

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required

This recall has been initiated out of an abundance of caution for a single lot of Heparin Sodium Injection, USP, due to mislabeling on the back panel of the secondary carton. The incorrect labeling omits the preservative and states the incorrect concentration, showing "Each mL contains: 1,000 USP units heparin sodium; 9 mg sodium chloride" instead of the correct labeling, which should state, "Each mL contains: 20,000 USP units heparin sodium; 0.01 mL benzyl alcohol (as a preservative)". No other lots of Heparin Sodium, Injection, USP are impacted.

Due to the incorrect concentration of 1,000 USP Units per mL instead of 20,000 USP Units per mL, there is a risk that a higher dose than intended may be administered if a healthcare provider uses the back panel of the secondary carton rather than the primary vial label or Prescribing Information insert to calculate the dose by concentration per mL. This could lead to significant health consequences that would require medical intervention to reverse the heparin effect. Additionally, there is a remote probability that the heparin with benzyl alcohol could inadvertently be administered to a premature neonate, infant, or patient with benzyl alcohol allergies which could lead to serious adverse events.

The product lot was distributed nationwide from June 2022 to January 2023.

Product: Heparin Sodium Injection, USP

Lot Number: WP201

NDC: 25021-404-01

Expiration Date: 02/2024

Strength: 20,000 USP units per mL