

September 11, 2026



PROVIDER ALERT

To: Health Plan of San Joaquin/Mountain Valley Health Plan
("Health Plan") Practitioners, Facilities, and Hospitals
From: Health Plan
Type: Informational/Educational
Subject: **FDA Drug Recall Alert – 3 Lots of Epinephrine Injection, USP 30 mg/ 30 mL (1 mg/mL) multi dose vial**
Business: Medi-Cal Managed Care and Medicare Dual Special Needs Plan (D-SNP)

On September 03, 2026, the Food and Drug Administration (FDA) released a recall announcement on **3 Lots of Epinephrine Injection, USP 30 mg/ 30 mL (1 mg/mL) multi dose vial**.

This is for informational purposes only. You may or may not have administered the medication. Please disregard if you have not been affected by this recall.

For the complete details regarding this recall announcement, please visit the following web link: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/american-regent-inc-issues-voluntary-nationwide-recall-three-lots-epinephrine-injection-usp-30-mg-30?utm_medium=email&utm_source=govdelivery

American Regent, Inc. Issues Voluntary Nationwide Recall of Three Lots of Epinephrine Injection, USP 30 mg/ 30 mL (1 mg/mL) Due to the Presence of Particulate Matter and Lack of Assurance of Sterility

Company Announcement

September 3, 2026 – New Albany, OH, American Regent, Inc. is conducting a nationwide voluntary recall of three lots of Epinephrine Injection, USP 30 mg/ 30 mL (1 mg/mL) multi dose vials to the consumer level. Customer complaints were received for leaking and cracked vials, resulting in lack of assurance of sterility. The firm's investigation also revealed the presence of particulate matter identified as Nylon, Cellulosic, Acrylic, Polyethylene and Glass.

Affected Products

Epinephrine Injection, USP 30 mg/ 30 mL (1 mg/mL) multi dose vial was distributed nationwide in the United States with a first ship date 09/04/2025 and last ship date of 07/31/2026. NDC, lot, and expiration date can be found on the table.

Product	NDC	Lot	Expiry	Distribution Date Range	
				Beginning	End
Epinephrine Injection, USP	0517-3030-01	25128L1C0	August 2026	September 04, 2025	December 18, 2025
		25280L1C0	October 2026	December 16, 2025	April 17, 2026
		26108L1C0	July 2027	June 15, 2026	July 31, 2026

What to Do

American Regent, Inc. is notifying its distributors and customers by letter and is arranging for return/replacement etc. of all recalled products. Distributors/retailers/healthcare facilities that have the product which is being recalled should stop using and return to place of purchase or discard the product.

Consumers and healthcare professionals with questions regarding this recall can contact American Regent Inc. using the below information. Patients that use this product which is being recalled should stop using them and contact their doctor or health care provider. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Contact Information

Consumers: Customer Service 1-800-645-1706
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If you have any further questions, please contact your Provider Services Representative, or call our Customer Service Department at 1-888-936-PLAN (7526). You may also visit <https://www.hpsj.com/alerts/> for online access to the documents shared. The most recent information about Health Plan and our services is always available on our website WWW.HPSJ-MVHP.ORG.