

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.

Lot No.'s 25128L1C0, 25280LL1C0, and 26108L1C0 of Epinephrine Injection, USP manufactured and distributed by American Regent, Inc. is the subject of a Recall. Recall of this product to USER LEVEL was initiated due to leaking and cracked vials, resulting in a loss of container closure integrity and a potential loss of sterility assurance.

Epinephrine Injection, USP is indicated for the emergency treatment of allergic reactions (Type I), including anaphylaxis, which may result from insect stings or bites, foods, drugs, sera, diagnostic testing substances, and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis. Epinephrine Injection, USP is also indicated to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock.

A crack present in a drug product glass vial could result in compromised product sterility and may result in the introduction of particulate matter. Epinephrine Injection, USP is administered by intravenous infusion in patients who could be critically ill so any impact to product sterility could expose patients to a significant risk of infection leading to bacteremia, fungemia, sepsis, or death. Additionally, the administration of an injectable product containing particulate matter could potentially result in phlebitis, capillary occlusion or thromboembolism. As of August 10, 2026, American Regent has not received any reports of adverse events related to this recall.

PRODUCT: Epinephrine Injection, USP 30 mg/30 mL (1 mg/mL)

NDC NUMBER: 0517-3030-01

Lot No: 25128L1C0

Expiration Date: August 2026

Lot No: 25280LL1C0

Expiration Date: October 2026

Lot No: 26108L1C0

Expiration Date: July 2027