

*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.*

This is to inform you of a recall involving three 100 mL yellow CADD™ cassette products within their expiry period distributed by QuVa Pharma’s Sugar Land, Texas outsourcing facility. QuVa Pharma recently has observed an increased trend in the failure at the seam of the internal bladder in these 100 mL yellow CADD™ medication-filled cassette products. As indicated in the table below, the affected products are comprised of 100 mL yellow CADD™ cassettes filled with Fentanyl Citrate 200 mcg in combination with either Bupivacaine HCl (0.1% or 0.125 %) or Ropivacaine HCl (0.2%).

QuVa Pharma has notified the supplier of the 100 mL yellow CADD™ cassettes, Smiths Medical ASD Inc., a subsidiary of ICU Medical, about the failure at the seam of internal bladders manufactured from specific identifiable batches unique to the 100 mL yellow CADD™ cassettes. We are assisting the supplier to determine the root cause of the leaking cassette products. At this stage, no other CADD™ products, other than the 100 mL yellow CADD™ cassettes, are impacted by this recall.

Safety is our top priority for all products that we distribute. In this instance, the bladder failure results in a gross leak of the cassette. However, out of an abundance of caution, we are initiating this recall across all 100 mL Yellow CADD™ cassettes. The specific product lots subject to this recall are listed below and were distributed from QuVa Pharma’s Sugar Land facility between January 22, 2025 and February 19, 2025.

A leaking 100 mL yellow CADD™ cassette may compromise the sterility of the medication within the cassette that is intended to be sterile. To date, QuVa Pharma has not received any reports of adverse events or patient injury related to the sterility of its drug products that are the subject of this Recall Notice and has not received reports that any leaking 100 mL yellow CADD™ cassettes have been used with any patient. This recall is being conducted to the customer level.

<b>Lot No.</b>	<b>Expiration Date</b>	<b>Product Description</b>	<b>Product Code</b>
10140259	04/08/2025	Fentanyl Citrate PF 200 mcg (2 mcg/ml) /Bupivacaine HCl PF 0.1 % in 100 ml NS Yellow CADD FSFF	70092125575
10140284	04/08/2025	Fentanyl Citrate PF 200 mcg (2 mcg/ml)/Bupivacaine HCl PF 0.125 % 100 ml NS Yellow CADD FSFF	70092120275
10140285	04/08/2025	Fentanyl Citrate PF 200 mcg (2 mcg/ml)/Bupivacaine HCl PF 0.125 % 100 ml NS Yellow CADD FSFF	70092120275
10140303	04/14/2025		

		Fentanyl Citrate PF 200 mcg (2 mcg/ml)/Ropivacaine HCl PF 0.2 % 100 ml NS Yellow CADD FSFF	70092125975
10140315	04/08/2025	Fentanyl Citrate PF 200 mcg (2 mcg/ml)/Bupivacaine HCl PF 0.125 % 100 ml NS Yellow CADD FSFF	70092120275
10140316	04/08/2025	Fentanyl Citrate PF 200 mcg (2 mcg/ml)/Bupivacaine HCl PF 0.125 % 100 ml NS Yellow CADD FSFF	70092120275
10140510	04/14/2025	Fentanyl Citrate PF 200 mcg (2 mcg/ml)/Bupivacaine HCl PF 0.125 % 100 ml NS Yellow CADD FSFF	70092120275
10140539	04/15/2025	Fentanyl Citrate PF 200 mcg (2 mcg/ml) /Bupivacaine HCl PF 0.1 % in 100 ml NS Yellow CADD FSFF	70092125575
10140687	04/17/2025	Fentanyl Citrate PF 200 mcg (2 mcg/ml) /Bupivacaine HCl PF 0.1 % in 100 ml NS Yellow CADD FSFF	70092125575
10140688	04/17/2025	Fentanyl Citrate PF 200 mcg (2 mcg/ml) /Bupivacaine HCl PF 0.1 % in 100 ml NS Yellow CADD FSFF	70092125575
10140867	04/24/2025	Fentanyl Citrate PF 200 mcg (2 mcg/ml)/Ropivacaine HCl PF 0.2 % 100 ml NS Yellow CADD FSFF	70092125975
10140868	04/24/2025	Fentanyl Citrate PF 200 mcg (2 mcg/ml)/Ropivacaine HCl PF 0.2 % 100 ml NS Yellow CADD FSFF	70092125975
10140916	04/24/2025	Fentanyl Citrate PF 200 mcg (2 mcg/ml)/Bupivacaine HCl PF 0.125 % 100 ml NS Yellow CADD FSFF	70092120275
10140965	04/28/2025	Fentanyl Citrate PF 200 mcg (2 mcg/ml)/Ropivacaine HCl PF 0.2 % 100 ml NS Yellow CADD FSFF	70092125975