

*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.*

SCA Pharmaceuticals (SCA) is announcing a voluntary recall of five lots of compounded product due to an out-of-specification stability test result for low potency, at the 60-day stability timepoint. Stability data for the subject lot, 1222043351 indicates that acceptable potency is not maintained through the currently labelled Beyond Use Date of 105 days. SCA's investigation has concluded that the out-of-specification stability test failure is applicable to all lots currently within expiry for this specific NDC.

SCA has not received any adverse event reports and/or product complaints associated with the products being recalled.

Based on a Health Hazard Assessment, the risk to the patient is low, as the provider has the option of redosing patients exhibiting inadequate pain relief if a sub-potent fentanyl dose is administered.

This recall is being carried out at the hospital level/direct account level with the knowledge and approval of the Food and Drug Administration.

<b>Product Name</b>	<b>NDC Number</b>	<b>Lot Number</b>	<b>Beyond Use Date</b>
		1222043351	3/29/2023
		1222043387	4/5/2023
Fentanyl 50 mcg/mL 30 mL fill	70004-0200-16	1222043352	4/5/2023
35 mL Plungerless Syringe		1222043463	4/6/2023
(1,500 mcg/30 mL)		1223043922	5/4/2023