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11 *B. BRAUN US PHARMACEUTICAL MANUFACTURING LLC*

12 **BEFORE THE HEARING BOARD OF THE SOUTH COAST AIR**

13 **QUALITY MANAGEMENT DISTRICT**

14 In the Matter of

15 B. BRAUN US PHARMACEUTICAL
16 MANUFACTURING LLC,

17 Petitioner,

18 v.

19 SOUTH COAST AIR QUALITY
20 MANAGEMENT DISTRICT,

21 Respondent.

CASE NO. 4780-5

FACILITY ID NO. 117290

**DECLARATION OF MAIA H. JORGENSEN
IN SUPPORT OF B. BRAUN US
PHARMACEUTICAL MANUFACTURING
LLC'S PETITION FOR MODIFICATION /
EXTENSION OF A FINAL COMPLIANCE
DATE**

Date: January 30, 2025

Time: 9:30 AM

Location: 21865 Copley Drive
Diamond Bar, CA 91765

1 I, Maia Jorgensen, declare:

2 1. This declaration is made, pursuant to Rule 4 of the SCAQMD Hearing Board Rules
3 and Procedures, in support of B. Braun US Pharmaceutical Manufacturing LLC's ("Pharma" or the
4 "Company") second Petition for Modification of an Existing Variance filed with the South Coast Air
5 Quality Management District ("SCAQMD" or the "District") Hearing Board in Case No. 4870-5 on
6 December 13, 2024.

7 2. I am an attorney at law duly licensed to practice in California and a member in good
8 standing of the California bar. I am a Senior Associate at the law firm of Hogan Lovells US LLP, and
9 counsel of record for Pharma in the above-captioned matter. I am familiar with the evidence,
10 pleadings, and filings on the docket for this case and assisted with the preparation of Pharma's present
11 petition. I have personal knowledge of the facts stated in this declaration and, if called and sworn,
12 could competently testify to the facts contained herein.

13 3. Attached hereto as **Exhibit A** is a true and correct copy of the September 26, 2024,
14 U.S. Department of Health and Human Services ("HHS") press release about Secretary Xavier
15 Becerra's declaration of a Public Health Emergency ("PHE") for Florida to address the health impacts
16 of Hurricane Helene.

17 4. Attached hereto as **Exhibit B** is a true and correct copy of the September 27, 2024,
18 HHS press release about Secretary Xavier Becerra's declaration of a PHE for Georgia to address the
19 health impacts of Hurricane Helene.

20 5. Attached hereto as **Exhibit C** is a true and correct copy of the September 29, 2024,
21 HHS press release about Secretary Xavier Becerra's declaration of a PHE for North Carolina to
22 address the health impacts of Hurricane Helene.

23 6. Attached hereto as **Exhibit D** is a true and correct copy of September 29, 2024, Baxter
24 International Inc. ("Baxter") press release about the impact of Hurricane Helene on Baxter's North
25 Cove facility in Marion, North Carolina (the "North Cove Facility"), stating, among other things, that
26 the Facility had been closed for production.

1 7. Attached hereto as **Exhibit E** is a true and correct copy of the September 30, 2024,
2 article published by the American Hospital Association about the impacts of Hurricane Helene in
3 North Carolina.

4 8. Attached hereto as **Exhibit F** is a true and correct copy of the October 8, 2024, HHS
5 press release about Secretary Xavier Becerra's declaration of a PHE for Florida to address the health
6 impacts of Hurricane Milton.


7 9. Attached hereto as **Exhibit G** is a true and correct copy of the October 30, 2024, article
8 published by the American Medical Associations about, among other things, the IV fluid shortage
9 caused by Hurricane Helene.

10 10. Attached hereto as **Exhibit H** is a true and correct copy of October 31, 2024, Baxter
11 press release providing a periodic update on recovery of the North Cove Facility following Hurricane
12 Helene.

13 11. Attached hereto as **Exhibit I** is a true and correct copy of the November 19, 2024,
14 article published by NPR about, among other things, the IV fluid shortage caused by Hurricane Helene.

15 12. Attached hereto as **Exhibit J** is a true and correct copy of December 19, 2024, Baxter
16 press release providing a periodic update on recovery of the North Cove Facility following Hurricane
17 Helene.

18 I declare under penalty of perjury under the laws of the State of California that the foregoing
19 is true and correct. Executed this 22nd day of January, 2025 at San Francisco, California.

20
21 

22 MAIA JORGENSEN
23 Attorney
24 Hogan Lovells US LLP
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28

Exhibit A



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Health and Human Services**Enhancing the health and well-being
of all Americans[Home <https://public3.pagefreezer.com:443/content/hhs.gov/02-01-2025t05:49/https://www.hhs.gov/...](https://public3.pagefreezer.com:443/content/hhs.gov/02-01-2025t05:49/https://www.hhs.gov/...)

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**FOR IMMEDIATE RELEASE****September 26, 2024****Contact: HHS Press Office**

202-690-6343

media@hhs.gov

HHS Secretary Xavier Becerra Declares Public Health Emergency, ASPR Deploys Personnel to Florida to Respond to Hurricane Helene

Emergency personnel will augment state and local response efforts

Today, U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra declared a Public Health Emergency (PHE) for Florida to address the health impacts of Hurricane Helene and the Administration for Strategic Preparedness and

Response (ASPR) deployed approximately 150 responders, along with medical equipment and supplies, to help protect the delivery of health care services in the storm's path.

The declaration follows President Biden's emergency declaration

<https://www.whitehouse.gov/briefing-room/presidential-actions/2024/09/24/president-joseph-r-biden-jr-approves-florida-emergency-declaration->

8/#:~:text=today%2c%20president%20joseph%20r.%20biden,23%2c%202024%2c%20and%20continuing.>

[i](#) and gives the Centers for Medicare & Medicaid Services' (CMS) health care providers and suppliers greater flexibility in meeting emergency health needs of Medicare and Medicaid beneficiaries.

"We will do all we can to assist Florida officials with responding to the health impacts of Hurricane Helene," said Secretary Becerra. "We are working closely with state and local health authorities, as well as our partners across the federal government, and stand ready to provide additional public health and medical support."

ASPR pre-positioned approximately 150 medical providers and disaster management professionals in Florida and Alabama to address the potential health impacts of Hurricane Helene. This includes two Health Care Situational Assessment Teams (HCSAT) who stand ready to assess the storm's impacts to hospitals, nursing homes, dialysis centers, and other health care facilities and two Health and Medical Task Forces and one Disaster Medical Assistance Team (DMAT) from the National Disaster Medical System (NDMS) <https://aspr.hhs.gov/ndms/pages/default.aspx> [i](#) for rapid response following assessment findings. One additional DMAT and additional HCSAT are on alert and ready to deploy if needed.


"ASPR is continuing to monitor Hurricane Helene and we have deployed personnel as part of the combined federal and state response," said Assistant Secretary for Preparedness and Response Dawn O'Connell. "Our teams are on the ground and prepared to support recovery requests in the coming days and weeks."


In addition to the NDMS and HCSA personnel, ASPR deployed an Incident Management Team and Regional Emergency Coordinators who integrate with the Federal Emergency Management Agency (FEMA), state health authorities, and

emergency response officials to anticipate and help the state meet public health and medical needs in the wake of the storm. Logisticians and security personnel are also pre-positioned to support.


The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry have shared vital health and safety messaging and communication materials with public health officials in Florida, Georgia, and Alabama and are ready to provide additional environmental public health resources and support as needed.

HHS has made information available from the HHS emPOWER

<https://empowermap.hhs.gov/>  program, a partnership between ASPR and CMS, to support public health emergency planning and response activities. The program provides valuable information on the number of Medicare beneficiaries who rely on electricity-dependent durable medical equipment and certain health care services, such as dialysis, oxygen tanks, or home health care, to help anticipate, plan for, and respond to the needs of at-risk residents in areas impacted by the storm.

The Disaster Distress Helpline <https://www.samhsa.gov/find-help/disaster-distress-helpline>  is available to provide disaster crisis counseling. Managed by the Substance Abuse and Mental Health Services Administration (SAMHSA), this toll-free, multilingual, crisis support service is available 24/7 to all residents in the U.S. and its territories who are experiencing emotional distress related to natural or human-caused disasters. To connect with a trained counselor, call or text 1-800-985-5990. Spanish speakers can press “2” for bilingual support. Callers also can connect with counselors in more than 100 other languages via third-party interpretation services by indicating their preferred language to the responding counselor.




HHS has also waived sanctions and penalties for violations of certain provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule against hospitals in the emergency areas. The HHS Office for Civil Rights (OCR) issued a bulletin explaining how this limited waiver

<https://public3.pagefreezer.com:443/content/hhs.gov/02-01-2025t05:49/https://www.hhs.gov/sites/default/files/2024-hipaa-bulletin-fl-hurricane-helene.pdf>  applies and its duration.

In declaring the public health emergency and authorizing flexibilities for CMS providers, suppliers, and beneficiaries, Secretary Becerra acted within his authority under the Public Health Service Act and Social Security Act. These actions and flexibilities are retroactive to September 23, 2024.

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Note: All HHS press releases, fact sheets and other news materials are available at <https://www.hhs.gov/about/news/index.html> <<https://public3.pagefreezer.com:443/content/hhs.gov/02-01-2025t05:49/https://www.hhs.gov/about/news/index.html>>.

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Exhibit B

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FOR IMMEDIATE RELEASE
September 27, 2024

Contact: HHS Press Office

202-690-6343
media@hhs.gov

HHS Secretary Xavier Becerra Declares Public Health Emergency for Georgia, Additional ASPR

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Personnel and Resources Deployed to the Region in Response to Hurricane Helene

Emergency personnel will augment state and local response efforts

Today, U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra declared a Public Health Emergency (PHE)





<https://aspr.hhs.gov/legal/phe/pages/default.aspx> ⓘ for Georgia to address the health impacts of Hurricane Helene following yesterday's announcement of a PHE for Florida [https://public3.pagefreezer.com:443/content/hhs.gov/02-01-](https://public3.pagefreezer.com:443/content/hhs.gov/02-01-2025t05:49/https://www.hhs.gov/about/news/2024/09/26/hhs-secretary-xavier-becerra-declares-public-health-emergency-aspr-deploys-personnel-florida-respond-hurricane-helene.html)

[2025t05:49/https://www.hhs.gov/about/news/2024/09/26/hhs-secretary-xavier-becerra-declares-public-health-emergency-aspr-deploys-personnel-florida-respond-hurricane-helene.html](https://public3.pagefreezer.com:443/content/hhs.gov/02-01-2025t05:49/https://www.hhs.gov/about/news/2024/09/26/hhs-secretary-xavier-becerra-declares-public-health-emergency-aspr-deploys-personnel-florida-respond-hurricane-helene.html)>. To date, the Administration for Strategic Preparedness and Response has pre-positioned approximately 200 medical providers and disaster management professionals in Florida, Alabama, with additional personnel in route to North Carolina, to address the potential health impacts of Hurricane Helene.

“We will do all we can to assist Georgia officials respond to the health impacts of Hurricane Helene,” said Secretary Becerra. “We are working closely with state and local health authorities, as well as our partners across the federal government, and stand ready to provide additional public health and medical support.”



ASPR's deployed personnel include multiple Health Care Situational Assessment Teams (HCSAT) who stand ready to assess the storm's impacts to hospitals, nursing homes, dialysis centers, and other health care facilities and four Health and Medical Task Forces and one Disaster Medical Assistance Team (DMAT) from the National Disaster Medical System (NDMS) <https://aspr.hhs.gov/ndms/pages/default.aspx> ⓘ for rapid response following assessment findings. A subject matter expert from NDMS' Disaster Mortuary Operational Response Team is providing virtual support.

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The PHE declarations follow President Biden's emergency declarations for Florida <<https://www.whitehouse.gov/briefing-room/presidential-actions/2024/09/24/president-joseph-r-biden-jr-approves-florida-emergency-declaration-8/>> , Alabama <<https://www.whitehouse.gov/briefing-room/statements-releases/2024/09/26/president-joseph-r-biden-jr-approves-alabama-emergency-declaration/>> , Georgia <<https://www.whitehouse.gov/briefing-room/speeches-remarks/2024/09/26/president-joseph-r-biden-jr-approves-georgia-emergency-declaration-2/>> , and North Carolina <<https://www.whitehouse.gov/briefing-room/statements-releases/2024/09/26/president-joseph-r-biden-jr-approves-north-carolina-emergency-declaration-3/>> , and give the Centers for Medicare & Medicaid Services' (CMS) health care providers and suppliers greater flexibility in meeting emergency health needs of Medicare and Medicaid beneficiaries.

“ASPR has deployed teams to assist in a rapid combined federal and multi-state response to Hurricane Helene,” said Assistant Secretary for Preparedness and Response Dawn O’Connell. “We are on the ground and ready to support local health requests.”

HHS has also taken the following proactive measures to help support the needs of the region:

- The HHS emPOWER <<https://empowermap.hhs.gov/>>  program, is available to identify the number of Medicare beneficiaries in affected zip codes who rely on electricity-dependent durable medical equipment and certain healthcare services, such as dialysis, oxygen tank, or home health, to help anticipate, plan for, and respond to the needs of at-risk citizens in potentially impacted areas.
- HHS offers free crisis counseling through the Substance Abuse and Mental Health Services Administration (SAMHSA) Disaster Distress Helpline <<https://www.samhsa.gov/find-help/disaster-distress-helpline>> . This toll-free, multilingual, crisis support service is available 24/7 to all residents in the U.S. and its territories who are experiencing emotional distress related to natural or human-caused disasters. To connect with a trained counselor, call or text 1-800-985-5990. Spanish speakers can press “2” for bilingual support. Callers also can connect with counselors in more than 100 other languages via third-party interpretation services by indicating their preferred language to the responding counselor.

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- The Centers for Disease Control and Prevention (CDC) has many safety materials available on their website <<https://www.cdc.gov/hurricanes/about/index.html>> , including storm safety, food safety, and power outage safety information. CDC has also shared vital health and safety messaging and communication materials with public health officials in Florida, Georgia, and Alabama and are ready to provide additional environmental public health resources and support as needed.
 - HHS has waived sanctions and penalties for violations of certain provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule against hospitals in the emergency areas. The HHS Office for Civil Rights (OCR) issued a bulletin explaining how this Florida limited waiver <<https://public3.pagefreezer.com:443/content/hhs.gov/02-01-2025t05:49/https://www.hhs.gov/sites/default/files/2024-hipaa-bulletin-fl-hurricane-helene.pdf>>  and the Georgia limited waiver <<https://public3.pagefreezer.com:443/content/hhs.gov/02-01-2025t05:49/https://www.hhs.gov/sites/default/files/2024-hipaa-bulletin-ga-hurricane-helene.pdf>>  applies and its duration.

In declaring the public health emergency and authorizing flexibilities for CMS providers, suppliers, and beneficiaries, Secretary Becerra acted within his authority under the Public Health Service Act and Social Security Act. These actions and flexibilities are retroactive to September 23, 2024.

###

Note: All HHS press releases, fact sheets and other news materials are available at <https://www.hhs.gov/about/news/index.html> <<https://public3.pagefreezer.com:443/content/hhs.gov/02-01-2025t05:49/https://www.hhs.gov/about/news/index.html>>.

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FOR IMMEDIATE RELEASE

September 29, 2024

Contact: HHS Press Office



202-690-6343

media@hhs.gov


HHS Secretary Xavier Becerra Declares Public Health Emergency for North Carolina

ASPR emergency personnel prepared to augment state and local response efforts


Today, U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra declared a Public Health Emergency (PHE)

<<https://aspr.hhs.gov/legal/phe/pages/default.aspx>>  for North Carolina to address the health impacts of Hurricane Helene. This follows recent announcements of PHE declarations for Florida <<https://aspr.hhs.gov/legal/phe/pages/fl-hurricane-helene-sept2024.aspx>>  and Georgia






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<https://aspr.hhs.gov/legal/phe/pages/ga-hurricane-helene-sept2024.aspx> . The Administration for Strategic Preparedness and Response (ASPR) is repositioning equipment and personnel to North Carolina to address the potential health impacts of Hurricane Helene.

“We will do all we can to help North Carolina officials respond to the health impacts of Hurricane Helene,” said Secretary Becerra. “We are working closely with state and local health authorities, as well as with our partners across the federal government, and stand ready to provide additional public health and medical support.”

The Administration for Strategic Preparedness and Response (ASPR) has deployed approximately 200 personnel. These experts include Health Care Situational Assessment Teams which are assessing the storm’s impacts to hospitals, nursing homes, dialysis centers, and other health care facilities, as well as Health and Medical Task Forces and Disaster Medical Assistance Teams (DMAT) from the National Disaster Medical System (NDMS) <https://aspr.hhs.gov/ndms/pages/default.aspx>  which are prepared to provide medical care.

After the Health Care Situational Assessment Teams completed assessments in Florida and Alabama, neither state requested federal public health or medical assistance. The ASPR teams currently are working with state and local officials to assess the storm-related needs of healthcare delivery systems in North Carolina. In addition, a subject matter expert from NDMS’ Disaster Mortuary Operational Response Team has been activated to provide additional expertise in North Carolina.

The PHE declarations followed President Biden’s emergency declarations for Florida <https://www.whitehouse.gov/briefing-room/presidential-actions/2024/09/24/president-joseph-r-biden-jr-approves-florida-emergency-declaration-8/> , Alabama <https://www.whitehouse.gov/briefing-room/statements-releases/2024/09/26/president-joseph-r-biden-jr-approves-alabama-emergency-declaration/> , Georgia <https://www.whitehouse.gov/briefing-room/speeches-remarks/2024/09/26/president-joseph-r-biden-jr-approves-georgia-emergency-declaration-2/> , North Carolina <https://www.whitehouse.gov/briefing-room/statements-releases/2024/09/26/president-joseph-r-biden-jr-approves-north-carolina-emergency-declaration-3/> , and Tennessee <https://www.whitehouse.gov/briefing-room/presidential-actions/2024/09/28/president-joseph-r-biden-jr-approves-tennessee-emergency-declaration-2/> . PHE declarations give the Centers for

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Medicare & Medicaid Services' (CMS) healthcare providers and suppliers greater flexibility in meeting emergency health needs of Medicare and Medicaid beneficiaries.

“ASPR will continue to deploy teams to assist the combined federal and multi-state response to Hurricane Helene in North Carolina and other impacted states,” said Assistant Secretary for Preparedness and Response Dawn O’Connell. “We are evaluating the impacts of the storm and requests for federal assistance as they come in.”

HHS has also taken the following proactive measures to help support the needs of the region:

- The HHS emPOWER <<https://empowermap.hhs.gov/>> ⓘ program, is available to identify the number of Medicare beneficiaries in affected zip codes who rely on electricity-dependent durable medical equipment and certain healthcare services, such as dialysis, oxygen tank, or home health, to help anticipate, plan for, and respond to the needs of at-risk citizens in potentially impacted areas.
- The HHS Substance Abuse and Mental Health Services Administration (SAMHSA) offers free crisis counseling through the Disaster Distress Helpline <<https://www.samhsa.gov/find-help/disaster-distress-helpline>> ⓘ. This toll-free, multilingual, crisis support service is available 24/7 to all residents in the U.S. and its territories who are experiencing emotional distress related to natural or human-caused disasters. To connect with a trained counselor, call or text 1-800-985-5990. Spanish speakers can press “2” for bilingual support. Callers also can connect with counselors in more than 100 other languages via third-party interpretation services by indicating their preferred language to the responding counselor.
- The Centers for Disease Control and Prevention (CDC) and Agency for Toxic Substances and Disease Registry have many website <<https://www.cdc.gov/hurricanes/about/index.html>> ⓘ health and safety materials available, including storm safety, food safety, and power outage safety information. CDC/ATSDR has shared vital health and safety messaging and communication materials with public health officials in impacted states.




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- CDC/ATSDR also worked with Gas Station TV to play a GO poisoning and generator safety Public Service Announcement at gas stations in the affected areas in Florida, Georgia, and the Carolinas. CDC/ATSDR is assessing if further support is needed.
 - HHS has waived sanctions and penalties for violations of certain provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule against hospitals in the emergency areas. The HHS Office for Civil Rights (OCR) issued bulletins <<https://public3.pagefreezer.com:443/content/hhs.gov/02-01-2025t05:49/https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/index.html>> explaining how limited waivers apply and the duration.

In declaring the public health emergency and authorizing flexibilities for CMS providers, suppliers, and beneficiaries, Secretary Becerra acted within his authority under the Public Health Service Act and Social Security Act. These actions and flexibilities are retroactive to September 25, 2024.

###

Note: All HHS press releases, fact sheets and other news materials are available at <https://www.hhs.gov/about/news/index.html> <<https://public3.pagefreezer.com:443/content/hhs.gov/02-01-2025t05:49/https://www.hhs.gov/about/news/index.html>>.

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Exhibit D

FOR IMMEDIATE RELEASE

**BAXTER PROVIDES UPDATE ON NORTH COVE, N.C., FACILITY AND HURRICANE HELENE
RELIEF PLANS FOR COMMUNITY**

- *Baxter's North Cove facility affected by flooding and currently closed for production as the company assesses extent of the impact*
- *Company is working closely with FDA, ASPR, HHS, FEMA, Department of Homeland Security and local and state officials*
- *Baxter and the Baxter International Foundation are committed to supporting recovery efforts in impacted local communities*

DEERFIELD, ILL., SEPT. 29, 2024 – Baxter International Inc. (NYSE:BAX), a global medtech leader, today shared updates regarding the impact of Hurricane Helene, which brought unprecedented rain and extensive flooding to Western North Carolina, on the operations of its North Cove facility in Marion, N.C.

Baxter's North Cove site was affected by flooding due to the storm and is currently closed for production. The company is working around the clock in close coordination with local, state and federal officials to assess the extent of the damage and implement a plan to bring the plant back online as quickly as possible to help mitigate supply disruption to patients.

"Our hearts and thoughts are with all those affected by Hurricane Helene," said José (Joe) E. Almeida, chair, president and chief executive officer at Baxter. "The safety of our employees, their families, and the communities in which we operate remains our utmost concern, and we are committed to helping ensure reliable supply of products to patients. Remediation efforts are already underway, and we will spare no resource – human or financial – to resume production and help ensure patients and providers have the products they need."

Ahead of the storm, Baxter implemented its hurricane preparedness plan, which included evacuation plans for colleagues, as well as proactively moving products to higher ground or secure storage where feasible. The heavy rain and storm surge triggered a levee breach, which led to water permeating the site. The bridges accessing the site have also been damaged.

Baxter is communicating with its customers about the actions the company is taking to minimize potential disruptions. These include actively managing inventory and implementing a



protective allocation process by product line to help support supply continuity and equitable product distribution. The company will leverage Baxter's global manufacturing network to help mitigate potential supply impact as it continues efforts to fully restore North Cove's manufacturing operations.

The Baxter International Foundation has committed \$1.5 million in donations to its humanitarian aid partners to help address recovery needs, including allocating additional funds to its Employee Disaster Relief Fund, and is matching employee donations \$2:\$1 to relief efforts.

Baxter is working diligently with and is grateful for the strong support of regulatory agencies, including HHS (Department of Health and Human Services), FDA (U.S. Food and Drug Administration), ASPR (Administration for Strategic Preparedness & Response), FEMA (Federal Emergency Management Agency), DHS (Department of Homeland Security), and local and state authorities, its partners on the ground, and the dedication and resilience of Baxter colleagues. Baxter will continue to provide updates as additional information becomes available and aims to provide an update on estimated timing to resume production as soon as it is able.

While the company is working expeditiously to restore its manufacturing operations and return to production, the disruption is anticipated to negatively impact the company's financial results. Once the company can more fully assess the damage, it will be in a better position to estimate any expected impact and plans to provide an update in its third quarter earnings announcement.

About North Cove, N.C.

Opened in 1972, North Cove is Baxter's largest manufacturing facility and includes more than 2,500 employees. The site primarily manufactures intravenous and peritoneal dialysis solutions and is the largest manufacturer of these solutions in the United States.

About Baxter

Every day, millions of patients, caregivers and healthcare providers rely on Baxter's leading portfolio of diagnostic, critical care, kidney care, nutrition, hospital and surgical products used across patient homes, hospitals, physician offices and other sites of care. For more than 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers who make it happen. With products, digital health solutions and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on [X](#), [LinkedIn](#) and [Facebook](#).



Forward-Looking Statements

This press release contains forward-looking statements related to the impact of Hurricane Helene on Baxter's North Cove, N.C. facility and Baxter's relief plans including Hurricane Helene's anticipated negative financial impact, Baxter's plans to provide further commentary during its third-quarter 2024 earnings announcement, Baxter's use of resources to resume production and help ensure that patients and providers have required resources, Baxter's actions and communication to minimize disruptions, mitigate the supply impact of Hurricane Helene and restore operations, Baxter's commitment to provide updates regarding the timing to resume production and Baxter International Foundation's commitment to help address recovery needs. These forward-looking statements are subject to risks and uncertainties that include, among other things, risks related to further disruption due to Hurricane Helene or other storm-related events and other risks identified in Baxter's most recent filings on Form 10-K and Form 10-Q and other SEC filings, all of which are available on Baxter's website. Actual results could differ materially from anticipated results. Baxter does not undertake to update its forward-looking statements or any of the statements contained in this press release.

Baxter is a registered trademark of Baxter International Inc. or its subsidiaries.

Media Contact

Stacey Eisen, (224) 948-5353
media@baxter.com

Investor Contact

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###

Exhibit E

North Carolina under PHE following Hurricane Helene, IV solutions plant closed

🕒 Sep 30, 2024 - 05:03 PM



The Department of Health and Human Services Sept. 29 declared a [public health emergency](https://www.hhs.gov/about/news/2024/09/29/hhs-secretary-xavier-becerra-declares-public-health-emergency-north-carolina.html) (<https://www.hhs.gov/about/news/2024/09/29/hhs-secretary-xavier-becerra-declares-public-health-emergency-north-carolina.html>) for North Carolina due to health impacts from Hurricane Helene after making similar declarations for Florida and Georgia. The Administration for Strategic Preparedness and Response deployed approximately 200 personnel to North Carolina, including health care situational assessment teams which are assessing the storm's impacts to hospitals, nursing homes, dialysis centers and other health care facilities, as well as health and medical task forces and disaster medical assistance teams from the National Disaster Medical System.

Among the facilities impacted in the state was [Baxter International's North Cove plant](https://www.baxter.com/baxter-newsroom/baxter-provides-update-north-cove-nc-facility-and-hurricane-helene-relief-plans) (<https://www.baxter.com/baxter-newsroom/baxter-provides-update-north-cove-nc-facility-and-hurricane-helene-relief-plans>), which manufactures 60% of the country's supply of IV solutions, producing 1.5 million bags per day. The facility was flooded and is closed for production while the company continues to assess the damage. The surrounding area [suffered](https://healthcareready.org/alert/2024-nc-baxter-plant/) (<https://healthcareready.org/alert/2024-nc-baxter-plant/>) damaged roads and a collapsed bridge which leads to the plant.

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Exhibit F

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FOR IMMEDIATE RELEASE

October 8, 2024

Contact: HHS Press Office

202-690-6343

media@hhs.gov


HHS Secretary Xavier Becerra Declares Public Health Emergency for Florida to Aid Health Care Response to Hurricane Milton

*Administration for Strategic Preparedness and Response emergency personnel
prepared to augment state and local response efforts*

This is archived HHS content.

Today, U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra declared a Public Health Emergency (PHE) for Florida to address the health impacts of Hurricane Milton, the second public health emergency declaration for the state to aid in a hurricane response within the past two weeks.


The declaration follows President Biden's emergency declaration

<https://www.whitehouse.gov/briefing-room/presidential-actions/2024/10/07/president-joseph-r-biden-jr-approves-florida-emergency-declaration-9/>  and gives the Centers for Medicare & Medicaid Services' (CMS) health care providers and suppliers greater flexibility in meeting emergency health needs of Medicare and Medicaid beneficiaries.

“We will do all we can to assist Florida officials with responding to the health impacts of Hurricane Milton,” said Secretary Becerra. “We are working closely with state and local health authorities, as well as our partners across the federal government, and stand ready to provide additional public health and medical support.”

In preparing to provide that support, the Administration for Strategic Preparedness and Response (ASPR) deployed approximately 100 responders, along with medical equipment and supplies.

Deployed personnel include experts from an ASPR Incident Management Team and ASPR Regional Emergency Coordinators who are integrating with the Federal Emergency Management Agency, state health authorities, and emergency response officials to anticipate and assist the state in meeting public health and medical needs.


ASPR also deployed three Health Care Situational Assessment Teams (HCSAT) who will work with state officials in assessing the storm's impacts to hospitals, nursing homes, dialysis centers, and other health care facilities, and ASPR positioned two Disaster Medical Assistance Teams (DMATs) from ASPR's National Disaster Medical System (NDMS) <https://aspr.hhs.gov/ndms/pages/default.aspx>  for rapid response following assessment findings. Logisticians and security personnel are pre-positioned to support these teams, and additional medical personnel are on alert and ready to deploy if needed.

“While our medical teams continue to support hospitals and shelters in areas devastated by Hurricane Helene, we are also prepared to provide support to Florida communities following Hurricane Milton,” said Assistant Secretary for Preparedness

This is archived HHS content.


and Response Dawn O'Connell. "Our teams are strategically positioned to go where needed in the state, and we have experts ready to support response and recovery requests in the coming days."

In addition to medical teams, HHS has a Disaster Distress Helpline

<https://www.samhsa.gov/find-help/disaster-distress-helpline>  available to provide disaster crisis counseling. Managed by the Substance Abuse and Mental Health Services Administration (SAMHSA), this toll-free, multilingual, crisis support service is available 24/7 to all residents in the U.S. and its territories who are experiencing emotional distress related to natural or human-caused disasters. To connect with a trained counselor, call or text 1-800-985-5990. Spanish speakers can press "2" for bilingual support. Callers also can connect with counselors in more than 100 other languages via third-party interpretation services by indicating their preferred language to the responding counselor.

The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry have shared vital health and safety messaging and communication materials with public health officials in Florida and are ready to provide additional environmental public health resources and support as needed.

HHS has made information available from the HHS emPOWER

<https://empowermap.hhs.gov/>  program, a partnership between ASPR and CMS, to support public health emergency planning and response activities. The program provides valuable information on the number of Medicare beneficiaries who rely on electricity-dependent durable medical equipment and certain health care services, such as dialysis, oxygen tanks, or home health care, to help anticipate, plan for, and respond to the needs of at-risk residents in areas impacted by the storm.

HHS has also waived sanctions and penalties for violations of certain provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule against hospitals in the emergency areas. The HHS Office for Civil Rights (OCR) issued a bulletin explaining how this limited waiver




<https://public3.pagefreezer.com:443/content/hhs.gov/02-01-2025t05:49/https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/index.html> applies and its duration.

This is archived HHS content.

In declaring the public health emergency and authorizing flexibilities for CMS providers, suppliers, and beneficiaries, Secretary Becerra acted within his authority under the Public Health Service Act and Social Security Act. These actions and flexibilities are retroactive to October 5, 2024.

###

Note: All HHS press releases, fact sheets and other news materials are available at <https://www.hhs.gov/about/news/index.html> <<https://public3.pagefreezer.com:443/content/hhs.gov/02-01-2025t05:49/https://www.hhs.gov/about/news/index.html>>.

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Last revised: October 8, 2024

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Exhibit G



Fixing IV fluid shortage only a start in addressing drug supply

OCT 30, 2024

Kevin B. O'Reilly

Senior News Editor

Nearly 90% of professionals surveyed by hospital group-purchasing alliance Premier Inc. reported experiencing shortages of sterile intravenous (IV) fluids in the aftermath of Hurricane Helene that halted production at a Baxter International manufacturing facility in North Cove, North Carolina.

Of the 250-plus survey respondents—those working with health care organizations with acute-care beds, nonacute-care beds, surgery centers and in physician offices and other settings—who reported shortages, 53.9% said they only had enough supply on hand to last up to 10 days. Nearly 20% of respondents said they had to postpone elective and other procedures, while 58% said they were considering taking that step.

“Baxter is the largest manufacturer of IV fluid and peritoneal dialysis and intravenous solution in the U.S.,” Andrea Garcia, MPH, the AMA’s vice president of science, medicine and public health, said during an episode of “AMA Update” that covered the news. “This closure caused massive supply disruptions. We know that hospitals and government agencies are now scrambling to cope with these shortages.”

The Food and Drug Administration (FDA) has added three IV fluids to its drug-shortage database, but the shortage problem in this area is not entirely new, Garcia noted.

“Even prior to Helene, supplies of several IV fluid products had been declared in shortage. And that goes back at least a couple of years,” she said. “But the closure of this North Cove facility has been particularly devastating and has had major repercussions for the supply chain. We know that—according to the American Hospital Association—the site produces about 60%, or 1.5 million bags, of the IV fluid used by U.S. hospitals. And that’s really a staggering amount.”

The AMA is closely monitoring the situation and has assembled a devoted webpage to help physicians address and manage drug shortages. Among other things, the resource page outlines:

URL: <https://www.ama-assn.org/delivering-care/public-health/fixing-iv-fluid-shortage-only-start-addressing-drug-supply>

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- Clinical guidance for practices on substitutions and practice changes, ordering and alternate product sourcing, and temporary importation sources and compounding guidelines.
- AMA communications on the impact of Hurricane Helene.
- Updates and resources on the ongoing drug shortage.
- General background and policy considerations.
- Resources from the Department of Health and Human Services (HHS).
- AMA advocacy efforts on drug shortages.

The Biden administration has invoked the Defense Production Act “to help speed up recovery efforts and get that North Cove plant back up and running,” Garcia noted. Hospitals, meanwhile, are turning to alternative options such as hydration tablets and sports drinks while prioritizing IV fluids for the higher-acuity and higher-risk patients.

The FDA, meanwhile, has “released new guidance that eases up on rules regarding the compounding of IV solutions,” she added. “That’s to make it easier for hospitals and other facilities to do this during the shortage period.”

At this article’s deadline, Baxter also moved to extend the expiration dates for some products manufactured before Sept. 30 (product codes and new expiration dates, in PDF).

HHS also has started airlifting additional sterile products into the country. By the end of 2024, that effort will encompass 200 flights, each carrying 150,000–200,000 units of IV fluid.

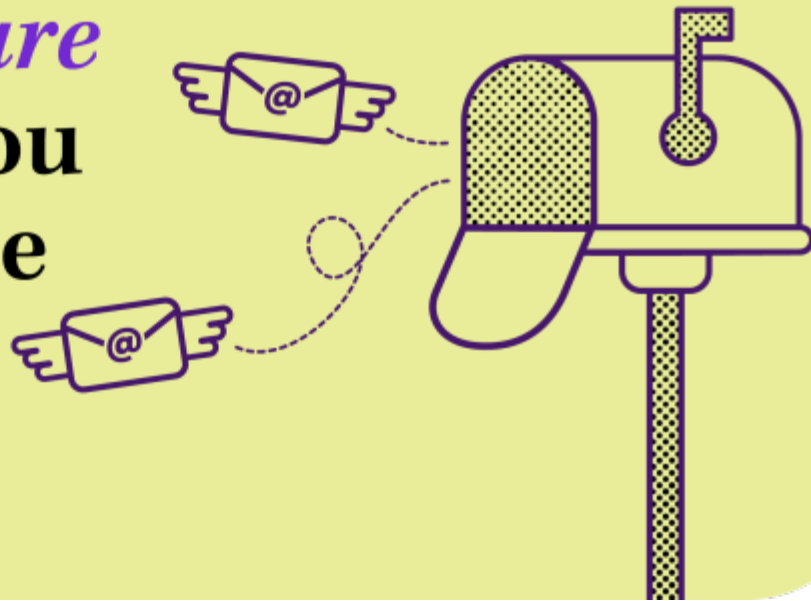
For physician practices struggling to source product, Baxter has a dedicated inbox for triage: HurricaneHeleneSupport@baxter.com. Pediatric hospitals can use the subject line “Pediatric Allocation Request” for expedited response.

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Get all the
health care
stories you
should be
reading



Don't wait for disaster to act

In a letter to HHS Secretary Xavier Becerra earlier this month (PDF), the AMA applauded the administration's "quick action" to address the immediate crisis.

But AMA Executive Vice President and CEO James L. Madara, MD, urged a more proactive approach "to ensure that supply chains for drugs at risk of shortages are bolstered before shortages actually occur."

The nation "should not let drugs fall into predictable shortages before we take action to maintain their availability," he wrote.

"The shortages of essential drug products have been a persistent issue that shows no sign of abating. Sterile injectables and intravenous solutions have seen supply constraints lasting years, frequently exacerbated by severe weather events directly impacting manufacturing facilities," Dr. Madara added.



“Given the serious impacts of recent storms on the drug manufacturing and supply chains, the AMA urges the administration to pull every available lever to help mitigate any potential shortages and ensure adequate supplies of drug products at risk of shortage.”

The AMA has previously declared drug shortages to be an urgent public health crisis and a national security threat. In a Leadership Viewpoints column published ahead of the Helene-related problems, AMA President Bruce A. Scott, MD, outlined the multifaceted approach that is needed to combat drug shortages.

“Reform should begin,” he wrote, “with far greater transparency of the drug-supply chain and all those who operate within it.”

The IV fluid shortage underscores the need to additional action to build resiliency and redundancy into the domestic supply chain. The AMA also is engaged in ongoing advocacy on this pressing public health issue, participating in a coalition with U.S. Pharmacopeia on drug shortages.

At the most recent AMA Interim Meeting, the House of Delegates adopted new policy to:

- Support activities which may lead to the stabilization of the generic drug market by nonprofit or public entities. Stabilization of the market may include, but is not limited to, activities such as government-operated manufacturing of generic drugs, the manufacturing or purchasing of the required active pharmaceutical ingredients, or fill-finish. Nonprofit or public entities should prioritize instances of generic drugs that are actively, at-risk of, or have a history of being, in shortage, and for which these activities would decrease reliance on a small number of manufacturers outside the United States.
- Encourage government entities to stabilize the generic drug supply market by piloting innovative incentive models for private companies which do not create artificial shortages for the purposes of obtaining said incentives.

Delegates also modified existing policy to support:

- Innovative approaches for diversifying the generic drug manufacturing base to move away from single-site manufacturing, increasing redundancy, and maintaining a minimum number of manufacturers for essential medicines.
- The public availability of FDA facility inspection reports to allow purchasers to better assess supply-chain risk.

“AMA Update” is your source for physician-focused news. Hear from physicians and other experts on trending public health concerns, practice issues and more—because who’s doing the talking matters. Catch every episode by subscribing to the AMA’s YouTube channel or listen to all AMA podcasts at [ama-assn.org/podcasts](https://www.ama-assn.org/podcasts).

Exhibit H



This update was published on www.baxter.com on 2024-10-31. For more up-to-date information, please go to [Hurricane Helene Updates | Baxter](#).

Baxter's North Cove manufacturing site was significantly impacted by the rain and storm surge from Hurricane Helene, which was unprecedented in Western North Carolina and resulted in water flooding the facility.

Supporting our employees in the impacted communities, bringing the North Cove facility back online and helping to ensure ongoing supply to patients are our top priorities.

"Recovery progress at our North Cove site continues to be very encouraging. In a matter of weeks, our team has advanced from the depths of Hurricane Helene's impact to restarting our highest-throughput manufacturing line. This is a pivotal milestone, but more hard work remains as we work to return the plant to full production. I want to recognize the dedication of our North Cove team as well as the countless Baxter employees globally who have committed themselves to helping contribute to supply continuity amid this unprecedented challenge. I also offer Baxter's gratitude for the steadfast support of ASPR, FDA, the State of North Carolina and HHS. And we are deeply appreciative of our customers' patience and partnership as progress continues."

-- José (Joe) E. Almeida, chair, president and chief executive officer

Below are the latest updates in each area:

Employees and Community: We salute our North Cove team, who are fueling our recovery while continuing to navigate the storm's personal toll.

- All 2,500+ North Cove employees have been accounted for following Hurricane Helene. Employees are returning to work at pre-hurricane staffing levels, working alongside remediation contractors that have been engaged on a temporary basis for site recovery.
- Our local colleagues are simultaneously continuing to navigate the storm's devastating personal and community impact. Baxter continues to offer critical employee assistance through a range of initiatives:
 - **NEW: The Baxter International Foundation has donated ~\$4 million to support employees and communities impacted by Hurricane Helene**, including \$1.5 million in grants to three humanitarian partners and nearly \$2.5 million in funding to employees through Baxter's Employee Disaster Relief Fund.
 - An employee support center provides basic supplies, such as food, water, and toiletries, as well as access to portable generators, showers, laundry machines, credit union services, and laptop workstations with internet access.
 - Colleagues at multiple Baxter sites across the U.S. have initiated clothing drives to collect cold weather gear and other items for delivery to the North Cove team.

Facilities and Infrastructure: As previously shared, and in coordination with FDA, our goal remains to begin resuming North Cove production in phases by the end of this year.

- **NEW:** We are pleased to announce that **Baxter has restarted the highest-throughput IV solutions manufacturing line**. At its peak operation (prior to Hurricane Helene), this line represented approximately 25% of the site's total production and approximately 50% of the site's production of one-liter IV solutions, the most commonly used size by hospitals and clinics.

- 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.
- It is important to note that the earliest that new North Cove product could start to ship is late November. This is ahead of our original expectations and a testament to the urgency, diligence and resiliency of the North Cove and broader Baxter teams as we've worked to accelerate recovery, with the coordination of FDA, ASPR and HHS.
- Assessment and repair of equipment with phased testing continues to progress across all other production lines, which will, in coordination with FDA, support resumption of operations in phases.
- We do not yet have a timeline for when we expect North Cove production to be fully restored to pre-hurricane levels.
- **NEW:** Our first temporary bridge has already transported **more than 885 truckloads** of finished product off site and to customers.
 - We continue to make progress on the second temporary bridge being installed at the site, thanks to the support of ASPR, North Carolina Department of Transportation and our local team. This bridge, currently estimated to be completed in early November, will enable additional truck and equipment traffic to enter and leave the site.

Supply Continuity: We are grateful for the ongoing partnership and efforts of our customers as we navigate this complex and challenging situation to prioritize patient care.

- **Global Manufacturing Network:** To date, we have activated nine plants across our global network to help increase available inventory, which is contemplated in current allocation levels.
- **U.S. Expiry Extensions for IV and Irrigation Products:** Baxter has received FDA authorization to extend the use dates of 50+ IV and irrigation codes to provide up to an additional 12 months of expiry. Products now have a 24-month expiry period from the date of manufacture. This extension only applies to products manufactured prior to the end of September 2024. Details have been communicated directly to customers.
- **U.S. Distribution for Products Authorized for Temporary Importation:** Baxter has communicated to customers its distribution plans for products authorized for temporary importation. We are carefully managing the availability of both previously finished goods coming out of North Cove and the import of product to the U.S., providing specific resources and training to those customers receiving product imported to the U.S.
- **Conservation:** Conservation efforts for IV and PD solutions across the healthcare system remain essential to supplement allocation levels and help preserve supply, and we are grateful for our customers' efforts in this area. Our Medical Affairs team is offering support and resources for product management and conservation strategies. Visit our [clinical webpage](#) for more information.
- **IV Solutions Allocations:**
 - In the U.S., allocation levels for both direct customers and distributors remain as previously communicated by Baxter on Oct. 9th.
 - Based on 1) the current status of our North Cove remediation efforts, 2) our expectations regarding our ability to reallocate capacity from other Baxter facilities, and 3) temporary importation on certain products, our goal remains to return to 90% to 100% allocation of certain IV solution product codes for U.S. customers by the end of 2024.
- **NEW: U.S. PD Patient Starts:** We have begun to expand our support for new peritoneal dialysis (PD) patients on a limited basis, beyond the highly restricted medical exceptions to date, to help providers address urgent medical needs. The volume of new patients should continue to increase in the coming weeks, with the goal of returning to pre-Hurricane Helene levels for new patient starts by the end of the year.
- **PD Solutions Allocations and Ongoing Patient Support:**



- o We are closely partnering with the kidney community, including physicians, nurses and care teams, to enhance our support for patients. This includes working to improve the ordering and delivery process to help reduce wait times and increase the accuracy of our target delivery dates and times. We are grateful to have excellent provider partners, who have been agile and proactive in helping us meet patient needs while conserving supply. Because PD patients have individualized prescriptions, this has allowed for some additional flexibility in our ongoing ability to support them within the allocation protocols already put in place.
- o While the allocations for PD solutions in the U.S. currently remain as communicated with patients and clinicians, thanks to FDA's recent temporary importation authorizations, we are temporarily importing additional product into the U.S. to help support supply. We will be providing training and education materials in the first part of November so that patients and care teams can prepare to use these imported PD solutions. Our global footprint and quality standards have allowed us to rapidly respond and shift supply accordingly, to help address the needs of existing and new patients in the U.S.

We are appreciative of the ongoing support and patience of our customers and partners as we continue to work diligently and with urgency to fulfill our Mission to Save and Sustain Lives for our employees, patients and communities.

Resources for U.S. Healthcare Professionals and Customers

- [Conservation and Medical Information Resources](#)
- Please reach out to your Baxter representative or distributor for questions regarding supply.
- For customers who need additional assistance beyond their existing Baxter communications channels, please contact HurricaneHeleneSupport@baxter.com.

Exhibit I



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Shots

SHOTS - HEALTH NEWS

Nationwide IV fluid shortage changing how hospitals manage patient hydration

NOVEMBER 19, 2024 · 8:00 AM ET

FROM **KFF** Health News

By Jackie Fortiér

3-Minute Listen

PLAYLIST Download

Transcript



Footage from Sept. 28 shows sand and debris left after flooding shut down operations at Baxter International's facility in Marion, N.C. The plant is the largest manufacturer of intravenous and peritoneal dialysis solutions in the United States.

Tommy Bumgarner/Aerial Lens via Facebook

Hospitals around the country are conserving critical intravenous fluid bags to cope with a shortage that may last months. Some hospital administrators say they are changing how they think about IV fluid hydration altogether.

Hurricane Helene, which hit North Carolina in September, flooded a Baxter International facility that produces 60% of the IV fluids used in the U.S., according to the American Hospital Association.

The company was forced to stop production and is rationing its products. In an update posted Nov. 7, Baxter said its facility in Marion, N.C., has resumed producing some IV fluids.

Sponsor Message

On Monday, Health and Human Services Secretary Xavier Becerra toured the damaged factory.

He spoke to reporters near a temporary bridge that was rebuilt after the storm. It's now being used by trucks to transport IV products.

"When Baxter said, 'We need to figure out how to transport product, we don't have a functioning bridge anymore,' everyone stepped up. And while HHS isn't

KFF Health News

recognized for building bridges, we were able to help with FEMA in making that all possible," Becerra said.

This story was produced in partnership with KFF Health News.

In an email to KFF Health News, the company wrote that customers will be able to order normal quantities of "certain IV solutions products" by the end of the year, but there is no timeline for when the North Cove facility will be back to pre-

hurricane production levels.

Meanwhile, hospitals are facing seasonal strains on their already limited IV fluid resources, said Sam Elgawly, chief of resource stewardship at Inova, a health system in the Washington, D.C., area.

"We've been very aggressive in our conservation measures," Elgawly said, stressing that he does not believe patient care has been compromised. He told KFF Health News that across the system IV fluid usage has dropped 55% since early October.

Elgawly called the shortage a crisis that he expects to have to continue managing for some time.

Sponsor Message

"We are going to operate under the assumption that this is going to be the way it is through the end of 2024 and have adopted our demand/conservation measures

accordingly," he said.

At the end of the calendar year, many patients with insurance hurry to schedule surgical procedures before their deductibles reset in January.

Elgawly is eyeing that typical surgical rush and the impending peak of respiratory virus season as he tries to stockpile IV fluid bags.

Hospitals such as Inova's are using different ways to conserve, such as giving some medications intravenously but without a dedicated IV fluid bag, known as a push medication.

"You don't even need a bag at all. You just give the medication without the bag," he said.

"There has been increasing literature over the last 10 to 20 years that indicates maybe you don't need to use as much. And this accelerated our sort of innovation and testing of that idea."

Monica Coleman is a nurse at a Department of Veterans Affairs hospital in North Chicago. She said using push medications takes more time out of a nurse's already hectic schedule because then they need to monitor the patient.

"This could increase adverse effects within the patient, because we're giving the medication at a faster rate," she said.

Elgawly is also interested in retooling electronic health records to question doctor orders for more IV hydration.

"Does the patient actually need that second bag? How did they do today with eating or drinking water or juice? They did well? They don't need the bag. So it's little conservation mechanisms like that that, when you add them across, you know, the 2,000-patient system that Inova is, make a significant dent," he said.

Simpler conservation measures could become common after the shortage abates, said Vince Green, chief medical officer for Pipeline Health, a small hospital system in the Los Angeles area that mainly serves people on Medicare and Medicaid.

Sponsor Message

First, Green would like to see data showing that patient outcomes aren't affected. But for now, some of the new strategies just make sense to him. He has directed hospital staff to use up the entire IV bag before starting another.

"If they come in with IV fluids that the paramedics have started, let's continue it. If it saves half a bag of fluids, so be it, but it adds up over time," he said.

Patients may be asked to take more accountability for their hydration, by drinking Gatorade or water rather than the default of hydrating through an IV, he said.

"From an environmental aspect, we don't need to have this much waste and fill up our landfills. If we could reduce stuff, I think it'd be wise," he said.

But he'll feel better when his hospitals receive a full order, which could be weeks away. Green said they are down to a two-week supply, with an expected increase in hospitalizations due to respiratory virus season.

"We're purchasing every IV fluid bag that we can get," he said.

This story comes from NPR's health reporting partnership with KFF Health News, a national newsroom that produces in-depth journalism about health issues. KFF Health News is one of the core operating programs at KFF — the independent source for health policy research, polling, and journalism.

hurricane helene iv fluids hydration american hospital association baxter international

Exhibit J



Hurricane Helene Updates

- ✓ **Baxter is providing periodic updates regarding its progress to restore operations at its North Cove, N.C., site following Hurricane Helene. The Dec. 19 update will be the company's last post for 2024. Baxter's next update is expected to be posted in early 2025.**

DEERFIELD, Ill. - 2024-12-19

Baxter's North Cove manufacturing site was significantly impacted by the rain and storm surge from Hurricane Helene, which was unprecedented in Western North Carolina and resulted in water flooding the facility.

Supporting our employees in the impacted communities, bringing the North Cove facility back online and helping to ensure ongoing supply to patients are our top priorities.

We are appreciative of the ongoing support and patience of our customers and partners as we continue to work diligently and with urgency to fulfill our Mission to Save and Sustain Lives for our employees, patients and communities.

Below are the latest updates in each area:



- All 2,500+ North Cove employees were accounted for following the storm; employees have returned to work across the facility.
- Baxter has responded to the hurricane's devastating local impact through a range of initiatives:
 - The Baxter International Foundation has donated more than \$4 million to support employees and communities affected by the hurricane, including \$1.5 million in grants to three humanitarian partners and more than \$2.5 million in funding to employees through Baxter's Employee Disaster Relief Fund.
 - A temporary employee support center helped provide for immediate needs in the wake of the storm, including basic supplies, such as food, water, and toiletries, as well as access to portable generators, showers, laundry machines, credit union services, and laptop workstations with internet access.
 - Colleagues at multiple Baxter sites across the U.S. initiated clothing drives to collect cold weather gear and other items that were delivered to the North Cove team.

Facilities and Infrastructure: Led by Baxter's commitment to product quality and patient safety, we are, in coordination with FDA, supporting resumption of North Cove operations in phases.

- **NEW:** We are making continued strong progress at North Cove and have now restarted 8 of the 10 manufacturing lines at the site, which represent ~85% of



- While the recently restarted lines will require time to ramp up, some of the earlier lines to restart are operating near pre-hurricane levels.
- We currently expect to be producing at pre-hurricane levels across the plant early in the first quarter of 2025.
- Note that it will take some time for product to flow through the distribution channels. To that end, we currently expect that North Cove's recovery to full production will translate to removal of allocations for the related product groups during the first quarter of 2025.
- These milestones were or should be achieved ahead of our original projections and made possible by the dedication and resilience of the North Cove and broader Baxter teams, working in coordination with FDA.

Supply Continuity: We are grateful for the ongoing partnership and efforts of our customers as we navigate this complex and challenging situation to prioritize patient care.

- **Global Manufacturing Network:** We have activated nine plants across our global network to help increase available inventory, which is contemplated in current allocation levels.
- **U.S. Distribution for Products Authorized for Temporary Importation:** Baxter continues to carefully manage the availability of newly manufactured goods coming out of North Cove and the import of product to the U.S., providing specific resources and training to those customers receiving product imported to the U.S.



authorization to extend the use dates of JOT IV and irrigation codes to provide up to an additional 12 months of expiry. Products now have a 24-month expiry period from the date of manufacture. This extension only applies to products manufactured prior to the end of September 2024. Details have been communicated directly to customers.

- **Conservation:** Conservation efforts for IV and PD solutions across the healthcare system remain essential to supplement allocation levels and help preserve supply, and we are grateful for our customers' efforts in this area. Our Medical Affairs team is offering support and resources for product management and conservation strategies. Visit our [clinical webpage](#) for more information.

- **U.S. IV Solutions Allocations:**

- **NEW: Baxter communicated additional allocation increases for several IV product groups to U.S. customers and distributors, effective in phases beginning Dec. 16 and Dec. 30.** Customers are advised that there is a typical 1 to 2-week lag time for product to flow through the full distribution network after allocation changes are implemented.

- Consistent with original year-end projections, Baxter has communicated its plans to reach 100% allocation for the majority of critical IV product groups by the end of 2024.

- Baxter's ability to adjust allocation levels is based on 1) the current and projected status of our North Cove remediation efforts, 2) our expectations regarding our ability to reallocate capacity from other Baxter facilities, and 3) temporary importation of certain products.



requests to help support neonatal and pediatric patient needs.

- **NEW: U.S. PD Solutions Allocations and Ongoing Patient Support:**
 - **Effective Dec. 16, we have increased product allocations for specific peritoneal dialysis (PD) solutions. These allocations have been communicated directly to our provider partners.**
 - **We have also significantly expanded new PD patient starts, as communicated with our provider partners.**
 - **We are grateful to have understanding provider partners, who have worked closely with us to deliver excellent patient care throughout this recovery process. In connection with Baxter's global response and temporary importation authorization from FDA, we have imported 4 million bags of PD solutions to supplement U.S. supply and support continued patient care. We have shipped more than 110,000 Customer Readiness Packets to patients and providers to guide their use of these globally supplied products.**

Resources for U.S. Healthcare Professionals and Customers

- **Conservation and Medical Information Resources**
- Please reach out to your Baxter representative or distributor for questions regarding supply.
- For customers who need additional assistance beyond their existing communications channels with Baxter, please contact