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.

SterRx LLC is conducting a recall for approximately 240 lots that are within their expiry period. The lot numbers being recalled were distributed to hospitals nationwide from December 2020 - October 2021. This recall has been initiated out of an abundance of caution to the hospital pharmacy level due to equipment and process issues that could lead to a lack of sterility assurance for products intended to be sterile. SterRx to date has not received reports of any product complaints or adverse events related to a lack of sterility assurance or sterility failure.

**TOPIC**: Certain SterRx Products by SterRx: Recall - Due to Lack of Sterility Assurance

AUDIENCE: Patient, Health Professional, Risk Manager, Pharmacy

**ISSUE**: SterRx is recalling approximately 240 lots due to equipment and process issues that could lead to a lack of sterility assurance. To date, SterRx has not received reports of any product complaints or adverse events associated with this issue. For more information about this recall, click link to the company announcement.

**BACKGROUND**: The lot numbers being recalled were distributed to hospitals nationwide from December 2020 - October 2021. The products impacted are specifically:

- 1 mg/mL Midazolam in 0.9% Sodium Chloride
- Fentanyl in 0.9% Sodium Chloride
- 1 mg/mL Morphine Sulfate in 0.9% Sodium Chloride
- 1 mg/mL Morphine Sulfate in 5% Dextrose
- 125 mg Diltiazem HCL in 0.7% Sodium Chloride
- 125 mg Diltiazem HCL in 5% Dextrose
- Norepinephrine in 0.9% Sodium Chloride
- Norepinephrine in 5% Dextrose
- Epinephrine in 0.9% Sodium Chloride
- Phenylephrine in 0.9% Sodium Chloride
- 150 mEg Sodium Bicarbonate in 5% Dextrose
- 200 mg Succinylcholine Chloride in 0.9% Sodium Chloride

## **RECOMMENDATIONS:**

- Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of, and return as directed the recalled lots of product.
- Customers or healthcare workers with questions about returning unused product should contact the company's customer call center.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online.
- <u>Download form</u> or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.