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Emergency Temporary Policies to Address Shortages of IV and Peritoneal Dialysis Solutions in Utah

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Hurricane Helene caused significant damage to the Baxter plant in North Carolina, leading to a shortage of IV fluids. The disruption in production at the plant has impacted the supply chain, resulting in a critical shortage of these essential medical supplies, most notably IV solutions. Hospitals across the U.S. are taking steps to conserve their supplies of IV fluids and carefully monitoring the situation to determine how long the shortage may last. Baxter is increasing production at its other global manufacturing sites and has inbound products and air shipments in the works to mitigate the shortage.

The Division of Professional Licensing (DOPL) in collaboration with the Utah Board of Pharmacy (BOP) recognize this natural disaster has the potential to negatively impact patient care. The following allowances are being issued to support conservation strategies in areas where the clinical judgement of the health care professional determines the practice is appropriate for the current situation.

Extension of IV Fluid Hang Times Inside an ISP Class 5 PEC:

1. A commercially manufactured IV solution punctured in an ISO Class 5 primary engineering control (PEC) in a licensed Utah Pharmacy via a sterile transfer device or utilized in an FDA approved solution pump set up may be used for up to 24 hours after initial puncture, unless the manufacturer's instructions specifically permit a timeframe longer than 24 hours. This practice is allowed if the pharmacist determines that the practice is appropriate for the situation and will conserve IV fluids.
    a. For example, the licensed Utah Pharmacy is preparing parenteral nutrition for multiple patients using a compounding pump device and the IV solution bags are punctured using sterile technique in an ISO 5 clean room when attached to the pump which is maintained in a PEC for the entire time of preparation.

Purchase of IV and Peritoneal Dialysis Solutions for Non-Utah Licensed Out-of-State-Facilities:

2. A licensed pharmacy or wholesaler (i.e., licensed purchaser) in Utah that meets the requirements of this emergency temporary policy may procure IV solutions and peritoneal dialysis (PD) solutions only from a

distributor*(i.e., seller) that is not currently licensed in the state of Utah if the distributor is actively licensed appropriately in the state where they are physically located with a license in good standing.

a. The IV solutions or PD solutions purchased shall be either FDA approved or, if imported by another country, listed on the FDA's temporary importation list; or
b. A compounded drug product prepared by a pharmacy or outsourcing facility.
c. The purchase shall meet all the requirements for documentation required by statute or rule in Utah.
d. The licensed purchaser in Utah shall ensure the validity of the product and only purchase due to an inability to obtain supply from a Utah licensed pharmacy or wholesaler due to Hurricane Helene.
e. The distributor that is not licensed in Utah shall provide a copy of their license in the state where they are located for each invoice which shall be stored with the invoice by the licensed purchaser in Utah.

Non-Patient Specific Drug Compounding by In-State Pharmacies for Hospitals and EMS:

3. A licensed Utah pharmacy may compound non-patient specific IV solutions as defined in the FDA's Temporary Policy for Compounding Certain Parenteral Drug Products
    a. A licensed Utah pharmacy may compound, according to USP <797> standards, non-patient specific IV solutions for emergency medical services (EMS) organizations if the EMS organization is not able to procure IV solutions to meet the needs of the patients served by the organization.
    b. The following drugs have been identified by the FDA and are the only drugs that may be compounded according to this exemption identified here and updated by FDA as appropriate.

* "Distributor" in this emergency temporary policy refers to a: unlicensed pharmacy, wholesale distributor, third-party logistics provider, outsourcing facility, or manufacturer.

This emergency temporary policy was authorized by the Division of Professional Licensing in collaboration with the Utah Board of Pharmacy under Utah Code § 58-1-307(4) and shall remain in effect until January 15, 2025, unless rescinded earlier by the Division of Professional Licensing in collaboration with the Utah Board of Pharmacy.

For questions regarding these emergency temporary policies, please email DOPL, B3@Utah.gov.

For more information from the U.S. Food and Drug Administration (FDA) about these shortages please visit: Hurricane Helene: Baxter's manufacturing recovery in North Carolina

United States Pharmacopeia (USP) is providing the following two resources, at no charge, to support healthcare professionals in addressing shortages of manufactured intravenous (IV) fluids resulting from the damage caused by Hurricane Helene:
1. Operational considerations for sterile compounding by pharmacy compounders not registered as outsourcing facilities during public health emergencies and natural disasters; and
2. Complimentary USP monographs for use during public health emergency.
Click here to request access to this information.
Contact USP Healthcare Quality and Safety staff at CompoundingSL@usp.org with any additional

questions.

References

1. https://www.nbcnews.com/health/health-news/hospitals-take-steps-conserve-iv-fluid-supply-helene-strikes-critical-rcna173861