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.

B. Braun Medical Inc., (BBMI) is issuing a **voluntary pharmaceutical recall** at the **hospital/healthcare facility leve**l for **one (1) lot of product STERILE WATER FOR INJECTION, USP, 2L BAG, S8505**, due to the potential for set port diaphragm leakage (see attachment 1 for product label).

Reason for the recall:

The affected lot failed reinspection testing due to set port diaphragm leakage and was placed under quarantine. However, this lot was inadvertently released and distributed into commercial channels.

Risk to Health:

To date there have been no reported injuries or death associated with this issue. If leakage is observed before or during use, a minor delay could occur while obtaining a replacement product. Product leakage could result in solution on the floor/surfaces creating potential for falls/slips. Unidentified leakage could lead to contamination with microorganisms causing the potential for bloodstream or surgical site infections from product usage which could become a life-threatening event.

Product Catalog Number	NDC Number	Product Description	Lot Number	Distribution Range	Expiration Date	Region Distributed
S8505	0264-7385-50	STERILE WATER FOR INJECTION, USP, 2L BAG	J5P180	27AUG2026 - 15SEP2026	310CT2028	United States