

*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.*

The purpose of this is to advise you that OurPharma LLC is recalling the following lots of NDC: 73013-1013-01, Fentanyl Citrate 1mg (10mcg/mL) in SWFI – added to 100mL 0.9% NaCl bag.

OurPharma identified two of the four 0.9% saline (NaCl) bag lots used in the compounding of lot 1013-01-2606-05 in which the IV bag expiry would occur before the 180-day expiry of the drug product. Lots P459204 and P461818 have expiry dates of 07/31/2026 and 11/30/2026, respectively. Due to the discrepancy in expiry between the IV bag lots and OurPharma's product expiry of 12/09/2026, a recall is being issued for lot 1013-01-2606-05.

While no adverse events have been reported to date, the use of a finished product containing a component beyond its manufacturer's expiration date presents a potential risk to patient safety. Specifically, OurPharma cannot assure the stability of the 0.9% sodium chloride component beyond the IV bag's labeled expiration dates (07/31/2026 and 11/30/2026). The finished product's labeled expiration of 12/09/2026 assumes all components remain within their validated expiry. Because certain units contain 0.9% sodium chloride that expires before the finished product label, there is an unknown risk to the safety, identity, strength, purity, and quality (SISPQ) of the finished drug product if used beyond the IV bag component's expiration. This recall eliminates that risk.

This recall should be carried out to the pharmacy level.

PRODUCT: Fentanyl Citrate 1mg (10mcg/mL) in SWFI – added to 100mL 0.9% NaCl bag

NDC NUMBER: 73013-1013-01

LOT NUMBER: 1013-01-2606-05

EXPIRATION DATE: 12/09/2026