

*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.*

Otsuka ICU Medical LLC is issuing a recall for one lot of 0.9% Sodium Chloride Injection, USP, 100mL due to the potential for flexible container leaks. This recall notification is being sent to retail and hospital level.

Solution from a leaking flexible container may have compromised sterility and may potentially lead to delay of therapy, infusion of biologic and non-biologic contaminants, spillage, skin, and mucous membrane exposure to allergenic or hazardous substances, or inadequate or inconsistent solution/medication dosing. As instructed in the product labels, prior to administration, healthcare professionals should inspect the product and not administer the product if the container is damaged. The reported incidents were identified prior to use, and there have been no reports of adverse events associated with this issue to date.

The affected product lot was manufactured on 28 March 2025 and distributed in the United States between June 19, 2025 through August 20, 2025. The affected product lot information is below.

PRODUCT: 0.9% Sodium Chloride Injection, USP, 100mL

NDC NUMBER: 0990-7984-37

LOT NUMBER: 1029921

EXPIRATION DATE: 2/28/2027