal dialysis.

The closure of the Baxter plant in North Carolina and the resulting disruption of the supply chain for both dialysate and IV fluids pose a serious threat to the health and well-being of a vulnerable population of Americans: the more than 550,000 people living with kidney failure who require both solutions to live. The federal government guarantees Medicare coverage for every American with kidney failure regardless of age, income, or disability.

ASN urges the Biden-Harris Administration to:

- Declare a shortage of PD fluid and sterile IV solutions.
- Declare a national Public Health Emergency under the National Emergencies Act and/or the Stafford Act allowing HHS Secretary Xavier Becerra to allow for waivers of Medicare/Medicaid rules and regulations.

The Impact of Hurricane Helene on the Production of Peritoneal Dialysis Fluid

PD is a form of kidney replacement therapy that uses the lining of the abdominal cavity, or peritoneum to filter waste and excess fluid from the blood, serving as an alternative to hemodialysis. The Centers for Medicare and Medicaid Services (CMS) has aimed to incentivize the use of PD since the mid-1980s, including an executive order in 2019, aiming to provide patients with options for dialysis care, acknowledging the potential benefits of PD for many people with kidney failure, including greater flexibility and potential for improved quality of life as well as better preservation of residual kidney function, fewer fluctuations in blood pressure, and no need for bloodstream access. PD is the most common home dialysis modality in the United States and worldwideⁱⁱ.

The Center for Medicare and Medicaid Innovation (CMMI) currently incentivizes the use of PD and other forms of home dialysis in both of its current kidney care models: the ESRD Treatment Choices (ETC) Model and the Kidney Care Choices (KCC) Model. According to the latest data from the US Renal Data System (USRDS), in 2021, nearly 63,000 patients in the United States utilized PD, which accounted for 12% of prevalent dialysis patientsⁱⁱⁱ. In 2022, potentially reflecting this new emphasis on home dialysis, 17% of new dialysis patients initiated at home^{iv}.

PD relies on a specialized fluid called dialysate, which is delivered directly to patients' homes for self-administration. In the United States, the primary producers of dialysate are Baxter and Fresenius Medical Care, each with distinct distribution and delivery networks. Most patients in the United States who rely on PD use a machine called a cyclor to assist with this process. The dialysate supplies from each of these companies are not immediately interchangeable as the tubing is specifically designed for use with their respective dialysis machines.

The devastation of Hurricane Helene is a national tragedy. This catastrophic event significantly impacts patients who rely on PD, as the disruption in production will limit the availability of this essential fluid, preventing additional patients who may be diagnosed with kidney failure in the months ahead from benefitting from PD. Due to the circumstances, many individuals currently using this modality may have to be shifted to hemodialysis (assuming adequate supplies of saline, as each hemodialysis session, on average, uses two 1L bags of normal saline), resulting in additional costs, requiring additional invasive procedures to obtain hemodialysis vascular access and impacting patient outcomes.

The manufacturing process for PD fluid is highly specialized and complex, with each company operating limited production lines. Maintaining sterility requires a lengthy manufacturing timeline, often taking several weeks to complete. Consequently, continuous operation of these production lines is crucial. Even if a manufacturer attempts to ramp up capacity to address shortages, it can take months or even years to implement the necessary changes and begin additional production. With the loss of this key facility, patients may face serious challenges in accessing the dialysate they need for their treatment.

Impact of Hurricane Helene on Intravenous (IV) Fluid Production

In addition to the challenges posed by Hurricane Helene on PD fluid, the storm has also significantly affected the production of other IV fluids, particularly saline. While IV fluids are a vital component of many medical aspects of medical care, ASN is particularly concerned about the potential shortages of IV saline impact on hemodialysis patients. The hemodialysis population relies heavily on saline for critical aspects of their treatment, making any disruption in supply particularly concerning their health and safety. Saline is indispensable in various stages of the hemodialysis procedure, for example:

- Saline is used to prime the dialysis circuit before hemodialysis is started for the patient.
- Saline is used during the hemodialysis procedure to treat low blood pressure (single or multiple boluses of saline) or prevention of clotting when a patient cannot receive a blood thinner medication (e.g. heparin).
- Saline is used during “rinse back” as an agent to return the blood back to the patient and clear the dialyzer of blood.

ASN supports the efforts of all involved to overcome the suffering inflicted by Hurricane Helene and echoes the nation’s concern for those impacted by Hurricane Milton. Based on current news reports, Hurricane Milton’s devastation across Florida will only exacerbate concerns about shortages of PD fluid (dialysate) and intravenous (IV) fluids.

On behalf of the kidney community, ASN's members, leadership, staff, and I stand ready to assist in these efforts and whatever efforts may be needed in the days, weeks, months ahead. To discuss this letter, ASN's requests on behalf of the more than 37 million Americans living with kidney diseases—including over 550,000 Americans living with kidney failure—or the society, please contact me at dcrews1@jhmi.edu.

Sincerely,



Deidra C. Crews, MD, ScM, FASN
President

CC: Xavier Becerra, JD
Chiquita Brooks-LaSure, MPP
Robert Califf, MD

ⁱ <https://www.kidney.org/kidney-topics/race-ethnicity-kidney-disease>

ⁱⁱ <https://homedialysis.org/home-dialysis-basics/peritoneal-dialysis-~:text=PD%20is%20the%20most%20common%20type%20of%20home,and%20about%20half%20train%20people%20to%20do%20PD.>

ⁱⁱⁱ <https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

^{iv} <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9972188/>