B. Braun Medical – Recall of heparin

- On June 13, 2019, B. Braun Medical announced a consumer level recall of one lot of heparin sodium in 5% dextrose injection due to a failure in ongoing stability data. During stability testing of batch J7B259, an out of specification result was identified at the 104 week stability interval for the drug anti-factor IIa potency.

- The recalled lot was distributed between March 27, 2017 and April 27, 2017.

Product Description	NDC#	Lot# (Expiration Date)
Heparin sodium 25,000 units per 250 mL (100 units/mL) in 5% dextrose injection in Excel® IV container	0264-9587-20	J7B259 (8/31/2019)

- Heparin sodium is indicated for: prophylaxis and treatment of venous thrombosis and pulmonary embolism; prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation; treatment of acute and chronic consumption coagulopathies (disseminated intravascular coagulation); prevention of clotting in arterial and cardiac surgery; prophylaxis and treatment of peripheral arterial embolism; anticoagulant use in blood transfusions, extracorporeal circulation, and dialysis procedures.

- Per B. Braun Medical, low potency of heparin may result in anti-coagulation effects. This may result in the need for additional doses or titrations to the patient. Depending on the patient's condition and treatment requirements, the reduced potency may range in outcomes from mild to moderate impact up to life-threatening circumstances in cases where thromboembolism is not adequately prevented.

- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled heparin.

- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.

- For more information regarding this recall, contact B. Braun Medical at **1-800-854-6851**.