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 is to inform you of a product recall for Nicardipine Hydrochloride Injection, USP manufactured and distributed by American Regent, Inc. Recall of this product to USER LEVEL was initiated due to a product leakage around the neck which could potentially result in a lack of sterility assurance.

Nicardipine Hydrochloride Injection, USP is indicated for the short-term treatment of hypertension when oral therapy is not feasible or not desirable.

Nicardipine Hydrochloride Injection, USP is approved for use in adults only, therefore the population most at risk would be critically ill patients and the elderly. It is indicated for short term use only for treatment of hypertension. Patients should be transitioned to oral therapy as soon as their clinical condition permits. Injectable products require protection from microbial contamination because they bypass most of the body's natural defenses (skin, mucous membranes, etc.). Nicardipine Hydrochloride Injection, USP is administered by intravenous infusion so any impact to product sterility could expose patients to a significant risk of adverse events, including infection or even death.

PRODUCT: Nicardipine Hydrochloride Injection, USP 25 mg/10 mL

NDC NUMBERS:

0517-0735-01
0517-0735-10

LOT NUMBERS AND EXPIRATION DATES:

Lot No: 24086N0C0
Expiration Date: July 2025

Lot No: 24076N0C0
Expiration Date: August 2025

Lot No: 25011N0C0
Expiration Date: June 2026