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 involving by Dr. Reddy's Laboratories Inc. for Morphine Sulfate Extended-Release Tablets 15 mg and 30 mg. This recall is being initiated due to an out-of-specification (OOS) result observed during the 18th-month long-term stability testing for related substances, under conditions of 25°C and 60% relative humidity for Lot FG14062. The obtained Morphinone Sulfate result was found to be 0.25%, exceeding the specification limit of not more than 0.2%. Lot FG13996 (18 Month, 25°C/60% RH) met the specification for the Morphinone Sulfate impurity peak in both the original and retest analyses, however, a trend of elevated levels of Morphinone Sulfate impurity over time was observed. This recall is being carried out to the Retail level.

Risk Assessment: Based on the toxicological profile, increased exposure to morphinone for a longer duration might contribute to hepatotoxicity or potential adverse events due to oxidative stress. This possibility is especially more relevant for at-risk patients like the elderly and those with liver dysfunction.

The product Distribution Dates: March 15th, 2023 -April 6th, 2023.

Product Name	Lot Number	Expiration date	NDC Number
Morphine Sulfate Extended-Release Tablets 15 mg,100 count	FG14062	10/2025	51862-185-01
Morphine Sulfate Extended-Release Tablets 30 mg, 100 count	FG13996	09/2025	51862-186-01